UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Criminal Number: 09 CR 10258-DPW**
	)	
PHARMACIA & UPJOHN COMPANY, INC.	)	
	)	
	)	
Defendant.	)	

UNITED STATES' SENTENCING MEMORANDUM

The United States of America submits this sentencing memorandum in support of the proposed Rule 11(c)(1)(C) plea agreement and sentence in this case. On September 15, 2009, the defendant, Pharmacia & Upjohn Company, Inc. pleaded guilty to one count of introducing into interstate commerce, with the intent to defraud and mislead, a misbranded drug by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(f). For the reasons set forth below, the government submits that the Court should accept the guilty plea and sentence Pharmacia & Upjohn Company, Inc. in accordance with the terms of the plea agreement.

I. THE PROPOSED GLOBAL RESOLUTION

The proposed global resolution in this case represents the culmination of a complex investigation regarding the marketing practices of Pharmacia & Upjohn Company, Inc. and its parent company, Pfizer Inc. The components of the resolution are as follows:

1. Pharmacia & Upjohn Company, Inc., a subsidiary of Pfizer Inc, agreed to plead guilty to one count of introducing into interstate commerce, with the intent to defraud and mislead, a misbranded drug by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(f) and to pay a criminal fine in the amount of one billion, one hundred ninety-five million dollars ($1,195,000,000) and forfeiture in the amount of one hundred five million dollars ($105,000,000) (Exh. 1, Att. 1).

2. Pfizer Inc agreed to settle its federal False Claims Act and other civil liability for a total amount of one billion dollars ($1,000,000,000). The civil agreement contemplates a payment to the government and state Medicaid fraud control units of five hundred and three million dollars ($503,000,000) with respect to its promotion of Bextra, plus applicable interest, and a payment of an additional four hundred and ninety-seven million dollars ($497,000,000) plus interest to resolve civil claims with respect to other drugs (Exh. 1, Att. 2);

3. The United States has agreed not to prosecute Pfizer Inc for conduct described in a side letter agreement between the United States and Pfizer Inc (Exh.1);

4. Pfizer Inc has agreed to comply with the terms of a new corporate compliance program. (Dkt. # 12).

All aspects of the agreement, including the civil and administrative remedies, are contingent upon the Court's acceptance of the plea and sentence as proposed by the parties.

II. APPLICABLE LEGAL FRAMEWORK

The United States Food and Drug Administration ("FDA") is the federal agency responsible for protecting the health and safety of the public by enforcing the Food, Drug and Cosmetic Act ("FDCA"), 21 United States Code, Section 301, *et seq.*, and ensuring, among other things, that drugs intended for use in humans are safe and effective for each of their intended uses and that the labeling of such drugs bears true and accurate information.

The FDCA and its implementing regulations require that, with certain exceptions not relevant here, before a new drug can legally be introduced into interstate commerce, a sponsor of a new drug must submit and obtain approval of a New Drug Application ("NDA") from the FDA. 21 U.S.C. § 355. The FDCA also requires that the NDA include proposed labeling for the intended uses of the drug which include, among other things, the conditions for therapeutic use. 21 U.S.C. § 355(b)(1). The NDA must also contain, to the satisfaction of FDA, data generated in

adequate and well-controlled clinical trials that demonstrates that the drug is safe and effective when used in accordance with the proposed labeling. *Id.*

An NDA sponsor is not permitted to promote and market a new drug until it has an approved NDA, including approval for the proposed labeling. *Id.* Moreover, if approved, the sponsor is permitted to promote and market the drug only for the medical conditions of use and dosages specified in the approved labeling. Uses not approved by the FDA, including dosages not approved in the drug's approved labeling, are known as "unapproved"or "off-label" uses.

The FDCA provides that, unless otherwise exempted, a drug is misbranded if, among other things, the labeling does not contain adequate directions for use. 21 U.S.C. § 352(f). Adequate directions for use cannot be written for uses for which the drug has not been approved, as unapproved uses cannot be included in the labeling. Accordingly, drugs that are promoted for uses that have not been approved by the FDA are misbranded under the FDCA. 21 U.S.C. § 352(f)(1). The FDCA prohibits the delivery for introduction and causing the delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 331(a). One who commits this violation with the intent to defraud or mislead is guilty of a felony offense. 21 U.S.C. § 333(a)(2).

III. FACTUAL BASIS FOR THE CHARGE

The United States submits that should this case have gone to trial, the evidence would prove the following:

Prior to April 2003, Pharmacia & Upjohn Company, Inc. was a Delaware corporation with a principal place of business in Kalamazoo, Michigan and was a wholly owned subsidiary of Pharmacia & Upjohn LLC, the successor to Pharmacia & Upjohn Company, which was a

successor of Pharmacia Corporation, all of which were acquired in April 2003 by Pfizer Inc (all of these entities and their subsidiaries hereinafter collectively "Pharmacia"). During the relevant time frame, Pharmacia developed, manufactured, distributed and sold pharmaceutical products nationwide and in the District of Massachusetts, including the drug Bextra.

Prior to the April 2003 acquisition, Pharmacia jointly promoted the drug Bextra with Pfizer Inc. Since April 2003, the Pharmacia entities have been wholly owned subsidiaries of Pfizer Inc. Pharmacia & Upjohn Company, Inc. holds the United States trademarks and patents for the drug Bextra, which was distributed from Puerto Rico into interstate commerce throughout the United States, including specifically into Massachusetts, from in or about February 2002 until approximately April 2005. During this time period, Pharmacia & Upjohn Company, Inc. also employed many of the sales employees and managers who promoted Bextra.

The Bextra Approval Process

Bextra was Pharmacia's trade name for the drug valdecoxib, a Cox-2 Inhibitor drug. At the time Bextra entered the market in February 2002, the “Cox-2” class of drugs included the previously released drug Celebrex, also marketed by Pharmacia, and Vioxx, manufactured and marketed by a competitor.

The Cox-2 class of drugs was designed to relieve various forms of pain and inflammation and was intended to offer pain relief equal to the predecessor pain relievers, but without the negative gastrointestinal side effects often associated with those drugs. Thus, for many patients, the justification for switching to a Cox-2 drug over the other available pain relievers was greater gastrointestinal safety, not better efficacy. Because many of the other pain relievers, such as ibuprofen or naproxen, were available as generic and over-the-counter drugs at the time Bextra

was launched, Bextra was much more expensive than many of these competitor drugs.

On or about January 15, 2001, Pharmacia submitted an NDA seeking approval of Bextra as a new drug. In that NDA, Pharmacia sought approval to market Bextra at dosages of 10, 20 and 40 mg for the following uses and claims:

1. For the prevention and treatment of acute pain in adults;

2. Preoperative administration of [Bextra] prevents or reduces post-operative pain;

3. [Bextra] has an opioid sparing effect when used concomitantly with opioids;

4. For the treatment of primary dysmenorrhea ("PD"); and

5. For relief of signs and symptoms of osteoarthritis ("OA") and adult rheumatoid arthritis ("RA").

The FDA Approval and Non-Approval of Bextra

On November 16, 2001, the FDA approved Bextra to treat only the signs and symptoms of OA, RA and for the treatment of PD, and specifically declined to approve its use for general acute pain, the preemption of the pain of surgery, and opioid sparing. Moreover, although Pharmacia sought approval from the FDA for the 10 mg, 20 mg and 40 mg doses for all uses, the FDA did not approve the 20 mg dose for OA and RA, but only for PD (20 mg twice a day as needed), and it did not approve the 40 mg dose at all. The FDA did not approve Bextra for any use or dosage other than OA, RA at 10 mg per day and PD at 20 mg (twice a day as needed).

The FDA informed Pharmacia that it was not approving Bextra for acute pain at least in part because of a safety concern about Bextra. The FDA told Pharmacia that the concern arose from the results of a study of Bextra, in which Bextra was used following the administration of

its injectable form, parecoxib, in patients undergoing coronary artery bypass graft surgery (the "CABG I" trial). The FDA indicated that the results of the study signaled an excess of serious cardiovascular thromboembolic events in the Bextra (after parecoxib) arm of the trial.

In its comments on the proposed label for Bextra, the FDA also informed Pharmacia that the FDA recommended against the use of 20 mg for treatment of arthritis based upon an increased potential for adverse events at higher dosages. Specifically, the FDA did not approve Bextra for dosages over 10 mg for OA and RA because it had concerns about safety. In its Medical Review, the FDA told Pharmacia:

> The safety profile with chronic use in RA [rheumatoid arthritis] and OA [osteoarthritis] is adequate at 10 mg/d. At higher total daily doses, the findings of more hypertension and edema are frequently reproduced, and they are formally affirmed in a prospective manner in Trial 47, which directly tested the hypothesis of renal safety at 40 and 80 mg/day. In the analysis of older subpopulations over the age of 65 years edema and hypertension appear to be greater at 20 mg/day compared to 10 mg/day. . . .

The FDA Medical Review further commented that the data from studies for pre-emption of post-operative pain:

> raises concern over the value of preoperative management of post-operative pain, particularly in regards to the risk versus potential benefit. Data from these two studies should not be considered for labeling until the overall clinical value of such treatments is further defined as well as the safety. . . .

With respect to the claim of opioid-sparing, the FDA Medical Review noted:

> Sparing of adverse events was not demonstrated in these studies. In study 035 there was a statistically significant excess of serious adverse events associated with the use of valdecoxib 40 mg bid [after parecoxib] when added to ad lib narcotic therapy compared with narcotic analgesia alone.

Accordingly, in its approval/non-approval letter in November, 2001, the FDA stated:

> 1. <u>Safety in the management of acute pain</u>
> The safety of [Bextra] for the management of acute pain in the

peri-operative setting has not been established based on the findings of study 035 (CABG). . . .

2. Safety and efficacy in the prevention of acute pain in adults
The studies of pre-operative dosing of [Bextra] did not demonstrate a difference in pain intensity compared to placebo during the early study period. . .

3. Safety and efficacy for opiod sparing
While lower mean opiod use (as needed) was demonstrated in three studies (035, 038, and 051) at 40 mg bid, results were not replicated at the 20 mg bid dose. Sparing of adverse events was not demonstrated in these studies. Of note is that in study 035, adverse events associated with opiods such as hypotension were seen more frequently in the valdecoxib [after parecoxib] treated patients. There was no clear evidence of less confusion, somnolence, respiratory depression, nausea and vomiting or constipation to suggest a clinical advantage associated with the lower doses of opiod used. The clinical benefit of post-operative co-administration of fixed dosing of [Bextra] and ad lib opiod dosing has not been demonstrated.

The FDA also specifically informed Pharmacia that it was not approving the higher dosages because there was no evidence of greater effectiveness in treating arthritis and there was evidence of increasing risk of hypertension and edema as the dosage level was increased.

In or about October 2004, the results of a second study of Bextra and parecoxib (the injectable form of Bextra) in coronary artery bypass graft surgery ("CABG II") became public. This study showed a statistically significant increase in thromboembolic cardiovascular events in CABG patients taking Bextra following the administration of parecoxib. As a result of this study, in or about November 2004, a warning was added to Bextra's product label which stated that Bextra was contraindicated for treatment of postoperative pain following CABG surgery. At the same time, the FDA required a black box warning on Bextra's label about reports of serious skin reactions, including Stevens-Johnson syndrome, in patients receiving Bextra. In April,

2005, at the FDA's request, Pharmacia withdrew Bextra from the market.

From in or about February 2002 through April 2005, Pharmacia promoted the sale of Bextra, as set forth below, for unapproved uses and dosages and/or with false and misleading claims of safety and efficacy and without disclosing the FDA's safety concerns. Pharmacia did this primarily in the following ways:

A. **Headquarters' Marketing Plans:** Pharmacia's marketing team positioned Bextra for unapproved uses and dosages, commissioned market research to test its sales materials, and confirmed these unapproved messages.

B. **Field Force Implementation, including Drafting Physician Orders**: Pharmacia's sales force promoted Bextra for unapproved uses and dosages and with false and misleading claims, including by drafting and distributing proposed physician standing orders and hospital wide protocols and pain pathways that called for unapproved uses and dosages of Bextra.

C. **Payments and other Remuneration to Physicians and Purported Consultants**: Pharmacia used so-called advisory boards, consultant meetings and other forums and remuneration to promote Bextra for unapproved uses and dosages.

D. **Sham Physician Requests for Off-Label Information**: Pharmacia's sales force created sham physician requests from physicians for medical information in order to send unsolicited information to physicians about unapproved uses and dosages.

E. **Distributing Samples for Unapproved Uses and Dosages:** Pharmacia's sales force provided promotional samples to surgeons and other medical prescribers who had no FDA-approved use for the Bextra samples, or at that dosage.

F. **Control of Purportedly Independent Medical Education:** Pharmacia sponsored purportedly independent continuing medical education programs ("CME") to disseminate specific messages about unapproved uses of Bextra.

G. **Use of a Publication Strategy to Disseminate Off-label Messages:** Pharmacia initiated, funded and sometimes drafted or paid vendors to draft articles about Bextra for unapproved uses without appropriately disclosing Pharmacia's role.

As a consequence of the unlawful promotion scheme, patients who received the drug for

unapproved and unproven uses had no assurance that their doctors were exercising their independent and fully informed medical judgment, or whether the doctor was instead influenced by misleading statements made by, or inducements provided by, Pharmacia. Potential problems that can arise from off-label use include the occurrence of unforeseen adverse effects if the drug is not studied and found to be safe and effective in the type of patient using it off-label, or the appropriate dosage and course of treatment has not been established. Here, with Bextra, the cardiovascular risk issues that initially caused the FDA to withhold approval for certain uses and dosages were confirmed in a later study and, that, plus other later-learned information, contributed to the FDA's request to halt sales of Bextra.

A. Pharmacia's Headquarters Direction for Off-Label Promotion of Bextra

In light of the limited indications received for Bextra, Pharmacia was concerned that if it marketed Bextra, it would simply cannibalize the market for its other Cox-2 drug, Celebrex, since their approved indications overlapped. Therefore, despite the lack of an acute pain indication for Bextra, Pharmacia attempted to position Bextra as the "acute" pain drug while emphasizing Celebrex for chronic pain. Pharmacia's headquarters marketing documents reflect that this was the intended message and that its own marketing research confirmed that the message was heard and effective.

1. Direction from Headquarters

The off-label campaign for Bextra began, among other ways, as early as February 2002 with the marketing department preparing and distributing scripts for the promotion of Bextra. In these scripts, Pharmacia gave the sales force explicit instructions to promote Bextra as a replacement for Vioxx, despite the fact that Vioxx had the acute pain indication and Bextra did

not. A February 5, 2002 script that was forwarded to Pharmacia managers, as "the final . . . approved positioning script" instructed the sales representatives to end their sales calls as follows:

> Close: Ask physicians to use Bextra where they would have used Vioxx. "Doctor, based on what you now know about BEXTRA, will you consider giving these experience kits to patients for whom you would have considered prescribing VIOXX?"

Bextra was officially launched at a national meeting for sales representatives in Atlanta, Georgia from April 9-12, 2002. During this meeting, the sales force was given a vivid message of how to promote Bextra for the "power" position. They were inundated with displays of music, light shows, acrobats and dancers. The marketing managers led the entire audience in thrusting their fists into the air (the marketing symbol of Bextra) and pounding them against their upraised hands in unison to symbolize the power of Bextra and to "Power Up" the sales force. Ultimately, simulated large steel doors crash down on the stage, and the Bextra fist symbol crashed through the doors. The events from the launch demonstrates the sales frenzy that accompanied Bextra, as the company strove to make the drug reach "blockbuster" (billion dollar a year sales) status.

The promotional materials prepared by Pharmacia demonstrates Pharmacia's goal to sell Bextra for both approved and unapproved uses, including surgical and acute non-arthritic pain. Indeed, Pharmacia tested these marketing materials repeatedly to insure that they conveyed this intended message. For example, in November 2002, Pharmacia prepared a new promotional visual aid for Bextra and Celebrex and ordered that a marketing survey be conducted to test the doctors' understanding of the intended messages. The report concluded that "after seeing the transition spread, almost all physicians clearly understood the intended use of Celebrex (for

chronic pain) and Bextra (for acute pain)." Another marketing survey that tested the Celebrex and Bextra sales aid in December, 2002 was summarized as follows: "[S]everal respondents [physicians] felt the sales aid communicated the idea that Celebrex is the best choice for long term, chronic pain, while Bextra is best in acute pain situations." On December 5, 2002, a Bextra marketing manager forwarded this report to senior marketing managers with the comment:

> [T]he bridging page copy with creative [images] and headlines clearly communicated where to use both products: Celebrex is for chronic pain; Bextra is for acute or tough to treat pain. Without creative [images] and headlines it was difficult for the physicians to see the intended message.

2. Market Research and Other Red Flags Put Pharmacia Headquarters On Notice of the Sales Force's Widespread Off-Label Messages

In addition to the marketing surveys mentioned above, Pharmacia headquarters also learned of the effectiveness of the off-label messages as the materials were utilized in the field. For example, during a District Managers Teleconference in June 2002, district managers reported messages that included: "10 mg is for OA and RA and 20 mg is for acute pain states," "20 mg is for acute pain states, such as the pain associated with PD," and "10 for persistent pain and 20 for acute pain." Furthermore, the district managers reported that they found ". . . specific reference to [the on-label indications] OA, RA and PD needlessly restrictive." The reports showed that by June 2002, managers at Pharmacia headquarters had knowledge that Bextra was being promoted for acute pain, and at the 20 mg dosage for uses other than PD. No corrective action was taken upon learning of this.

In March 2003, the problem was reflected very clearly in another market research report which explained that, with respect to the marketing material on primary dysmenorrhea ("PD"):

> The PD page, while largely irrelevant in terms of patient population ("I don't

> know nothin' about birthin' no babies"), supported Bextra's acute pain relief message. It suggests that Bextra can be prescribed for pain relief other than arthritis. . . . It moves it in my mind to other types of pain, menstrual pain, maybe even nerve pain, headaches.

Thus, the report confirmed that Pharmacia was promoting Bextra for acute pain and that the physicians perceived the message clearly from the sales material.

On or about March 25, 2003, a Pharmacia marketing manager summarized the key points learned from interviews of the sales representatives as follows:

> [T]here is a slight indication that product co-positioning varies between sales forces. The majority of [sales representatives] use a "chronic/acute" or "persistent/acute" distinction to describe how the physician can use Celebrex and Bextra. . . . A few participants from both companies voice discomfort in delivering the acute/chronic positioning. They point out that Celebrex has the acute pain indication and data supporting that indication in the [master visual aid], while Bextra is only approved for primary dysmenorrhea. They are looking for more clinical support for Bextra's acute pain positioning with materials they can show and leave with physicians.

Despite the receipt of this report, Pharmacia's sales and marketing leadership took no steps at that time to investigate the promotion of this off-label messaging or to stop it. To the contrary, their direction continued to be to position Celebrex for chronic pain, and Bextra for acute pain, and where the physician would otherwise use Vioxx.

In fact, in or about March 2003, Pharmacia marketing managers, in a presentation to other marketing managers, highlighted as a success factor the fact that Pharmacia had promoted Bextra for acute pain and Celebrex for chronic pain and set forth as an opportunity for improvement the "Need to Emphasize Chronic Use of Celebrex, Acute use of Bextra."

Again, in or about August 2003, Pharmacia commissioned a market research report on another visual aid to be used by the representatives. The report confirmed that the visual aid

conveyed the message to physicians that Pharmacia intended Bextra to be used for acute pain, and concluded that "[a]fter seeing the positioning statement for Bextra, virtually all physicians concluded that Pharmacia was trying to differentiate Bextra as a product for acute pain."

In or about September 2003, Pharmacia again commissioned a market research report to confirm that the final version of the new visual aid conveyed Pharmacia's intended message for the use of Bextra. The report stated:

> More so than in other research conducted by this moderator for this team to date, physicians are starting to extract a "chronic/long-term" message for Celebrex and an "acute" message for Bextra from the visual aid materials, which will likely become more apparent over time through continued exposure to the new visual aid.

Thus, Pharmacia continued to promote Bextra for unapproved uses and dosages even after senior marketing managers received this market research and internal reports indicating that the sales force was promoting Bextra for unapproved uses and dosages.

3. Pharmacia Incentivized Its Sales Force to Sell Off-Label and Rewarded the Sales Force for Doing So

The fundamental structure of the sales force, including their compensation, contributed to encouraging off-label promotion of Bextra. Sales representatives were given quotas for the amount of a drug that had to be purchased in their district, without regard to whether those sales were on or off-label for use or dosage. Moreover, because sales representatives were judged on a competitive basis, they would have been negatively affected if they did not capture the off-label sales but their colleagues did. If the doctors in a sales representative's district failed to prescribe a certain amount of the drug, Pharmacia determined that the representative was underperforming because he or she was below quota. Likewise, if the doctors in that area prescribed more Bextra,

the sales representative received a high performance rating. Sales numbers substantially above quota resulted in significant bonuses annually. Thus, rather than encouraging its representatives to stay within the bounds of the law, Pharmacia actually rewarded its sales force for causing off-label sales throughout the entire time period Bextra was sold.

In addition, frequent contests were held for sales representatives and districts that created incentives to accomplish certain goals. Many of these rewarded high-performing representatives, managers and districts with trips to places like the Carribean and Europe. One such contest, the aptly named "OPERATE FOR CASH" contest, specifically rewarded sales representatives for obtaining protocols and standing orders that included Celebrex and Bextra, and thus specifically rewarded the off-label promotion of Bextra. In fact, the winners of the contest secured numerous protocols providing for off-label use of Bextra.

B. Pharmacia's Sales Force's Promotion of Bextra for Off-Label Uses, Including By Drafting Physician Orders, and With False and Misleading Claims of Safety and Efficacy

1. Promotion of Bextra For Off-Label Uses, Including Surgical Pain

Pharmacia sales managers instructed their sales teams to promote Bextra for acute pain, including the pain of surgery, even though they knew that Bextra was not FDA-approved for these uses. Moreover, the sales force failed to disclose to physicians, customers and others that the FDA specifically declined to approve Bextra for those uses and doses, and that the FDA's refusal was due in part to a safety concern about potential serious adverse events, including cardiovascular events, in some surgeries based upon the results of the CABG I study.

Following direction from the headquarters marketing department, Pharmacia managers trained and directed their sales teams to seek written surgical and pain management protocols,

standing orders and pathways from physicians, hospitals, and other customers for use in surgical situations. Pharmacia managers circulated an electronic template of a hospital-wide pain management pathway that provided for administration of Bextra for unapproved uses and at unapproved dosages. They gave instructions to members of the sales force on how to get such pathways printed on laminated color paper and distributed in hospitals and other institutions. Representatives preprinted the pathways and protocols and distributed them throughout the hospital as "how this hospital treats pain." This tactic was used particularly with newer doctors, residents, and doctors perceived by the sales representatives to be less knowledgeable.

Pharmacia managers routinely praised and rewarded representatives who obtained the surgical and pain management protocols for unapproved uses and dosages of Bextra. For example, in or about June or July 2002, when a Pharmacia sales representative in Massachusetts drafted and recommended a written protocol to an OB/GYN physician in Massachusetts that called for the unapproved use of Bextra to control pain in OB/GYN surgeries, including at unapproved dosages, the Regional Manager sent an email to the other sales representatives in the entire Northeast region that praised the sales representative for the “fantastic protocol,” even though the protocol called for the unapproved use of Bextra six separate types of OB/GYN surgery. Similarly, on or about February 19, 2003, a Pharmacia District Manager sent an email to the sales representatives in the district, with a copy to a Regional Manager, that instructed the representatives to sell Bextra for pre- and post-operative pain to orthopedic surgeons, podiatrists, oral surgeons, and “anyone that use[d] a scalpel for a living” even though Bextra was not approved to treat the acute pain of surgery.

Pharmacia also encouraged its sales force to promote Bextra with the unapproved claim

that Bextra was effective in the surgical setting to reduce the risk of blood clots known as deep vein thrombosis ("DVTs") that can form during or after surgery. For example, on April 24, 2002, Regional Manager sent an email to sales representatives and managers in that division that instructed them to promote the use of Bextra to reduce [the] risk of DVTs to surgeons. The April 24, 2002 email, which is titled "Read this ONLY if you want to win!," provided the representatives with a script on how to sell Bextra using the DVT message, and included a reminder that only those who "think outside the box" will win the contests and trips then available. The email began:

> This is so great - its scary . . . you are helping [orthopedic surgeons] to solve a BIG problem that they deal with - and that is how to manage DVTs.
>
> * * *
>
> But I caution you - if you are not dedicated to winning don't read the attached. It might make you think outside the box! . . . You might also actually win some award trips . . .
>
> * * *
>
> Success belongs to those who risk failure to win! The ball is now officially in your court.

The script that the manager distributed with the email is especially concerning because it specifically instructed the sales team to tell the physicians that the physicians could use Bextra as part of their regimen "to reduce your risk of DVTs" and then seemingly ridiculed those representatives who did not attempt this off-label message, as it concluded with the sentence: "See you at the award trips! (The reps at home that don't try this will still be trying to figure out which visual aid page to put first!)"

In at least one region, sales representatives and managers promoted Bextra to physicians to reduce the risk of DVTs during and after surgery, without disclosing to these physicians the safety concern that the FDA had raised about the use of Bextra in surgery, or the fact that the

FDA had concluded that no decrease in the side effects of surgery such as DVTs had been shown from the use of Bextra. Sales representatives who carried out this message understood that the message was misleading to physicians because not only had Bextra not been approved for this use, but also it had not even been studied for the prevention of the onset of DVTs.

2. False and Misleading Safety and Comparative Claims

Another way Pharmacia sales representatives promoted Bextra was to request physicians to replace Vioxx with Bextra even though Vioxx had an FDA-approved acute pain indication and Bextra did not. They also told physicians that Bextra was safer and more effective than Vioxx, despite the fact that Pharmacia knew there were no head-to-head studies of Bextra and Vioxx for the approved uses of Bextra that showed that Bextra was safer or more effective.

Pharmacia sales representatives promoted Bextra with false and misleading claims of safety, including that Bextra had no dose proportional increase in hypertension and edema, that "there is not one shred of evidence showing a CV concern with Bextra," that Bextra had no cardiovascular risks unlike Vioxx, and that Bextra had placebo-like side effects. For example, on or about January 16, 2004, a Pharmacia Regional Manager circulated to other Pharmacia managers in the Northeast a Product Action Guide that listed as core messages for the promotion of Bextra that "Vioxx's problems are not a class effect. [. . . With] Bextra there is no dose proportional response with hypertension and edema."

Pharmacia sales representatives delivered these messages and promoted Bextra to physicians with the claims that "Vioxx's problems are not a class effect" and "there is no dose proportional response with hypertension and edema" with Bextra, even though these claims were not proven or supported by Bextra's label. In fact, the evidence in Bextra's label demonstrated

that it did cause a dose proportional increase of hypertension and edema.

The evidence in this case demonstrated that physicians prescribed Bextra for unapproved uses, including in surgery, based upon the recommendation of Pharmacia sales representatives and that sales representatives did not disclose to them that the FDA had affirmatively declined to approve Bextra for those uses and had done so at least in part for safety reasons. Moreover, the evidence demonstrated that had these physicians been aware of these facts, they would not have prescribed Bextra for these unapproved uses.

C. Promotion of Bextra for Unapproved Uses Through Remuneration to Physicians and Purported Physician Consulting Arrangements

Pharmacia also promoted Bextra for unapproved uses and dosages by convening so-called advisory boards, consultant meetings, and other such programs. Pharmacia targeted physicians to participate in these meetings, as part of what Pharmacia termed a "cascade of influence" in order to turn high-prescribing physicians into Pharmacia Cox-2 "advocates." Exhs. 2-6. Pharmacia used these meetings to invite physicians to serve as "consultants" but the goal was to develop them to be "advocates" on behalf of Pharmacia. Exhs. 2-3. An advocate, as a Pharmacia slide set explained, provides a solid and positive product message rather than just presenting "balanced information, not advocating one product over the other." Exh. 3. The slide set demonstrated with sports images how the physicians were to be developed into advocates who could rise from the "Farm League" to ultimately be on the Pharmacia "All Star Team." Thus, the image of a treating physician is shown transformed into a Pharmacia team member and talking head behind a lectern. Exh. 3.

Pharmacia's 2002 planning documents described the activities that it planned to use that

year to disseminate its Bextra messages, including National Advisory Boards, and National and Regional Consultant Meetings, all in order to "Deliver Product Messages with Data Support for Both Brands" and "Maximize Cost Synergies & ROI [Return on Investment]." Exh. 4 at 12. Pursuant to these plans, Pharmacia paid targeted physicians both airfare and two to three days' accommodations at lavish resorts in the Bahamas, Virgin Islands and across the United States; entertained them with golf, massages and other recreational activities; and paid them honoraria in the range of $1,000 to $2,000 for their attendance. The number of attendees at these events often ranged from 50 to 100 health care professionals.

As part of this process, Pharmacia conducted what it termed "Influence Mapping" in which it conducted market research to identify "influential specialists in the areas of arthritis and pain" and to provide an "Advocate Concierge" or a "High level service to aid key Advocates in managing their interaction" with Pharmacia. Pharmacia ranked key physicians in terms of their ability to influence key professional societies, regulatory agencies, guideline committees, and specialty journals. *See, e.g.*, Exh. 6. Pharmacia also paid these physicians and other physician "advocates" to present at lunches, dinners, and other entertainment venues, where in many instances Pharmacia further spread its messages about unapproved uses and dosages of Bextra.

These consultant meetings consistently included the presentation of off-label information. Each agenda reflected off-label topics such as use of Cox-2's for acute pain or in the peri-operative setting. Significantly, some of the agendas also contained predetermined conclusions that the attendees were supposed to reach as a result of the presentation. The fact that the conclusion was already stated in the agenda prior to the series of meetings is evidence of the real purpose of the meeting – to relay the off-label message and have these physicians continue to

pass on that message in a "cascade of influence."

Moreover, the Pharmacia-sponsored speakers affirmatively misled the attendees as to the reason for Bextra's lack of an acute pain indication. For example, at a March 2002 meeting at the Hilton Walt Disney Resort, the physician-speaker closed the meeting with a review of a few "key facts" learned by the participants during the weekend, including: "Why FDA not approve valde for acute pain: FDA absence of leadership, superslow, not approving drugs . . . what want for acute pain - no one can figure out." Since Pharmacia knew exactly why the FDA did not approve Bextra for acute pain and the additional longer term larger safety studies which FDA requested, this statement was both false and misleading.

Similarly, at an Advisory Board Meeting in the spring of 2002 at the Charleston Place, Charleston, SC, one of the same physician consultants/advocates who had previously enjoyed a meeting at the Bahamas Atlantis Resort in the "cascade of influence," presented off-label information on the use of Bextra for "PeriOperative Analgesia & Multimodal Therapy" in surgery. His slides state that the "Primary Goal" of this session is "To Aid [Pharmacia] in Improving PeriOp Usage of [Bextra] . . . And with Lack of Formal Indication for Pain for Valde!" His slides continued:

> Minor Problem #1: No Formal Pain Indication for Valde
> Minor Problem # 2: Celebcoxib 400 mg I$ co$tly.
>
> No Formal Valdecoxib Pain Indication . . .
> -- Sales reps can NOT! (Does it matter?)
> -- It is possible to help the sales rep?
>
> Parecoxib: FDA Not Quite Yet Approved: Acute Pain
> Parecoxib – Injectable form of Valdecoxib

Thus, these consultant meetings explicitly promoted off-label uses of Bextra and treated

the FDA's non-approval of Bextra for acute pain as a mere "formality" which the attendees could help the company to circumvent.

All of this was done despite Pharmacia's written policy that consultant meetings could not be used "to influence" or educate the attendees. The policy specifically stated "[i]n other words, the purpose cannot be to influence the invited consultants or change their prescribing." Nonetheless, Pharmacia's planning documents clearly reflect that these meetings were used to "influence" the attendees. *See, e.g.* Exh. 4 at 9, 13.

Pharmacia policy also provided that locations could not be lavish, and this policy was also violated. Indeed, many of the meeting locations were indisputably lavish, including the Atlantis resort in the Bahamas, and the five-diamond Broadmoor resort in Colorado Springs, Colorado. In the two years from the pre-launch of Bextra in late 2001 until late 2003, Pharmacia held almost 100 so-called "consultant meetings" with, as predicted, a reach of over 5,000 doctors.

D. Promotion of Bextra Through Falsely Claiming that Physicians Had Asked for Information About Unapproved Uses

At the direction of their managers, Pharmacia's sales representatives also created sham physician requests for medical information in order to send unsolicited information to physicians about unapproved uses and dosages of Bextra. For example, Pharmacia managers instructed the sales force to send out unsolicited medical inquiry response letters to, among others, groups of physicians who prescribed a lot of Vioxx. These letters were issued by Pharmacia as if they were responses to physicians' unsolicited inquiries and contained medical information relating to unapproved uses and dosages of Bextra. Pharmacia managers instructed their sales teams to send

these letters to top Vioxx prescription writers who had not made requests for the letters, including by instructing their teams to send them to "Every Vioxx Loyalist," even though they knew it was improper to send these letters unsolicited and knew that the letters, which appeared to be a response to an unsolicited inquiry, were a disguise for improper promotion.

In the Medical Letters, Pharmacia did not disclose the FDA's safety concern with the use of Bextra for unapproved uses. Nor did Pharmacia disclose that the FDA raised a concern about the use of Bextra in surgery based upon the CABG I study and the excess of serious cardiovascular thromboembolic events in the Bextra (after parecoxib) arm of the study.

E. Pharmacia's Off-Label Promotion of Bextra By Distribution of Samples for Unapproved Uses/Doses

Pharmacia also promoted off-label uses of Bextra through its distribution of samples. Pharmacia headquarters created and allocated approximately 25% of its free samples to the 20 mg dosages – even though the 20 mg dose was approved only for Primary Dysmenorrhea and these sales were not projected to be nor did they exceed approximately 3-4% of uses. Moreover, Pharmacia allocated 20 mg samples to sales forces whose members only called on specialists in areas such as rheumatology, orthopedics and neurology, where there was no on-label use for the 20 mg samples. Moreover, throughout the marketing of Bextra, the sales force received incentive compensation based upon sales of 20 mg, even if the physicians to whom they promoted had no on-label use for 20 mg dosages.

The FDCA provides that a sample is a unit of a drug that is not intended to be sold and is "intended to promote the sale of the drug." 21 U.S.C. § 353(c)(1). Thus, the distribution of these 20 mg samples to doctors was by definition promotion and, when provided to doctors who had

no on-label use for the drug, it was promotion for an off-label use.

In addition, Pharmacia affirmatively encouraged its sales representatives to provide 20 mg samples to physicians with no on-label use through computerized reports and instructions on sampling. For example, in November of 2003, every representative received from company headquarters a "Cox-2 Starter Optimization Report" which detailed the prescribing and sampling activities of top physicians in the representative's territory in every quarter. The report was designed to "help representatives fine-tune sampling efforts." The representatives were to "[u]se this report to identify physicians who, based on the number of starters they are giving to patients, should be writing more Nrxs [new prescriptions]." Included in the report was the symbol "▲" by certain names which represented ". . . physicians who are making efficient use of starters at the current level and would benefit from an increase in sampling . . ." Moreover, through these reports, representatives were directed by headquarters to increase 20 mg samples to, among others, surgeons who had no on-label use for 20 mg samples.

Pharmacia records reflect that the practice of providing the 20 mg dosage to physicians with no on-label use for that sample was rampant. For example, an analysis of the call notes maintained by the sales representatives reflected that, up until the summer of 2004, Pharmacia representatives provided 20 mg samples of Bextra to surgeons 255,733 times, and to anesthesiologists 28,489 times. Since surgeons and anesthesiologists do not treat primary dysmenorrhea, such sampling was obviously to promote the drug for an off-label use.

F. Use of Purportedly Independent Continuing Medical Education to Promote Bextra for Unapproved Uses and Dosages

Pharmacia also funded purportedly independent continuing medical education programs

("CME") with the stated purpose of disseminating messages promoting Bextra for unapproved uses, including specifically for acute pain and surgical pain. Pharmacia accomplished this by incorporating CME planning into its marketing messaging strategy for Bextra. Pharmacia hired advertising agencies to prepare standard promotional slides for Bextra, and then had these slides certified by other vendors as "CME." It then caused these Bextra slide sets to be distributed to the "advocates" it had trained so that they could use the slides for CME events. *See, e.g.*, Exh. 4 at 20. Pharmacia's headquarters-based marketing teams also created annual medical education plans in which they reflected the intention to "leverage CME" to provide data beyond the approved label. The plans listed the specific messages for Bextra to be relayed, including messages such as Bextra power for "Acute pain, Opiod-sparing." In 2002 alone, Pharmacia funded CME programs for Bextra designed to reach 30,000 physicians, including, in many instances, with the unapproved messages.

G. Promotion of Bextra for Unapproved Uses and Dosages by Supporting and Drafting Publications

Pharmacia also promoted Bextra for unapproved uses and dosages through a publication strategy whereby Pharmacia initiated, funded, sponsored and sometimes drafted or hired medical writer vendors to draft articles about Bextra for unapproved uses and dosages in order to promote these uses and dosages, without always appropriately disclosing Pharmacia's role in the process. Pharmacia implemented a "manuscript development" process whereby a core team at Pharmacia would plan potential publications and recruit authors for them. Exh. 7. Some of those listed in the publication plans were listed with authors as "TBD" (to be determined) or "TBC" (to be chosen). Pharmacia also created an overall list of its goals for this process, which included

relaying unapproved messages for Bextra such as "Acute Pain: BEXTRA Provides Rapid, Powerful Pain Relief." Exh. 8.

IV. SENTENCING GUIDELINES ANALYSIS AND PLEA AGREEMENT

A. Determination of the Criminal Fine

1. The Gain Resulting from Pharmacia's Illegal Conduct

Sections 8C2.3 and 8C2.4 of the Sentencing Guidelines provide the framework for determining a corporate criminal fine. First, Section 8C2.4(a) provides that the base fine is the greatest of: (1) the amount determined by Section 8C2.3; (2) the pecuniary gain to the organization from the offense; or (3) the pecuniary loss from the offense to the extent the loss was caused intentionally, knowingly or recklessly. This section further provides that to the extent the calculation of loss or gain would unduly complicate the sentencing process, that amount (i.e., either loss or gain) should not be used. U.S.S.G. § 8C2.4(c).

In this case, the government and Pharmacia believed that a loss analysis would unduly complicate the proceedings, and therefore, based their agreed upon fine on a gain analysis. During the period of criminal conduct, Pharmacia's net gain from the sales of Bextra was determined to be one billion, seven hundred ninety-one million dollars ($1,791,000, 000). This figure reflects the revenues from the sale of Bextra minus the costs of its production and distribution, based upon information provided by Pharmacia from its books and records.

However, not all of the net gain was due to off-label sales of Bextra. Based upon data available from third party vendors, it appeared that approximately 43% of the sales were attributable to on-label uses for OA, RA and PD. Thus, 57% of the net gain, or one billion, twenty-one million dollars ($1,021,000,000), is attributable to off-label sales.

In addition, not all of the off-label sales of Bextra were caused by Pharmacia's illegal conduct, as some physicians would have exercised their independent decision-making in prescribing Bextra even without being influenced by Pharmacia's marketing. Based upon the evidence as to the extent and effectiveness of the conduct in this case, as well as available data concerning the amount of off-label use of drugs of this type, the parties concluded that a reasonable estimate of this "background" rate was 35% of the off-label sales. After applying this credit to the off-label sales number of one billion, twenty-one million dollars ($1,021,000,000), the parties determined that the pecuniary gain attributable to Pharmacia from its illegal conduct was six hundred sixty-four million dollars ($664,000,000).

2. Determination of the Culpability Score and Criminal Multiplier

The next step in determining the appropriate criminal fine is to determine the culpability score of the defendant, and the appropriate multiplier, as set forth in Sections 8C2.5 and 8C2.6 of the Guidelines.

The parties agreed that the appropriate culpability score in this instance was 8, based upon the following additions to the base culpability score of 5:

First, Pharmacia provided information to the government that, at the time of the illegal conduct, it had 5,000 or more employees. In addition, the evidence showed that tolerance of the illegal conduct by substantial authority personnel was pervasive throughout the organization. Indeed, as set forth above, the conduct was not just tolerated by the senior marketing members within Pharmacia's headquarters, but also urged by them, in that their marketing materials suggested off-label messages to the sales representatives. Also, a sample optimization program was established at headquarters which encouraged and directed the sales representatives to

distribute 20 mg samples of Bextra to physicians that had no on-label use for Bextra at 20 mgs, or, in many instances, no on-label use for Bextra at all. Further, regional directors and district managers not only encouraged their representatives to obtain off-label sales, but also actually participated in making off-label pitches to physicians themselves. For these reasons, the parties agreed that a 5-level increase was appropriate.

Second, the parties agreed that Pharmacia's cooperation and acceptance of responsibility warranted a two (2) point deduction from the culpability score. During the investigation, Pharmacia provided to the government certain documents that suggested its conduct was problematic, provided access to its employees, including, to the extent it was able, its former employees, for government interviews, and, most significantly, cooperated in the obstruction trial of one of its former employees. This cooperation included voluntarily waiving attorney-client privilege as to the obstruction issues, self-reporting the conduct and having its outside counsel testify to a confession by the defendant.

The government notes that a criminal judgment was entered against Pharmacia & Upjohn Company, Inc. on April 26, 2007, in the case United States v. Pharmacia & Upjohn Company, Inc., Criminal No. 07-10099-RGS, in which the defendant pled guilty to an Information charging it with a violation of 42 U.S.C. §1320a-7b(b)(2)(B) (payment of kickbacks). Section 8C2.5(c) (Prior History), which requires additional points for instances of similar misconduct, is inapplicable here, however, because the instant offense was completed prior to that criminal adjudication. The United States also notes that the earlier plea, unlike this one, related solely to conduct by Pharmacia & Upjohn Company, Inc. before its acquisition by Pfizer Inc.

Therefore, pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with

a culpability score of eight (8) is 1.6 to 3.2 and the fine range is therefore $1,062,400,000 to $1,328,000,000. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c) and (d). The parties agreed that a 1.8 multiplier is the appropriate multiplier and the resulting fine of one billion, one hundred ninety-five million dollars ($1,195,000,000) represents a fair and reasonable penalty that achieves the goals of sentencing. *See* 18 U.S.C. § 3553. As described above, the illegal conduct was pervasive throughout the company and stemmed from messages created at high levels within the national marketing team. The corporate culture contributed to causing the conduct and allowing it to continue. Sales employees explained that off-label promotion was tolerated and no big deal, even though they knew it was illegal. The goal was to avoid getting caught. Employees, including district managers, explained that they did not question their supervisors about the illegal conduct that they were being instructed to carry out, because to do so would be considered a "CLM" or "Career Limiting Move." A CLM meant that an employee took an action that possibly ended his/her promotion potential or led to being disfavored by management and, ultimately, fired.

The criminal fine would be, to the best of the government's knowledge, the largest criminal fine ever imposed against a defendant in any criminal proceeding. The magnitude of this fine, however, is necessary in light of the magnitude of the profits arising from the illegal conduct to deter such conduct in the future and make sure that the fine is not treated by such companies as merely a cost of doing business. Thus, as set forth here, the fine is significantly more than the gain from Pharmacia's illegal promotion of Bextra. Given the potentially huge profits from this type of conduct, this historic fine is appropriate to punish the conduct here and deter future violations of the FDCA by this company and others.

B. Probation

The government did not seek a period of probation because of the comprehensive five-year Corporate Integrity Agreement ("CIA") that was executed between Pfizer Inc and the Office of the Inspector General of the Department of Health and Human Services ("OIG"). *See* Dkt. No. 12. As part of the CIA, Pfizer Inc is obligated to conduct extensive internal and external monitoring, train its employees, report regularly to OIG, and fulfill other obligations as set forth in the agreement. Among other CIA obligations, the heads of Pfizer Inc's business units and individual members of the Audit Committee of Pfizer Inc's Board of Directors must sign, respectively, annual certifications regarding compliance and Pfizer Inc's compliance program. In addition, the CIA requires Pfizer Inc to post on its website information about payments that it makes to physicians. The OIG has entered CIAs with hundreds of other providers and has a well-established CIA monitoring process. Accordingly, the government submits that OIG is in the best position to effectively monitor the conduct of the relevant entity, Pfizer Inc going forward.

C. Victims and Restitution

Pharmacia has pled guilty to distributing a misbranded drug into interstate commerce with the intent to defraud and mislead, a violation of the Food, Drug, and Cosmetic Act. 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f). The Victim and Witness Protection Act, 18 U.S.C. § 3663 ("VWPA") and the Mandatory Victim Restitution Act ("MVRA"), 18 U.S.C. § 3663A, are not directly applicable in this case because the misbranding offense to which Pharmacia pleaded guilty is not covered by these statutes. See 18 U.S.C. § 3663(a) (covering restitution only for offenses under Title 18; 21 U.S.C. §§ 841, 848(a), 849, 856, 861 & 863; and 49 U.S.C.

§§ 5124, 46312, 46502 & 46504 except when the MVRA applies); 18 U.S.C. § 3663A(c)(1) (covering restitution only for crimes of violence under 18 U.S.C. § 16; offenses against property under Title 18 or 21 U.S.C. § 956(a); and offenses described in 18 U.S.C. § 1365). Although the Court has the authority to order restitution as a condition of probation, 18 U.S.C. § 3563(b)(2), or supervised release, 18 U.S.C. § 3583(d), and pursuant to U.S.S.G. § 5E1.1(a)(2), as mentioned above, the government does not seek a period of probation or supervised release in this case because of the existence of a comprehensive Corporate Integrity Agreement ("CIA") between Pfizer Inc and the Department of Health and Human Services ("HHS").

More importantly, however, under any of these provisions, even if they were to apply, the Court may decline to make an order of restitution if it determines that the complication and prolongation of the sentencing process outweighs the need for restitution. 18 U.S.C. §§ 3663(a)(1)(B)(ii), 3663A(c)(3)(B). *See also* U.S.S.G. § 5E1.1(b)(2). Determining actual victims from the conduct, and the harm resulting therefrom, is a complicated process. Indeed, should even a single entity or individual make a claim for restitution in this matter, the Court would likely be required to hold a mini-trial to determine whether the claimant is a victim at all, and, if so, whether the claimant suffered any losses. The parties contend that determining complex issues of fact related to the cause or amount of any victim's losses would complicate and 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.

Furthermore, the parties contend that the Court should decline to issue a restitution order in this matter in light of the pending civil settlements. On October 17, 2008, Pfizer Inc reached agreements in principle to resolve substantially all personal injury and class action cases alleging

that Bextra was the cause of injury or improper payment. These agreements were approved as fair and reasonable by the United States District Court in the Northern District of California on September 25, 2009. In addition, as part of this proposed settlement, Pfizer Inc and the United States have reached an agreement as to civil claims, which requires the payment of one billion dollars ($1,000,000,000), plus interest. Of this amount, five hundred three million dollars ($503,000,000) plus interest is for civil claims relating to Bextra and provides for multiple damages recovery as to the United States' and the state Medicaid programs' claimed losses relating to Bextra. Thus, through these civil actions, it appears that a process is in place under which all identifiable victims have had the opportunity to be recompensed.

Between the civil settlement with the United States and relators, and the class actions pending in California, potential victims have largely pursued or had the opportunity to pursue against Pfizer Inc a more fulsome recovery than would be provided through the criminal restitution process. Accordingly, the Court should decline to issue a restitution order.

Nonetheless, given the public interest in this case, the United States has alerted potential victims of upcoming proceedings through its computerized Victim Notification System. See Dkt. No. 10 (Order Granting the United States' Motion for Alternative Victim Notification Procedures). The United States has provided written notice to the lead counsel in the pending multi-district civil litigation, MDL M:05-cv-01699, *In re Bextra and Celebrex Marketing and Sales Practices and Product Liability Litigation*, before the Honorable Charles R. Breyer, in the United States District Court for the Northern District of California and requested that the notice be posted in the electronic filing system for those cases.

D. Forfeiture

The forfeiture component of the plea agreement and Information arises from the FDCA's provision for seizing misbranded drugs. 21 U.S.C. § 334 (allowing proceedings on libel of information, for condemnation, against drugs that are misbranded or adulterated so that the government can seize, destroy or sell them). These proceedings are by their nature classic civil forfeiture proceedings. Under federal forfeiture law, the government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress which contains a civil forfeiture remedy. See 28 U.S.C. § 2461(c) (allowing criminal forfeiture where the defendant is charged "in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized . . . ."). Thus, if civil forfeiture is authorized in a statute such as the FDCA, then criminal forfeiture is as well. As the misbranded drugs are no longer available for seizure or destruction, the government can seek substitute assets as it has done here. *See* 28 U.S.C. § 2461(c) (the procedures set forth in 21 U.S.C. §853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available).

V. CONCLUSION

The United States therefore respectfully recommends and requests that the Court accept Pharmacia & Upjohn Company, Inc.'s plea of guilty and enter the agreed-upon sentence set forth in the Plea Agreement and herein.

Dated this 9th day of October, 2009.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Sara Miron Bloom