

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

UNITED STATES OF AMERICA	:	
	:	
v.	:	CRIMINAL NO. 09-020
	:	
ELI LILLY AND COMPANY	:	

**GOVERNMENT’S SUPPLEMENTAL MOTION IN
ANTICIPATION OF SENTENCING**

The United States of America, by and through its attorneys, Laurie Magid, Acting United States Attorney for the Eastern District of Pennsylvania, and J. Alvin Stout, III, and Denise S. Wolf, Assistant United States Attorneys, respectfully submits this Supplemental Motion in Anticipation of Sentencing. The purpose of this motion is two-fold: first, to request the entry of a Judgment and Order of Forfeiture; and second, to inform the Court that there are no victims within the meaning of the Crime Victims Rights Act (CVRA) of the misbranding offense to which defendant Eli Lilly and Company (Eli Lilly) is pleading guilty.

A. Request for Judgment and Order of Forfeiture

In support of the request for Judgment and Order of Forfeiture, the government represents as follows:

1. On January 15, 2009, defendant Eli Lilly was charged by information with one count of distribution of misbranded drugs in interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1). The Notice of Forfeiture alleged that defendant’s interest in certain property was forfeitable as a result of that offense.

2. Defendant Eli Lilly has signed a plea agreement with the United States, whereby Eli Lilly will plead guilty to the offense charged in the information.

3. On January 30, 2009, defendant will plead guilty to the information.

4. As a result of its conviction, defendant is required, and has also agreed, pursuant to 28 U.S.C. § 2461(c) and 21 U.S.C. § 334, to criminally forfeit its interest in any drug that was misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce.

5. Based upon defendant's plea agreement, the government avers that the following property is subject to forfeiture as a result of defendant's conviction, and that the government has established the requisite nexus between this property and the charged offense:

Any quantities of Zyprexa, which between September 1999 and March 31, 2001 were misbranded when introduced into or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce.

6. Pursuant to 21 U.S.C. § 853(p), the government is entitled to the forfeiture of any other property of defendant, up to the value of any property, which, as a result of any act of defendant, is unavailable for forfeiture because (A) it 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. Defendant has sold or transferred to third parties the quantities of misbranded Zyprexa subject to forfeiture as a result of the offense to which it has agreed to plead guilty, making the property unavailable for forfeiture. Pursuant to the plea agreement, the value of the Zyprexa subject to forfeiture is \$100,000,000. Because defendant has dissipated the forfeitable property, as further agreed in the

plea agreement, the government is entitled to the forfeiture of substitute assets valued at \$100,000,000, pursuant to Rule 32.2(e) of the Federal Rules of Criminal Procedure and 21 U.S.C. § 853(p).

7. Defendant has agreed, in its guilty plea agreement, to the entry of a judgment and preliminary order of forfeiture on the date of the guilty plea. Defendant has agreed that, within 10 business days of sentencing, it will make payment to the United States in the amount of \$100,000,000, in full satisfaction of the judgment and preliminary order of forfeiture, this sum representing the value of the substitute assets forfeitable as a result of the offense to which it is pleading guilty.

B. No Victims within the Meaning of the CVRA

1. The Crime Victims Rights Act (CVRA) provides certain procedural and substantive rights to the victims in criminal cases. To qualify as a “victim” under the CVRA, a person must be “directly and proximately harmed as a result of the commission of a Federal offense” 18 U.S.C. § 3771(e). The harm must result from “conduct underlying an element of the offense of conviction.” United States v. Blake, 81 F.3d 498, 506 (4th Cir. 1996) (discussing Victim and Witness Protection Act).

2. Defendant Eli Lilly will plead guilty to the offense of distributing a misbranded drug in interstate commerce. Eli Lilly admits that it promoted its drug Zyprexa to health care providers between September 1999 and March 31, 2001, for uses not approved by the Food and Drug Administration (FDA). 21 U.S.C. § 331. Specifically, Eli Lilly admits that it promoted Zyprexa in elderly populations as treatment for dementia, including Alzheimer’s dementia. This promotion resulted in the drug being misbranded under 21 U.S.C. § 352(f).

3. The offense of misbranding as charged in the information here did not result in direct and proximate harm to a victim as defined in the CVRA.¹ The offense is established by proof that Eli Lilly introduced a misbranded drug into interstate commerce. The information charges that the Zyprexa was misbranded because Eli Lilly promoted the drug intending that it be used for purposes other than what the FDA had approved. The crime is complete regardless of the success of the company's promotional efforts. While a person may allege harm from the use of Zyprexa, a variety of potential intervening factors here renders any harm to a person taking Zyprexa too attenuated in this case for such a person to qualify as a victim under the CVRA. See In re: Jane Doe, 264 Fed. Appx. 260, 263 (4th Cir. 2007) (holding that consumer of Oxycontin was not a victim for purposes of restitution within the meaning of Victim and Witness Protection Act where there was no evidence that her injuries flowed directly and proximately from the misbranding); see also United States v. Kones, 77 F.3d 66, 69, 71 (3d Cir. 1996) (holding that patient was not a "victim" within the meaning of the federal Victim and Witness Protection Act of defendant doctor's scheme to submit false insurance claims).² The offense of misbranding, as charged in the information here, did not result in direct and proximate harm to a victim under CVRA.

¹ Two other victim rights' statutes – the Victim and Witness Protection Act, 18 U.S.C. § 3663 (VWPA), and the Mandatory Victims Restitution Act, 18 U.S.C. § 3663A (MVRA), are not directly applicable in this case because the misbranding offense to which Eli Lilly is pleading guilty is not covered by these statutes. Consequently, there are no available avenues for restitution for alleged victims under the VWPA or the MVRA. Nor would any restitution be possible as a condition of probation, because the plea agreement specifies that Eli Lilly will not be placed on probation in light of the Corporate Integrity Agreement. (Plea Agreement para. 2(D)).

² As a general matter, given the public interest in this case, the United States Attorney's Office will post on its official website the date, time and location of upcoming court proceedings.

C. Conclusion

For the reasons stated above, the government requests that this Court enter the attached Judgment and Order of Forfeiture.

Respectfully submitted,

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Acting United States Attorney

J. ALVIN STOUT, III
Assistant United States Attorney
Chief, Asset Forfeiture

DENISE S. WOLF
MARILYN MAY
CATHERINE VOTAW
Assistant United States Attorneys

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JUDGMENT AND ORDER OF FORFEITURE

The United States of America, pursuant to Rule 32.2(e) of the Federal Rules of Criminal Procedure, and 21 U.S.C. § 853(p), has moved for entry of a Judgment and Order of Forfeiture. In consideration of the motion, and the plea agreement entered into between the government and defendant Eli Lilly and Company (Eli Lilly), the Court finds as follows:

1. As a result of defendant's conviction for violating 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1), for which the government sought forfeiture, all defendant's right, title, and interest in any quantity of Zyprexa that is misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce, is subject to forfeiture to the United States pursuant to 28 U.S.C. § 2461(c) and 21 U.S.C. § 334.

2. Based upon defendant's plea agreement, the following property is subject to forfeiture as a result of defendant's conviction, and the government has established the requisite nexus between this property and the charged offense:

Any quantities of Zyprexa, which between September 1999 and March 31, 2001 were misbranded when introduced into or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce.

3. As agreed in the plea agreement, because of the acts or omissions of defendant, forfeitable property, that is, quantities of misbranded Zyprexa (“the unavailable property”) is no longer available for forfeiture for one or more of the reasons set forth in 21 U.S.C. § 853(p).

4. As a result, pursuant to Rule 32.2(e) of the Federal Rules of Criminal Procedure and 21 U.S.C. § 853(p), the United States is entitled to an order forfeiting other property of defendant up to the value of the unavailable property.

5. As agreed in the plea agreement, the value of the unavailable property is \$100,000,000.

6. Under the terms of the plea agreement, defendant has agreed to pay the \$100,000,000 to the government within 10 business days of the date of sentencing, this sum representing the value of the substitute assets forfeitable as a result of the offense to which it is pleading guilty, in full satisfaction of the judgment and preliminary order of forfeiture.

THEREFORE IT IS HEREBY ORDERED THAT:

1. A personal forfeiture money judgment is entered against defendant Eli Lilly and Company in the amount of \$100,000,000, in favor of the United States pursuant to 28 U.S.C. § 2461(c) and 21 U.S.C. §§ 334 and 853(p).

2. Upon payment by defendant of the \$100,000,000 to the government, all right, title and interest of defendant in the \$100,000,000 is forfeited to the United States.

3. Pursuant to Fed.R.Crim.P. 32.2(b)(3), this Judgment and Order of Forfeiture shall become final as to defendant at sentencing and shall be made part of the sentence and included in the judgment.

4. The Court shall retain jurisdiction to enforce this Judgment and Order of Forfeiture,

CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and that a paper copy will be sent by first class mail, postage prepaid, to:

Thomas M. Gallagher, Esquire
Pepper Hamilton
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799

DENISE S. WOLF
Assistant United States Attorney

Date: January 23, 2009