U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
1 Courthouse Way
Suite 9200
Boston, Massachusetts 02210

September 15, 2010

Mary Jo White, Esq.
Christopher K. Tahbaz, Esq.
Andrew J. Ceresney, Esq.
Kristin D. Kiehn, Esq.
Debevoise & Plimpton LLP
919 Third Avenue
New York, NY 10022

Re: United States v. Forest Pharmaceuticals, Inc.

Dear Counsel:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney") and the United States Department of Justice (collectively, the "United States") and your client, Forest Pharmaceuticals, Inc. (hereinafter "Forest"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date Forest shall waive indictment and plead guilty to the three-count Information attached hereto as Exhibit A. Count One of the Information charges that on or about November 17, 2003, Forest corruptly endeavored to influence, obstruct, and impede an agency proceeding in violation of 18 U.S.C. § 1505. Count Two charges that beginning as early as August 14, 2001, and continuing thereafter until on or about August 9, 2003, Forest introduced and caused to be introduced for delivery into interstate commerce various quantities of the unapproved new drug Levothroid in violation of 21 U.S.C. §§ 331(d), 333(a)(1) and 355(a). Count Three charges that beginning as early as 1998 and continuing thereafter through in or about December 2002, Forest introduced and caused to be introduced for delivery into interstate commerce various quantities of a misbranded drug Celexa, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1). Forest expressly and unequivocally admits that it committed these offenses and further admits that, with respect to Count One, it acted knowingly and corruptly. Defendant expressly and unequivocally

further admits that it is in fact guilty of these offenses, and agrees that it will not make any statements inconsistent with this explicit admission. Forest agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

Forest faces the following maximum penalties on each count of the Information:

a. Count One (18 U.S.C. § 1505)

i. A maximum fine of $500,000, twice the gross gain derived from the offense, or twice the gross loss to a person other than Forest, whichever is greatest. *See* 18 U.S.C. §§ 3571(c) and (d). In this case, the maximum fine is $500,000;

ii. A term of probation of not less than one (1) year and not more than five (5) years. *See* 18 U.S.C. § 3561(c)(1);

iii. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556, 3563, and 3663; and

iv. A mandatory special assessment in the amount of $400. *See* 18 U.S.C. § 3013(a)(2)(B).

b. Count Two (21 U.S.C. §§ 331(d), 333(a)(1), and 355(a)):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given Forest's gross gain from its sales of the unapproved new drug Levothroid between August 14, 2001, and August 9, 2003, totaled $70,326,246, the maximum possible fine in connection with this count is $140,652,492;

ii. A term of probation of not more than five (5) years, *see* 18 U.S.C. § 3561(c)(2), one of the terms of which may include an order of restitution, *see* 18 U.S.C. § 3563; and

iii. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

c. Count Three (21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given Forest's sales of the misbranded drug Celexa totaled approximately $28,040,000, the maximum possible fine in connection with this count is $56,080,000;

ii. A term of probation of not more than five (5) years, *see* 18 U.S.C. § 3561(c)(2), one of the terms of which may include an order of restitution, s*ee* 18 U.S.C. § 3563; and

iii. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

3. Sentencing Guidelines

The parties agree that while the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for obstruction of justice under 18 U.S.C. § 1505, or for misdemeanor violations of the Food, Drug, and Cosmetic Act, see U.S.S.G. § 8C2.1, the agreed-upon fine is consonant with those guidelines and takes into account Forest's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

a. Count One

i. The parties agree that the base fine is $85,000 which was determined as follows:

A. There was no pecuniary gain or loss associated with the offense, and base fine therefore is determined pursuant to U.S.S.G. § 8C2.4(a)(1);

B. Pursuant to U.S.S.G. § 8C2.3, the applicable Chapter Two guideline is U.S.S.G. § 2J1.2, which has a base offense level of 14;

C. No other adjustments contained in U.S.S.G. § 2J1.2 are applicable; and

D. Pursuant to U.S.S.G. § 8C2.4(d), the base fine associated with an offense level of 14 is $85,000.

ii. Taking into account the nature and circumstances of the offense, among other factors, the parties agree that, pursuant to U.S.S.G. § 8C2.5, the culpability score is five (5).

iii. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of five (5) is 1.00 to 2.00.

iv. Thus, the Guideline Fine Range is $85,000 to $170,000. *See* U.S.S.G. §§ 8C2.7(a) and (b); 18 U.S.C. §§ 3571(c) and (d).

b. Count Two

i. The parties agree that the base fine is $70,326,246, which is the pecuniary gain to the organization from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.

ii. Taking into account the nature and circumstances of the offense, among other factors, the parties agree that, pursuant to U.S.S.G. § 8C2.5, the culpability score is seven (7).

iii. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of seven (7) is 1.40 to 2.80.

iv. Thus, the Guideline Fine Range is $98,456,744.40 to $196,913,488.80. *See* U.S.S.G. §§ 8C2.7(a) and (b); 18 U.S.C. §§ 3571(c) and (d).

c. Count Three

i. The parties agree that the base fine is $28,040,000, which is the pecuniary gain to Forest from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.

ii. Taking into account the nature and circumstances of the offense, among other factors, the parties agree that, pursuant to U.S.S.G. § 8C2.5, the culpability score is seven (7).

iii. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of seven (7) is 1.40 to 2.80.

iv. Thus, the Guideline Fine Range is $39,256,000 to $78,512,000. *See* U.S.S.G. §§ 8C2.7(a) and (b); 18 U.S.C. §§ 3571(c) and (d).

d. The parties agree that (1) disgorgement pursuant to U.S.S.G. § 8C2.9 is not necessary, and (2) there is no basis for a downward departure or deviation under the United States Sentencing Guidelines.

4. Agreed Disposition

The United States and Forest agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the appropriate disposition of this case is as follows, and will result in imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration of all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

a. A criminal fine of $150,000,000 to be imposed as follows:

i. Count One: $ 500,000.

ii. Count Two: $110,000,000.

iii. Count Three: $ 39,500,000.

This criminal fine is to be paid within one week of the date of sentencing.

b. Mandatory special assessments totaling $650 pursuant to 18 U.S.C. § 3013, to be imposed as follows:

i. Count One: $400.

ii. Count Two: $125.

iii. Count Three: $125.

c. Criminal Forfeiture in the amount of $14,000,000.

d. In light of the pending civil actions, *United States ex rel. Gobble, et al., v. Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc.*, No. 03-10395-NMG (D. Mass.), *United States ex rel. Piacentile, et al., v. Forest Laboratories, Inc.*, No. 05-10201-NMG (D. Mass.), and *United States ex rel. Conrad v. Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc., et al.*, No. 02-11738-NG (D. Mass.), and the Civil Settlement Agreement between Forest and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B) which requires the payment of $149,158,057.66, plus interest, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to any non-federal victims in this case given the difficulty of

determining whether, and to what extent, any unknown individual or payor suffered any injury as a result of the offenses. *Cf.* 18 U.S.C. § 3663(a)(1)(B)(ii). Accordingly, the United States agrees that it will not seek a separate restitution order as to Forest as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement that this paragraph constitutes the appropriate disposition of this case, if at any time between Forest's execution of this Agreement and sentencing, Forest:

a. Fails to admit a complete factual basis for the plea;

b. Fails to truthfully admit its conduct in the offenses of conviction;

c. Falsely denies, or frivolously contests, relevant conduct for which Forest is accountable under U.S.S.G. § 1B1.3;

d. Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Forest is accountable under U.S.S.G. § 1B1.3;

e. Engages in acts which form a basis for finding that Forest has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1; or

f. Attempts to withdraw its guilty plea.

Forest expressly understands that it may not withdraw its plea of guilty unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

5. No Further Prosecution of Forest

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charges in the attached Information, it shall not further prosecute Forest for any additional federal criminal charges against Defendant with respect to the conduct that:

a. falls within the scope of the Information to which Forest is pleading guilty; or

b. was a subject of the grand jury investigation in the District of Massachusetts relating to Levothroid (as manufactured prior to August 14, 2003), or relating to the sale, promotion, or marketing of Celexa and Lexapro in the United States; or

c. was known to the United States Attorney's Office for District of Massachusetts or the Office of Consumer Litigation of the Department of Justice prior to the date of this agreement, and which concerned the sale, promotion, manufacture, or marketing of Levothroid (as manufactured prior to August 14, 2003) in the United States, or which concerned the sale, promotion, or marketing of Celexa or Lexapro in the United States through December 31, 2005.

This declination is expressly contingent upon:

a. the guilty pleas of Forest to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and

b. Forest's performance of all of its material obligations as set forth in this Agreement and the attached Civil Settlement Agreement.

If Forest's guilty plea is not accepted by the Court or is withdrawn for any reason, or if Forest should fail to perform any material obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Forest, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the United States.

6. Payment of Mandatory Special Assessment

Forest shall pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

7. Waiver of Right to Appeal and to Bring Other Challenge

a. Forest has conferred with its attorney and understands that it has the right to challenge its convictions in the United States Court of Appeals for the First Circuit ("direct appeal"). Forest also understands that it may, in some circumstances, be able to challenge its convictions in a future proceeding (such as, for example, in a collateral challenge pursuant to 28 U.S.C. § 2255 or 28 U.S.C. § 2241). Forest waives any right it has to challenge its conviction on direct appeal or in any future proceeding.

b. Forest has conferred with its attorney and understands that defendants ordinarily have a right to appeal their sentences and may sometimes challenge their sentences in future proceedings. Forest understands, however, that once

the Court accepts this Rule 11(c)(1)(C) plea agreement, the Court is bound by the parties' agreed-upon sentence. Forest may not contest the agreed-upon sentence in an appeal or challenge the sentence in a future proceeding in federal court. Similarly, the Court has no authority to modify an agreed-upon sentence under 18 U.S.C. § 3582(c), even if the Sentencing Guidelines are later modified in a way that appears favorable to Defendant. Given that a defendant who agrees to a specific sentence cannot later challenge it, and also because Forest desires to obtain the benefits of this Agreement, Forest agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. Forest also agrees that it will not seek to challenge the sentence in an appeal or future proceeding even if the Court rejects one or more positions advocated by any party at sentencing.

c. The United States agrees that it will not appeal the imposition by the Court of the sentence agreed to by the parties as set out in Paragraph 4, even if the Court rejects one or more positions advocated by a party at sentencing.

8. Cooperation

Forest shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal or administrative investigation of its current and former officers, agents, employees, and customers in connection with the matters described in the Information. Forest shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. Forest shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, Forest shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing federal investigation, trial or other criminal proceeding in connection with matters described in the Information, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) Forest is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Forest is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) Forest is not required to waive any privilege or claim of work product protection.

Forest expressly and unequivocally further admits that it committed the offenses charged in the Information and is in fact guilty of those offenses. Forest agrees that it will not make any statements inconsistent with its explicit admission of guilt to these offenses. This agreement

concerning inconsistent statements is not intended to apply to any statement made by any individual in the course of any criminal, regulatory or civil matter against such individual, unless such individual is speaking on behalf of Forest.

9. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

10. Forfeiture

Forest will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c) as a result of its guilty plea.

Forest admits that the value of the quantities of Celexa which were misbranded and distributed in violation of 21 U.S.C. § 331, plus the value of the quantities of the unapproved new drug Levothroid which were distributed in violation of 21 U.S.C. § 331 totaled at least $14,000,000 in United States currency. Forest acknowledges and agrees that the quantities of Celexa which were misbranded and distributed in violation of 21 U.S.C. § 331 and the quantities of the unapproved new drug Levothroid which were distributed in violation of 21 U.S.C. § 331 cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, Forest agrees that the United States is entitled to forfeit as "substitute assets" any other assets of Forest up to the value of the now missing directly forfeitable assets.

Forest agrees that, no later than one week after sentencing, it shall remit the amount of $14,000,000 in United States currency to the United States Marshals Service pursuant to wire instructions provided by the United States Attorney's Office. Forest and the United States agree that this payment shall satisfy any and all forfeiture obligations that Forest may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of Forest's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon Forest, nor shall the forfeiture be used to offset Forest's tax liability or any other debt owed to the United States.

Forest agrees to consent to the entry of orders of forfeiture for the $14,000,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding the notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Forest acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the court to advise it of this, pursuant to Rule 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this Agreement, Forest hereby waives any and all claims arising from or relating to the forfeitures set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment, to the United States Constitution, or any other provision of state or federal law.

The United States District Court for the District of Massachusetts shall retain jurisdiction to enforce the provisions of this section.

11. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Forest's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Forest cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States or Forest, with the exception of paragraph 13 (Waiver of Defenses) which shall remain in full effect.

Forest may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Forest immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Forest understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

12. Civil and Administrative Liability

By entering into this Agreement, the United States does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability, which Forest may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

Forest's civil liability to the United States in connection with certain of the matters under investigation by the United States is resolved in the Civil Settlement Agreement with Forest, attached as Exhibit B, according to the terms set forth in that Agreement.

13. Waiver of Defenses

If Forest's guilty plea is not accepted by the Court for whatever reason, if Forest's guilty plea is later withdrawn or otherwise successfully challenged by Forest for whatever reason, or if Forest breaches this Agreement, Forest hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except Forest retains any such defense that Forest specifically reserved in the parties' tolling agreement dated July 20, 2010, attached hereto as

Exhibit C. This waiver is effective provided that charges are filed within six months of the date on which such guilty plea is rejected, withdrawn, or successfully challenged, or a breach is declared by the United States.

14. Breach of Agreement

If the United States determines that Forest has failed to comply with any material provision of this Agreement, or has committed any crime following its execution of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying Forest, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this Agreement. Forest recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. Forest understands that should it breach any material provision of this Agreement, the United States will have the right to use against Forest before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by Forest, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

Forest understands and agrees that this Rule 11(c)(1)(C) plea agreement and its agreed-upon criminal disposition:

a. are wholly dependent upon Forest's timely compliance with the material provisions of the attached Civil Settlement Agreement, and that

b. failure by Forest to comply fully with the material terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement, provided however, that a breach of the Corporate Integrity Agreement (the "CIA"), referred to in the Civil Settlement Agreement, does not constitute a breach of this Plea Agreement, and any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions of the CIA.

In the event Forest at any time hereafter breaches any material provision of this Agreement, Forest understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute Forest as set forth in this Agreement; and (2) Forest will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it be entitled to return of any monies already paid. Moreover, in the event of a breach, Forest understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and Forest hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except Forest retains any such defenses that Forest specifically reserved in the parties' tolling agreement dated July 20, 2010.

15. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 5, this Agreement is binding upon Forest and the Office of the United States Attorney for the District of Massachusetts, the United States Attorney's Offices for each of the other 93 judicial districts of the United States, and the Office of Consumer Litigation of the Department of Justice. The non-prosecution provisions in Paragraph 5 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of Forest that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of Forest's products to foreign customers, which investigations are specifically excluded from the release in Paragraph 5. A copy of the letter to United States Attorney Carmen M. Ortiz from the Deputy Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit D. Forest understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

16. Corporate Authorization

Forest's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit E. Forest shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the governing authority of Forest Pharmaceuticals, Inc., affirming that it has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Forest to plead guilty to the charges specified in the Information; and (5) voted to authorize the corporate representative identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit F. Forest agrees that either a duly-authorized corporate representative or a duly-authorized attorney employed by Forest, at the discretion of the Court, shall appear on behalf of Forest and enter the guilty plea and will also appear for the imposition of sentence.

17. Complete Agreement

This Agreement and the attachments hereto, together with the Civil Settlement Agreement and attachments thereto, and the separate Side Letter Agreement with Forest Laboratories, Inc. and attachments thereto, set forth the complete and only agreement between the parties relating to the disposition of this case. No promises, representations or agreements have been made other than those set forth in this Agreement and its attachments, and the Civil Settlement Agreement and its attachments, and the separate Side Letter Agreement with Forest Laboratories, Inc. and its attachments. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the United States and your client, Forest, please have the authorized representative of Forest sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney James E. Arnold.

Very truly yours,

Jack W. Pirozzolo, First Assistant U.S. Attorney
on behalf of

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: James E. Arnold

JAMES E. ARNOLD
Assistant U.S. Attorney
District of Massachusetts

TONY WEST
ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
U.S. DEPARTMENT OF JUSTICE

By: James E. Arnold for

JEFFREY I. STEGER
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice

ACKNOWLEDGMENT OF AGREEMENT

The Board of Directors of Forest Pharmaceuticals, Inc. (the "Board") has directed and authorized the officers of Forest Pharmaceuticals, Inc., or their authorized representatives, to execute this Plea Agreement on behalf of Forest Pharmaceuticals, Inc., and to take all such actions as may be necessary to effectuate this Plea Agreement. The Board has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement including all attachments in their entirety and has discussed them fully in consultation with Forest's attorney. The Board acknowledges that these documents fully set forth Forest's agreement with the United States. The Board further states that no additional promises or representations have been made to Forest by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: 9/15/2010

HERSCHEL S. WEINSTEIN
General Counsel
Forest Laboratories, Inc.

Dated: _____

Mary Jo White, Esq.
Christopher K. Tahbaz, Esq.
Andrew J. Ceresney, Esq.
Kristin D. Kiehn, Esq.
Debevoise & Plimpton LLP
Counsel for Defendant

ACKNOWLEDGMENT OF AGREEMENT

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Dated: _____

HERSCHEL S. WEINSTEIN
General Counsel
Forest Laboratories, Inc.

Dated: 9/15/10

Mary Jo White, Esq.
Christopher K. Tahbaz, Esq.
Andrew J. Ceresney, Esq.
Kristin D. Kiehn, Esq.
Debevoise & Plimpton LLP
Counsel for Defendant

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	**CRIMINAL NO.**
v.	**VIOLATIONS:** **18 U.S.C. § 1505** **(obstruction of agency proceedings)** **21 U.S.C. §§ 331(d), 333(a)(1), 355(a)** **(distribution of an unapproved new drug)** **21 U.S.C. §§ 331(a), 333(a)(1), 352(f)(1)**
FOREST PHARMACEUTICALS, INC.,	**(distribution of a misbranded drug;** **inadequate directions for use)**
Defendant.	

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times material hereto, unless otherwise alleged:

1. **FOREST PHARMACEUTICALS, INC.** (hereafter **"FOREST PHARMACEUTICALS"**) was a wholly owned subsidiary of Forest Laboratories, Inc. (hereafter "Forest Labs") and had its principal place of business in St. Louis, Missouri.

2. **FOREST PHARMACEUTICALS** was engaged in, among other things, the manufacture, promotion, sale and interstate distribution of prescription drugs intended for human use throughout the United States, including the District of Massachusetts. **FOREST PHARMACEUTICALS** employed individuals, including sales representatives, throughout the United States, including the District of Massachusetts. **FOREST PHARMACEUTICALS** had manufacturing and packaging facilities in various locations, including Cincinnati, Ohio.

FOREST PHARMACEUTICALS' distribution center for shipping its various drug products was located in St. Louis, Missouri.

3. Forest Labs was a Delaware corporation with its principal place of business in New York, New York, with publicly traded shares listed on the New York Stock Exchange (ticker symbol: FRX).

THE FDA AND THE FDCA

4. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA") and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs bore true and accurate information. Pursuant to such responsibility, the FDA published and administered regulations relating to the approval, manufacture, and distribution of drugs.

5. As part of its mission to enforce the FDCA and protect the public health, the FDA had the authority to enter and inspect at reasonable times all establishments where drugs were manufactured, processed, packed, or held for introduction into interstate commerce or after shipment in interstate commerce. 21 U.S.C. § 374(a)(1).

6. The FDCA defined drugs as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and articles intended to affect the structure or any function of the body of man. 21 U.S.C. §§ 321(g)(1)(B) and (C).

7. Prescription drugs under the FDCA were any drugs intended for use in humans which, because of their toxicity or other potentiality for harmful effect, or the method of their

use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A).

8. A "new drug" was defined, in relevant part, as a drug that was not generally recognized among qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling. 21 U.S.C. § 321(p).

9. With certain limited exceptions not pertinent here, the FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of, or introducing or delivering for introduction into interstate commerce of, "new drugs" that were not the subject of an FDA-approved new drug application ("NDA") or an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d), 355.

10. The FDCA required that an NDA include proposed labeling for the proposed intended uses of the drug which included, among other things, the conditions for therapeutic use. The NDA was also required to provide, to the satisfaction of the FDA, data generated in adequate and well-controlled clinical investigations that demonstrated that the drug was safe and effective when used in accordance with the proposed labeling.

11. An NDA sponsor was not permitted to promote or market the drug until the FDA had approved its NDA, including the proposed labeling. Once approved, the sponsor was permitted to promote and market the drug only for the conditions of use and dosages specified in the approved labeling. Uses not approved by the FDA, including uses in patient populations beyond those in the drug's approved labeling, were known as "unapproved"or "off-label" uses.

12. The FDCA, and its implementing regulations, required the sponsor to file a new NDA, or a supplement to the existing NDA, in order to label or promote a drug for uses and

dosages different from the conditions for use and dosages specified in the approved labeling. The new or supplemental NDA was required to include a description of the newly proposed indications for use and evidence, from adequate and well-controlled clinical investigations, sufficient to demonstrate that the drug was safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA, or supplement, could the sponsor promote the drug for the new intended use.

13. The FDCA provided that a drug was misbranded if, among other things, its labeling did not contain adequate directions for use. 21 U.S.C. § 352(f)(1). As the phrase was used in the FDCA and its regulations, adequate directions for use could not be written for medical indications or uses for which the drug had not been proven to be safe and effective through adequate and well-controlled clinical investigations.

14. The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of, or introducing or delivering for introduction into interstate commerce of, any drug that was misbranded. 21 U.S.C. § 331(a).

LEVOTHROID AND THE FDA APPROVAL PROCESS

15. Levothroid was an orally administered levothyroxine sodium drug product (hereafter "orally administered levothyroxine sodium drug products" are referred to as "levothyroxine drugs"). In the 1950s, drug manufacturers first introduced levothyroxine drugs in the United States to treat patients suffering from hypothyroidism – that is, a medical condition in which an individual has a thyroid hormone deficiency. Manufacturers introduced levothyroxine drugs in the market without first obtaining FDA approval in part because the manufacturers believed that their drugs were not "new drugs" within the meaning of the FDCA. The product

that became Levothroid was introduced in the United States in or around 1965 by a drug manufacturer other than **FOREST PHARMACEUTICALS** without first obtaining FDA approval.

16. In or about 1991, Forest Labs bought the rights to Levothroid. Several years later, **FOREST PHARMACEUTICALS** moved the manufacturing processes for Levothroid to its manufacturing facility in Cincinnati, Ohio. Thereafter, **FOREST PHARMACEUTICALS** manufactured and packaged Levothroid at its Cincinnati manufacturing facility. After manufacture and packaging, **FOREST PHARMACEUTICALS** transferred the Levothroid finished product to its distribution facility in St. Louis, Missouri, from which it sold and distributed Levothroid to customers throughout the United States, including within the District of Massachusetts. At no time through and including August 9, 2003, did **FOREST PHARMACEUTICALS** have an approved NDA to manufacture and distribute Levothroid using the formulation and manufacturing processes then being utilized at its Cincinnati manufacturing facility.

A. The FDA's 1997 Determination That Levothyroxine Drugs Were New Drugs

17. On August 14, 1997, the FDA issued a public notice in the Federal Register (hereafter, "1997 Federal Register notice") announcing its conclusion that all levothyroxine drugs on the market were "new drugs" within the meaning of the FDCA. In this notice, the FDA stated that although levothyroxine drugs had been on the market for years, new information showed that there were significant stability and potency problems with these products. As a result, the FDA concluded that more regulation was needed to ensure that the drugs then being commercially marketed were safe and effective as manufactured.

18. In the 1997 Federal Register notice, the FDA explained that thyroid replacement therapy, the principal therapeutic use of levothyroxine drugs, needed to be established carefully on an individualized basis for each patient, with gradual increases in dosages until an optimal response was achieved as determined by clinical evaluation and laboratory testing. Levothyroxine drugs were "narrow therapeutic index" drugs – that is, a very small difference in potency could make the difference between a therapeutic dosage and a potentially suboptimal or toxic dosage. As a result, overtreatment or undertreatment with levothyroxine drugs could present significant health risks to patients: if a patient received too little medication, the patient could remain hypothyroid; conversely, if a patient received too much medication, the patient could become hyperthyroid and could suffer adverse health consequences including potentially cardiac pain, heart palpitations, or cardiac arrhythmias. Given this risk, the FDA characterized as "critical" the importance that patients receive levothyroxine drugs that were consistent in potency and bioavailability.

19. As described by the FDA in the 1997 Federal Register notice, there had been a history in the 1990s of continuing significant potency and stability problems with levothyroxine drugs that were on the market. These problems included at least ten recalls involving 150 lots and more than 100 million tablets by different manufacturers, including at least one recall by **FOREST PHARMACEUTICALS**, adverse drug experience reports, and reports indicating that, even when a physician consistently prescribed the same brand and labeled dosage strength of a specific levothyroxine drug product, patients received varying dosage strengths of the drug.

20. In the 1997 Federal Register notice, the FDA also expressed concern that, because levothyroxine sodium was unstable in the presence of higher temperatures and humidity levels,

proper manufacturing controls were needed to ensure that the drugs remained fully potent through the labeled expiration date and to ensure that the drugs were of consistent potency from lot to lot. The FDA observed that the "lack of stability and consistent potency has the potential to cause serious health consequences to the public."

21. The FDA further noted that, because levothyroxine drugs were being marketed without approved NDAs, manufacturers of these products were not seeking or obtaining FDA approval each time they reformulated their products. This meant that manufacturers were releasing reformulated products with significant differences in potency before and after reformulation. According to the FDA, these potency differences resulted in serious adverse health consequences for some patients whose conditions had otherwise been safely controlled on the drug prior to reformulation.

22. In light of the particular importance of consistent potency and stability to levothyroxine drugs, and because none of the levothyroxine drugs on the market had been shown to demonstrate consistent potency and stability, the FDA determined that none of these drugs were generally recognized as safe and effective and thus that all of the drugs in this class were "new drugs" within the meaning of the FDCA. As a result, the FDA announced that manufacturers of these products needed to file an NDA and obtain FDA approval to permit continued marketing of their products. The FDA further advised manufacturers that, if they wanted to challenge the determination that their drug product was a "new drug," they needed to file a citizen petition by not later than October 14, 1997.

23. Because the FDA deemed levothyroxine drugs to be medically necessary for millions of patients and given the lack of any available alternative drug that was relied upon by

the medical community as an adequate substitute for the treatment of hypothyroidism, the FDA advised manufacturers that it would allow them three years, until August 14, 2000, to obtain approved NDAs for their products. Until that date, in order to meet patients' medical needs, the FDA stated it would permit manufacturers to continue commercial distribution of their unapproved drugs. The 1997 Federal Register notice provided clear warning to manufacturers about the consequences of distribution thereafter:

> After August 14, 2000, any orally administered drug product containing levothyroxine sodium, marketed on or before the date of this notice, that is introduced or delivered for introduction into interstate commerce without an approved application, unless found by the FDA to be not subject to the new drug requirements of the act under a citizen petition submitted for that product, will be subject to regulatory action.

24. The FDA subsequently concluded that levothyroxine drug manufacturers needed additional time to complete studies and to prepare the NDAs needed to establish that their drugs were safe and effective. In an April 2000 Federal Register notice, the agency extended the previously stated compliance date one year – from August 14, 2000, to August 14, 2001 – during which manufacturers could continue marketing their drugs without approved applications.

B. <u>The FDA's 2001 Guidance for Industry and Phase-Down Plan</u>

25. On July 13, 2001, the FDA issued a Guidance for Industry entitled "Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications" (hereafter "Guidance"). In a concurrent Federal Register announcement, FDA explained that it had approved two NDAs for levothyroxine drugs. The agency noted, however, that "it will take time for the millions of patients taking unapproved products to switch to approved products, and for manufacturers of approved products to scale up

their production and to introduce this increased production into the distribution chain." To provide manufacturers with adequate scale-up time, and to permit patients and physicians time to make a reasonable transition from unapproved to approved products, the FDA announced that, in the exercise of its enforcement discretion, it was establishing a gradual phase-down plan for the unapproved drugs.

26. In the Guidance, the FDA reiterated that marketing levothyroxine drugs without an approved NDA was illegal and could subject a company to various enforcement actions, including "injunction, prosecution, or seizure." The FDA advised, however, that it did not intend to take enforcement action against companies for marketing levothyroxine drugs without an approved NDA, if those companies complied with all aspects of the phase-down plan set forth by FDA in the Guidance. In effect, the Guidance created a voluntary "safe harbor" for companies that wished to continue to distribute levothyroxine drugs without an approved NDA.

27. The phase-down plan announced by FDA in the Guidance was as follows. To qualify for the "safe harbor," manufacturers first had to have an NDA pending, if not already approved, by August 14, 2001. The Guidance explicitly warned manufacturers without an approved or pending NDA that they should cease distribution immediately on August 14, 2001, and it further warned manufacturers who had an NDA pending that they should stop distributing their drug immediately if, after August 14, 2001, they withdrew their pending NDA. Second, the Guidance provided that manufacturers without approved NDAs should gradually reduce commercial distribution of their drugs, over two years, pursuant to a specific phase-down schedule, with all distribution terminating as of August 14, 2003. Third, the Guidance stated that manufacturers without an approved NDA should submit quarterly amendments to their pending

NDAs certifying that they had reduced average monthly distribution in accordance with the phase-down schedule.

28. In a section entitled "Basis for Enforcement Action," the Guidance explicitly discussed the potential legal consequences associated with distributing an unapproved levothyroxine drug without following the phase-down plan:

> Orally administered levothyroxine sodium drug products are new drugs. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) states: "No person may introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." A manufacturer who introduces or delivers for introduction into interstate commerce an unapproved drug product is subject to injunction, prosecution, or seizure as authorized by sections 302, 303, and 304 of the Act (21 U.S.C. §§ 332, 333, 334). Violation of an injunction could result in a contempt proceeding or such other penalties as a court may order (e.g., fines). However, FDA does not intend to take action for marketing without an approved application against a manufacturer of levothyroxine sodium drug product who complies with the plan for phased reduction of distribution described in [the Guidance]."

C. FOREST PHARMACEUTICALS' Response to the Federal Register Notices and the Guidance

29. In response to the Federal Register notice, **FOREST PHARMACEUTICALS** did not file a citizen petition challenging the FDA's determination that Levothroid was a new drug within the meaning of the FDCA. Instead, so that **FOREST PHARMACEUTICALS** could continue to manufacture and distribute Levothroid, Forest Labs submitted NDA 21-125 for Levothroid (levothyroxine sodium tablets, USP) on or about September 27, 2000.

30. As part of the NDA process, **FOREST PHARMACEUTICALS** knew and understood that the FDA needed to be provided with stability data that supported the expiration

dates that the company was proposing for Levothroid. Stability testing was a form of laboratory testing that was designed to demonstrate the shelf-life of a drug, that is, the length of time during which the drug had the appropriate identity, strength, quality, purity and potency. **FOREST PHARMACEUTICALS** further knew and understood that the FDA required that this stability data be obtained under specific, controlled temperature and relative humidity conditions – namely, temperature between 25 +/- 2° Celsius and relative humidity between 60% +/- 5% (these conditions will hereafter be referred to as "ICH conditions"). From conversations with FDA representatives, **FOREST PHARMACEUTICALS** knew that, because levothyroxine sodium was highly sensitive to both temperature and humidity, the FDA wanted adequate assurances that the drugs that were going to remain on the market were sufficiently robust to maintain potency even under relatively warm and humid conditions.

31. **FOREST PHARMACEUTICALS** knew that satisfying ICH conditions for stability presented a significant challenge for its Levothroid product. **FOREST PHARMACEUTICALS** discovered during testing of the *commercially distributed* Levothroid (the product being manufactured and sold by **FOREST PHARMACEUTICALS** at the time, as opposed to the *developmental* Levothroid being manufactured and tested as part of the NDA submission) that the drugs lost potency much more rapidly under ICH conditions and thus failed stability testing. As a result, after consulting with FDA, **FOREST PHARMACEUTICALS** had stopped subjecting its commercially distributed Levothroid to ICH conditions during stability testing.

32. **FOREST PHARMACEUTICALS** also knew that obtaining valid stability data for Levothroid under ICH conditions for the NDA was going to present significant difficulties for

a second reason. **FOREST PHARMACEUTICALS** (like some other manufacturers of unapproved product) manufactured its commercially distributed Levothroid with a stability overage – that is, with excessive active ingredient added solely to ensure that the drug would have sufficient potency throughout its entire shelf-life. **FOREST PHARMACEUTICALS** justified this stability overage on the basis that the USP monograph for levothyroxine sodium products indicated that the acceptable range for potency was between 90% and 110%. **FOREST PHARMACEUTICALS** interpreted that requirement to mean that it could release its product with excess active ingredient, as long as the excess was less than 110% of the strength represented on the label.

33. The FDA was aware that **FOREST PHARMACEUTICALS** was distributing levothyroxine drugs with stability overages and, in fact, stability overages were one of the reasons why the FDA imposed the new NDA requirements. While stability overages enabled manufacturers to extend their products' shelf-life artificially, stability overages also meant that manufacturers were distributing product that was super-potent. This presented problems as a patient with the exact same prescription could receive varying amounts of active ingredient over time, depending strictly upon the age of the drug received from the pharmacy. As a result, the FDA repeatedly advised various manufacturers, including **FOREST PHARMACEUTICALS**, that they would need to remove the stability overages from the formulation of their drugs in order to obtain NDA approval for their levothyroxine drugs.

34. Thus, **FOREST PHARMACEUTICALS** knew that it was going to have to overcome two substantial hurdles to obtain NDA approval of Levothroid : first, it needed to remove its stability overages (which in and of itself would cause the product to fail stability

testing even under ambient conditions); and second, it needed to reformulate Levothroid to make it more stable so that it would pass stability testing under the more rigorous ICH conditions.

D. The Levothroid NDA Submission

35. Despite this knowledge, **FOREST PHARMACEUTICALS** never ultimately met the FDA's requirements with respect to the Levothroid NDA. **FOREST PHARMACEUTICALS** repeatedly submitted data to the regulatory personnel at Forest Labs for inclusion in the NDA and in various amendments to the NDA that were based on Levothroid manufactured with stability overages. Moreover, **FOREST PHARMACEUTICALS** repeatedly submitted stability data to Forest Labs for inclusion in the NDA and various amendments to the NDA that purported to have been obtained under ICH conditions when, in fact, it was well-known by plant management personnel and others within **FOREST PHARMACEUTICALS'** Cincinnati plant (where the stability studies were conducted in a room called CRT-5) that serious equipment malfunctions in CRT-5 had resulted in humidity levels significantly below ICH conditions for extended periods of time totaling hundreds of days and thousands of hours. These "humidity excursions" resulted in testing results that misrepresented and overstated Levothroid's potency relative to its expiration date.

36. In an attempt to remedy these significant humidity excursions, on or around January 21, 2003, certain **FOREST PHARMACEUTICALS** management personnel at the Cincinnati plant decided to put a portable home humidifier in CRT-5 as a temporary fix to the humidity problem. **FOREST PHARMACEUTICALS** knew and understood that this temporary fix would not maintain the relative humidity in CRT-5 at ICH levels as the portable

humidifier, which required constant monitoring and refills of water, did not work effectively through the night or through an entire weekend.

COUNT ONE

(Obstruction of an Agency Proceeding
18 U.S.C. § 1505)

37. The allegations in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Between November 17, 2003, and December 3, 2003, the FDA conducted a regulatory inspection of **FOREST PHARMACEUTICALS'** facility in Cincinnati, Ohio pursuant to FDA's statutory inspection authority set forth at 21 U.S.C. § 374.

39. During this inspection, the FDA discovered a portable humidifier in CRT-5, the controlled room **FOREST PHARMACEUTICALS** used for its ICH stability studies in support of the Levothroid NDA. When the FDA investigators asked about this portable humidifier, certain **FOREST PHARMACEUTICALS** management personnel at the Cincinnati plant falsely stated that the portable humidifier was being stored in CRT-5 and falsely denied that the portable humidifier had ever been used for humidity control in CRT-5.

40. The following day, certain **FOREST PHARMACEUTICALS** management personnel at the Cincinnati plant admitted to the FDA investigators that the regular humidifier in CRT-5 was not functioning properly and that the portable humidifier had been used in CRT-5 to increase the humidity level in the room.

41. On or about November 17, 2003, in the Southern District of Ohio and elsewhere, the defendant,

FOREST PHARMACEUTICALS, INC.,

corruptly obstructed, impeded, and endeavored to influence the due and proper administration of the law under which a pending proceeding was being had before an agency of the United States, to wit, an inspection by the FDA of **FOREST PHARMACEUTICALS**, by causing the withholding and concealing of material information that was sought in the course of the FDA's regulatory inspection relating to the data submitted in support of NDA 21-125, Levothroid (levothyroxine sodium, USP) Tablets.

All in violation of 18 U.S.C. § 1505.

COUNT TWO

**(Distribution of an Unapproved New Drug
21 U.S.C. §§ 331(d), 333(a)(1) & 355(a))**

42. The allegations in paragraphs 1 through 29 are realleged and incorporated herein as if set forth in full.

A. FOREST PHARMACEUTICALS' Decision Not to Avail Itself of the Safe Harbor Created in the FDA Guidance

43. Although the FDA's Guidance document created a "safe harbor" through which manufacturers could continue distributing their unapproved levothyroxine drugs while their NDA was pending, **FOREST PHARMACEUTICALS** did not, at any time between in or about August 14, 2001, and in or about August 9, 2003, take any affirmative steps to comply with the Guidance's phase-down plan. Initially, **FOREST PHARMACEUTICALS** hoped that it would, through market forces alone, fall into compliance with the phase-down schedule. **FOREST PHARMACEUTICALS** also hoped that it would obtain NDA approval quickly and that the issue would simply fade away.

44. However, by in or about April 2002, it was clear to **FOREST PHARMACEUTICALS** that the Levothroid NDA was not going to be approved quickly. By in or about April 2002, **FOREST PHARMACEUTICALS** was aware of, among other things, the following facts:

a. In a letter dated January 11, 2002, FDA's Cincinnati District Office had advised Forest Labs that the District Office was recommending to FDA's Center for Drugs Evaluation and Research that it not approve the company's Levothroid NDA 21-125 because of manufacturing deficiencies identified during an inspection of **FOREST PHARMACEUTICALS'** Cincinnati plant that the FDA had conducted in October through December of 2001.

b. During a meeting in January 2002, individuals in the FDA's Cincinnati District Office informed **FOREST PHARMACEUTICALS** that there would be no additional warnings and that FDA might resort to legal action if the company did not remedy manufacturing deficiencies identified in its Cincinnati plant.

c. In a follow-up letter dated March 29, 2002, FDA advised **FOREST PHARMACEUTICALS** that some of its proposed remedies for its Cincinnati plant were inadequate. The problems identified by FDA were numerous and significant, and included the fact that certain Levothroid tablets manufactured by **FOREST PHARMACEUTICALS** had tested sub-potent.

45. Realizing that the FDA had identified only some, but not all, of the known manufacturing deficiencies at the Cincinnati plant, **FOREST PHARMACEUTICALS** did not want to draw further attention to the plant. Several individuals at **FOREST PHARMACEUTICALS** also were concerned that the company's continued failure to comply with the Guidance might bring renewed FDA attention to the Cincinnati plant. Accordingly, after receipt of FDA's January and March 2002 letters, **FOREST PHARMACEUTICALS** began reconsidering whether it should begin complying with FDA's phase-down schedule.

46. On or about April 18, 2002, **FOREST PHARMACEUTICALS** decided internally not to comply with the Guidance's phase-down schedule. In making this decision, **FOREST PHARMACEUTICALS** weighed the legal risk of non-compliance (i.e., enforcement action) against the financial risk of compliance (i.e., lost business), and decided to risk an FDA enforcement action rather than lose sales.

47. After April 2002, **FOREST PHARMACEUTICALS** did not reconsider whether to comply with phase-down. Instead, **FOREST PHARMACEUTICALS** continued distributing its unapproved Levothroid product at rates well over the levels established in the Guidance.

48. During an FDA regulatory inspection of **FOREST PHARMACEUTICALS'** Cincinnati plant beginning in January 2003, FDA investigators asked **FOREST PHARMACEUTICALS** to provide distribution figures for Levothroid. This request was motivated in part by the fact that the FDA had not received any quarterly Levothroid distribution information from the company since **FOREST PHARMACEUTICALS'** April 2002 decision not to comply with the phase-down schedule set forth in the Guidance.

49. On February 5, 2003, FDA investigators learned that **FOREST PHARMACEUTICALS** had deliberately chosen not to comply with, and had, in fact, not complied with, the phase-down schedule set forth in the Guidance.

B. FOREST PHARMACEUTICALS' Decision to Increase Production and Distribution of Levothroid

50. By the spring of 2003, **FOREST PHARMACEUTICALS** employees realized that the FDA was not likely to approve the pending Levothroid NDA before August 14, 2003. As a result, in or about May through in or about July 2003, **FOREST PHARMACEUTICALS** dramatically increased its manufacture of Levothroid and offered its customers special purchase terms in an attempt to induce customers to purchase enough unapproved Levothroid to satisfy demand for the several months between August 14, 2003, when **FOREST PHARMACEUTICALS** knew it would be required to stop commercially distributing Levothroid and a date later that year when it believed its NDA might be approved.

C. FOREST PHARMACEUTICALS' Continued Distribution of Levothroid after Receiving an FDA Warning Letter

51. On August 7, 2003, the FDA issued a Warning Letter to Forest Labs addressing two issues: (1) **FOREST PHARMACEUTICALS'** failure to limit its distribution of its

unapproved new drug Levothroid consistent with the phase-down schedule in the Guidance; and (2) multiple manufacturing problems that the FDA had identified during the January/February 2003 inspection at the Cincinnati plant where **FOREST PHARMACEUTICALS** manufactured Levothroid for commercial distribution.

52. The August 7, 2003 Warning Letter advised Forest Labs that the FDA inspectors had determined during their inspection that **FOREST PHARMACEUTICALS** "made a deliberate decision not to follow the agency's gradual phase-out plan that allows for the continued distribution of unapproved orally administered levothyroxine sodium products under limited circumstances." As a result, the FDA advised Forest Labs that "you are no longer entitled to the enforcement discretion granted by the agency, and are hereby on notice that the distribution of your unapproved product, Levothroid, remains in violation of Section 505 of the Act."

53. **FOREST PHARMACEUTICALS** received the Warning Letter by late morning on Friday, August 8, 2003. Rather than immediately stop Levothroid distribution, **FOREST PHARMACEUTICALS** – which had recently booked many large orders because of the special terms it was offering – instead directed its employees to continue shipping as much Levothroid product as possible. Throughout the day, **FOREST PHARMACEUTICALS** employees at the St. Louis distribution center placed a priority on filling Levothroid orders to the exclusion of filling orders for other drugs that typically would have had priority. Similarly, **FOREST PHARMACEUTICALS** employees overrode the computer system and placed a priority on filling the largest Levothroid orders first. **FOREST PHARMACEUTICALS** also made special arrangements to have its trucking carriers pick up extra trailers full of Levothroid shipments from

the St. Louis distribution center. In addition, **FOREST PHARMACEUTICALS** directed its second shift employees to work overtime that day and into the early hours of the following morning. At approximately 1:00 a.m. on August 9, 2003, **FOREST PHARMACEUTICALS** stopped packaging and shipping Levothroid drug product to its customers. By that time, **FOREST PHARMACEUTICALS** had filled the Levothroid orders for all of its primary larger customers.

54. Beginning as early as August 14, 2001, and continuing thereafter until on or about August 9, 2003, in the District of Massachusetts and elsewhere, the defendant,

FOREST PHARMACEUTICALS, INC.,

did introduce, deliver for introduction, and cause the introduction and delivery for introduction into interstate commerce into Massachusetts and elsewhere, of various quantities of Levothroid, a new drug within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(p), which was intended to treat hypothyroidism. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Levothroid for use in this condition or any other condition.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(1), and 355(a).

COUNT THREE

(Distribution of a Misbranded Drug: Inadequate Directions for Use 21 U.S.C. §§ 331(a), 333(a)(1) & 352(f)(1))

55. The allegations in paragraphs 1 through 14 are realleged and incorporated herein as if set forth in full.

FOREST PHARMACEUTICALS' OFF-LABEL PROMOTION OF CELEXA

56. Celexa was the brand name for the prescription drug citalopram, which was a selective serotonin reuptake inhibitor ("SSRI") drug. A Danish company developed Celexa and licensed Celexa to another subsidiary of Forest Labs for marketing in the United States.

57. In 1998, the FDA approved Celexa for the treatment of adult depression. The FDA never approved Celexa for treatment of any conditions other than adult depression, or for any use in children or adolescents.

58. In 1998, after the FDA approved Celexa for treatment of adult depression, **FOREST PHARMACEUTICALS** began promoting, distributing and selling Celexa throughout the United States, including in the District of Massachusetts.

59. From the outset, **FOREST PHARMACEUTICALS** was well-aware that the FDA had not approved Celexa for treatment of any conditions other than adult depression. Moreover, in or about April 2002, Forest Labs, in an attempt to obtain, *inter alia*, a pediatric indication for Celexa, submitted data to the FDA from two double-blinded, placebo-controlled studies involving the use of Celexa in children. One of these studies (hereafter referred to as the "Forest study"), which had been sponsored by Forest Labs, had been conducted in the United States. The Forest study had positive results, that is, the study indicated that Celexa was more

effective than placebo in treating pediatric patients suffering from depression. The other study (hereafter referred to as the "European study"), had been conducted in Europe and sponsored by the Danish company that developed and owned the rights to Celexa. The European study had negative results, that is, the study did not show Celexa to be any more effective than placebo in treating pediatric depression. On or about September 23, 2002, the FDA denied Forest Labs' request for a pediatric indication for Celexa, stating in part that the European study "is a clearly negative study that provides no support for the efficacy of citalopram in pediatric patients with [major depressive disorder]."

60. **FOREST PHARMACEUTICALS** was equally well-aware that promoting a drug product for indications other than those explicitly approved by the FDA was illegal. For example, in or about August 2000, a Regulatory Affairs employee at Forest Labs circulated a document entitled "Promotion Guidelines for Sales Representatives" and strongly recommended that the document be incorporated into sales training at **FOREST PHARMACEUTICALS**, along with a signature page for each representative to sign confirming that he or she had in fact been trained on permissible and impermissible sales promotion. This draft document made clear that off-label promotion was illegal: "Sales representatives should never initiate, or engage in, discussions about off-label uses or solicit these requests from physicians." The draft document explained that "Indications, dosing, or formulations that are not approved and are not part of the Package Insert have not met the regulatory testing requirements for safety and effectiveness and cannot be promoted as such by Forest." The draft document further affirmatively advised that **FOREST PHARMACEUTICALS** could not hire speakers to provide off-label discussions:

> Forest-organized product-related events are legally promotional in nature even if primarily designed as an educational event for healthcare professionals. If Forest sets the agenda and selects and pays the speaker, the event must abide by the same rules as if a Forest sales representative presented the information and must comply with all FDA promotional regulations. . . . The speaker must be advised prior to the presentation about his/her obligation to only address topics such as uses and doses that are within the approved labeling. Do not select a speaker with the intent that he/she will address off-label uses.

FOREST PHARMACEUTICALS did not adopt this draft document, nor did it for several years thereafter require sales representatives to sign a document that discussed the prohibition against off-label marketing.

61. Beginning in 1998 and continuing thereafter through at least September 2002, **FOREST PHARMACEUTICALS** promoted Celexa for use in treating children and adolescents suffering from depression, even though Celexa was not FDA-approved for pediatric use. **FOREST PHARMACEUTICALS'** off-label promotion consisted of various sales techniques including: (1) directing **FOREST PHARMACEUTICALS** sales representatives who promoted Celexa to make sales calls to physicians who treated children and adolescents; (2) promoting Celexa by various **FOREST PHARMACEUTICALS** sales representatives for use in children and adolescents; (3) hiring outside speakers to talk to pediatricians, child psychiatrists, and other medical practitioners who specialized in treating children and adolescents about the benefits of prescribing Celexa to that patient population; and (4) publicizing and circulating the positive results of the double-blind, placebo-controlled Forest study on the use of Celexa in adolescents while, at the same time, failing to discuss the negative results of the second double-blind, placebo-controlled European study on the use of Celexa in adolescents.

A. FOREST PHARMACEUTICALS Sales Representatives Promoted Celexa for Use in Children and Adolescents

62. **FOREST PHARMACEUTICALS** assigned its sales representatives to specific geographic regions throughout the United States. The sales representatives were supervised by Division Managers, who in turn were supervised by Regional Directors.

63. In order to identify the potential market for Celexa, **FOREST PHARMACEUTICALS** obtained data identifying medical practitioners who prescribed SSRIs. Using this data, **FOREST PHARMACEUTICALS** created "call panels," which were lists of medical practitioners who prescribed SSRIs. **FOREST PHARMACEUTICALS** directed its sales representatives to make sales calls promoting Celexa to the medical practitioners on the "call panels." These Celexa "call panels" included, among others, thousands of child psychiatrists and pediatricians who specialized in treating children and adolescents. **FOREST PHARMACEUTICALS** also directed its Celexa sales representatives to call on physicians who worked in the pediatric wards of hospitals.

64. During sales calls, various **FOREST PHARMACEUTICALS** sales representatives, acting at times with the knowledge and encouragement of their Division Managers and Regional Directors, promoted Celexa for use in treating not only adult patients suffering from depression, but also for use in treating children and adolescents who were suffering from depression. **FOREST PHARMACEUTICALS** sales representatives often documented these details through "call notes," thousands of which reflected off-label promotional activity directed at the use of Celexa in children and adolescents.

65. In certain regions of the country, including New England, various **FOREST PHARMACEUTICALS** Division Managers actively encouraged off-label promotion of Celexa for use in children and adolescents. In 2001, for example, a **FOREST PHARMACEUTICALS** Division Manager in Massachusetts distributed sample "opening statements" to various Celexa sales representatives. One of the "opening statements" recommended Celexa for treatment of "a female adolescent [who] presents with obsessive behavior, an[d] is neurotic about her eating habits, and gets really down on herself when she eats." A **FOREST PHARMACEUTICALS** Regional Director subsequently forwarded these sample opening statements to other **FOREST PHARMACEUTICALS** Division Managers and field sales personnel in the Northeast, with a copy to **FOREST PHARMACEUTICALS** national Vice President of Sales, and included a cover observation that "There are some good opening statements here."

66. Similarly, in February 2002, a different **FOREST PHARMACEUTICALS** Division Manager in Massachusetts required a **FOREST PHARMACEUTICALS** sales representative, as part of that representative's personal development plan, to prepare sample "closing statements" for various patient types, including children. After the sales representative provided these written closing statements to the **FOREST PHARMACEUTICALS** Division Manager (e.g., "I have provided you with some information on treating children with mood and anxiety disorders. . . . Will you prescribe [Celexa] to your pts in this pt population to gain more comfort and experience with it?"), the Division Manager commended the sales representative and forwarded the closing statements to a **FOREST PHARMACEUTICALS** Regional Director.

67. At various times and in New England, certain **FOREST PHARMACEUTICALS** Regional Directors and Division Managers provided their sales representatives with copies of posters and journal articles on studies of Celexa for use in children and adolescents and directed the sales representatives to read the studies, and use them as sales aids in their details to physicians. Various **FOREST PHARMACEUTICALS** Division Managers also directed sales representatives to show off-label studies to physicians, but not leave copies of those studies with the physicians so as to avoid detection that would get the sales representative and **FOREST PHARMACEUTICALS** in trouble.

B. FOREST PHARMACEUTICALS' Use of Outside Speakers to Promote Celexa for Use in Children and Adolescents

68. **FOREST PHARMACEUTICALS** sales representatives and Division Managers identified speakers from lists maintained and approved by **FOREST PHARMACEUTICALS** to organize promotional lunches and dinners as part of which speakers were paid to give a talk about Celexa. Certain of **FOREST PHARMACEUTICALS'** approved speakers were medical practitioners who specialized in treating children and adolescents suffering from depression, and **FOREST PHARMACEUTICALS** paid these practitioners to give promotional talks on the use of Celexa in children and adolescents. Various promotional programs for Celexa organized by **FOREST PHARMACEUTICALS** sales representatives explicitly focused on off-label pediatric and adolescent use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Assessment and Treatments of Suicidal Adolescents," "Treatment of Child/Adolescent Mood Disorders," "Treatments in Child Depression," "New Treatment Options in Depressive Disorders in Adolescents," "Use of Antidepressants in

Adolescents," "New Topics in the Treatment of Children with Depression," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children, Adolescents and Adults," "Celexa in CHP/Ped Practice," "Uses of Celexa in Children," "Treating Difficult Younger Patients,""Treating Pediatric Depression," and "Treating Adolescent Depression."

69. To obtain funding support for these promotional programs, **FOREST PHARMACEUTICALS** sales representatives were required to submit paperwork to their Division Managers describing the proposed program, identifying the medical practitioners who were to be invited to the program, and predicting the expected return on investment from the attendees – that is, the anticipated increase in the number of Celexa prescriptions resulting from the attendees' attendance at the program. **FOREST PHARMACEUTICALS** Division Managers and others within **FOREST PHARMACEUTICALS** consistently approved these requests for funding for promotional programs focusing on the use of Celexa in children and adolescents that were directed to child psychiatrists and other medical practitioners who specialized in treating children and adolescents.

C. FOREST PHARMACEUTICALS Communicated Incomplete and Potentially Misleading Information Concerning the Efficacy of Celexa in Treating Children and Adolescents

70. In or about mid-2001, Forest Labs learned of the positive results from the Forest study and the negative results from the European study, and Forest Labs shared these results with the FDA. Although both studies concerned the use of Celexa to treat children and adolescents suffering from depression, **FOREST PHARMACEUTICALS** treated the studies differently: **FOREST PHARMACEUTICALS** aggressively publicized and promoted the results from the positive Forest study, while at the same time **FOREST PHARMACEUTICALS** did not

publicize or disclose the results of the negative study to persons outside the FDA or the Danish company which sponsored the negative study. As a result, doctors and psychiatrists received incomplete and misleading information concerning all available known data pertaining to the efficacy of using Celexa to treat depression in children and adolescents. **FOREST PHARMACEUTICALS** communicated this incomplete and misleading information in, among others, the following ways: (1) via discussions that **FOREST PHARMACEUTICALS** sales representatives had with medical practitioners about the use of Celexa in treating children; (2) via promotional speeches made by pediatric specialists who were hired by **FOREST PHARMACEUTICALS** to talk about the use of Celexa in treating children and adolescents; and (3) via letters sent by **FOREST PHARMACEUTICALS** Professional Affairs Department to medical practitioners who had requested from **FOREST PHARMACEUTICALS** all available information and data concerning the use of Celexa in treating children and adolescents.

71. Beginning as early as 1998, and continuing thereafter through in or about December 2002, in the District of Massachusetts and elsewhere, the defendant,

FOREST PHARMACEUTICALS, INC.

did introduce, deliver for introduction, and cause the introduction and delivery for introduction into interstate commerce into Massachusetts and elsewhere, of various quantities of Celexa, a drug within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g), for unapproved use in pediatric and adolescent patients, which was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that Celexa's labeling lacked adequate direction for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1).

FORFEITURE ALLEGATIONS

1. Upon conviction of the violations of Title 21, United States Code, Sections 331(d), 333(a)(1), and 355(a), and Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) alleged in this information, defendant,

FOREST PHARMACEUTICALS, INC.,

shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c) the following:

(a) any quantities of Levothroid which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331 and/or 355(a); and

(b) any quantities of Celexa which were misbranded when introduced into interstate commerce or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), incorporated by reference in Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853 and Title 28, United States Code, Section 2461(c), and Rule 32.2 of the Federal Rules of Criminal Procedure.

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

TONY WEST
ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
U.S. DEPARTMENT OF JUSTICE

By: _____
JAMES E. ARNOLD
ASSISTANT U.S. ATTORNEY

_____ for
JEFFREY I. STEGER
TRIAL ATTORNEY
OFFICE OF CONSUMER LITIGATION

EXHIBIT B

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release (the "Settlement Agreement") is entered into by and among: the United States of America, acting through the United States Department of Justice on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), the Veterans' Affairs Administration ("VA"), and the United States Office of Personnel Management ("OPM") (collectively, the "United States"); Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc. (collectively, "Forest"); and Christopher Gobble, Joseph Piacentile, Constance Conrad, and Jim Conrad (collectively, the "Relators"). Collectively, all of the above will be referred to as the "Parties."

II. PREAMBLE

As a preamble to this Settlement Agreement, the Parties agree to the following:

A. At all relevant times, Forest Laboratories, Inc., was a Delaware corporation headquartered in New York, New York, and Forest Pharmaceuticals, Inc., a Delaware corporation headquartered in St. Louis, Missouri, was a wholly owned subsidiary of Forest Laboratories, Inc.

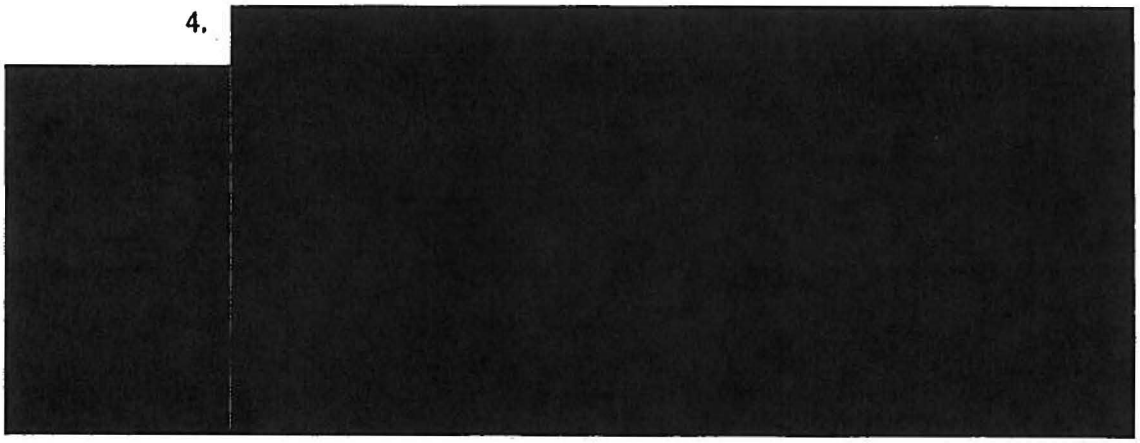
B. At all relevant times, Forest distributed, marketed, and sold pharmaceutical products in the United States, including the drugs sold under the trade names Celexa (generic name citalopram hydrobromide), Lexapro (generic name escitalopram oxalate), and Levothroid (generic name levothyroxine sodium tablets, USP).

C. The Relators listed herein have filed the following *qui tam* actions against Forest (collectively the "Civil Actions"):

1. *United States ex rel. Christopher R. Gobble, et al. v. Forest Laboratories, Inc. & Forest Pharmaceuticals, Inc.*, Civil Action No. 03–10395–NMG (D. Mass.) (the "Gobble *qui tam* action");

2. *United States ex rel. Joseph Piacentile, et al. v. Forest Laboratories, Inc.*, Civil Action No. 05–10201–NMG (D. Mass.) (the "Piacentile *qui tam* action");

3. *United States ex rel. Constance Conrad v. Forest Pharmaceuticals, Inc., et al.*, Civil Action No. 02–11738–NG (D. Mass.) (the "Conrad *qui tam* action"); and

4. 

D. The United States intervened in the Gobble *qui tam* action and the Piacentile *qui tam* action on November 14, 2008. The District of Columbia and the states of California, Delaware, Florida, Illinois, Massachusetts, Michigan, New York, Oklahoma, Texas, Virginia, and Wisconsin filed notices of intervention in those actions on February 13, 2009. The United

States filed its Complaint in Intervention in those actions (the "United States Complaint in Intervention") on February 13, 2009.

E. On such date as may be determined by the Court, Forest Pharmaceuticals, Inc. ("FPI") will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information, attached as Exhibit A to a plea agreement into which FPI is entering simultaneously with the execution of this Settlement Agreement, to be filed in *United States of America v. Forest Pharmaceuticals, Inc.*, Criminal Action No. [to be assigned] (D. Mass.) (the "Criminal Action").

F. The United States alleges that Forest caused claims for payment for the drugs Celexa, Lexapro, and Levothroid to be submitted to the Medicaid program, 42 U.S.C. §§ 1396–1396w–5, the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services), 10 U.S.C. §§ 1071–1110a, and the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901–8914, and that Forest caused the VA to purchase those drugs (collectively "the Federal Health Care Programs").

G. The United States contends that it and the Medicaid Participating States (as defined below) have certain civil claims against Forest, as specified below, for engaging in the following alleged conduct (hereinafter referred to as the "Covered Conduct"):

1. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs by promoting the sale and use of Celexa and Lexapro to physicians for pediatric uses (including by disseminating false and misleading information about the safety and efficacy of Celexa and Lexapro in treating pediatric patients), as set forth in the

United States Complaint in Intervention, when those uses were not approved by the Food and Drug Administration ("FDA"), were not medically accepted indications (as defined by 42 U.S.C. § 1396r–8(k)(6)), and were not covered by Federal Health Care Programs.

2. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs and caused the VA to purchase those drugs by offering and paying illegal remuneration to physicians as set forth in the United States Complaint in Intervention to induce the physicians to promote and to prescribe Celexa and Lexapro, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a–7b(b)(2).

3. During the period August 2001 through December 2005, Forest knowingly caused false or fraudulent claims to be submitted to the Federal Health Care Programs and caused purchases by the VA through its distribution of a drug, Levothroid, that did not qualify as a covered outpatient drug (as defined in 42 U.S.C. § 1396r–8(k)(2)). In 1997, FDA determined that oral levothyroxine sodium products, including Levothroid, were "new drugs." FDA later announced that it would exercise its discretion not to take enforcement action against a manufacturer for distribution of an unapproved oral levothyroxine sodium product if, among other things, the manufacturer phased down distribution of its unapproved oral levothyroxine sodium product over a two-year period following August 14, 2001. Notwithstanding FDA's announcement, Forest increased distribution of its unapproved oral levothyroxine sodium product, Levothroid, after August 14, 2001, and failed to advise CMS that unapproved Levothroid no longer qualified as a covered outpatient drug under 42 U.S.C. § 1396r–8(k)(2).

H. The United States also contends that it has certain administrative claims against Forest for engaging in the Covered Conduct.

I. Forest has entered into or will be entering into separate settlement agreements, described in Paragraph III.1(b) below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Forest executes a Medicaid State Settlement Agreement in the form to which Forest and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by Forest and an individual state, shall be defined as "Medicaid Participating States."

J. This Settlement Agreement is made in compromise of disputed claims. This Settlement Agreement is neither an admission of facts or liability by Forest, nor a concession by the United States that its claims are not well-founded. Forest expressly denies the contentions and allegations of the United States and Relators as set forth herein and in the Civil Actions and denies that it engaged in any wrongful conduct, except as to such admissions that FPI is required to make under the terms of the plea agreement into which FPI is entering simultaneously with the execution of this Settlement Agreement. Neither this Settlement Agreement or its execution, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by any party to this Settlement Agreement.

K. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Settlement Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Subject to the terms and conditions set forth below, Forest agrees to pay to the United States and the Medicaid Participating States, collectively, the total amount of $149,158,057.66 in principal, plus interest as described herein ("Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States as follows:

a. Forest shall pay to the United States the principal sum of $88,833,560.18 plus interest accrued on that sum at a rate of 3.25% per annum, beginning June 1, 2009, and continuing through the day before full payment ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States. Forest shall make this electronic funds transfer no later than seven business days after the Effective Date of this Settlement Agreement.

b. Forest shall deposit the principal sum of $60,324,497.48 plus interest accrued on that sum at a rate of 3.25% per annum, beginning June 1, 2009, and continuing through the day before such deposit ("State Settlement Amount"), into one or more interest-bearing money market or bank accounts held in the name of Forest but segregated from other Forest accounts (the "State Settlement Accounts"), and shall administer funds from those accounts pursuant to terms and conditions to be agreed upon by Forest and the NAMFCU Negotiating Team and as set forth in the individual Medicaid State Settlement Agreements. Forest shall make this deposit on a date to be agreed with the NAMFCU Negotiating Team. Funds not released to Medicaid Participating States and remaining in the State Settlement Accounts at the conclusion of the State settlement process agreed upon by Forest and the NAMFCU Negotiating Team shall, together with any accrued interest thereon, revert to Forest at the conclusion of the State settlement process and shall thereupon be deducted from the amount referred to herein as the Settlement Amount.

c. Contingent upon the United States receiving the Federal Settlement Amount from Forest and as soon as feasible after receipt, the United States agrees to pay the following Relators the following amounts plus their proportionate share of interest accrued on the Federal Settlement Amount described in (a) above as Relator's Share of the proceeds pursuant to 31 U.S.C. § 3730(d):

(1) Christopher Gobble: $10,948,312;

(2) Joseph Piacentile (by agreement, Piacentile's share shall be included in Gobble's Relator Share above); and

(3) Constance Conrad: $3,664,758.

All Relators in the Civil Actions listed in Preamble Paragraph C, above, represent and agree that no other Relator payments shall be made, due, or owed by the United States with respect to the matters covered by this Agreement.

2. Forest agrees to pay Relators' attorneys' fees and costs, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms set forth in separate agreements being entered into simultaneously with the execution of this Settlement Agreement with each of Relator Gobble, Relator Piacentile, and Relators Constance Conrad and Jim Conrad.

3. Subject to the exceptions in Paragraph III.8, below, in consideration of the obligations of Forest set forth in this Settlement Agreement, and conditioned upon Forest's full payment of the Settlement Amount in accordance with the terms of Paragraph III.1, above, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Forest, its predecessors, and its current and former divisions, parents, affiliates, subsidiaries, successors and assigns, and their current and former directors, officers, and employees from any civil or administrative monetary claim that the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a–7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812, any statutory provision creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d), and

common law claims for fraud, disgorgement, payment by mistake, breach of contract and unjust enrichment.

4. In consideration of the obligations of Forest set forth in this Settlement Agreement, and conditioned upon Forest's full payment of the Settlement Amount in accordance with the terms of Paragraph III.1, above, Relators, for themselves and for their heirs, successors, attorneys, agents, assigns, and any other person or entity acting on their behalf or asserting their rights, agree to dismiss with prejudice any currently pending claims against Forest in any federal or state court or in any other forum, and fully and finally release, waive and forever discharge Forest, its predecessors, and its current and former divisions, parents, subsidiaries, affiliates, successors and assigns, and their current and former directors, officers, and employees from any claims or allegations that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729–3733, for the Covered Conduct, and from all liability, claims, allegations, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or under common law or that they otherwise would have standing to bring, including, without limitation, any claim that the Relators asserted or could have asserted in the Civil Actions, and, conditioned upon receipt of payment for attorneys' fees and costs as contemplated in Paragraph III.2, above, any claims they might assert for expenses, attorneys' fees, and costs under 31 U.S.C. § 3730(d) or any similar federal or state statute; provided, however, that this Agreement does not resolve Relator Gobble's claims for retaliatory discharge and associated fees and expenses pursuant to 31 U.S.C. § 3730(h), which are explicitly preserved in the Stipulation of Dismissal described in

Paragraph III.19 below, and Forest reserves any claims or defenses that it may assert relating in any way to such claims.

5. In consideration of the obligations of Forest set forth in this Settlement Agreement and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Forest Laboratories, Inc., and conditioned upon Forest's full payment of the Settlement Amount in accordance with the terms of Paragraph III.1, above, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a–7b(f)) against (a) Forest under 42 U.S.C. § 1320a–7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a–7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph III.8 (concerning excluded claims), below, and as reserved in this Paragraph; or (b) FPI under 42 U.S.C. § 1320a–7(b)(1) (permissive exclusion for conviction relating to fraud) based on FPI's agreement to plead guilty to the charges in the Criminal Action referenced in Preamble Paragraph E, except as reserved in Paragraph III.8 (concerning excluded claims), below, and as reserved in this Paragraph. OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Forest from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a–7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph III.8, below.

6. In consideration of the obligations of Forest set forth in this Settlement Agreement, and conditioned upon Forest's full payment of the Settlement Amount in accordance with the terms of Paragraph III.1, above, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Forest under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph III.8 (concerning excluded claims), below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude Forest from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph III.8, below.

7. In consideration of the obligations of Forest set forth in this Settlement Agreement, and conditioned upon Forest's full payment of the Settlement Amount in accordance with the terms of Paragraph III.1, above, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion against Forest under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph III.8 (concerning excluded claims), below, and except if excluded by OIG-HHS pursuant to 42 U.S.C. § 1320a–7(a). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph III.8, below.

8. Notwithstanding any term of this Settlement Agreement, the United States specifically does not release hereby any person or entity (including Forest and Relators) from any of the following claims or liabilities:

a. Any civil, criminal, or administrative liability arising under Title 26, United States Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Settlement Agreement, any administrative liability, including mandatory exclusion from Federal Health Care Programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon such obligations as are created by this Settlement Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due; and

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. Relators and their heirs, successors, attorneys, agents, and assigns agree not to object to this Settlement Agreement and agree and confirm that this Settlement Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waive the opportunity for a hearing on any objections to this

Settlement Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon receipt of his or her Relator's Share, each Relator, for himself/herself individually, and for his/her heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730, from any claims arising from the filing of the Civil Actions, and from any other claims for a share of the Settlement Amount, and in full settlement of any claims Relators may have under this Settlement Agreement. Relator Gobble's claims for damages, costs, and attorney's fees from Forest pursuant to 31 U.S.C. § 3730(h) are not waived or released and shall survive the execution of this Settlement Agreement. This Settlement Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relators arising under Title 26, United States Code (Internal Revenue Code), or any claims arising under this Settlement Agreement.

10. Forest waives and shall not assert any defenses Forest may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal or administrative action. Nothing in this Paragraph or any other provision of this Settlement Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

11. Forest fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Forest has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution of civil claims arising out of or in connection with the Covered Conduct.

12. Forest fully and finally releases the Relators from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Forest has asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct or the Relators' investigation and prosecution thereof, but expressly reserves any claims or defenses Forest may assert relating in any way to the claims set forth in the Gobble *qui tam* action that are not dismissed pursuant to the Stipulations of Dismissal described in Paragraph III.19 below.

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, any TRICARE, FEHBP, or VA carrier, or any state payer, related to the Covered Conduct; and Forest shall not resubmit to any Medicare carrier or intermediary, any TRICARE, FEHBP, or VA carrier, or any state payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.

14. Forest agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205–47, in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395–1395iii and 1396–1396w–1, and in the regulations and official program directives promulgated thereunder) incurred by or on behalf of Forest, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, FEHBP, and VA health care program:

(1) the matters covered by this Settlement Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Settlement Agreement;

(3) Forest's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Settlement Agreement (including attorneys' fees);

(4) the negotiation and performance of this Settlement Agreement;

(5) the payment Forest makes to the United States pursuant to this Settlement Agreement and any payments that Forest may make to Relators, including costs and attorney's fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to:

(i) retain an independent review organization to perform annual reviews as described in Section III.D of the CIA; and

(ii) prepare and submit reports to the OIG-HHS.

However, nothing in this paragraph III.14.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Forest. (All costs described or set forth in this Paragraph III.14.a. are hereinafter "Unallowable Costs.")

b. Future Treatment of Unallowable Costs: These Unallowable Costs shall be separately determined and accounted for by Forest, and Forest shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Forest or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, FEHBP, or VA Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Forest further agrees that, within 90 days of the Effective Date of this Settlement Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, FEHBP, and VA fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Forest or any of its

subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Forest agrees that the United States, at a minimum, shall be entitled to recoup from Forest any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after any such adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Forest or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Forest or any of its subsidiaries' or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Settlement Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Forest's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. Forest agrees to cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Settlement Agreement. Upon reasonable notice, Forest shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to

make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals.

16. This Settlement Agreement is intended to be for the benefit of the Parties only. Other than as set forth in this Settlement Agreement, the Parties do not release any claims against any other person or entity.

17. Forest agrees that it waives and shall not seek payment for any of the health care billings covered by this Settlement Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

18. Forest warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Forest, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Forest was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

19. Upon receipt of the payments described in Paragraph III.1, above, the United States will file a Notice of Intervention in the Conrad *qui tam* action wherein the United States will intervene as to claims asserted against Forest concerning the Covered Conduct, and the Parties will file Stipulations of Dismissal, in the form attached hereto as Attachments 1 and 2, (a) with prejudice as to the United States' claims as to the Covered Conduct as to Forest in each of the Gobble *qui tam* action, the Piacentile *qui tam* action, and the Conrad *qui tam* action, and with prejudice as to the United States' Complaint in Intervention in its entirety, (b) without prejudice as to the United States as to all other claims in each of the Gobble *qui tam* action, the Piacentile *qui tam* action, and the Conrad *qui tam* action, and (c) with prejudice as to the Relators' claims in each of the Gobble *qui tam* action, the Piacentile *qui tam* action, and the Conrad *qui tam* action (provided, however, that Gobble's retaliatory termination claims pursuant to 31 U.S.C. § 3730(h) shall be preserved). If the Court enters Orders of Dismissal that differ from the proposed Orders of Dismissal attached hereto as Attachments 1 and 2, the Parties agree to take all reasonable and necessary steps to seek modifications of the entered Orders to conform with the attached Orders of Dismissal.

20. As soon as practicable after the Effective Date of this Settlement Agreement, Relators Constance Conrad and Jim Conrad agree to take all necessary actions to secure the dismissal with prejudice of all claims asserted against Forest, its predecessors, and/or its current and former divisions, parents, subsidiaries, affiliates, successors and assigns and/or their current and former directors, officers, and employees in the Civil Actions listed in Paragraph II.C.4, above.

21. Except as expressly provided to the contrary in this Settlement Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Settlement Agreement.

22. Forest represents that this Settlement Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

23. Relators represent that this Settlement Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

24. This Settlement Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Settlement Agreement is the United States District Court for the District of Massachusetts, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

25. For purposes of construction, this Settlement Agreement shall be deemed to have been drafted by all Parties to this Settlement Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

26. This Settlement Agreement constitutes the complete agreement between the Parties with respect to the Covered Conduct. This Settlement Agreement may not be amended except by written consent of the Parties.

27. The individuals signing this Settlement Agreement on behalf of Forest represent and warrant that they are authorized by Forest to execute this Settlement Agreement. The individuals signing this Settlement Agreement on behalf of Relators represent and warrant that

they are authorized by Relators to execute this Settlement Agreement. The United States signatories represent that they are signing this Settlement Agreement in their official capacities and that they are authorized to execute this Settlement Agreement.

28. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Settlement Agreement. Facsimiles of signatures and/or electronic signatures in portable document format (.pdf) shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

29. This Settlement Agreement is binding on Forest's successors, transferees, heirs, and assigns.

30. This Settlement Agreement is binding on Relators' successors, transferees, heirs, and assigns.

31. All parties consent to the disclosure of this Settlement Agreement, and information about this Settlement Agreement, to the public on or after the Effective Date.

32. As used in this Settlement Agreement, the "Effective Date" shall mean the date of the signature of the last signatory to the Settlement Agreement.

THE UNITED STATES OF AMERICA

DATED:_____ **BY:** _____

JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/15/10 **BY:** _____

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

DATED:_____ **BY:** _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: 9/15/2010 **BY:** _____

JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____ **BY:** _____

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

DATED:_____ **BY:** _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED:_____ **BY:** _____

JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____ **BY:** _____

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

DATED: 9/15/10 **BY:** _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 14 Sep 2010 BY: _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: _____ BY: _____

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
United States Office of Personnel Management

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ **BY:** _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 9/14/10 **BY:** Shirley R. Patterson

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
United States Office of Personnel Management

9/15/10

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

FOREST LABORATORIES, INC. & FOREST PHARMACEUTICALS, INC. - DEFENDANTS

DATED: 9/14/2010 **BY:** _____

HERSCHEL S. WEINSTEIN
Vice President - General Counsel
Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022

DATED: 9/14/2010 **BY:** _____

MARY JO WHITE
CHRISTOPHER K. TAHBAZ
ANDREW J. CERESNEY
KRISTIN D. KIEHN
Debevoise & Plimpton LLP
919 Third Avenue
New York, NY 10022

CHRISTOPHER R. GOBBLE - RELATOR

DATED: 9/14/10 **BY:** Marlan B. Wilbanks /SED

MARLAN B. WILBANKS
Wilbanks & Bridges LLP
3414 Peachtree Rd., NE, Suite 1075
Atlanta, GA 30326

DATED: 9/14/10 **BY:** Philip S. Marstiller /SED

PHILIP S. MARSTILLER
Philip S. Marstiller, P.C.
16 Second Street
Richmond, VA 23219

DATED: 9/14/10 **BY:** Suzanne E. Durrell

SUZANNE E. DURRELL
Durrell Law Office
180 Williams Ave.
Milton, MA 02186

DR. JOSEPH PIACENTILE - RELATOR

DATED:_____ **BY:** _____

DAVID S. STONE
Stone & Magnanini, LLP
150 John F. Kennedy Parkway, 4th Floor
Short Hills, NJ 07078

CHRISTOPHER R. GOBBLE - RELATOR

DATED:_____ **BY:** _____

MARLAN B. WILBANKS
Wilbanks & Bridges LLP
3414 Peachtree Rd., NE, Suite 1075
Atlanta, GA 30326

DATED:_____ **BY:** _____

PHILIP S. MARSTILLER
Philip S. Marstiller, P.C.
16 Second Street
Richmond, VA 23219

DATED:_____ **BY:** _____

SUZANNE E. DURRELL
Durrell Law Office
180 Williams Ave.
Milton, MA 02186

DR. JOSEPH PIACENTILE - RELATOR

DATED: 9/14/2010 **BY:** _____

DAVID S. STONE
Stone & Magnanini, LLP
150 John F. Kennedy Parkway, 4th Floor
Short Hills, NJ 07078

CONSTANCE CONRAD AND JIM CONRAD - RELATORS

DATED: 9/14/10 **BY:** _____

KENNETH J. NOLAN
MARCELLA AUERBACH
Nolan & Auerbach, P.A.
435 North Andrews Avenue
Suite 401
Ft. Lauderdale, FL 33301

DATED:_____ **BY:** _____

JOHN RODDY
Roddy, Klein & Ryan
727 Atlantic Ave., 2d Floor
Boston, MA 02111

CONSTANCE CONRAD AND JIM CONRAD - RELATORS

DATED:_____ **BY:**_____

KENNETH J. NOLAN
MARCELLA AUERBACH
Nolan & Auerbach, P.A.
435 North Andrews Avenue
Suite 401
Ft. Lauderdale, FL 33301

DATED: 9/14/10 **BY:**_____

JOHN RODDY
Roddy, Klein & Ryan
727 Atlantic Ave., 2d Floor
Boston, MA 02111

EXHIBIT C

U.S. Department of Justice

United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

United States Courthouse, Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210

July 20, 2010

Christopher K. Tahbaz, Esq.
Andrew J. Ceresney, Esq.
Debevoise & Plimpton LLP
919 Third Avenue
New York, NY 10022

Re: Forest Laboratories, Inc.: Tolling Agreement on Statute of Limitations

Dear Counsel:

This letter confirms and sets forth an agreement between the Office of the United States Attorney for the District of Massachusetts and your client, Forest Laboratories, Inc., and its present and former divisions and subsidiaries (hereafter "Forest"). The terms of the agreement are as follows:

1. As you are aware, this Office and the Civil Division of the Department of Justice currently are conducting a joint criminal and civil investigation of your client, Forest, and its officers, employees, and agents. The conduct being investigated includes, without limitation, the possible violation by Forest and certain of its officers, employees, and agents of various federal criminal statutes, including, but not limited to, 18 U.S.C. § 371 (conspiracy to defraud the United States), 42 U.S.C. § 1320a-7b (criminal penalties for acts involving the Medicare and State health care programs), 18 U.S.C. § 1001 (making false or fraudulent statements), 21 U.S.C. §§ 301, et seq. (Food Drug & Cosmetic Act), mail and/or wire fraud (18 U.S.C. §§ 1341, 1343), health care fraud offenses (e.g., 18 U.S.C. §§ 669, 1035, 1347), and certain civil statutes including, but not limited to, 31 U.S.C. § 3729 (civil False Claims Act) and 42 U.S.C. § 1396r-8 (Medicaid drug rebate statute), by (a) directly or indirectly offering or paying remuneration to customers, including, but not limited to, physicians, physician practice groups, pharmacies, and hospitals to induce those entities or individuals to recommend, prescribe, and/or purchase Forest's pharmaceutical products; (b) introducing or delivering for introduction into interstate commerce unapproved, adulterated, and/or misbranded drugs; (c) making false or fraudulent statements to, and/or concealing material information from, the Food and Drug Administration; (d) promoting, marketing and selling pharmaceutical products in violation of law; (e) fraud on various federal programs and private insurers through knowingly causing unnecessary,

expensive, and ineffective treatment of patients with particular anti-depressant drugs; and (f) making false or fraudulent statements to, and/or concealing material information from, Congress. This Office has reached no conclusion on whether Forest has engaged in any of the violations of law described in this paragraph, or any other violations of law.

2. In the course of our discussions, this Office has expressed its intention to afford you and your client the fullest opportunity to provide information to this Office which you deem relevant to matters relating to the investigation. In response, you have advised us that you intend to provide certain information to this Office, and that you wish such information to be considered prior to a prosecution decision concerning potential criminal and civil charges resulting from that investigation. Toward that end, you have advised this Office that you and members of your firm will require a further time period to prepare any materials and gather information for presentation to this Office. As a result, this Office and your client have agreed, as more fully set forth below, (1) to toll the applicable statutes of limitations for the time period July 21, 2006 (the date set forth in the first statute of limitations tolling agreement executed by you and your client), through and including October 1, 2010, for the conduct noted in subsections (a) - (e) of paragraph one, and (2) to toll the applicable statutes of limitations for the time period June 24, 2009, through and including October 1, 2010, for the conduct noted in subsection (f) of paragraph one.

3. With respect to any federal violation related to the conduct described in subsections (a) - (e) of paragraph one: Your client, Forest, hereby agrees that it will not at any time interpose a statute of limitations defense that includes the time period from July 21, 2006, through October 1, 2010, in the calculation of the limitations period as to any indictment, information, or count thereof, to any civil complaint filed by or on behalf of the United States government (or any branch thereof), or count thereof, or to any administrative action -- any of which charge your client or alleges your client committed any federal violation related to the conduct described in subsections (a) - (e) of paragraph one. Similarly, Forest agrees not to plead, argue, or otherwise raise any defense based upon pre-indictment delay, laches, estoppel or other similar defenses or time limitations (whether constitutional, statutory, contractual, or otherwise) based upon pre-charging delay that includes the time period from July 21, 2006, through October 1, 2010, as part of the defense. By entering into this tolling agreement, Forest does not admit any liability in connection with any matter and reserves its right to raise any and all defenses, except as limited by this paragraph. Forest specifically reserves its right to assert the defense that any limitations periods applicable to one or more of the matters identified in subsections (a) - (e) of paragraph one expired prior to July 21, 2006.

4. With respect to any federal violation related to the conduct described in subsection (f) of paragraph one: Your client, Forest, also hereby agrees that it will not at any time interpose a statute of limitations defense that includes the time period from June 24, 2009, through October 1, 2010, in the calculation of the limitations period as to any indictment, information, or count thereof, to any civil complaint filed by or on behalf of the United States government (or any branch thereof), or count thereof, or to any administrative action -- any of which charge your client or alleges your client committed any federal violation related to the

conduct described in subsection (f) of paragraph one. Similarly, Forest agrees not to plead, argue, or otherwise raise any defense based upon pre-indictment delay, laches, estoppel or other similar defenses or time limitations (whether constitutional, statutory, contractual, or otherwise) based upon pre-charging delay that includes the time period from June 24, 2009, through October 1, 2010, as part of the defense. By entering into this tolling agreement, Forest does not admit any liability in connection with any matter and reserves its right to raise any and all defenses, except as limited by this paragraph. Forest specifically reserves its right to assert the defense that any limitations periods applicable to subsection (f) of paragraph one expired prior to June 24, 2009.

5. Your client, Forest, enters into this agreement knowingly and voluntarily. Forest acknowledges that the statute of limitations and the United States Constitution regarding prejudicial pre-indictment delay confers benefits on it, and it is not required to waive those benefits, and that Forest is doing so after consulting with you because Forest believes it is in its best interest to do so. Forest also acknowledges its understanding that it may be charged with the foregoing offenses or violations and/or any other offenses at any time prior to and including October 1, 2010. Forest further acknowledges its understanding that it may be charged with any criminal or civil offenses for conduct not specifically described above at any time during the relevant statute of limitations period. Your client also acknowledges that by signing this agreement, it is waiving any argument that it may have that (1) the Government may, in any way, have breached any prior Statute of Limitations Waiver Agreements executed between this Office and your client in connection with this investigation that remain effective as of this date, or (2) that any such breach may provide it with any defense to any charges arising out of the conduct described in paragraph one that may be brought against it.

6. This agreement relates only to the conduct referred to in paragraph one above. This writing contains the entire agreement between this Office and your client and can be modified or supplemented only by means of a writing signed by this Office and your client.

If your client is willing to enter into this agreement on the terms set forth above, you and Forest should indicate the same by signing on the spaces provided below. Please return an executed original to the undersigned by Wednesday, July 28, 2010.

Very truly yours,

CARMEN M. ORTIZ
United States Attorney

By: _____
JAMES E. ARNOLD
Assistant U.S. Attorney

I, Howard Solomon, am Chairman of the Board of Forest Laboratories, Inc. ("Forest"), and I hereby acknowledge that I have read this letter in full. I am entering into this agreement freely and voluntarily after consultation with Forest's attorney, who also has signed below. I hereby disclose and represent that I am duly authorized by the Board of Directors of Forest to enter into this agreement on behalf of that corporation.

_____ Dated: _____

HOWARD SOLOMON
Chairman of the Board
Forest Laboratories, Inc.

_____ Dated: August 4, 2010

CHRISTOPHER K. TAHBAZ, ESQ.
ANDREW J. CERESNEY, ESQ.
Debevoise & Plimpton LLP
Attorneys for Forest Laboratories, Inc.

EXHIBIT D

U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

AUG 17 2010

The Honorable Carmen Milagros Ortiz
United States Attorney
District of Massachusetts
1 Courthouse Way
John Joseph Moakley Courthouse
Boston, MA 02210

Attention: James Arnold
Assistant United States Attorney

Re: Global Non-Prosecution Agreement for Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc.

Dear Ms. Ortiz:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entities known as Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc.

I hereby approve the terms of the plea agreement with Forest Pharmaceuticals, Inc., including Paragraphs 5 and 15, and the Side Letter Agreement with Forest Laboratories, Inc., including Paragraphs 1 and 3, in which the United States Attorney's Offices and, with the exception of the Fraud Section, the Criminal Division of the Department of Justice agree not to initiate further criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Lanny A. Breuer
Assistant Attorney General

John C. Keeney
John C. Keeney
Deputy Assistant Attorney General
Criminal Division

EXHIBIT E

ACKNOWLEDGMENT OF AGREEMENT

The Board of Directors of Forest Pharmaceuticals, Inc. (the "Board") has directed and authorized the officers of Forest Pharmaceuticals, Inc., or their authorized representatives, to execute this Plea Agreement on behalf of Forest Pharmaceuticals, Inc., and to take all such actions as may be necessary to effectuate this Plea Agreement. The Board has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement including all attachments in their entirety and has discussed them fully in consultation with Forest's attorney. The Board acknowledges that these documents fully set forth Forest's agreement with the United States. The Board further states that no additional promises or representations have been made to Forest by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: 9/15/2010

HERSCHEL S. WEINSTEIN
General Counsel
Forest Laboratories, Inc.

Dated: _____

Mary Jo White, Esq.
Christopher K. Tahbaz, Esq.
Andrew J. Ceresney, Esq.
Kristin D. Kiehn, Esq.
Debevoise & Plimpton LLP
Counsel for Defendant

ACKNOWLEDGMENT OF AGREEMENT

The Board of Directors of Forest Pharmaceuticals, Inc. (the "Board") has directed and authorized the officers of Forest Pharmaceuticals, Inc., or their authorized representatives, to execute this Plea Agreement on behalf of Forest Pharmaceuticals, Inc., and to take all such actions as may be necessary to effectuate this Plea Agreement. The Board has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement including all attachments in their entirety and has discussed them fully in consultation with Forest's attorney. The Board acknowledges that these documents fully set forth Forest's agreement with the United States. The Board further states that no additional promises or representations have been made to Forest by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: _____

HERSCHEL S. WEINSTEIN
General Counsel
Forest Laboratories, Inc.

Dated: 9/15/10

Mary Jo White, Esq.
Christopher K. Tahbaz, Esq.
Andrew J. Ceresney, Esq.
Kristin D. Kiehn, Esq.
Debevoise & Plimpton LLP
Counsel for Defendant

EXHIBIT F

FOREST PHARMACEUTICALS, INC.

SECRETARY'S CERTIFICATE

I, Lawrence S. Olanoff, do hereby certify that I am Secretary of Forest Pharmaceuticals, Inc. (the "Company"), and do hereby further certify that:

Attached hereto as Annex A is a true, correct, and complete copy of resolutions adopted by the Unanimous Written Consent of the Board of Directors of the Company as of September 14, 2010. Such resolutions have not been modified, amended, or rescinded and remain in full force and effect as of the date hereof.

IN WITNESS WHEREOF, I have executed this Certificate on behalf of the Company on this 15th day of September 2010.

FOREST PHARMACEUTICALS, INC.

By: _____
Name: Lawrence S. Olanoff
Title: Secretary

ANNEX A

RESOLUTIONS OF THE BOARD OF DIRECTORS OF

FOREST PHARMACEUTICALS, INC.

SEPTEMBER 14, 2010

WHEREAS, the United States Attorney's Office for the District of Massachusetts and the Department of Justice, Office of Consumer Litigation, have been conducting an investigation into the Company's conduct relating to its manufacture, distribution, and promotion of its pharmaceutical products Levothroid, Celexa, and Lexapro;

WHEREAS, the Board of Directors has consulted with legal counsel in connection with this matter;

WHEREAS, the Company's legal counsel has been negotiating a resolution of this matter;

WHEREAS, the Company's legal counsel has reported to the Board of Directors the terms and conditions of a proposed resolution of this matter;

WHEREAS, the Board of Directors has reviewed the contents of the Information and Plea Agreement (collectively, the "Plea Documents") in this matter;

WHEREAS, the Board of Directors has reviewed the contents of the proposed Settlement Agreement and Release and State Settlement Agreement in this matter;

NOW THEREFORE, BE IT:

RESOLVED, that the Company is hereby authorized and directed to enter into the Plea Agreement between the United States Attorney for the District of Massachusetts and Forest Pharmaceuticals, Inc.

FURTHER RESOLVED, that the Company is authorized and directed to plead guilty to the charges specified in the Information.

FURTHER RESOLVED, that the Company is authorized and directed to enter into the Settlement Agreement and Release and settlement agreements with individual States as contemplated by the Settlement Agreement and Release and the State Settlement Agreement.

FURTHER RESOLVED, that the Officers of the Company, or their authorized representatives (specifically including but not limited to Herschel S. Weinstein, Esq., Vice President – General Counsel of FLI), are hereby authorized and directed to take all

actions and deliver any agreements, certificates, and documents and instruments with respect to or contemplated by the Agreements (including such agreements and instruments as may be necessary or advisable to complete the dismissal of certain *qui tam* litigation referred to in the Settlement Agreement and Release) and matters set forth above, including, without limitation, the payment of all amounts, fees, costs, and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the resolutions contemplated hereby.

FURTHER RESOLVED, that the Officers of the Company, or their authorized representatives (specifically including but not limited to Vice President – General Counsel of FLI), and Andrew J. Ceresney, a duly authorized attorney for the Company, are hereby authorized and directed to acknowledge, on behalf of the Company, that the Plea Documents fully set forth the agreements made between the Company and the United States and that no additional promises or representations have been made to the Company by any officials of the United States in connection with the Plea Agreement, other than those set forth in the Plea Documents.

FURTHER RESOLVED, that any actions taken by the Officers of the Company prior to the adoption of these resolutions, that are within the authority conferred hereby, are hereby fully ratified, confirmed and approved as the act and deed of the Company.