UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	
	)	
v.	)	
PHARMACIA & UPJOHN	)	CRIMINAL NO. 07-10099-RGS
COMPANY, INC.,	)	
	)	
Defendant.	)	
	)	

GOVERNMENT'S SENTENCING MEMORANDUM

The United States submits this sentencing memorandum in support of the Rule 11(c)(1)(C) plea agreement entered into between the United States Attorney's Office for the District of Massachusetts and the defendant Pharmacia & Upjohn Company, Inc. ("Pharmacia"). Before this Court is the proposed Rule 11(c)(1)(C) plea agreement and whether that agreement fairly and adequately punishes Pharmacia for its criminal conduct.

Pharmacia has been charged with, and has agreed to plead guilty to, one count of offering a kickback in violation of 42 U.S.C. §1320a-7b(b), and has agreed to pay a criminal fine of $19,680,000. Set forth below is a description of the charge and an explanation of the parties' sentencing guideline calculations yielding the criminal fine of $19,680,000.

I. The Offer to Pay a Kickback

The felony charged in the Information, and to which Pharmacia has agreed to plead guilty, is an offer to pay a kickback in violation of 42 U.S.C. §1320a-7b(b)(2)(B). That subsection provides, in pertinent part:

> whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order, or arrange for

> or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony. . .

This statute, sometimes known as the Anti-Kickback Act, was enacted to prevent the corruption of medical decisionmaking and prevent fraud, abuse and waste on the Medicare/Medicaid system. E.g., United States v. Greber, 760 F.2d 68, 70-71 (3d Cir. 1985).

The Information charges that Pharmacia offered a kickback to a subsidiary of a pharmacy benefit manager in order to induce the pharmacy benefit manager to recommend Pharmacia's drug products to the pharmacy benefit manager's clients. A pharmacy benefit manager ("PBM") is a middleman between pharmaceutical companies and health plans. Typically, pharmacy benefit managers, the largest of which are publicly traded companies, have various health plans as their "clients." On behalf of these clients, PBMs often negotiate volume discounts with pharmaceutical companies for their pharmaceutical products. PBMs also develop and recommend "formularies" to some of their health plan clients. A formulary is a list of drug products. Often formularies rank drugs in the same class or designate a certain drug as the preferred one in its class. The selection of drugs for inclusion on a formulary is supposed to be based on the independent judgment of the PBM based on factors such as cost, efficacy and safety. Placing a drug on a formulary or improving its position on a formulary constitutes "recommending the purchasing or ordering" of a drug within the meaning of the Anti-Kickback statute. As discussed further herein, Pharmacia's offer of a kickback was designed to undermine the independent judgment of the PBM in reaching formulary decisions with respect to Pharmacia drug products.

A. The Defendant

Pharmacia & Upjohn Company, Inc. is a Delaware corporation with a principal place of business in Kalamazoo, Michigan and is a wholly owned subsidiary of Pharmacia & Upjohn Company LLC, the successor to Pharmacia & Upjohn Company, which was a subsidiary of Pharmacia Corporation (collectively "Pharmacia"). In April 2003, Pfizer acquired Pharmacia Corporation and all of its subsidiaries. Before its acquisition by Pfizer, Pharmacia Corporation was publicly traded on the New York Stock Exchange.

During the relevant time frame, namely the year 2000, Pharmacia developed, manufactured, distributed and sold pharmaceutical products nationwide and in the District of Massachusetts. Among those pharmaceutical products were Celebrex, Detrol, Genotropin and Xalatan. Pharmacia was organized in business units. One of the business units was called the Endocrine Care Business Unit, which was responsible for the sale and promotion of Genotropin.

B. The Bridge Program

Genotropin was a human growth hormone product, initially approved by the FDA in 1995 for treatment of children with growth failure due to inadequate secretion of endogenous growth hormone. Genotropin was an injectable drug and was extremely expensive, costing as much as $20,000 per year. Accordingly, third party payors such as insurers and federal health care programs scrutinized Genotropin prescriptions closely. In addition, the drug required special handling, such as refrigeration. Given the difficulties in distribution and insurance reimbursement, Pharmacia outsourced those administrative duties to a third party vendor. Pharmacia called this outsourced program the "Bridge Program."

In early 2000, Pharmacia determined that its then-current Bridge Program vendor was not performing to Pharmacia's satisfaction. As a result, Pharmacia announced that it was putting the contract for administration of its Bridge Program out to bid. Thereafter, Pharmacia put together a Bridge Program Request for Proposal ("Bridge Program RFP"). The Bridge Program RFP was widely hailed within Pharmacia as being one of the most comprehensive RFPs ever developed by Pharmacia.

In spring of 2000, Pharmacia met with various companies that it viewed as potentially interested in the Bridge Program RFP. In that same time frame, Pharmacia sent the RFP out to a handful of interested bidders. In June 2000, Pharmacia received bids in response to the Bridge Program RFP from three entities.

Shortly after receiving those bids, a number of Pharmacia employees rated the bids, each using a matrix with over a dozen criteria. Those criteria included the following:

- understanding the Bridge Program and its needs
- ability to deliver Bridge Program needs
- cost competitiveness
- quality systems, products and services
- responsiveness

Every Pharmacia evaluator judged Company P to be the best overall bidder. Moreover, Company P's bid was judged by Pharmacia to be at least $20 million less expensive over the life of the 3 year Bridge Program contract than another bidder, the subsidiary of a pharmacy benefit manager referred to in the Information and herein as "Company Q" or "the PBM." Significantly,

even if one ignored the "cost competitiveness" criterion, Company P would still have prevailed because its quality of services was determined by Pharmacia to be highest.

By memorandum dated July 19, 2000, the Endocrine Care Business Unit at Pharmacia recommended to Pharmacia's senior management that Company P be selected to manage the Bridge Program. A portion of that recommendation stated:

> A team of representatives from Pharmacia's Procurement, Auditing Services, Accounting, Distribution, Legal, Sales, Accounting and Marketing functions was composed to perform site visits and review RFP responses and presentations. Based on input from Marketing, Accounting, Distribution, Auditing Services and Procurement through their individual completion of the RFP evaluation form, and internal financial analysis of proposed program costs, collectively the team recommends [Company P] as Pharmacia's new Genotropin Bridge Program outsourcing partner.

Around the same time, senior management of Pharmacia's Endocrine Care Unit contacted senior management at Company P to notify Company P that it had been awarded the Bridge Program.

C. The Offer of a Kickback

While the Endocrine Care Unit was recommending Company P for selection (and notifying Company P of its selection), others within Pharmacia were working at cross purposes. In mid-July 2000, certain employees of Pharmacia were engaged in a dialogue with certain employees of Company Q, one of the largest and most influential pharmacy benefit managers or "PBMs" in the country. In terms of influence, this PBM claimed through its contracts with a large number of health plans that it had tens of millions of American "lives under management." Through its formulary recommendations, this PBM had the power to influence the drug choice of tens of millions of Americans and Pharmacia was well aware of this fact in mid-July of 2000.

Based on its conversations with this PBM (Company Q) in July 2000, Pharmacia believed that the PBM was willing to improve the formulary position of certain Pharmacia drug products in return for Pharmacia awarding the Bridge Program contract to the subsidiary of this PBM. This belief was informed by a number of conversations and meetings. One such conversation took place on July 13, 2000 by means of a conference call, initiated by the PBM, between employees of the PBM and employees of Pharmacia. During that conversation, certain of the PBM employees emphasized the interest of its subsidiary in obtaining the Bridge Program contract. They also described assistance that the PBM could provide in generating sales for Pharmacia's drug products. Some of that assistance revolved around formulary placement for certain drugs, some that assistance involved "formulary ancillary benefits," such as special disease based web sites and services to notify patients by mail that their prescriptions were running out and should be refilled.

One week later, on July 20, 2000, a group of the PBM employees and Pharmacia employees met at Pharmacia's Skokie, Illinois offices. At this meeting, the PBM employees reiterated their interest in seeing the Bridge Program contract awarded to the PBM's subsidiary. Pharmacia informed them that their bid was $20 million more expensive than that of another bidder. The PBM employees again discussed assistance that the PBM could provide in generating sales of Pharmacia's drug products, though this time with more specificity. In addition, a high level employee of the PBM provided the Pharmacia employees with a private tutorial on the PBM's formulary bidding process. Further dialogue between Pharmacia and the PBM narrowed the price difference between Company P's Bridge Program contract bid and that

of the PBM's subsidiary to $12.3 million.

In the wake of these discussions, in late July 2000, Pharmacia prepared financial analyses to evaluate and value the anticipated financial benefits for Pharmacia resulting from improved formulary positioning and formulary ancillary benefits by the PBM. These analyses showed that the anticipated financial benefits to Pharmacia resulting from more sales of Pharmacia drugs due to the expected improved formulary positioning and formulary ancillary benefits for those drugs were worth millions of dollars. In short, Pharmacia determined that the expected formulary improvements on Company Q's (the PBM's) formulary would enable Pharmacia to earn millions of dollars in extra profit based on increased sales of those drugs. In other words, Pharmacia knowingly and willfully offered to pay an inflated price to a subsidiary of the PBM to administer the Bridge Program to induce the PBM to recommend purchasing or ordering Pharmacia's drugs that were paid for in whole or in part under a Federal health care program.

There were a number of different voices within Pharmacia which did not want to offer the Bridge Program contract to the subsidiary of Company Q, let alone at a cost of $12.3 million more than Company P's bid. There were people who objected on the basis that Company P was a higher quality service provider (and significantly less costly). There were people who worried that the subsidiary of Company Q would be difficult to manage because the Bridge Program contract would pale in significance to the extra drug sales that could be generated by Company Q's formulary decisions. There were people who objected because the Endocrine Care Unit, which had its financial performance evaluated by Pharmacia corporate on a stand alone basis, would be penalized by having to pay out $12.3 million more over 3 years on the Bridge Program

contract than it would have had it selected Company P.

A financial analysis by Pharmacia concluded that when the bids of Company P and Company Q's subsidiary were analyzed side by side, Company P was the clear choice. However, the Pharmacia financial analysis also concluded that when factoring in the benefits of expected formulary positioning and formulary ancillary benefits that would be obtained from Company Q, an award to Company Q's subsidiary "maximized" the total "corporate value" to Pharmacia. Moreover, in an effort to assuage the Endocrine Care Business Unit's concern that it would have to incur $12.3 million in excess costs over 3 years if Pharmacia awarded Company Q's subsidiary the Bridge Program contract, Pharmacia promised the Endocrine Care Business Unit that another business unit within Pharmacia that expected to benefit from the improved formulary positioning and formulary ancillary benefits would reimburse the Endocrine Care Business Unit for these excess costs. This promise was made with the knowledge and approval of Pharmacia's senior business executives.

On or about August 1, 2000, Pharmacia retracted the award of the Bridge Program contract to Company P, despite believing that Company P's bid price for the contract was millions of dollars lower, and that Company P's ability to deliver quality service was higher, than the bid presented by Company Q's subsidiary. Company P's Vice-President asked the reason for Pharmacia's about-face, and was told by a Pharmacia employee that Company P was losing out because Company Q (the PBM) had formularies and Company P did not.

Instead, on or about August 1, 2000, Pharmacia offered the Bridge Program contract to Company Q's subsidiary, at an inflated price of $12.3 million more than Company P's higher

quality bid. Pharmacia made this offer to induce Company Q to recommend the purchasing or ordering of Pharmacia drug products by improved formulary positioning and/or formulary ancillary benefits. Pharmacia expected, as its financial analysis had concluded, that Company Q's recommendation to purchase or order Pharmacia's drug products through formulary positioning would increase sales of Pharmacia's drugs by many millions of dollars.

Pharmacia acted knowingly and willfully in committing this crime. In the First Circuit, the "knowingly and willfully" standard under the statute has been defined by the following jury instruction:

> Knowingly simply means to do something voluntarily, to do it deliberately, not to do something by mistake or by accident or even negligently. Willfully means to do something purposely, with the intent to violate the law, to do something purposely that [the] law forbids.

United States v. Bay State Ambulance, 874 F.2d 20, 33 (1st Cir. 1989).

Pharmacia's 2000 Legal and Regulatory Policies specifically warned of Fraud and Abuse in the context of the Anti-Kickback Statute. Those policies articulated the "Key Legal Principles" of a violation and included: (1) the language of the anti-kickback law is broad; (2) the one purpose test -- there is a violation even if there are legitimate purposes to the payment; (3) there does not have to an actual direct increase in Medicare or Medicaid costs for a violation; and (4) the fact that a particular arrangement is common in the industry is not a defense. The policies go on to warn that care must be taken to "ensure that service is not tied to value/volume of referrals, purchases, or appear as a quid pro quo." Pharmacia was aware of the Anti-Kickback Act, trained its employees on the law, and understood it was wrong to offer to offer or pay remuneration to induce a PBM to recommend purchasing or ordering Pharmacia's drugs.

II. <u>Application of the Sentencing Guidelines</u>

Under the Rule 11(c)(1)(C) plea agreement, the parties agree that Pharmacia should pay $19,680,000.00 as a criminal fine, a fine at the low end of the Guideline range. The Guideline Manual in effect as of November 1, 2000, was used because the conduct at issue took place in June/July/August of 2000 and that book may be more lenient to the defendant. See U.S.S.G. §§1B1.11(a) and (b)(1) (November 1, 2000 and November 1, 2006), and particularly U.S.S.G. §2B4.1(b) (specific offense characteristics for a $12.3 million bribe/kickback would result in increase of 20 levels under 2006 book and only 15 levels under 2000 book).

With respect to the count of conviction, offer of a kickback in violation of 42 U.S.C. §1320a-7b(b)(2)(B), Pharmacia is subject to a maximum possible fine of $500,000, twice the gross pecuniary gain derived by any person from the offense, or twice the gross pecuniary loss to a person resulting from the offense. 18 U.S.C. §§3571(c) and (d). The gross gain (and loss) from the offense is $12,300,000, and thus the maximum fine is $24,600,000.

A. Base Fine Calculation

Pursuant to U.S.S.G. §8C2.4(a) (November 1, 2000), the base fine is the greatest of the amount of fine determined by reference to U.S.S.G. §8C2.3 corresponding to the calculated offense level, the pecuniary gain from the offense, or the pecuniary loss from the offense caused by the organization, to the extent the loss was caused intentionally, knowingly or recklessly.

Fine Table: The calculated offense level is 25 with a corresponding offense level fine table amount of $2,800,000, determined as follows:

a. The value of the unlawful payment (kickback), and therefore the

pecuniary gain,[1] was $12.3 million.

b. The applicable Guideline is U.S.S.G. §2B4.1 (Commercial Bribery and Kickbacks).

c. Pursuant to U.S.S.G. §2B4.1(a), the base offense level is 8.

d. The value of the unlawful payment of $12.3 million results in adding 15 levels under U.S.S.G. §2F1.1(b)(1)(P). See U.S.S.G. §§2B4.1(b)(1) and (c)(1)(A).

e. More than minimal planning was involved, increasing the offense level by 2 levels, U.S.S.G. §2F1.2(b)(2).

f. The total base offense level of 25 has a corresponding fine of $2,800,000 pursuant to U.S.S.G. §8C2.4(d).

Pecuniary Gain: Pursuant to U.S.S.G. §8C2.4(a)(2), the base fine can be based on pecuniary gain to the organization from the offense. Application note 3(h) of U.S.S.G. §8A1.2 makes clear that "pecuniary gain" "is derived from 18 U.S.C. §3571(d) and means the additional before-tax profit to the defendant resulting from the relevant conduct of the offense." See also U.S.S.G. §2B4.1, Application Note, Background ("The base offense level is to be enhanced based upon the value of the unlawful payment or the value of the action to be taken or effected in

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[1]The pecuniary gain can be looked at two ways. First, and simplest, is that the unlawful payment (kickback) by Pharmacia to Company Q would result in gain to Company Q. In the alternative, Pharmacia performed financial analyses to show that its gain upon paying the $12.3 million kickback would meet or exceed that $12.3 million due to increased sales of its drug products. See U.S.S.G. §2B4.1, Application Note, Background ("The base offense level is to be enhanced based upon the value of the unlawful payment or the value of the action to be taken or effected in return for the unlawful payment, whichever is greater.").

return for the unlawful payment, whichever is greater."). Here, there the expected gain from the offer of the kickback was at least equal to the value of the offered kickback – $12.3 million. Pharmacia's own financial analyses confirm this, as does Pharmacia's conduct, namely its willingness to set up a reimbursement from one business unit within Pharmacia, which was expected to benefit from the formulary benefits sought in return for the kickback, to the Endocrine Care Business Unit which was saddled with having to offer to pay the subsidiary of Company Q $12.3 million more than necessary to manage the Bridge Program contract. Thus the pecuniary gain to Pharmacia from the offense was at least $12.3 million.

Pecuniary Loss: Pursuant to U.S.S.G. §8C2.4(a)(3), the base fine can be based on pecuniary loss from the offense caused by the organization intentionally, knowingly or recklessly. See also U.S.S.G. §8C2.4(b)(directing that special organizational guideline instructions in Chapter Two "shall be applied, as appropriate."). The Guidelines provide a special instruction for organizations at U.S.S.G. §2B4.1(c), namely that "[i]n lieu of the pecuniary loss under subsection (a)(3) of §8C2.4 (Base Fine), use the greatest of: (A) the value of the unlawful payment; (B) the value of the benefit received or to be received in return for the unlawful payment; or (c) consequential damages resulting from the unlawful payment." The value of the unlawful payment was $12.3 million.

Therefore based on either pecuniary gain or pecuniary loss, the base fine is $12.3 million.

B. Calculating the Multiplier

Pursuant to U.S.S.G. §8C2.5, the culpability score is 8 as determined as follows:

1. Base culpability score is five (5) pursuant to U.S.S.G. §8C2.5(a);

2. Add four (4) points in that the unit of the organization within which the offense was committed had 1,000 or more employees, and an individual within the high-level personnel of the unit participated in or condoned the offense;

3. Deduct one (1) point pursuant to U.S.S.G. §8C2.5(g)(3) for affirmative acceptance of responsibility.

Pursuant to U.S.S.G. §8C2.6, the appropriate multiplier range associated with a culpability score of 8 is 1.6 to 3.2.

C. The Fine Range

Thus, the Guideline Fine range is $19,680,000 to $24,600,000. See U.S.S.G. §§8C2.7(a) and (b); 18 U.S.C. §§3571(c) and (d). The agreed upon fine is $19,680,000, a fine at the low end of the Guideline range.

D. Supervised Release

The United States did not seek a period of supervised release, in part because of the existence of the Corporate Integrity Agreement between Pfizer Inc. and the Department of Health and Human Services entered into as of May 11, 2004. As part of that Corporate Integrity Agreement, Pfizer is obliged to undertake certain internal monitoring, training and reporting. HHS has a branch devoted to creating and enforcing such agreements and accordingly, the United States believes that HHS is in the best position to monitor Pfizer (and in turn Pharmacia's) conduct on a going-forward basis.

III. Victims and Restitution

The Mandatory Victim Restitution Act, 18 U.S.C. §3663A, requires the District Court to order a defendant to make restitution to a victim, defined as any person directly and proximately harmed as a result of the commission of the offense for which restitution may be ordered. 18 U.S.C. §3663A(a)(2). Here the crime charged is the offer of a kickback. While the crime had the potential to corrupt the judgment of the PBM and change the drugs available to members of certain of the PBM's health plan clients, the United States is unable to identify any person directly or proximately harmed as a result of the offer of this kickback. Accordingly, no restitution is required.

Conclusion

For the foregoing reasons, the United States respectfully requests that the Court accept the plea agreement and impose a sentence consistent therewith.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

By: /s/ Jeremy M. Sternberg
Jeremy M. Sternberg
Assistant U.S. Attorney

Dated: April 24, 2007

Certificate of Service

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to counsel for defendant, who is a registered participant as identified on the Notice of Electronic Filing.

/s/ Jeremy M. Sternberg
Jeremy M. Sternberg
Assistant U.S. Attorney