

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

UNITED STATES OF AMERICA)	
)	
)	Case No. 1:07CR00029
v.)	
)	OPINION AND ORDER
THE PURDUE FREDERICK COMPANY, INC., ET AL.,)	
)	By: James P. Jones
)	Chief United States District Judge
Defendants.)	
)	

John L. Brownlee, United States Attorney, Rick A. Mountcastle and Randy Ramseyer, Assistant United States Attorneys, Roanoke, Virginia, for United States; Howard M. Shapiro and Kimberly A. Parker, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C., for The Purdue Frederick Company, Inc.; Mark F. Pomerantz, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, N.Y., for Michael Freidman; Mary Jo White, Debevoise & Plimpton LLP, New York, N.Y., for Howard R. Udell; and Andrew Good, Good & Cormier, Boston, Massachusetts, for Paul D. Goldenheim.

The issue before the court is whether or not to accept the plea agreements in this case.¹

The Purdue Frederick Company, Inc. (“Purdue”) has pleaded guilty to misbranding OxyContin, a prescription opioid pain medication, with the intent to defraud or mislead, a felony under the federal Food, Drug, and Cosmetic Act. 21 U.S.C.A. §§ 331(a), 333(a)(2) (West 1999). The individual defendants, Michael

¹ This Opinion elaborates on the court’s oral opinion.

Friedman, Howard R. Udell, and Paul D. Goldenheim, have pleaded guilty to the misdemeanor charge of misbranding, solely as responsible corporate officers.² 21 U.S.C.A. § 333(a)(1) (West 1999); *see United States v. Park*, 421 U.S. 658, 676 (1975). The individual defendants are not charged with personal knowledge of the misbranding or with any personal intent to defraud.

The Information in this case charges, among other things, that

[b]eginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:

- a. Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;
- b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
- c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level

² Friedman is the former president and CEO of Purdue, Udell is the executive vice president and chief legal officer, and Goldenheim is the former chief scientific officer.

effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

- d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
- e. Told certain health care providers that OxyContin did not cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.

(Information ¶ 19.) Purdue has agreed that these facts are true, and the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the court may accept these facts in support of their guilty pleas. (Agreed Statement of Facts ¶ 46.)

The plea agreements have been submitted pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), which allows the parties to agree to a specific sentence to be imposed. The court is not bound by the plea agreements, and may reject them. If a plea agreement is rejected, that defendant must be given an opportunity to withdraw the guilty plea. Fed. R. Crim. P. 11(c)(5)(B). The government has agreed in this case that if the court rejects any of the plea agreements, the government will dismiss the Information filed in the case, without prejudice to the government’s right to later

indict the defendants or any other entity or individual on any charge. (Plea Agreements ¶ 2.) Accordingly, if the court rejects any of the plea agreements, the present case may end, and it will be up to the government to decide whether to re-prosecute the defendants, or any of them.

In addition to a lengthy hearing on the present issue, the parties were required to submit extensive written material, including financial information, for the court's consideration.

The Supreme Court has held that defendants have “no absolute right to have a guilty plea accepted.” *Santobello v. New York*, 404 U.S. 257, 262 (1971). The Court stated, “A court may reject a plea in exercise of sound judicial discretion.” *Id.* “[I]t is not only permitted but expected that the court will take an active role in evaluating the agreement.” *United States v. Kraus*, 137 F.3d 447, 452 (7th Cir. 1998). But as the Sixth Circuit stated, “By leaving the decision whether to accept or reject a plea to the exercise of sound judicial discretion, the Supreme Court did not intend to allow district courts to reject pleas on an arbitrary basis.” *United States v. Moore*, 916 F.2d 1131, 1136 (6th Cir. 1990) (internal quotations and citation omitted).

While the court's decision must not be arbitrary, “Rule 11 does not limit the reasons for which the district court may reject a proposed plea agreement.” *United States v. Skidmore*, 998 F. 2d. 372, 376 (6th Cir. 1993). “The authority to exercise

judicial discretion implies the responsibility to consider all relevant factors and rationally construct a decision.” *Moore*, 916 F.2d at 1136. Rule 11 explicitly states that a court cannot accept a plea if it is not supported by the factual record or if the court believes that that the plea is not voluntary. Fed. R. Crim. P. 11(b)(2),(3). But Rule 11 also allows a district judge to reject a plea agreement if it is too lenient or too harsh. *Skidmore*, 998 F.2d at 376.

In determining the proper criminal sentence, the court must consider certain factors set forth by statute. I must consider “the nature and circumstances of the offense and the history and characteristics of the defendant,” as well as

the need for the sentence imposed—(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; (C) to protect the public from further crimes of the defendant; and (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

18 U.S.C.A. § 3553(a) (West 2000 & Supp. 2004). The court’s obligation is to impose “a sentence sufficient, but not greater than necessary, to comply with” these purposes. *Id.*

Under the law, Purdue is subject to a penalty of five years probation and a fine of up to \$500,000. In its plea agreement, Purdue has agreed to substantial additional

monetary sanctions totaling \$600 million, reported to be one of the largest in the history of the pharmaceutical industry. The amount includes the following:

1. \$100,615,797.25 payable to federal government health care agencies under a Civil Settlement Agreement;
2. \$59,384,202.75 in escrow for those states that elect to settle their claims against Purdue. These civil settlements to the federal and state government total \$160 million, of which the federal government is receiving sixty percent;
4. \$3,471,220.68 to Medicaid programs for improperly calculated rebates;
5. \$500,000 fine to the United States;
6. \$20 million in trust to the Commonwealth of Virginia for operating the Virginia Prescription Monitoring Program;
7. \$5.3 million to the Virginia Medicaid Fraud Control Unit's Program Income Fund;
8. \$276.1 million forfeiture to the United States;
9. \$130 million to settle private civil claims related to OxyContin; and
10. \$4,628,779.32 to be expended by Purdue for monitoring costs in connection with a Corporate Integrity Agreement with the U.S. Department of Health and Human Services.

The individual defendants are subject to a punishment of twelve months imprisonment and a fine of up to \$100,000. In their plea agreements, they have agreed to pay a total of \$34.5 million to the Virginia Medicaid Fraud Unit's Program

Income Fund.³ In return, the government has agreed to sentences for them without any imprisonment.

There have been several reasons suggested why the court should reject the plea agreements.

Lack of Restitution. The plea agreements preclude restitution other than as set forth in the agreements and a number of alleged victims object to this provision, contending that the amounts allocated to private parties are insufficient, compared to the recovery by governmental victims. BlueCross BlueShield of Tennessee has filed a Request for Notice, an Opportunity to be Heard at Sentencing, and an Order of Restitution. Other third-party health care payors have joined in this motion. In addition, an individual who considers herself a victim because of her addiction to OxyContin has objected to the plea agreements and has filed a formal Motion to Assert Victim's Rights, in which she complains about restitution, as well as other matters.

These parties have received notice of this present proceedings and the court has allow them an opportunity to speak.⁴

³ Defendant Friedman has agreed to pay \$19 million, whereas defendants Udell and Goldenheim have agreed to pay \$8 million and \$7.5 million, respectively.

⁴ It is argued that the Crime Victims Rights Act, 18 U.S.C.A. § 3771(a)(2) (West Supp. 2007), has not been complied with in this case because general notice to potential

The government and the defendants, in agreeing to preclude other restitution, rely on the Victim and Witness Protection Act of 1982 (“VWPA”), which states in relevant part as follows:

To the extent that the court determines that the complication and prolongation of the sentencing process resulting from the fashioning of an order of restitution under this section outweighs the need to provide restitution to any victims, the court may decline to make such an order.

18 U.S.C.A. § 3663 (a)(1)(B)(ii) (West 2000 & Supp. 2007).⁵

victims has been insufficient. In fact, there has been extensive national publicity about the case, *see, e.g.*, Barry Meier, *Narcotic Maker Guilty of Deceit Over Marketing*, N.Y. Times, May 11, 2007, at A1, with widespread comment by victims rights blogs and Web sites. Notice of the sentencing and of the right of victims to attend and speak was published on the court’s Web site, and all of the pleadings and other documents filed in the case have been available for viewing without charge on that site. The court received numerous letters and e-mails from interested members of the public concerning the scheduled sentencing. Any person known to be a possible victim was given individual notice of the hearing and of the right to speak, and over twenty people accepted this opportunity. The main courtroom was full, and a second courtroom equipped with an audio and video feed was used for the overflow. I find that notice to potential victims was adequate.

⁵ The plea agreements cite to this provision of the VWPA. The Mandatory Victims Restitution Act of 1986 (“MVRA”) has nearly identical language:

This section shall not apply in the case of an offense described in paragraph (1)(A)(ii) if the court finds, from facts on the record, that—

- (A) the number of identifiable victims is so large as to make restitution impracticable; or
- (B) determining complex issues of fact related to the cause or amount of the victim’s losses would

In order to award an alleged victim restitution under either the VWPA or the MVRA, the court would have to determine whether that person was “directly and proximately” harmed by the misbranding offense that was the subject of the plea agreements. The Fourth Circuit has held that to be considered “directly and proximately harmed” under either the VWPA or the MVRA, a person must show that the harm resulted from “conduct underlying an element of the offense of conviction.” *United States v. Blake*, 81 F.3d 498, 506 (4th Cir. 1996) (construing the phrase “directly and proximately harmed” under the VWPA); *see also United States v. Davenport*, 445 F.3d 366, 374 (4th Cir. 2006) (citing to *Blake* but interpreting the phrase “directly and proximately harmed” as used in the MVRA).

Purdue argues that third-party payors cannot show that they were directly and proximately harmed by Purdue’s misbranding, unless they can prove the following:

1. That a Purdue sales representative misstated to a specific prescribing physician that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance or withdrawal than other pain medications;

complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

18 U.S.C.A. § 3663A (c)(3) (West 2000 & Supp. 2007). The Crime Victims Rights Act confirms the general right of victims to “full and timely restitution as provided in law.” 18 U.S.C.A. § 3771(a)(6) (West Supp. 2007).

2. That specific prescribing physician relied upon that misstatement by that Purdue sales representative and, in reliance on that misstatement, prescribed OxyContin rather than an alternative pain medication (e.g. Percocet) for one of the private third-party payor's insured individuals;
3. That the physician prescribed OxyContin for the insured because of the misstatement and not because of the other attributes of OxyContin (e.g., twelve-hour dosing or the absence of acetaminophen, which risks liver toxicity);
4. That the private third-party payor paid for that prescription of OxyContin; and
5. That the private third-party payor paid more for the OxyContin prescription than the particular alternative pain medication that the prescribing physician would have prescribed if he or she had not relied on the misstatement and prescribed OxyContin.

(Purdue's Resp. July 9, 2007, at 9-10.)

Purdue further argues that the chain of causation between the harm alleged and the misbranding offense could have been broken by any intervening act on behalf of the insured patient or the prescribing health care professional. For example, if patients obtained OxyContin improperly by deceiving their physicians or by altering an otherwise proper prescription, the third-party payors would not be entitled to restitution for those prescriptions since the misbranding did not directly and proximately caused any financial loss to the third-party payor. Or if a physician negligently prescribed OxyContin, the third-party payor that paid for that prescription

is also not entitled to restitution because the misbranding once again did not directly and proximately cause the third-party payor's financial loss.

Even if third-party payors can show that they were directly harmed by Purdue's misbranding, Purdue claims that each payor would have to present to this court the facts of every instance of overpayment in order for the Court to determine the proper amount of restitution for each third-party payor.

As to any individuals injured by the use of OxyContin, the difficulties of establishing causation are demonstrated by the numerous civil suits that have been filed by such persons against Purdue, including two before this court, *McCauley v. Purdue Pharma, L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004), and *Ewing v. Purdue Pharma, L.P.*, No. 2:02CV00150, 2004 WL 1856002 (W.D. Va. Aug. 19, 2004). Courts have consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding proximately caused their injuries. *See, e.g., Bodie v. Purdue Pharma Co.*, No. 05-13834, 2007 WL 1577964, at *3 (11th Cir. June 1, 2007) (affirming the district court's conclusion that the plaintiff's claims failed because he could not show that he was proximately harmed by Purdue's allegedly inadequate warnings); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 556 (N.D. Tex. 2006) ("Because plaintiffs have failed to show that an adequate warning would have changed [the physician]'s decision to prescribe OxyContin, and

because [the physician] testified that he would not have changed his decision, the Court finds that Plaintiffs have failed to raise a genuine fact issue.”); *Timmons v. Purdue Pharma Co.*, No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, at *4 (M.D. Fla. Feb. 2, 2006) (“Even if OxyContin were considered unreasonably dangerous, which it has not been deemed so, Plaintiff has failed to show any evidence of causation.”); *McCauley*, 331 F. Supp. 2d at 465 (granting Purdue’s motion for summary judgment and stating “[t]he plaintiffs’ burden is greater than merely showing a temporal link between their use of OxyContin and any injuries they sustained. Instead, it is evidence of the causal link between OxyContin and their injuries that the plaintiffs lack.”); *Foister v. Purdue Pharma, L.P.*, No. 01-268-JBC, 2001 U.S. Dist. LEXIS 23765, at *27 (E.D. Ky. Dec. 27, 2001) (denying the plaintiffs’ motion for injunctive relief and noting that the “plaintiffs have failed to produce any evidence showing that the defendant’s marketing, promotional, or distribution practices have ever caused even one table of OxyContin to be inappropriately prescribed or diverted.”).

It is argued that restitution might be handled in this case as with a civil class action claim, but class certification has been generally denied in OxyContin claims because of the variety of causation issues. *See, e.g., Hurtado v. Purdue Pharma Co.*, No. 12648/03, 2005 WL 192351, at *1 (N.Y. Sup. Ct. Jan. 24, 2005) (denying class

certification “because of the different reasons and methods by which the drug was prescribed and used.”).

It is true that the governmental health care providers have been allotted a portion of Purdue’s payment in settlement of their civil claims for the misbranding of OxyContin (\$160 million) that is greater than the portion to be used by Purdue to settle private claims (\$130 million). However, Purdue’s liability for private claims is not capped by the plea agreements. Purdue agrees to pay at least \$130 million to settle private claims, but no maximum limit is imposed. I do not find that the plea agreements are inherently unfair in this regard.

Accordingly, in spite of the arguments by putative victims, I agree that the restitution process would unduly complicate and prolong the sentencing process. In order to prove causation, litigation over many months, if not years, would be required before final judgment in this case could be entered. Such delay would be contrary to the basic principles of our criminal justice system.

I would have preferred that the plea agreements had allocated some amount of the money for the education of those at risk from the improper use of prescription drugs, and the treatment of those who have succumbed to such use. Prescription drug abuse is rampant in all areas of our country, particularly among young people,

causing untold misery and harm. The White House drug policy office estimates that such abuse rose seventeen percent from 2001 to 2005. That office reports that currently there are more new abusers of prescription drugs than new users of any illicit drugs. As recently reported, “Young people mistakenly believe prescription drugs are safer than street drugs . . . but accidental prescription drug deaths are rising and students who abuse pills are more likely to drive fast, binge-drink and engage in other dangerous behaviors.” Carla K. Johnson, *Arrest Puts Spotlight on Prescription Drug Abuse*, The Roanoke Times, July 6, 2007, at 4A. It has been estimated that there are more than 6.4 million prescription drug abusers in the United States.

On the other hand, I am forbidden by law to participate in plea discussions, Fed. R. Crim. P. 11(c)(1), and I will not reject these agreements simply because they do not contain provisions that I would have preferred. The government has represented that it did not demand inclusion of a treatment provision in the plea agreements because national drug policy has been placed by Congress in the Substance Abuse and Mental Health Service Administration, an agency of the U.S. Department of Health and Human Services. The government prosecutors were reluctant to direct treatment funds in a manner beyond their expertise and possibly contrary to national policy. I will not second-guess their decision in this regard.

Political Interference. It has been suggested that Purdue may have received a favorable deal from the government solely because of politics.

I completely reject this claim. I have had long experience with the United States Attorney for this district, and I am convinced that neither he nor the career prosecutors who handled this case would have permitted any political interference. In fact, I am sure that they would have refused to accept a plea agreement that they did not sincerely feel was in the best interests of justice.

Lack of Incarceration. The plea agreements provide for no incarceration for the individual defendants. The government points out that a sentence of incarceration under the federal sentencing guidelines would be unusual based on the facts of the case. The government is also convinced that the nature of the convictions of the individual defendants—based on strict liability for misbranding—will send a strong deterrent message to the pharmaceutical industry. The defendants point to their lack of prior criminal record, their strong commitment to civic and charitable endeavors, as well as their other positive personal attributes. On the other hand, the potential damage by the misbranding disclosed in this case was substantial and I do not minimize the danger to the public from this crime. The defendants voluntarily accepted responsibility over this business enterprise, for which they were generously rewarded. However, while the question is a close one, I find that in the absence of

government proof of knowledge by the individual defendants of the wrongdoing, prison sentences are not appropriate.

Summary. In summary, I find that the plea agreements are supported by the facts and the law and impose adequate punishment on the defendants and I accept them. Moreover, for the reasons stated, I will deny the third party motions. (Dtk. Nos. 35, 42, 43, 44, 48, 49 and 65.)

It is so **ORDERED**.

ENTER: July 23, 2007

/s/ JAMES P. JONES
Chief United States District Judge