



U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

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Boston, Massachusetts 02210

December 8, 2010

Joshua S. Levy, Esq.
Ropes & Gray LLP
800 Boylston Street
Boston, MA 02199-3600

John C. Dodds, Esq.
Morgan Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103

Re: United States v. Elan Pharmaceuticals, Inc.

Dear Mr. Levy:

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, Elan Pharmaceuticals, Inc. (hereinafter "EPI"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date, EPI shall waive indictment and plead guilty to the one-count Information attached hereto as Exhibit A. Count One of the Information charges that beginning in or about May 2000 and continuing until on or about April 28, 2004, EPI introduced for delivery into interstate commerce various quantities of a misbranded drug Zonegran, in violation of Title 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1) (introduction into interstate commerce of a misbranded drug). EPI expressly and unequivocally admits that it committed this offense. Defendant expressly and unequivocally further admits that it is in fact guilty of the offense, and agrees that it will not make any statements inconsistent with this explicit admission. EPI agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

EPI faces the following maximum penalties on Count One of the Information (21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1):

- a. 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), (d). Given EPI's gross gain of the misbranded drug Zonegran totaled approximately \$80,875,222, the maximum possible fine in connection with this count is \$161,750,444;
- b. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);
- c. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556, 3663;
- d. Asset forfeiture; and
- e. 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 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 EPI's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

- a. The parties agree that the base fine is \$80,875,222, which is the pecuniary gain to EPI from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.
- b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is six (6), which is determined as follows:
 - i. Base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(A);
 - ii. Add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(3) in that the organization had 200 or more employees and tolerance of the offense by substantial authority personnel was pervasive throughout the organization; and
 - iii. Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(3) in recognition of EPI's full cooperation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

- c. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of six (6) is 1.20 to 2.40.
- d. Thus, the Guideline Fine Range is \$97,050,266 to \$161,750,444. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).
- e. 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 or upward departure or deviation under the United States Sentencing Guidelines.

4. Agreed Disposition

The United States and EPI 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 all of the factors set forth in 18 U.S.C. §§ 3553(a), 3572:

- a. a criminal fine in the amount of ninety-seven million fifty thousand two hundred sixty-six dollars (\$97,050,266) to be paid no later than one week after the date of sentencing;
- b. a mandatory special assessment of \$125 pursuant to 18 U.S.C. § 3013, which shall be paid to the Clerk of Court on or before the date of sentencing;
- c. criminal forfeiture in the amount of \$3,600,000; and
- d. In light of the pending civil action, *United States of America ex rel. Chartock v. Elan Corporation, plc, et al.*, C.A. No. 04-11594-RWZ (D. Mass.) (the "Civil Action"), and the Civil Settlement Agreement between Elan Corporation plc ("Elan") and the United States relating to the Civil Action which is being signed contemporaneously with this plea agreement, (and is attached hereto as Exhibit B) which requires the payment of \$102,890,517, plus interest, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to potential victims in this case, especially where, as here: (1) any loss suffered by government payers will be compensated fully as defined in the Civil Settlement Agreement, which amount is subject to review and approval by the District Court in the Civil Action, and (2) given the numerous unknown individuals and insurance companies that purchased the products in question, tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the product at issue would be extraordinarily complicated, if not impossible. *See* 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 EPI 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 Defendant's execution of this Agreement and sentencing, EPI:

- 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 EPI 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 EPI is accountable under U.S.S.G. § 1B1.3;
- e. engages in acts which form a basis for finding that EPI has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;
- f. commits a crime; or
- g. attempts to withdraw its guilty plea.

EPI 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 EPI

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 EPI for any additional federal criminal non-tax charges against Defendant with respect to conduct relating to the drug Zonegran which (a) falls within the scope of the Information; (b) was the subject of the grand jury investigation in the District of Massachusetts; or (c) pertains to facts currently known to the United States based upon EPI's conduct between the years 2000 and 2005 relating to the marketing and/or promotion of Zonegran, an Anti Epileptic medication, within the United States. This declination is expressly contingent upon:

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

- b. EPI's performance of all of its material obligations as set forth in this Agreement and Elan's performance of all of its material obligations as set forth in the Civil Settlement Agreement attached as Exhibit B.

If EPI's guilty plea is not accepted by the Court or is withdrawn for any reason, or if EPI should fail to perform any material obligation under this Agreement, or if Elan should fail to perform any material obligation under the attached 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 EPI, 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

EPI 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. EPI 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"). EPI 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). EPI waives any right it has to challenge its conviction on direct appeal or in any future proceeding.
- b. EPI 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. EPI 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. EPI 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 EPI desires to obtain the benefits of this Agreement, EPI agrees that it will not challenge the sentence imposed in an appeal or other future proceeding, if the Court imposes the agreed-upon sentence. EPI 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. 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.

9. Forfeiture

EPI 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. EPI admits that the value of the quantities of Zonegran that it misbranded and distributed in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1) totaled at least \$3,600,000 in United States currency. EPI acknowledges and agrees that the quantities of Zonegran that it distributed in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1) 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, EPI agrees that the United States is entitled to forfeit as "substitute assets" any other assets of EPI up to the value of the now missing directly forfeitable assets.

EPI agrees that it shall remit the amount of \$3,600,000 in United States currency to the United States Marshals Service no later than one week after the date of sentencing pursuant to wire instructions provided by the United States Attorney's Office. EPI and the United States agree that this payment shall satisfy any and all forfeiture obligations that EPI may have as a result of its guilty plea. In the event that EPI fails to make such payment, the United States will proceed with forfeiture of any other property of EPI, up to the value of \$3,600,000. EPI agrees to assist law enforcement agents and government attorneys in locating, liquidating, recovering, returning to the United States, and forfeiting all forfeitable assets, wherever located, and in whatever names the assets may be held. EPI shall promptly take whatever steps are deemed necessary by the U.S. Attorney and, as applicable, the United States Marshals Service, to transfer possession of, and clear title to, all forfeitable assets to the United States. Such steps may include, but are not limited to, executing and surrendering all title documents, and signing consent decrees of forfeiture, deeds, sworn statements relating the factual bases for forfeiture, and any other documents deemed necessary by the government to complete the criminal, civil, or administrative forfeiture proceedings which may be brought against the assets identified in this section and against any other forfeitable assets involved in or related to any of the criminal acts charged in the Information.

Forfeiture of substitute assets shall not be deemed an alteration of EPI's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or

other penalty imposed upon EPI, nor shall the forfeiture be used to offset EPI's tax liability or any other debt owed to the United States.

EPI agrees to consent to the entry of orders of forfeiture for the \$3,600,000 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. EPI 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, EPI 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 pertaining to forfeiture.

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

EPI's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). EPI 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 EPI, with the exception of paragraph 12 (Waiver of Defenses) which shall remain in full effect.

EPI may seek sentencing by the Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence EPI immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. EPI 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.

11. Civil and Administrative Liability

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

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

12. Waiver of Defenses

If EPI's guilty plea is not accepted by the Court for whatever reason, if EPI's guilty plea is later withdrawn or otherwise successfully challenged by EPI for whatever reason, or if EPI breaches this Agreement, EPI 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 any such defense that EPI may already have for conduct occurring before July 14, 2004, as further described in a tolling agreement dated September 17, 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.

13. Breach of Agreement

If the United States determines that EPI has failed to comply with any 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 EPI, 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. EPI recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. EPI understands that should it breach any provision of this Agreement, the United States will have the right to use against EPI before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by EPI, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

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

- a. are wholly dependant upon Elan and EPI's timely compliance with the provisions of the attached Civil Settlement Agreement, including the requirement in the agreement that Elan pay to the United States and to the various state Medicaid Programs the amount of \$102,890,517, plus interest continuing until and including the day before complete payment is made in accord with the terms of the Civil Settlement Agreement; and that
- b. failure by EPI to comply fully with the terms of this Agreement or the failure by Elan to comply fully with 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 resolute provisions of the CIA.

In the event EPI at any time hereafter breaches any provision of this Agreement, EPI 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 EPI as set forth in this Agreement; and (2) EPI will not be relieved of its obligation to make the payments set forth in this Agreement and Elan will not be relieved of its obligation to make the payments set forth in the attached Civil Settlement Agreement, nor will it be entitled to return of any monies already paid. Moreover, in the event of a breach, EPI understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and EPI 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 any such defense that EPI may already have for conduct occurring before July 14, 2004.

14. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 5, this Agreement is binding upon EPI 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 EPI 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 EPI'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 on behalf of the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit D. EPI 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.

15. Corporate Authorization

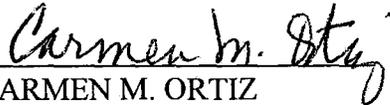
EPI's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached below. EPI shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the governing authority of EPI affirming that it has authority to enter into the Plea Agreement 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 EPI to plead guilty to the charge specified in the Information; and (5) voted to authorize the corporate officer 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 E. EPI agrees that either a duly authorized corporate officer or a duly authorized attorney for EPI, at the discretion of the Court, shall appear on behalf of EPI and enter the guilty plea and will also appear for the imposition of sentence.

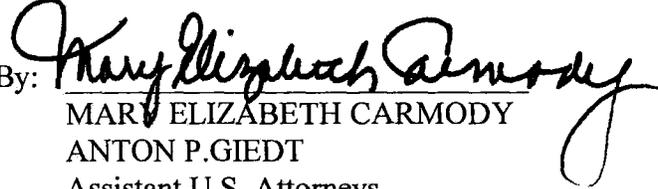
16. Complete Agreement

This Agreement and the attachments hereto, together with the Side Letter Agreement, the Civil Settlement Agreement, the Corporate Integrity Agreement, the Escrow Agreement between Elan Corporation plc and the United States, and the Tolling Agreement between EPI, Elan and the United States Attorney dated September 17, 2010 (incorporating prior tolling agreements), set forth the complete and only agreements 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. 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.

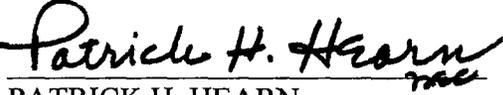
If this letter accurately reflects the Agreement between the United States and your client, EPI, please have the authorized representative of EPI sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Mary Elizabeth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

Very truly yours,


CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: 
MARY ELIZABETH CARMODY
ANTON P. GIEDIT
Assistant U.S. Attorneys
District of Massachusetts

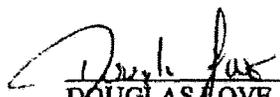
TONY WEST
ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
U.S. DEPARTMENT OF JUSTICE

By: 
PATRICK H. HEARN
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice

ACKNOWLEDGMENT OF AGREEMENT

The Officers and Members of the Board of Directors of Elan Pharmaceuticals, Inc. (the "Board") have authorized me to execute this Plea Agreement on behalf of Elan Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Elan Corporation plc. The Board is authorized to act on behalf of Elan Pharmaceuticals, Inc. The Board has read this Plea Agreement, the attached criminal information, and the Civil Settlement Agreement including all attachments in their entirety or has been advised of the contents thereof, and has discussed them fully in consultation with EPI's attorney. The Board acknowledges that these documents fully set forth EPI and Elan's agreement with the United States. The Board further states that no additional promises or representations have been made to EPI by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement, the attached Civil Settlement Agreement and the Side Letter.

Dated: 12/15/10



DOUGLAS LOVE
Director & Vice President
ELAN PHARMACEUTICALS, INC.

Dated: 12/15/10



JOSHUA S. LEVY, ESQ.
Ropes & Gray LLP
Counsel for Defendant

Dated: _____

JOHN C. DODDS, ESQ.
Morgan Lewis & Bockius LLP
Counsel for Defendant

ACKNOWLEDGMENT OF AGREEMENT

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Dated: _____

DOUGLAS LOVE
Director & Vice President
ELAN PHARMACEUTICALS, INC.

Dated: 12/13/10



JOSHUA S. LEVY, ESQ.
Ropes & Gray LLP
Counsel for Defendant

Dated: 12/15/10



JOHN C. DODDS, ESQ
Morgan Lewis & Bockius LLP
Counsel for Defendant