

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA :
 :
 v. : **CRIMINAL NO.**
 :
ELI LILLY AND COMPANY :

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the government, the defendant, Eli Lilly and Company (hereinafter “Eli Lilly”), and Eli Lilly's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Department of Justice.

1. Eli Lilly agrees to plead guilty to Count One of an Information, waiving prosecution by indictment, charging it with the introduction into interstate commerce of drugs that were misbranded, a misdemeanor, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1), and not to contest forfeiture as set forth in the notice of forfeiture seeking forfeiture of \$100,000,000 in substitute assets, in lieu of the drugs which were promoted illegally and are no longer available, all arising from Eli Lilly’s illegal promotion of its drug Zyprexa in the United States between September 1999 and March 31, 2001. Eli Lilly further acknowledges its waiver of rights, as set forth in Exhibit A to this agreement.

2. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition

of this case. Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon sentence is as follows:

A. Eli Lilly agrees to pay the special assessment in the amount of \$125 on the date of sentencing.

B. Eli Lilly agrees to pay \$615,000,000 to resolve this Information, of which \$515,000,000 will be applied as a criminal fine, and \$100,000,000 will be applied as substitute assets to satisfy the forfeiture obligation described in paragraph 2(C) below. Eli Lilly will pay these amounts within 10 business days of the date of sentencing. Eli Lilly and the government agree that this fine and forfeiture represent a fair and just resolution of all issues associated with loss, fine and forfeiture calculations.

C. Eli Lilly agrees that as a result of its acts or omissions, the forfeitable property, that is the drugs which were promoted off-label, are no longer available for forfeiture as the drugs cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, Eli Lilly agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of \$100,000,000 as substitute assets for the pertinent drugs. Eli Lilly agrees that, within 10 business days of the date of sentencing, Eli Lilly will make payment to the United States, by means of a wire transfer to the United States Marshal Service or check payable to same, in the amount of \$100,000,000, this amount representing substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

D. In light of the anticipated Corporate Integrity Agreement, Eli Lilly will not be placed on probation.

3. Eli Lilly and the United States intend to execute a separate civil settlement agreement. Eli Lilly waives any and all defenses and objections in this matter or in that civil proceeding which might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. The parties agree that, in light of the separate civil settlement agreement, and to avoid unduly complicating and prolonging the sentencing process, the appropriate disposition of this case does not include a restitution order.

4. Eli Lilly waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

5. Eli Lilly understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence: a fine of \$200,000, or twice the gross gain or gross loss, whichever is greater; a special assessment of \$125; restitution as ordered by the Court; and a five-year term of Court supervision; in addition, forfeiture may be ordered. Eli Lilly further understands that the terms and conditions of any Court supervision may be changed, and extended, by the Court if Eli Lilly violates any of the terms and conditions of that supervision.

6. With respect to Eli Lilly's conduct:

A. The parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture:

- (1) Eli Lilly marketed Zyprexa, which was a drug within the meaning of 21 U.S.C. § 321(g)(1).
- (2) Shipments of a drug in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the drug's intended uses.
- (3) In September 1996, Zyprexa was approved by FDA for the short term management of the manifestations of psychotic disorders. In March 2000, FDA approved the addition of the subheading "schizophrenia" to the short term management of the manifestations of psychotic disorders. Also in March 2000, FDA approved Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder. In November 2000, FDA approved new labeling for Zyprexa for the short term treatment of schizophrenia in place of the management of the manifestations of psychotic disorders. Also in November 2000, FDA approved Zyprexa for maintaining treatment response in schizophrenic patients who had been stable for approximately eight weeks and were then followed for a period of up to eight months.
- (4) **Between September 1999 and March 31, 2001, Eli Lilly promoted Zyprexa in elderly populations as treatment for**

dementia, including Alzheimer's dementia. Zyprexa is not approved by the FDA for treatment of dementia or Alzheimer's dementia. Eli Lilly's promotion of Zyprexa for these additional intended uses violated 21 U.S.C. § 352(f)(1), because Zyprexa's labeling did not bear adequate directions for each of the drug's intended uses.

B. The United States contends that, as a matter of relevant conduct, the conduct which forms the basis for this plea agreement, as set forth in subsection (A) above, continued past March 31, 2001. Eli Lilly does not admit that this conduct extended past March 31, 2001.

7. Eli Lilly and the United States retain the right to withdraw from this guilty plea agreement, and this plea agreement will be null and void, if the civil settlement agreement and Corporate Integrity Agreement are not executed prior to the filing of the Information.

8. Except as provided herein, the United States agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges against Eli Lilly, its present and former parents, affiliates, divisions, and subsidiaries; their predecessors, successors and assigns for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to Eli Lilly's drug Zyprexa; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Office of Consumer Litigation of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of Zyprexa in the United

States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Office of Consumer Litigation of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions are also binding on the Criminal Division of the United States Department of Justice, except that the investigation of Eli Lilly and its affiliates, divisions, and subsidiaries, being conducted 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 Eli Lilly's products to foreign customers is specifically excluded from the non-prosecution provisions and release provided by this paragraph and agreement. Attached as Exhibit B is a copy of the letter to Acting United States Attorney Laurie Magid from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

9. Eli Lilly understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice except as specified in paragraph 8 of this guilty plea agreement. Further, Eli Lilly understands that the United States takes no position as to the proper tax treatment of any of the payments made by Eli Lilly pursuant to this plea agreement, the civil settlement agreement, or the Corporate Integrity Agreement referenced in this plea agreement.

10. Eli Lilly agrees to waive the statute of limitations, and any other time-related defense, to the charge to which it is agreeing to plead guilty under this plea agreement, provided that the guilty plea is accepted by the Court.

11. Eli Lilly understands and agrees that, should it withdraw its plea or if Eli Lilly's guilty plea is not accepted by the Court for whatever reason, Eli Lilly may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, notwithstanding the expiration of any applicable statute of limitations between the time period when Eli Lilly signed this plea agreement and either Eli Lilly's withdrawal of its plea or the Court's rejection of its plea. In that event, Eli Lilly agrees that it will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of a Tolling Agreement between the parties effective October 7, 2008, all subsequent extensions of the Tolling Agreement, and this paragraph.

12. In exchange for the undertakings made by the government in entering this plea agreement, Eli Lilly voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

13. Eli Lilly also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

14. Eli Lilly is satisfied with the legal representation provided by its lawyers; Eli Lilly and its lawyers have fully discussed this guilty plea agreement; and Eli Lilly is agreeing to plead guilty because Eli Lilly admits that it is guilty of the misdemeanor described in paragraph 1.

15. Eli Lilly will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of an authorized corporate officer. **Eli Lilly shall provide to the government for attachment as Exhibit C to this plea agreement a notarized resolution by Eli Lilly's Board of Directors authorizing the corporation to enter a plea of guilty, and authorizing a corporate officer to execute this agreement.**

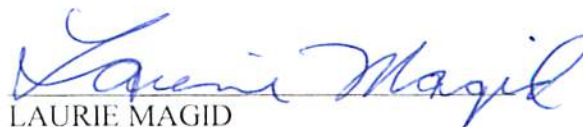
16. If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that Eli Lilly be sentenced at the time the guilty plea is entered.


17. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements or understandings will be entered into unless in writing and signed by all parties.

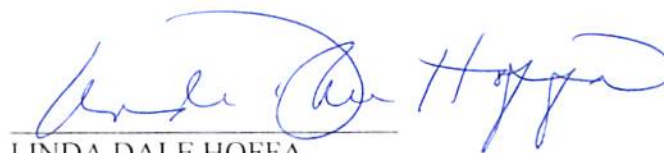
SIGNATURES FOR THE UNITED STATES

GREGORY G. KATSAS
Assistant Attorney General
Civil Division
United States Department of Justice

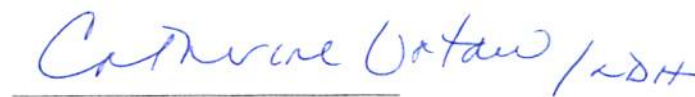

EUGENE M. THIROLF
Director, Office of Consumer Litigation
United States Department of Justice



LAURIE MAGID
Acting United States Attorney


JEFFREY I. STEGER
Trial Attorney
Office of Consumer Litigation
United States Department of Justice

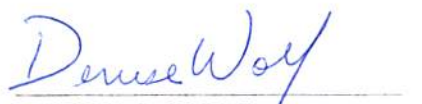

LINDA DALE HOFFA
Chief, Criminal Division
Assistant United States Attorney


ROSS S. GOLDSTEIN
Trial Attorney
Office of Consumer Litigation
United States Department of Justice


CATHERINE VOTAW
Assistant United States Attorney



MARILYN S. MAY
Assistant United States Attorney

DATE: 1-14-09


DENISE S. WOLF
Assistant United States Attorney

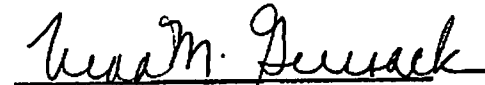
SIGNATURE FOR ELI LILLY

DATE: 14 Jan. 2009



ROBERT A. ARMITAGE
Senior Vice President and General Counsel
Eli Lilly and Company

SIGNATURES OF ELI LILLY'S ATTORNEYS

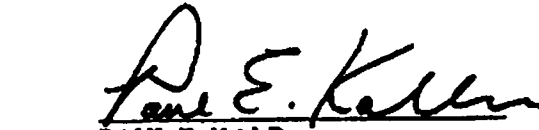
DATE: 1/14/09


NINA M. GUSSACK
Pepper Hamilton LLP
Counsel for Defendant

DATE: 1/14/09


THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Defendant

DATE: 1/14/09


PAUL E. KALB
Sidley Austin LLP
Counsel for Defendant

DATE: 1/14/09



BRADFORD A. BERENSON
Sidley Austin LLP
Counsel for Defendant

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA :

v. :

CRIMINAL NO.

ELI LILLY AND COMPANY :

ACKNOWLEDGMENT OF RIGHTS

Eli Lilly and Company ("Eli Lilly"), through its properly authorized officer, hereby acknowledges that it has certain rights that it will be giving up by pleading guilty.

1. Eli Lilly understands that it does not have to plead guilty.
2. Eli Lilly may plead not guilty and insist upon a trial.
3. At that trial, Eli Lilly understands:
 - a. that Eli Lilly would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with its attorney, Eli Lilly would have the right to participate in the selection of that jury;
 - b. that the jury could only convict Eli Lilly if all twelve jurors agreed that they were convinced of Eli Lilly's guilt beyond a reasonable doubt;
 - c. that the government would have the burden of proving Eli Lilly's guilt beyond a reasonable doubt and that Eli Lilly would not have to prove anything;
 - d. that Eli Lilly would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that Eli Lilly was guilty;
 - e. that Eli Lilly would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if Eli Lilly could not afford to hire a lawyer, the court would appoint one for Eli Lilly free of charge;
 - f. that through Eli Lilly's lawyer Eli Lilly would have the right to confront and cross-examine the witnesses against Eli Lilly;

- g. that Eli Lilly could call witnesses to testify in its defense if Eli Lilly wanted to, and Eli Lilly could subpoena witnesses for this purpose if Eli Lilly wanted to; and
 - h. that Eli Lilly would not have to call witnesses to testify or otherwise present any defense if Eli Lilly did not want to, and that if Eli Lilly did not present any evidence, the jury could not hold that against Eli Lilly.
4. Eli Lilly understands that if Eli Lilly pleaded guilty, there will be no trial and Eli Lilly would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.
 5. Eli Lilly understands that if Eli Lilly decides to enter a plea of guilty, the judge will ask Eli Lilly representatives questions under oath, and that if any of those representatives lie on behalf of Eli Lilly in answering those questions, those persons could be prosecuted for the crime of perjury, that is, for lying under oath.
 6. Eli Lilly understands that if Eli Lilly pleads guilty, Eli Lilly has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.
 7. Understanding that Eli Lilly has all these rights and that by pleading guilty Eli Lilly is giving them up, Eli Lilly still wishes to plead guilty.


ROBERT A. ARMITAGE
Senior Vice President and General Counsel
Eli Lilly and Company

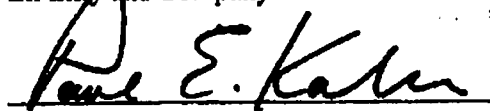

PAUL E. KALB
Sidley Austin LLP
Counsel for Defendant

Exhibit B



U.S. Department of Justice

Criminal Division

Acting Assistant Attorney General

Washington, D.C. 20530

JAN 9 2009

The Honorable Laurie Magid
Acting United States Attorney
Eastern District of Pennsylvania
Philadelphia, Pennsylvania 19106

Attention: Catherine Votaw
Assistant United States Attorney

Re: Global Non-prosecution Agreement for Eli Lilly and Company

Dear Ms. Magid:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entity known as Eli Lilly and Company.

I hereby approve the terms of the Plea Agreement, including Paragraph 8, in which the United States Attorney's Offices and 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,

Matthew W. Friedrich
Acting Assistant Attorney General

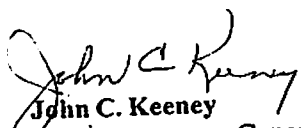

John C. Keeney
Deputy Assistant Attorney General
Criminal Division

Exhibit C

**CERTIFICATE OF SECRETARY
ELI LILLY AND COMPANY**

I, James B. Lootens, certify that I am Secretary of Eli Lilly and Company, an Indiana Corporation (the "Company"), and that I am authorized to give this Certificate on behalf of the Company.

I further certify that the resolutions set forth below were adopted by the Board of Directors of the Company at a meeting duly held on January 14, 2009, and that such resolutions remain in full force and effect as the date of this certificate.

WHEREAS, Eli Lilly and Company has found that it is in the best interest of the company to enter into proposed federal and related state settlements regarding Zyprexa, including entering into:

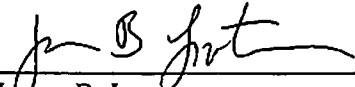
- (1) a plea agreement with the United States Attorney's Office for the Eastern District of Pennsylvania and the Office of Consumer Litigation to plead guilty to a single misdemeanor count of violation of the Federal Food, Drug, & Cosmetic Act ("FDCA") substantially in the form presented to the meeting, initialed by the secretary, and ordered to be filed with the records of the meeting as Attachment 1;
- (2) civil settlement agreements with the federal government and the coordinating states;
- (3) a Corporate Integrity Agreement with the HHS Office of Inspector General substantially in the form presented to the meeting, initialed by the secretary, and ordered filed with the records of the meeting as Attachment 2; and
- (4) all other documents necessary to effectuate the settlement;

it is

RESOLVED, That the company, having been counseled on the company's legal rights and the factual basis for the plea as set forth in Federal Rule of Criminal Procedure 11(b), does hereby authorize to cause its General Counsel, Mr. Robert A. Armitage, and such of its outside counsel as Mr. Armitage shall designate, to enter into and execute a plea agreement substantially in the form of Attachment 1 and the other settlement documents referenced above.

RESOLVED, FURTHER, That any and all agreements executed on behalf of the company in connection with the transactions contemplated, and all further actions necessary to complete and effectuate those transactions, including the personal appearance in court to enter a plea of guilty on behalf of the company by a corporate officer of at least the level of vice president as designated by Mr. Armitage, hereby are ratified and approved.

This certificate is executed on January 14, 2009.

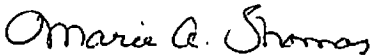


James B. Lootens
Secretary

UNITED STATES OF AMERICA

STATE OF INDIANA)
) SS
COUNTY OF MARION)

Before me, a Notary Public for Marion County, State of Indiana, personally appeared James B. Lootens and acknowledged the execution of the foregoing instrument this 14th day of January, 2009.



NOTARY PUBLIC
Marie A. Thomas
My Commission Expires
February 10, 2009
Resident of Marion County

