U.S. Department of Justice

Criminal Division

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INTERNAL MEMORANDUM

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FROM: Kirk Ogrosky
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SUBJECT: Proposed Indictment of Purdue Pharma LP, The Purdue Frederick Company, Michael Friedman (COO), Howard R. Udell (EVP GC), Paul D. Goldenheim (EVP); Conference scheduled for October 11, 2006

This memorandum summarizes my review of the proposed Indictment of the above named entities and individuals in preparation for a conference with defense counsel. It is my understanding that negotiations with the parties have continued and that a Deferred Prosecution Agreement ("DPA") has been contemplated. My observations are based strictly on the line prosecutors summary of the evidence as articulated in the Prosecution Memorandum dated September 28, 2006. I have not been provided or reviewed testimony or documents, nor have I conducted independent legal research related to the legal analysis contained therein.

Based upon my review of the summary and cited testimonial and documentary evidence, and the material submitted to the government by the defendants on September 21 and 22, 2006, I concur with the recommendation that authorization be granted to charge the defendants with: (1) Conspiracy, in violation of 18 U.S.C. § 371; (2) Mail Fraud, in violation of 18 U.S.C. §§ 2 and 1341; (3) Wire Fraud, in violation of 18 U.S.C. §§ 2 and 1343; (4) Interstate Distribution of Misbranded Drug With Intent to Defraud, in violation of 18 U.S.C. § 2 and 21 U.S.C. §§ 21 U.S.C. §§ 21 U.S.C. § 331(a), 352(a), and 333(a)(2); (5) Conspiracy to Commit Money Laundering, in violation of 18 U.S.C. § 1956(h); and (6) Money Laundering, in violation of 18 U.S.C. § 1957.

There does not appear to be a reasonable basis for further delay in this prosecution. In addition, there are compelling reasons to move forward with indictment given public health considerations. Endangering public health has been and continues to be a strong factor for consideration in the criminal law enforcement process. *See generally* U.S.S.G. 5K2.14 (authorizing sentencing enhancements for endangering public health). Courts frequently enhance the sentences of defendants that engage in criminal conduct that poses a significant threat to public health and safety. Perhaps no case in our history rivals the burden placed on public health and safety as that articulated by our line prosecutors in the Western District of Virginia. OxyContin abuse has significantly impacted the lives of millions of Americans, and the fraudulent scheme and conduct articulated in this matter has a direct correlation to this threat.

With knowledge of the severe potential for abuse and addiction, the named defendants knowingly targeted and marketed OxyContin in a scheme designed to increase company profit by telling physicians throughout this country that OxyContin was less addictive than alternative medicines due to delayed absorption. Further, the defendants buttressed these false claims with additional false statements that patients could quickly stop taking the OxyContin without suffering significant withdrawal side-effects. Based on the evidence, these false statements were willingly and knowingly made to promote and market OxyContin and significantly contributed to the sales of approximately $9 billion worth of OxyContin since 1996. I see no basis to delay this matter further unless new and compelling issues are raised on October 11, 2006.

A. FDA Approval of OxyContin

While not part of the proposed Indictment, Perdue's conduct in the early 1990s in seeking approval for OxyContin evidences criminal intent. The FDCA required Purdue to obtain FDA approval of a New Drug Application ("NDA") and all labeling or package insert ("PI") material prior to the distribution of OxyContin. Purdue submitted applications on December 28, 1994 for its 10, 20, and 40 milligram tablets. In those applications, the evidence of OxyContin's safety and efficacy relied on clinical studies comparing OxyContin to the then current approved regiment of immediate-release oxycodone ("Roxicodone"). Within two months of submission, Purdue learned that Roxicodone's dosing schedule had been changed and the clinical studies in their submission were no longer a valid basis for comparison. Despite significant internal discussion and evaluation, Purdue failed to alert the FDA to this change or the impact on its studies.

On December 12, 1995, the FDA approved the OxyContin NDA based on Purdue's application. The key consideration is whether this intentional failure to disclose was material to the FDA approval. While Purdue believed it material at the time, there is debate among individuals associated with the FDA approval process as to whether these facts, had they been known, would have derailed or impacted the approval process. Given conflicting evidence, WDVA and OCL have proposed to not pursue charges related to this misconduct. Nevertheless, it begins the story of how OxyContin gained approval and entered the market. As of today, OxyContin is one of the most widely abused products in the country and has generated

approximately 9 billion in sales for Purdue.

B. Conspiracy to Defraud Through Marketing of OxyContin

The Indictment charges a multi-object conspiracy with the overall goal of maximizing the revenues from the sale of OxyContin through fraud, deceit, and false statement. The fraudulent marketing scheme was that the conspirators trained Purdue's sales force, and provided them with training and marketing materials, to sell OxyContin as better than other pain medications already in use, particularly immediate-release, or short-acting, medications. The primary claims of superiority were that OxyContin was less abusable, less addictive, and less subject to diversion, caused fewer side effects, such as euphoria, and, that at low doses (20-60 mg), could be discontinued without tapering since patients would experience no withdrawal symptoms.

The clear evidence is that the FDA approval process was tainted with efforts to position OxyContin to be marketed as less addictive, less abusable, and less divertable than other opioids. Once approved and the marketing scheme was underway, Purdue began receiving reports from providers and the media that indicated widespread abuse and diversion. Even at that time, the company took the position that it needed a strategy to contain negative press. Purdue told sales representatives that it was the company's position that the public debate about OxyContin abuse and diversion was "a direct result of the hysteria and fear created by exaggerated media coverage of this problem . . ." Fearing further bad publicity and efforts by the government, including Congress, FDA, and DEA, to more stringently regulate OxyContin marketing and promotional activities, Purdue implemented a strategic plan to focus on voluntary efforts to limit access of OxyContin to patients with a legitimate medical need so that the government would not interfere with the doctor-patient relationship. Given the data from the approval process, the ultimate question was whether there was any need for OxyContin at all given the data related to available products in the market. Consistent with this plan, defense counsel are still raising similar arguments today as a reason to discourage prosecution.

As a preliminary matter, Purdue publicly stated that it had no knowledge of the abuse and diversion of OxyContin until the first half of 2001. During their testimony in Congressional hearings on August 28, 2001, December 11, 2001, and February 12, 2002 the conspirators falsely and fraudulently told Congress that they had no knowledge of the extensive abuse and diversion of OxyContin before 2001.

The government has developed compelling evidence that defendants Friedman, Udell and Goldenheim, all senior executives at Purdue who had primary responsibility for running the company, reached an agreement to promote and market OxyContin through their sales force using marketing information containing known false and misleading information. These individuals also made false statements to Congress to further and conceal the extent of Purdue's prior knowledge of the underlying falsity.

To address its market research findings that physicians treating non-cancer pain were likely to hesitate in prescribing OxyContin due to concerns about addiction and abuse, the conspirators promoted OxyContin as superior to immediate-release pain medicines by claiming that it produced significantly less fluctuation, or "peaks and troughs," in oxycodone blood plasma concentrations than the immediate-release medicines.

The conspirators first sought to use this promotion angle in its OxyContin launch marketing materials, submitted to the FDA for review and approval. On October 12, 1995, PURDUE submitted some of its proposed launch marketing materials for review by FDA. The FDA responded on December 20, 1995, objecting to the "fewer peaks and valleys" claim and suggested "that the blood levels for both dosage forms be presented" so that data could be accurately interpreted. Purdue replied that "[t]he comparative statement, 'Fewer peaks and valleys' than with immediate-release oxycodone' was deleted." Nevertheless, sales representatives were taught to tell physicians that OxyContin provided more favorable oxycodone blood levels than other pain medications, they were not taught to show physicians the graph of the actual comparison of blood levels.

On November 4, 1996, the Training & Development Department sent a memorandum to the entire field force advising them to tell healthcare providers that "OxyContin can provide pain relief to your patients allowing them to sleep through the night, while potentially creating less chances for addiction than immediate-release opioids." Purdue knew that the FDA had opined that there was not enough evidence to claim that OxyContin was superior to other pain medications in adverse events, that there was actually a potential that OxyContin's slower fall and slightly higher trough blood levels might result in greater development of tolerance and/or withdrawal, and that OxyContin had not been shown to have a significant advantage beyond reduction in frequency of dosing. Purdue's top executives expressed the importance of marketing OxyContin as better than other medications because it was less addictive and less abusable. Evidence establishes that sales representatives did in fact promote OxyContin as having less euphoria, or buzz, than other pain medications, or as causing no euphoria at all.

The individual defendants appeared before House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigation, and gave false testimony in hearings chaired by Congressman Greenwood and entitled "OxyContin: Its Use and Abuse. On December 17, 2001, to further the strategy of claiming ignorance about the abuse of OxyContin, Friedman disseminated Goldheim's false testimony to the entire field force claiming no knowledge of OxyContin abuse and diversion before early 2000, and its false claim of OxyContin's superiority over short-acting analgesics.

C. Fraudulent Sales and Marketing Campaign Based on False Statements in FDA Applications and Labeling Materials

The FDA Medical Officer tasked with reviewing the OxyContin applications was Dr. Curtis Wright, IV. Dr. Wright's review included writing Medical Officer Reviews ("MOR") of the Integrated Summary of Safety ("ISS") and Integrated Summary of Efficacy ("ISE") submitted as part of the NDA. His MOR of the ISS was completed May 19, 1995, and signed October 16, 1995. His MOR of the ISE was completed June 19, 1995, and signed October 16, 1995. In sum, he initially concluded that OxyContin was "as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing." Based on this, he did not support claims that OxyContin was less likely to produce addiction. Nevertheless, two key and misleading statements were contained in the PI that became the basis of Purdue's aggressive OxyContin marketing campaigns. These statements were (1) "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" ("the Delayed Absorption Statement"); and (2) "When the patient no longer requires therapy with OxyContin tablets, patients receiving doses of 20-60 mg/day can usually have the therapy stopped abruptly without incident" ("the Stop Therapy Abruptly Statement").

The origin of the Delayed Absorption Statement is unclear. As late as July 21, 1995, the draft OxyContin PI had no language like this. However, it first appeared in an August 16, 1995 letter Purdue sent to the FDA. This language was amended and submitted to the FDA on September 13, 1995. Dr. Wright testified that this statement was included as a result of his request that Purdue include information in the PI about the abuse liability of OxyContin. An FDA employee questioned the accuracy of this statement on November 21, 1995, but deferred to Dr. Wright. The inclusion of the Delayed Absorption Statement is at odds with Wright's conclusions in his MORs of the ISE and the ISS; however, he later testified that the PI language is "literally true." Ultimately, Purdue built its scheme to falsely and fraudulently market OxyContin around this false statement, among others, describing it as "so valuable and promotional that it easily served as principal selling tool."

The Stop Therapy Abruptly Statement has similarly mysterious origins. Dr. Wright originally stated that the data in his review of the ISS led him to conclude that "the reaction to abrupt withdrawal of oxycodone was typical for opioid analgesics." Again in apparent contradiction to the conclusions of the MOR of the ISS, the Stop Therapy Abruptly Statement was allowed to remain in the OxyContin PI. Dr. Wright could not recall when, how, or why that language was included in the PI.

Questions have been raised about Dr. Wright's dealings with Purdue. Purdue recorded the content of certain contacts with Dr. Wright. The records suggest that Wright solicited Purdue's help in writing his MORs. Further, Dr. Wright told Perdue that the NDA review could be accelerated if the company traveled to FDA's location in Rockville, Maryland, in January or February 1995, rented a room nearby, and spent three to five days helping him write the reviews of the clinical study reports and the integrated summaries of efficacy and safety. This

was done during January 31 through February 2, 1995. Interestingly, a March 24, 1995 email, within three months after the submission of the NDA and nearly nine months before it was actually approved, a Perdue employee advised Udell and others that Dr. Wright "has confirmed that we will receive an APPROVAL letter for OxyContin (NDA 20-553) by the end of December 1995." On October 9, 1998, a year after he left the FDA, Purdue offered Dr. Wright a job as an Executive Medical Director, with a first year compensation package of at least $379,000. Dr. Wright started in this position on December 1, 1998.

D. No Reason to Further Extend the SOL

The alleged conspiracy began in October of 1992 and continues to date. The proposed indictment is scheduled to be sought on October 25, 2006. It is my understanding that this date is based on the government's prior accommodation of the Defendants requests for additional time. Given the scope of the investigation, there appears to be no valid reason to further extend the SOL. Given Purdue's reported OxyContin revenue, a further delay will merely allow the continued fraudulent sales and marketing of OxyContin and substantial additional revenue to the Defendants. There is a direct financial incentive for seeking an extension – which appears to be in excess of 100 million per month.

Based upon the summary in the prosecution memorandum, it appears that the government has interviewed the key identified witnesses and has assembled the relevant documentary evidence. Given the nature of the alleged crimes, it is my opinion that a misguided investigation could continue for decades without adding any new or more valuable evidence to that already in the possession of the government. While I have heard no factual proposition that appears to merit further investigation, I am always open to hearing from all parties as to the state of the evidence and whether more should be done. At this time, I simply see no reason to delay given the evidence and potential danger associated with OxyContin abuse.