

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA)
) Case No. 1:07CR00029
)
v.)
) UNITED STATES' RESPONSE TO
THE PURDUE FREDERICK) COURT'S ORDER DIRECTING PARTIES
COMPANY, INC., ET AL.,) TO PROVIDE INFORMATION
)
Defendants.)

On May 18, 2007, the Court entered an order noting that the plea agreements in this case were entered into pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C). Accordingly, the Court has only two options as to each defendant: (1) accept the plea agreement and sentence the defendant as agreed to in the plea agreement; or (2) reject the plea agreement and allow the defendant to withdraw his guilty plea.

The United States recommends acceptance of the plea agreements. The Court's acceptance of the plea agreements will result in the following: Purdue's three top executives will be convicted criminals and subject to court supervision; The Purdue Frederick Company, Inc., will stand convicted of a felony; Purdue Pharma L.P. will be subject to an extensive corporate integrity agreement to ensure compliance with all federal laws; Purdue will be required to set aside \$130 million to settle private civil law suits concerning OxyContin; and the defendants will pay a total of over \$634,000,000 which represents approximately 90% of the profits for sales of OxyContin during the time period of the offense.

In its order, the Court directed the parties to provide certain information for the Court to

consider in making its decision regarding acceptance of the plea agreements. The issues raised by the Court and the government's responses are set forth below:

- 1. The Plea Agreements preclude court-ordered restitution to any individual victims of the crimes charged, such as the costs of medical care and rehabilitation. As stated in the Plea Agreements, the parties rely on the provision of the Mandatory Victims Restitution Act, 18 U.S.C. § 3663(a)(1)(B)(ii), which provides that the complication and prolongation of the sentencing process resulting from the fashioning of an order of restitution may outweigh the need to provide restitution. State the facts that support the application of this provision.**

In preparing the plea agreements for Purdue and its executives, the government recognized that there were potentially thousands of individuals who were harmed by OxyContin. Providing monetary compensation for those individuals deserving of such was an important consideration for the United States. After careful review and study, we determined that the better forums for identifying and compensating those individuals are the federal and state civil judicial systems. Accordingly, the government insisted that Purdue set aside not less than \$130 million, as of the date of the agreement in principle, October 25, 2006, to be used to settle appropriate private civil actions brought by those harmed by OxyContin use. We also demanded that Purdue pay to the United States any part of the \$130 million that it failed to use for private civil claims within two years.

Title 18, United States Code, Section 3663(a)(3), permits the Court to order restitution "to the extent agreed to by the parties in a plea agreement."¹ In considering this restitution provision,

¹18 U.S.C. § 3663 does not appear to grant authority for restitution to be ordered for criminal misbranding, in violation of 21 U.S.C. §§ 331 and 333, in the absence of an agreement by the parties. See 18 U.S.C. § 3663(a)(1)(A) (21 U.S.C. §§ 331 and 333 not listed among offenses for which restitution may be ordered). However, it appears the Court has the authority, as a condition of probation or supervised release, to order that a defendant make restitution to a victim of an offense beyond the limitations of 18 U.S.C. §§ 3663(a) and 3663A(c)(1)(A). See 18 U.S.C. §§ 3563(b)(2) and 3583(d); see also *United States v. Coleman*, 370 F. Supp.2d 661, 678-79 (S.D. Ohio 2005) (restitution can be ordered as a condition of probation for violations of 21

the parties determined that, under the facts and circumstances of this case, 18 U.S.C. § 3663(a)(1)(B)(ii) should be applied because the complication and prolongation of the sentencing process resulting from the fashioning of an order of restitution outweighs the need to provide court ordered restitution to any apparent victims.

It would be legally difficult and burdensome for this court to attempt to identify all those who may be victims of Purdue's crimes. A "victim" is "a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered" 18 U.S.C. § 3663(a)(2). Restitution is permitted "only for the loss caused by the specific conduct that is the basis of the offense of conviction." *United States v. Kones*, 77 F.3d 66, 69 (3rd Cir. 1996), quoting *Hughey v. United States*, 495 U.S. 411, 413 (1990). The facts underlying this guilty plea as set forth in the Agreed Statement of Facts indicate that certain supervisors and employees of the defendant company used prescription drug labeling, as defined by 21 C.F.R. § 202.1(l)(2), to make false or misleading sales presentations to health care providers for purposes of promoting and marketing OxyContin. Without the ability to identify or quantify the impact on prescribing health care providers, it follows that there is no practicable way to identify specific patients who may have suffered loss that was the proximate result of an unlawful sales presentation, since these presentations were made to health care providers. Restitution is permissible only to specifically identifiable victims who suffer harm that directly results from the defendant's criminal conduct - in this case, the misbranding of OxyContin. *Kones*, 77 F.3d at 70.

The government believes there is no practical and efficient process by which the Court could

U.S.C. §§ 331 and 333). Also, Courts have held that in civil enforcement actions there is equitable authority to order restitution for misbranding. *See, e.g., United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 762 (6th Cir. 1999), cert. denied, 530 U.S. 1274 (2000); *United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 220 (3d Cir. 2005).

identify and appropriately compensate all the victims of the offenses to which the defendants have pled guilty.² A hearing would have to be held in Abingdon as to each alleged victim from throughout the nation to determine if the person was injured and whether such injuries were directly and proximately caused by the actions set forth in the charging documents. The complication and prolongation of the sentencing process would be immense. Given the unique facts and circumstances of this case, in our view, the federal and state civil judicial systems are more efficient venues for assessing liability and compensating those individuals who were harmed by OxyContin use. In fact, since the date of the agreement in principle, October 25, 2006, Purdue has paid over \$120 million to settle private civil actions brought against Purdue concerning OxyContin use.

2. What efforts has the Government undertaken in this case to comply with the Crime Victims Rights Act, 18 U.S.C. § 3771, and in particular, the right to notice to individual victims of court proceedings and the right to be reasonably heard by the court?

The United States does not have the ability to provide notice to all individual victims of court proceedings because it cannot properly and completely identify all those who may be “crime victims,” as defined by statute. 18 U.S.C. § 3771, the Crime Victims Rights Act (“CVRA”) provides for certain rights of crime victims. A “crime victim” is defined as “a person directly and proximately harmed as a result of the commission of a Federal offense” 18 U.S.C. § 3771(e).

The CVRA's legislative history provides little help for these types of cases in further defining the scope of who is to be included in the definition of “crime victim.” The only legislative history

²In the misbranding cases where a court has ordered restitution pursuant to 18 U.S.C. § 3663, the defendants were also convicted of offenses under Title 18 and the court was able to identify a discrete number of victims and an easily quantifiable economic harm. *See, e.g., United States v. Caputo*, 456 F. Supp. 2d 970 (N.D. Ill. 2006) (ordering restitution of \$17,209,074.50 to 144 hospitals that had purchased 167 uncleared medical devices). *See also United States v. Milstein*, 481 F.3d 132 (2d Cir. 2007) (ordering restitution of \$3.5M to two drug manufacturers whose trademark was misappropriated).

concerning the reach of the term “crime victim” is the statement of one of the CVRA’s primary sponsors during floor debate noting that the definition of "victim" in the CVRA is an "intentionally broad definition because all victims of crime deserve to have their rights protected, whether or not they are the victim of the count charged." 150 Cong. Rec. S10910, 10912 (daily ed. Oct. 9, 2004) (statement of Sen. Kyl). While the definition is to be interpreted broadly, the CVRA only applies to individuals who were “directly and proximately harmed” as a result of the defendants’ offense.

The Fourth Circuit has interpreted nearly identical language in both the Victim and Witness Protection Act of 1982 ("VWPA"), 18 U.S.C. § 3663, and the Mandatory Victims Restitution Act of 1986 ("MVRA"), 18 U.S.C. § 3663. Both the VWPA and MVRA define a “victim” as

a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered including, in the case of an offense that involves as an element a scheme, conspiracy, or pattern of criminal activity, any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern.

18 U.S.C. § 3663(a)(2); 18 U.S.C. § 3663A(a)(2). Interpreting both the VWPA and MVRA, the Fourth Circuit has held that an individual is only “directly and proximately harmed” when the harm results from “conduct underlying an element of the offense of conviction.” *See United States v. Blake*, 81 F.3d 498, 506 (4th Cir. 1996); *United States v. Davenport*, 445 F.3d 366, 374 (4th Cir. 2006).

In the instant case, it is clear that OxyContin has been the source of harm for a great number of people, both directly and indirectly. It is more difficult to determine who, as to the misbranding offenses in this case, are “crime victims” as defined by statute. In this case, the government has proved that certain supervisors and employees of Purdue made false or misleading representations about OxyContin with the intent to defraud. Determining whether a certain individual was directly and proximately harmed as a result of these representations is a complicated and difficult issue.

Almost uniformly, federal courts have ruled, in civil actions, that the plaintiffs in those cases, as a matter of law, could not prove that Purdue's actions caused the harm the plaintiffs suffered as the result of their OxyContin use. *See, e.g., Bodie v. Purdue Pharma Co.*, No. 05-13834, 2007 WL 1577964 (11th Cir. Jun 01, 2007); *McCauley v. Purdue Pharma L.P.*, 331 F. Supp.2d 449 (W.D. Va. 2004); *Ewing v. Purdue Pharma L.P.*, 2004 WL 1856002 (W.D. Va. 2004); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp.2d 693 (E.D. Ky. 2003); *Koenig v. The Purdue Pharma Company*, 435 F. Supp.2d 551 (N.D. Tex. 2006); *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp.2d 1346 (S.D. Fla. 2003); *Timmons v. The Purdue Pharma Company*, 2006 WL 263602 (M.D. Fla. 2006).

It may well be that Purdue's fraudulent conduct caused a greater amount of OxyContin to be available for illegal use than otherwise would have been available. However, a court may find that a person who subsequently illegally used OxyContin was not directly and proximately harmed by Purdue's illegal conduct, for purposes of the CVRA. *See, e.g., U.S. v. Sharp*, 463 F. Supp.2d 556 (E.D. Va. 2006) (individual was not directly and proximately harmed by defendant's conspiracy to distribute marijuana, and thus did not qualify as a "victim" under the CVRA despite her contention that a user who obtained marijuana from the defendant was abusive to her because of his marijuana use).

While the United States is not able to specifically determine all those who may be "crime victims" as defined by statute, it intends to present testimony of a representative sampling of individuals who have been harmed by the use of OxyContin. The United States believes that presenting such testimony to the Court prior to the Court's decision on accepting or not accepting the plea agreement will be in keeping with the spirit of the CVRA.

3. Why do the Plea Agreements not provide for payments to fund professional assistance to those addicted to OxyContin or harmed by it or other prescription drug abuse, such as drug counseling or other medical or rehabilitative treatment?

The United States recognizes that the prevention and treatment of substance abuse is a national priority. It is also a complex, medical and scientific problem. National policy regarding substance abuse prevention and treatment is established and administered by the Substance Abuse and Mental Health Service Administration (“SAMHSA”), an agency of the Department of Health and Human Services. *See* <http://www.samhsa.gov/About/background.aspx>. For each of fiscal years 2006 and 2007, Congress appropriated more than \$2.3 billion for substance abuse programs, including more than \$1.6 billion for substance abuse block grants. *See* SAMHSA FY 2008 Congressional Justification, <http://www.samhsa.gov/Budget/FY2008/index.aspx>. SAMHSA’s fiscal year 2008 Congressional budget submission provides for more than \$2.2 billion for substance abuse programs, with more than \$1.6 billion for block grants. *Id.*

SAMHSA administers programs to promote the quality and availability of community-based substance abuse treatment services for individuals and families through the Center of Substance Abuse Treatment (“CSAT”). *See* <http://csat.samhsa.gov/mission.aspx>. Congress created CSAT with the specific mission of expanding the availability of effective treatment and recovery services for alcohol and drug problems. *Id.* Moreover, CSAT’s Congressionally supported initiatives and programs are “based on research findings and the general consensus of experts in the addiction field that, for most individuals, treatment and recovery work best in a community-based coordinated system of comprehensive services.” *Id.*

It was evident, therefore, that Congress vested authority and extensive funding to SAMHSA and its subsidiary agency to provide for substance abuse prevention and treatment. In considering

whether to include provisions for substance abuse prevention and treatment in the plea agreements, the United States believed that it lacked the expertise to do so, and questioned its authority to do so given Congressional funding and oversight of the national strategy for substance abuse prevention and treatment as implemented by CSAT. Moreover, the government lacked the expertise and knowledge to properly direct such funding, even if it had the authority to do so, and recognized that drug abuse prevention and treatment should be carried out consistently with the national strategy established by SAMHSA and the United States Congress. Accordingly, it was determined that the plea agreements should not directly provide for the funding of substance abuse prevention and treatment.

4. Describe the nature of the improperly calculated Medicaid rebates as set forth in paragraph 3.a(1) of the Purdue Plea Agreement and describe how the payment figure was arrived at.

Medicaid is a joint federal/state program administered by the Centers for Medicare and Medicaid Services (CMS) that provides eligible beneficiaries with certain health care benefits, including prescription drug coverage. In an effort to help defray costs associated with the Medicaid program, pharmaceutical manufacturers are required to pay rebates to the states based on their covered product's classification (i.e., Single Source, Innovator and Non-Innovator) and relevant pricing data (i.e., Average Manufacturer Price (AMP) and Best Price). The manufacturer submits pricing data to CMS on a quarterly basis. CMS uses the pricing data to calculate a rebate per unit (RPU) for each covered product and sends this data to the individual states participating in the Medicaid program. The individual states determine the amount of utilization for each covered product by their respective Medicaid beneficiaries. This utilization is multiplied by the covered product's RPU to determine the amount of rebate owed by the manufacturer.

In mid-2003, Purdue, on its own initiative, engaged KPMG and the law firm Sidley & Austin

to review its methodologies for calculating the pricing data Purdue submitted to CMS. Based on the recommendations received through those reviews, and a meeting and subsequent correspondence with CMS, Purdue revised its methodologies for calculating the pricing data starting in the 1st Quarter of 2004. At that time, Purdue implemented the following key changes:

- Excluded non-mail order Pharmacy Benefit Manager rebates in calculating AMP. Result: Higher AMP/Higher Rebates;
- Excluded Indirect Hospital Sales in calculating AMP (correction of a programming error). Result: Higher AMP/Higher Rebates;
- Excluded Group Purchasing Organization fees in calculating Best Price. Result: Higher Best Price/Lower Rebates; and
- Adopted additional method to determine Best Price (Net Realizable Value). Result: Lower Best Price/Higher Rebates.

Purdue voluntarily recalculated and paid additional Medicaid rebates for the years 2000 through 2004 based upon the revised methodologies. The rebate payments made in 2004 and 2005 totaled approximately \$93 million.

As part of its resolution with the Government, Purdue agreed to extend the revised rebate methodologies to the calendar years 1998 and 1999 to the extent they were applicable. The \$3,087,277.60 contained in Paragraph 3.a(1) of the Purdue Frederick Plea Agreement reflects the additional amount of rebates owed for the years 1998 and 1999. This amount was paid in early April of 2007.

5. Does the Civil Settlement Agreement limit the ability of beneficiaries of federal health care programs to obtain payment or reimbursement for prescriptions for OxyContin?

The Civil Settlement Agreement does not limit the ability of beneficiaries of federal health care programs to obtain payment or reimbursement for prescriptions for OxyContin. Purdue Pharma, L.P., has entered into a Corporate Integrity Agreement (“CIA”) with the Department of

Health and Human Services, Office of Inspector General (“HHS-OIG”). *See* Attachment E to the Plea Agreement. HHS-OIG has agreed that so long as Purdue Pharma, L.P. complies with its obligations under the CIA it will not exclude Purdue Pharma, L.P. Accordingly, payment and reimbursement from federal health care programs will not be limited by the Civil Settlement Agreement.

6. Describe the expected use of the funds allocated in the Plea Agreements for operating the Virginia Prescription Monitoring Program.

See Attachment A to this document.

7. Describe the expected use of the funds allocated to the Virginia Medicaid Fraud Control Unit’s Program Income Fund.

The Virginia Medicaid Fraud Control Unit (“MFCU”) is operated pursuant to a federal grant that is administered by the Department of Health and Human Services (“HHS”). The grant is funded 75% by the federal government and 25% by the Commonwealth of Virginia. The regulations governing the grant (45 C.F.R. §§ 92.1 *et seq.*) classify funds received by a MFCU for investigative cost reimbursement as Program Income Funds. *See* 45 C.F.R. § 92.25. With prior written approval from HHS, a MFCU may spend Program Income Funds in a manner consistent with the purpose of the MFCU. For instance, 45 C.F.R. § 92.25(g) allows state MFCUs to spend Program Income Funds for their 25% state match of their budget, for their combined federal/state budget, or non-budgeted equipment, training, software and contractual service purchases.

The Virginia Attorney General’s Medicaid Fraud Control Unit intends to use the Program Income Funds set out in the Plea Agreement to pay for the 25% state share of the budget until those funds are exhausted. Currently, Virginia’s 25% share of the grant is \$930,157 per year. If properly invested by the Commonwealth, these Program Income Funds should allow the MFCU to fund its state share of the MFCU budget indefinitely. The MFCU also intends to use these funds to increase

the size and improve the capabilities of the Unit in an attempt to more effectively investigate other similar allegations of fraud and abuse in the pharmaceutical industry.

8. Describe the nature of the expected “monitoring costs” set aside to be expended by Purdue in connection with the Corporate Integrity Agreement.

Purdue Pharma L.P. expects to incur significant costs associated with implementing its Corporate Integrity Agreement (“CIA”) with HHS-OIG. It is expected that those costs incurred over the next six years, as provided by the plea agreement, will completely consume the \$5,012,722.40 set aside for that purpose. Included among those expected costs are: fees to be paid to an Independent Review Organization; third party Application Service Provider compliance suite software and personnel costs to assist with ensuring compliance with the CIA; costs associated with developing and delivering in person and online training as mandated by the CIA; and expenses related to maintaining the compliance hotline including outside provider costs; and an allocation of the personnel costs associated with the five person corporate compliance department, and fees and expenses associated with obtaining legal counsel on issues that arise in connection with the CIA, among other expenses.

Pursuant to the terms of the plea agreement, Purdue must provide to the United States an accounting of the moneys paid and will certify that all payments are paid as part of a monitoring program as set forth by the CIA between Purdue Pharma L.P. and HHS-OIG or otherwise to prevent future criminal activity by Purdue Pharma L.P. Any money not spent for these purposes, will be paid to the United States Treasury.

9. State why it is appropriate in this case that the individual defendants receive non-incarcerative sentences.

Michael Friedman, Paul Goldenheim, and Howard Udell (“Corporate Officials”) pled guilty to strict liability misdemeanor offenses based on the fact that they were responsible corporate officials at the time these offenses occurred. Under the *United States Sentencing Guidelines*, § 2N2.1, violations of 21 U.S.C. §§ 331 and 333(a)(1) have a base offense level of 6. This statute uniquely requires no proof of intent or actual knowledge of the violations by the Corporate Officials to establish their guilt for the misdemeanor offense. The intent of the statute is to impose the highest standard of care on certain corporate officials having authority over business organizations involved in activities regulated by the Federal Food, Drug, and Cosmetic Act. *United States v. Park*, 421 U.S. 658, 676 (1975). While it certainly is appropriate for the Corporate Officials to be held accountable for the actions of the company, a sentence of incarceration based on a strict liability offense, a Sentencing Guidelines’ total offense level of 6 or less, and a Criminal History Category of I would be unusual.

Even without a sentence of incarceration, conviction of the Corporate Officials will have significant consequences. Each Corporate Official will bear the stigma of being a convicted criminal, and the Court may impose a term of probation of up to five years. During the time period of probation, each defendant will live with the knowledge that any violation of probation can result in a sentence of imprisonment. Also, these unique guilty pleas by the company’s three top executives are likely to have a significant positive impact on the pharmaceutical industry by emphasizing the high standard of care that the law recognizes for those with authority over the activities of business organizations. While the strict liability misdemeanor for misbranding has been in effect for a great number of years, it has rarely been used against company executives for

misbranding a pharmaceutical product. The court's acceptance of the plea agreements and the resulting finding of guilt against the Corporate Officials will serve as a strong warning to executives of other pharmaceutical companies that they, too, will be expected to exercise the highest standard of care and diligence in the supervision and management of company activities and the actions of their subordinates to avoid the potential for appearance in a federal courtroom to face criminal charges. In addition, the contemplated non-incarcerative sentences are part of an overall negotiated resolution of a criminal investigation that will accomplish the objective of holding accountable a company and its executives for criminal conduct that previously had not been addressed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 6, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to Howard M. Shapiro, counsel for The Purdue Frederick Company, Inc., and I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

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