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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA *Ex rel.* Law Project for Psychiatric Rights, an Alaskan non-profit corporation, Plaintiff, vs. OSAMU H. MATSUTANI, MD, *et al*., Defendants.	)	Case No. 3:09-CV-00080-TMB

OPPOSITION TO MOTION TO DISMISS UNDER RULE 12(b)(6)

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) opposes the Defendants' Motion to Dismiss under Rule 12(b)(6), Dkt. No. 92, (12(b)(6) Motion). The 12(b)(6) Motion directly raises the question of whether PsychRights is correct that Congress restricted reimbursement for outpatient drugs by the federal government under Medicaid to those that are "medically accepted indications," defined as indications approved by the Food and Drug Administration (FDA), or the use of which is supported by one or more citations included or approved for inclusion in (i) American Hospital Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System (Covered

Outpatient Drugs). 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6); 42 USC § 1396r-8(g)(1)(B)(i).

I. CONGRESS RESTRICTED FEDERAL MEDICAID REIMBURSEMENT FOR OUTPATIENT DRUGS TO MEDICALLY ACCEPTED INDICATIONS.

A. Congress Limited Medicaid Federal Financial Participation to Covered Outpatient Drugs

42 USC 1396R-8(k)(3) provides in pertinent part, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) provides:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 USC § 1396R-8(g)(1)(B)(i), in turn, designates the compendia as

> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System.

(Compendia).

In sum, Medicaid is only permitted by Congress to reimburse the states for expenditures on outpatient drugs for "medically accepted indications," defined as indications approved by the FDA or "supported" by a citation in any of the three Compendia.

In their 12(b)(6) Motion, the Defendants assert Congress did not limit Medicaid coverage of outpatient drugs to "covered outpatient drugs" as set forth above, citing 42 U.S.C. §1396d(a)(12), which includes "prescribed drugs" in the definition of "medical assistance," for the proposition that Medicaid pays for all drugs prescribed by someone

licensed to do so, and §1396r-8(d)(1)(B)(i) for the proposition that because it allows states to limit coverage to covered outpatient drugs, prescription drug coverage under Medicaid must not otherwise be limited to covered outpatient drugs. They assert Congress established "covered outpatient drugs" as a floor or minimum, not a ceiling or maximum, also stating that the sections cited by PsychRights nowhere say or even imply that Medicaid payments are limited to "covered outpatient drugs." This is simply not true. States are not required to offer drug coverage, although they all have elected to do so, and federal reimbursement for such prescription drug coverage is limited under §1396b(i)(10) to "covered outpatient drugs," except as otherwise specifically allowed.[1]

The structure of the Medicaid Statutes, which are found at 42 U.S.C. §1396 to 42 U.S.C. §1396w-2,[2] is that §1396a sets forth the requirements of "State Plans," §1396b sets forth how reimbursement to the states is determined, §1396d defines certain terms, and other provisions of the statutes set forth specific requirements for what medical assistance is authorized to be reimbursed by the Medicaid program. §1396r-8, which is at issue here, defines the scope and requirements for prescription drug coverage, and other sections address other types of medical assistance. That a service or product is included in the definition of "medical assistance" in §1396d(a) does not mean that Medicaid pays for all of such service or product.

For example, while §1396(d)(15) includes "services in an intermediate care facility for the mentally retarded" in the definition of "medical assistance," §1396a(a) requires that "a State plan for medical assistance must," at §1396a(a)(30)(B)(i)

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[1] At §1396r-8(a)(3)(A) Congress allowed Medicaid to pay for drugs that are not covered outpatient drugs

> if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d) of this section.

[2] Hereafter, citations to sections within this statutory range omit the Title Number.

> (30) provide, under the program described in subparagraph (A), that-- (i) each admission to a[n] . . . intermediate care facility for the mentally retarded . . . is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved,

and at §1396a(a)(31) that

> (31) with respect to services in an intermediate care facility for the mentally retarded (where the State plan includes medical assistance for such services) provide, with respect to each patient receiving such services, for a written plan of care, prior to admission to or authorization of benefits in such facility, in accordance with regulations of the Secretary, and for a regular program of independent professional review (including medical evaluation) which shall periodically review his need for such services.[3]

In §1396i, Congress mandated an entire certification and approval process for intermediate care facilities for mentally retarded Medicaid beneficiaries. This is analogous to the restrictions on prescription drug coverage, including to medically accepted indications, contained in §1396r-8, and is an illustration of the principle that, contrary to the Defendants' assertion, the Medicaid statutes do not allow payment for everything defined as "medical assistance" in 1396d(a).

Similarly, the inclusion of "prescription drugs" in the definition of "medical assistance," at §1396d(a)(12) does not allow Medicaid to pay for all prescriptions by a licensed prescriber as asserted by the Defendants. Instead, §1396a(a)(54) requires that if a state elects to provide prescription drug coverage, it must comply with the requirements concerning "covered outpatient drugs" contained in §1396r-8, and at §1396b(i)(10)(A) prohibits payment "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8 of this title with respect to such drugs or unless section §1396r-8(a)(3) of this title applies." The exception in §1396r-8(a)(3)[4] makes no sense whatsoever under the Defendants' interpretation.

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[3] *See*, also §1396a(B)(i)(44).
[4] *See*, note 1, *infra*.

The Defendants are simply wrong when they assert at page 7 of their 12(b)(6) Motion that "covered outpatient drugs" establishes a floor or minimum, not a ceiling or maximum. There are a number of provisions that allow or mandate the states to restrict payment for "covered outpatient drugs." §1396r-8(d)(1)(A) allows states to establish prior authorization programs for covered outpatient drugs so long as they comply with §1396r-8(d)(5). §1396r-8(d)(1)(B) allows states to exclude or otherwise restrict coverage of covered outpatient drugs used for anorexia, weight loss, weight gain, cosmetic purposes or hair growth, smoking cessation, and sexual or erectile dysfunction, or to promote fertility. §1396r-8(d)(4) allows states to establish formularies under specified rules.

B. The United States District Courts for the Districts of Massachusetts and Illinois, and the United States Department of Justice Agree With PsychRights' Interpretation

In contesting this straightforward interpretation, the Defendants, rely on 42 USC §1396r-8(d)(1)(B)(i), which provides:

> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
>
> > (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

The Defendants' argument is this language implies Medicaid must cover more than for "medically accepted indications," because otherwise there is no reason for this provision allowing the States to exclude or restrict coverage to medically accepted indications. In other words, the Defendants' argument is that PsychRights' interpretation renders §1396r-8(d)(1)(B)(i) superfluous and an interpretation that a statutory provision is superfluous is disfavored.

In support of this contention, Defendants cite to the following in the unpublished decision in *U.S. ex rel. Franklin v. Parke Davis*, 2003 U.S. Dist. LEXIS 15754, 2003 WL 22048255, p 3 (D.Mass. 2003):

> Thus, in Relator's view, § 1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation.

(citation omitted). However, the *ex rel Franklin* district court specifically declined to rule on the issue:

> It is not clear which side gets the better of the statutory-tail-chases-cat debate. The Court would appreciate an amicus brief from federal officials, providing the federal government's understanding of the extent to which the Medicaid statute empowers states to provide coverage of off-label, non-compendium prescriptions.

Id.

Most importantly the district court there did not overrule its previous published opinion where it concluded PsychRights' interpretation is correct:

> Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id*. §1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. Id. § 1396r-8(k)(6). See also *id*. § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

U.S. ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44,45 (D.Mass 2001) (footnote omitted).

In a later published decision, *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008) the District Court for the District of Massachusetts again agreed with PsychRights' interpretation, holding:

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported

by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).

Similarly, the US District for the District of Illinois *U.S. v. Ortho-McNeil Pharmaceutical, Inc.*, 2007 WL 2091185, p. 2 (N.D.Ill. 2007), has held that Medicaid coverage is limited to "covered outpatient drugs," which excludes indications that are not for a medically accepted indication.

While not filing the *amicus* brief desired by the Massachusetts District Court in the 2003 unpublished *Franklin* opinion,[5] the Department of Justice has since taken a consistent position, repeatedly asserted, that agrees with PsychRights' interpretation. For example, in September of 2009 the Department of Justice issued a news release announcing a $2.3 Billion settlement with Pfizer, stating, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs." Exhibit 1, p.1.

Similarly, the Government's February 13, 2009, Complaint in Intervention in *U.S. ex rel Gobble v. Forest Laboratories*, Case No. 03-cv-10395-NMG, District of Massachusetts, Exhibit 2, p. 9, at ¶s 26-30, sets forth the Government's position that prescriptions caused to be presented to Medicaid that are not for medically accepted indications are false claims. Paragraph 37, Exhibit 2, p.10, also recites that Celexa (citalopram) and Lexapro (escitalopram) have no medically accepted indications for children and youth[6] and at p.31, ¶97, specifically alleges that claims presented to

[5] 2003 U.S. Dist. LEXIS 15754, 2003 WL 22048255, p 3.

[6] The FDA subsequently approved Lexapro for Major Depressive Disorder. In the First Amended Complaint herein, Dkt. No. 107, that Celexa has no medically accepted indication for children and youth is set forth at p. 34, ¶166(c), and that the only medically accepted indication for Lexapro is Major Depressive Disorder at ¶167(m).

Medicaid as a result of prescriptions of Celexa and Lexapro by physicians for use in children and youth are false or fraudulent for that reason. *See*, also ¶100, Ex. 2, p. 32. The settlement agreement in *U.S. ex rel Wetta v. AstraZeneca Pharmaceuticals,* Case No. 04-cv-3479-BMS, Eastern District of Pennsylvania, Exhibit 3, p. 6, also sets forth the Government's position that claims presented to Medicaid for outpatient drugs not for a medically accepted indication are false or fraudulent.

Thus, the Massachusetts and Illinois US District Courts and the Department of Justice all agree with the interpretation that Congress has limited federal reimbursement for outpatient drugs to "medically accepted indications."

C. Statutory Construction Principles Confirm PsychRights,' The Massachusetts and Illinois District Courts,' and the Department of Justice's Interpretation

The Defendants rely on the maxim or canon of statutory construction that an interpretation that anything in a statute is superfluous is disfavored, but of course, there are competing maxims of statutory construction.

> [A]s every judge knows, the canons of construction are many and their interaction complex. The canons "are not mandatory rules." *Chickasaw Nation v. United States,* 534 U.S. 84, 94, 122 S.Ct. 528, 151 L.Ed.2d 474 (2001). They are guides "designed to help judges determine the Legislature's intent."

Xilinx, Inc. v. C.I.R. ,598 F.3d 1191, 1196 (9th Cir. 2010).

In *Chickasaw Nation,* 453 U.S. at 94, the Supreme Court specifically rejected the canon of construction that an interpretation rendering part of a statute superfluous was controlling there:

> The canon requiring a court to give effect to each word "if possible " is sometimes offset by the canon that permits a court to reject words "as surplusage" if "inadvertently inserted or if repugnant to the rest of the statute ...."

Of course, the first thing to examine is the language of the statute itself:

> In interpreting the statute we look to general principles of statutory construction and begin with the language of the statute itself. *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241, 109 S.Ct. 1026, 103 L.Ed.2d 290 (1989)

Siripongs v. Davis, 282 F.3d 755 (9th Cir. 2002).

Defendants' interpretation of the statute immediate falls apart when looking at the provision upon which they rely, §1396r-8(d)(1)(B)(i), which states:

> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
>
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

This is circular because, "covered outpatient drug" is defined in 42 USC 1396R-8(k)(3) to "not include any . . . drug . . . used for a medical indication which is not a medically accepted indication."

Thus, substituting the definition of "medically accepted indication" the statutory provision relied upon by the Defendants states,

> A State may exclude or otherwise restrict coverage of a covered outpatient drug to a covered outpatient drug.

or, substituting the definition of "covered outpatient drug:"

> A State may exclude or otherwise restrict coverage of drugs prescribed for a medically accepted indication to drugs prescribed for a medically accepted indication.

There is thus simply no avoiding the conclusion that 42 U.S.C. §1396r-8(d)(1)(B)(i) is superfluous. Most importantly, it can not be used to override Congress' explicit limitation of Medicaid coverage for outpatient drugs to medically accepted indications.

Defendants cite to *Boise Cascade Corp. v. U.S. E.P.A.*, 942 F.2d 1427, 1432 (9th Cir. 1991), for the proposition that courts " must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous."

PsychRights respectfully suggests this maxim supports PsychRights' position rather than Defendants' because Defendants' position writes out of the statute that part of the definition of "covered outpatient drugs" that limits it to medically accepted indications, doing violence to the whole Medicaid statutory scheme in the process. The Defendants' interpretation that all prescribed drugs are covered under Medicaid because prescribed drugs are one of the elements of medical assistance is contrary to the whole structure and intent of the Medicaid statutes and the intent of Congress to limit prescription drug coverage in OBRA 1990.

For example, §1396b(i)(10)(A), provides, "Payment under the preceding provisions of this section shall not be made . . . with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8 of this title with respect to such drugs or unless §1396r-8(a)(3) of this title applies.[7] This evinces Congress' intent to restrict payments for outpatient drugs, among quite a few other things,[8] to "medically accepted indications."

PsychRights respectfully suggests its, the Massachusetts and Illinois District Courts,' and the Department of Justice's interpretation that Congress restricted coverage for outpatient drugs to covered outpatient drugs is correct.

II. THAT ALASKA'S PLAN HAS BEEN SEEKING REIMBURSEMENT FOR DRUGS THAT ARE NOT FOR A MEDICALLY ACCEPTED INDICATION IS IRRELEVANT

In Part II.C., of their 12(b)(6) Motion, the defendants demonstrate that Alaska has been obtaining reimbursement under its approved plan for prescription drugs that are not for medically accepted indications, arguing this means the reimbursements are

[7] It seems worth noting here that the title to §1996(b)(i), includes "other restrictions," and "Titles are also an appropriate source from which to discern legislative intent." *United States v. Nader*, 542 F.3d 713, 717 (9th Cir. 2008). Moreover, §1396r-8 is contained in §4401 of OBRA 1990, which is the first section in, "Part 1-Reductions in Spending," and itself is titled, "Reimbursement for prescribed drugs," denoting that the whole section pertains to the requirements for reimbursement for prescribed drugs.

[8] *See* §1396r-8(k)(3) which has quite a few restrictions in addition to the one that restricts coverage to "medically accepted indications."

authorized. This is a reason for granting a preliminary injunction against the practice rather than shedding any light on whether the practice is permitted under Medicaid.

> Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law

Heckler v. Community Health Services, 467 U.S. 51, 63, 104 S.Ct. 2218, 2225 (1984).

Citing to *Heckler*, in *U.S. ex rel Hagood v. Sonoma County Water Agency*, 929 F. 2d 1416, 1422 (9th Cir 1991), in a False Claims Act case such as this, the Ninth Circuit held that United States government officials' approval of a contract based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's dismissal under Rule 12(b)(6). That the State of Alaska has promulgated regulations and acts thereunder contrary to the law, and the officials who approved the State of Alaska's Medicaid Plan have acquiesced, is no defense--it is an admission.

III. CONCLUSION

For the foregoing reasons, the Defendants' Motion to Dismiss under Rule 12(b)(6), Dkt. No. 92, should be denied.

RESPECTFULLY SUBMITTED this 7th day of May, 2010.

Law Project for Psychiatric Rights, an Alaskan non-profit corporation

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 7, 2010, a true and correct copy of this document was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN

Department of Justice

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Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

WASHINGTON – American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668,514,830 and the state Medicaid share of the civil settlement is $331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky triggered this investigation. As a part of today's resolution, six whistleblowers will receive payments totaling more than $102 million from the federal share of the civil recovery.

The U.S. Attorney's offices for the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, and the Civil Division of the Department of Justice handled these cases. The U.S. Attorney's Office for the District of Massachusetts led the criminal investigation of Bextra. The investigation was conducted by the Office of Inspector General for the Department of Health and Human Services (HHS), the FBI, the Defense Criminal Investigative Service (DCIS), the Office of Criminal Investigations for the Food and Drug Administration (FDA), the Veterans' Administration's (VA) Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management (OPM), the Office of the Inspector General for the United States Postal Service (USPS), the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

"Today's landmark settlement is an example of the Department of Justice's ongoing and intensive efforts to protect the American public and recover funds for the federal treasury and the public from those who seek to earn a profit through fraud. It shows one of the many ways in which federal government, in partnership with its state and local allies, can help the American people at a time when budgets are tight and health care costs are increasing," said Associate Attorney General Tom Perrelli. "This settlement is a testament to the type of broad, coordinated effort among federal agencies and with our state and local partners that is at the core of the Department of Justice's approach to law enforcement."

"This historic settlement will return nearly $1 billion to Medicare, Medicaid, and other government insurance programs, securing their future for the Americans who depend on these programs," said Kathleen Sebelius, Secretary of Department of Health and Human Services**.** "The Department of Health and Human Services will continue to seek opportunities to work with its government partners to prosecute fraud wherever we can find it. But we will also look for new ways to prevent fraud before it happens. Health care is too important to let a single dollar go to waste."

"Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars," said Tony West, Assistant Attorney General for the Civil Division. "This civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient welfare."

"The size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer's crimes," said Mike Loucks, acting U.S. Attorney for the District of Massachusetts. "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

"Although these types of investigations are often long and complicated and require many resources to achieve positive results, the FBI will not be deterred from continuing to ensure that pharmaceutical companies conduct business in a lawful manner," said Kevin Perkins, FBI Assistant Director, Criminal Investigative Division.

"This resolution protects the FDA in its vital mission of ensuring that drugs are safe and effective. When manufacturers undermine the FDA's rules, they interfere with a doctor's judgment and can put patient health at risk," commented Michael L. Levy, U.S. Attorney for the Eastern District of Pennsylvania. "The public trusts companies to market their drugs for uses that FDA has approved, and trusts that doctors are using independent judgment. Federal health dollars should only be spent on treatment decisions untainted by misinformation from manufacturers concerned with the bottom line."

"This settlement demonstrates the ongoing efforts to pursue violations of the False Claims Act and recover taxpayer dollars for the Medicare and Medicaid programs," noted Jim Zerhusen, U.S. Attorney for the Eastern District of Kentucky.

"This historic settlement emphasizes the government's commitment to corporate and individual accountability and to transparency throughout the pharmaceutical industry," said Daniel R. Levinson, Inspector General of the United States Department of Health and Human Services. "The corporate integrity agreement requires senior Pfizer executives and board members to complete annual compliance certifications and opens Pfizer to more public scrutiny by requiring it to make detailed disclosures on its Web site. We expect this agreement to increase integrity in the marketing of pharmaceuticals."

"The off-label promotion of pharmaceutical drugs by Pfizer significantly impacted the integrity of TRICARE, the Department of Defense's healthcare system," said Sharon Woods, Director, Defense Criminal Investigative Service. "This illegal activity increases patients' costs, threatens their safety and negatively affects the delivery of healthcare services to the over nine million military members, retirees and their families who rely on this system. Today's charges and settlement demonstrate the ongoing commitment of the Defense Criminal Investigative Service and its law enforcement partners to investigate and prosecute those that abuse the government's healthcare programs at the expense of the taxpayers and patients."

"Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S.

Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that it must observe those standards and reflects the commitment of federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Health care fraud has a significant financial impact on the Postal Service. This case alone impacted more than 10,000 postal employees on workers' compensation who were treated with these drugs," said Joseph Finn, Special Agent in Charge for the Postal Service's Office of Inspector General. "Last year the Postal Service paid more than $1 billion in workers' compensation benefits to postal employees injured on the job."

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09-900

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHRISTOPHER R. GOBBLE, *et al.*, **Plaintiff,** **v.** **FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. 03-10395-NMG** **FILED UNDER SEAL**
UNITED STATES OF AMERICA *ex rel.* JOSEPH PIACENTILE, *et al.*, **Plaintiff,** **v.** **FOREST LABORATORIES, INC.,** **Defendant.**	**Civil Action No. 05-10201-NMG**

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of the defendants, Forest Laboratories, Inc. ("Forest Labs"), and Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") (collectively, "Forest"). Over the course of more than half a decade, Forest illegally marketed two related antidepressant drugs, Celexa and Lexapro, for off-label use in pediatric patients when both drugs had been approved only for adult use. During much of that

time, Forest misled physicians by promoting the results of a positive study on pediatric use of Celexa while failing to disclose the results of a contemporaneous negative study for the same pediatric use. Forest also illegally paid kickbacks to physicians to induce them to prescribe the drugs. By knowingly and actively promoting these antidepressants for off-label pediatric use without disclosing the results of the negative pediatric study and by paying kickbacks, Forest caused false claims to be submitted to federal health care programs in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*.

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

2. The United States bases its claims on Forest causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1).

3. Within the time frames detailed below, Forest engaged in a fraudulent scheme to market and promote Celexa (citalopram) and Lexapro (escitalopram) off-label to treat depression and other psychiatric conditions in pediatric patients. Forest did so even though the Food and Drug Administration ("FDA") had not approved the drugs as safe and effective for any use in the pediatric population. In the case of Celexa, the FDA had specifically denied approval for any pediatric use.

4. In furtherance of its off-label marketing scheme, Forest disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety

and efficacy of Celexa and Lexapro in treating pediatric patients. At the same time that Forest was actively touting pediatric use of the drugs, the company failed to disclose the negative results of a large, placebo-controlled study that found Celexa no more effective than placebo for pediatric use and in which more patients taking Celexa attempted suicide or reported suicidal ideation than those taking only placebo. The negative data that Forest failed to disclose was among the data later considered by the FDA when mandating that Forest add a "black box" warning to both the Celexa and Lexapro labels for pediatric use.

5. In addition to its illegal off-label marketing scheme, Forest sought to induce physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment, and other valuable goods and services, all in violation of the federal anti-kickback statute, 42 U.S.C. § 3120a-7b(b) ("AKS").

6. As the direct, proximate, and foreseeable result of Forest's fraudulent course of conduct, as set forth above and herein, Forest caused thousands of false or fraudulent claims to be submitted to the federal health care programs for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use and/or were ineligible for payment as a result of illegal kickbacks.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345.

8. This Court may exercise personal jurisdiction over Forest pursuant to 31 U.S.C.

§ 3732(a) and because Forest transacts business in the District of Massachusetts.

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Forest has transacted business in this District.

III. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"); the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administers the Medicaid program; and the Department of Defense, which administers the TRICARE/CHAMPUS program ("TRICARE") (collectively, "federal health care programs").

11. Relator Christopher R. Gobble is a resident of Virginia and a former employee of Forest. In March 2003, Mr. Gobble filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

12. Relator Joseph Piacentile is a resident of New Jersey. On August 20, 2001, Mr. Piacentile filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

13. Defendant Forest Labs is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York. Forest Labs has a license from H. Lundbeck A/S ("Lundbeck"), a Danish company, to promote and sell Celexa and Lexapro in the United States.

14. Defendant Forest Pharmaceuticals is a wholly owned subsidiary of Forest Labs

with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals manufactures, distributes, and sells Forest prescription products in the United States.

IV. THE LAW

A. The False Claims Act

15. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government. 31 U.S.C. § 3729(a)(1).

16. The FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

17. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for

violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

18. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The statute was enacted in 1972; Congress strengthened it in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

19. The AKS prohibits any person or entity from offering, making, or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> * * *
>
> (2) 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 --

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) 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 and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

20. Under the AKS, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to prescribe drugs for which payment may be made by federal health care programs.

21. The AKS not only prohibits outright bribes, but also prohibits any remuneration by a drug company to a physician that has as one of its purposes inducement of the physician to write prescriptions for the company's pharmaceutical products.

V. THE FEDERAL HEALTH CARE PROGRAMS

A. The Medicaid Program

22. The Medicaid program is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program and receives funding from the federal government, known as federal financial participation, based upon a formula set forth in the federal Medicaid statute.

23. Before the beginning of each calendar quarter, each state submits to CMS an

estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as actual provider claims are presented for payment). After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding (to reconcile the estimated expenditures to actual expenditures).

24. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

25. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

26. While federal drug coverage is an optional benefit available to the states, most states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

27. The Medicaid Rebate Statute generally prohibits federal financial participation for a covered outpatient drug unless there is a rebate agreement in effect with the manufacturer for that drug. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a state is generally required to cover that drug under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

28. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for

inclusion in any of the compendia" set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

29. A drug does not generally meet the definition of a "covered outpatient drug" if it is being prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. §§ 1396r-8(k)(2)(A), (k)(3).

30. Thus, even if a drug is FDA-approved for a certain indication, Medicaid ordinarily does not cover off-label uses that do not qualify as medically accepted indications. Many state Medicaid programs prohibit covering such uses. *See, e.g.*, 40-850-026 DEL. CODE REGS. § 3.5.4.1 (2008); IND. CODE § 12-15-35-4.5 (2008); N.J. ADMIN. CODE § 83C-1.14(1) (2008); N.M. CODE R. § 8.325.4 (2008).

B. The TRICARE Program

31. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

32. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

33. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. §199.4(g)(15)(i)(A)(Note). TRICARE will not knowingly provide reimbursement for off-label use if the prescriptions result from illegal off-label marketing.

VI. FOREST'S SCHEME

A. The Celexa And Lexapro Labels

34. Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRIs") drugs. Lundbeck developed both Celexa and Lexapro, which contains the active agent in Celexa, and subsequently licensed both drugs to Forest for marketing in the United States. Forest began selling Celexa in 1998. In 2002, with Celexa soon due to face generic competition, Forest began selling Lexapro.

1. The FDA Has Not Approved Celexa Or Lexapro For Pediatric Use.

35. In 1998, the FDA approved Celexa for the treatment of adult depression. The FDA never approved Celexa for treatment of any conditions other than adult depression, or for any pediatric use.

36. In 2002, the FDA approved Lexapro for the treatment of adult depression. In 2003, Lexapro received approval for treatment of Generalized Anxiety Disorder ("GAD") in adults. Lexapro has not been approved for any other conditions and was not approved for pediatric use.

37. The use of Celexa and Lexapro in pediatric patients is not supported by a citation included or approved for inclusion in any of the compendia. The use of Celexa and Lexapro in pediatric patients is not a "medically accepted" indication for those drugs.

38. If a manufacturer conducts pediatric clinical studies on a drug, a manufacturer may obtain an additional six months of patent exclusivity for the previously-approved, on-label

indications for that particular drug subject to certain FDA requirements. 21 U.S.C. § 355a. In such circumstances, the FDA issues a "Written Request" that details the studies that should be performed. 21 U.S.C. § 355a(c)(2)(A).

39. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa." On April 28, 1999, the FDA issued a Written Request to Forest to conduct "two independent, adequate and well-controlled clinical trials in pediatric depression" for Celexa.

40. On September 24, 1999, Forest submitted to the FDA protocols for two pediatric studies: 1) a double-blind, placebo-controlled pediatric study being conducted in Europe by Lundbeck (the "Lundbeck study"); and 2) a double-blind, placebo-controlled pediatric study to be conducted in the United States by Forest through University of Texas child psychiatrist Karen Wagner (the "Wagner study").

41. In mid-2001, the Wagner and Lundbeck studies were unblinded and their results were disseminated to senior Forest executives. The Wagner study was positive, *i.e.*, it indicated that Celexa was more effective than placebo in treating pediatric patients suffering from depression, but the Lundbeck study was negative, *i.e.*, it did not show Celexa to be any more effective than placebo in treating pediatric depression. Furthermore, in the Lundbeck study, 14 of the patients taking Celexa attempted suicide or reported suicidal ideation (*i.e.*, contemplation of suicide) compared to only 5 patients taking placebo. Under one statistical test, this result was "significant," and, under another statistical test, it was "borderline significant."

42. On April 18, 2002, Forest submitted the results of both the Lundbeck and Wagner studies to the FDA in support of requests for both a six-month extension of patent exclusivity

and a pediatric indication for Celexa. Forest's submission to the FDA was not public.

43. On July 15, 2002, the FDA granted Celexa six additional months of patent exclusivity for the on-label use of treating depression in adults.

44. On September 23, 2002, the FDA denied Forest's request for a pediatric indication for Celexa. The FDA concluded that the Lundbeck study "is a clearly negative study that provides no support for the efficacy of citalopram in pediatric patients with [major depressive disorder]."

2. The FDA-Mandated Black Box Warnings On The Celexa And Lexapro Labels

45. On March 22, 2004, the FDA issued a public health advisory requesting that certain SSRI manufacturers, including Forest, change the labels on their SSRI drugs to include "a [w]arning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality."

46. Later that year, the FDA directed the SSRI manufacturers, including Forest, to include on their labels a black box warning and expanded statements to alert physicians about the potential for increased risk of suicidality in children and adolescents taking SSRIs. The black box warning specifically stated that "[a]ntidepressants *increased the risk* of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." (Emphasis added). In addition, the FDA required SSRI manufacturers to state, in relevant part, that:

> The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in

> children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants.

47. The Lundbeck study on pediatric use of Celexa was one of the 24 trials considered by the FDA in mandating this warning.

48. Forest revised the Celexa and Lexapro labels in early 2005 to include the required black box warning and to state under each label's "Pediatric Use" subheading that "[s]afety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS-Clinical Worsening and Suicide Risk)." The Celexa label further stated that "[t]wo placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients," while the Lexapro label stated that "[o]ne placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients."

49. In 2007, the Celexa and Lexapro labels were again modified to state that, after evaluating the pooled analyses of placebo-controlled SSRI trials in children and adolescents and of trials in adults, "[t]here was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied."

50. To date, Forest has not obtained FDA approval for a pediatric indication for Celexa or Lexapro. Both the Celexa and Lexapro labels currently include black box warnings explicitly indicating that the safety and efficacy of the drugs in the pediatric population have not

been established.

B. Forest's Dissemination Of Half Truths As A Result Of Its Failure To Disclose The Results Of The Negative Lundbeck Study

51. Although Forest submitted the Lundbeck study to the FDA in 2002 in order to seek a six-month extension of patent exclusivity for Celexa (which Forest later valued at $485 million), Forest failed otherwise to disclose the negative study beyond a small group of its senior executives. At the same time, Forest aggressively promoted the Wagner study, thereby relaying the false impression that the only available pediatric data on Celexa was positive.

52. Although the Forest senior executives learned about the negative Lundbeck results in mid-2001, Forest failed for the next three years to disclose that negative data to, among others: its thousands of sales representatives who were detailing pediatric specialists; pediatric specialists whom it hired to give promotional speeches on Celexa and Lexapro; the members of its Executive Advisory Board of leading psychiatrists upon whom it ostensibly relied for advice concerning new data and upon whom it also relied to convey information to others; its own Professional Affairs Department, which it charged with disseminating "balanced" information in response to physician requests for available data on Forest drugs; or even its own pediatric researchers such as Dr. Wagner.

53. During this same time period, Forest took aggressive steps to publicize the positive results of the Wagner study. On August 27, 2001, Forest presented the Wagner study results to its Executive Advisory Board without making any mention of the contemporaneous negative Lundbeck results. Forest thereafter arranged for Dr. Wagner to present a poster summary of the Wagner study to various professional groups, including the American Psychiatric

Association, the American College of Neuropsychopharmacology, and the Collegium Internationale Neuro-Psychopharmalogicum. In conjunction with these presentations, Forest coordinated the "placement" of news stories about the positive Wagner data in numerous national and local media outlets.

54. Over the course of 2002, Forest arranged for Dr. Wagner to give promotional presentations on the pediatric use of Celexa and to serve as the chair of a seven-city Continuing Medical Education ("CME") program on treating pediatric depression. Forest also sponsored 20 CME teleconferences that addressed the Wagner study results.

55. Forest's simultaneous failure to disclose the negative Lundbeck study results and wide publication of the positive Wagner study results caused Forest and its consultants to make false or misleading statements. For example, because not even Dr. Wagner was aware of the negative Lundbeck data, she never discussed that data in her many Forest-sponsored talks addressing the pediatric use of Celexa and Lexapro. Her slide presentations addressed negative studies on pediatric use of other SSRIs, but falsely indicated that there were no negative studies on the pediatric use of Celexa.

56. Forest's failure to disclose the negative Lundbeck results to the members of Forest's Executive Advisory Board caused those members to make false or misleading statements in promotional teleconferences on Celexa and Lexapro. During the teleconferences, which were targeted to large numbers of physicians across the country, the Forest Executive Advisory Board members represented, based on the Wagner data, that Celexa was safe and effective for pediatric use even though, unbeknownst to them, the FDA had specifically rejected

Forest's attempt to gain approval for such a claim because of the negative Lundbeck data.

57. During details to physicians, Forest's sales representatives made false or misleading representations by distributing off-label publications on the pediatric use of Celexa and Lexapro that did not include the negative Lundbeck data. Forest sales managers, also unaware of the Lundbeck data, directed the dissemination of these publications.

58. Forest had a Professional Affairs Department that responded to health care provider inquiries. Under the company's own written policy, the Professional Affairs Department was:

> *required to provide balanced information* to help the health care practitioner (HCP) make the best decision on behalf of the patient. For this reason, *there is an ethical prohibition in "cherry picking" studies that are favorable to Forest products*. The Food and Drug Administration Division of Drug Marketing, Advertising, and Communications (DDMAC) monitors drug information departments to insure information provided to HCPs is balanced, and that it is not selective.

(Emphasis added.) Forest's failure to disclose the negative Lundbeck data to its Professional Affairs Department caused it to disseminate misleading information to physicians on the pediatric use of Celexa and Lexapro. When physicians sought information from Forest's Professional Affairs Department in the years following the un-blinding of the Wagner and Lundbeck studies, the Professional Affairs Department responded with letters that cited only positive data. The letters cited just one double-blind placebo-controlled trial on the use of Celexa to treat pediatric depression, the Wagner Study. The letters never mentioned that there was another, negative, double-blind placebo-controlled trial, the Lundbeck study.

59. Several senior Forest executives – including Lawrence Olanoff (then Forest's

Chief Scientific Officer and now its President), Ivan Gergel (Vice President of Clinical Development and Medical Affairs), and Amy Rubin (Director of Regulatory Affairs) – reviewed the letters before the Professional Affairs Department disseminated them. All of these senior Forest executives knew about the negative Lundbeck data.

60. Forest paid a medical writing firm to ghost-write an academic article on the Wagner study, and Forest arranged to have the article published in the June 2004 issue of *The American Journal of Psychiatry*, with Dr. Wagner listed as the lead author. The article did not mention that the only other double-blind, placebo-controlled trial on pediatric use of Celexa had shown no efficacy and had an incidence of suicide attempts and suicidal ideation among those taking Celexa that was almost three times higher than in the group taking the placebo.

61. On June 21, 2004, *The New York Times* published a news story titled "Medicine's Data Gap – Journals in a Quandry; How to Report on Drug Trials." The story featured *The American Journal of Psychiatry* article on the Wagner study, revealing the negative results of the Lundbeck study and noting that the Wagner article failed to mention them.

62. Three days after the story ran, Forest issued a press release acknowledging the existence of the Lundbeck study and its finding that Celexa "did not show efficacy versus placebo." That same day, Forest also disclosed the results of an earlier double-blind placebo-controlled study of Lexapro in children and adolescents. That study also failed to show efficacy in comparison to placebo.

63. By failing to disclose the Lundbeck study results, which raised serious questions about the efficacy and safety of Celexa, while simultaneously promoting the Wagner study,

Forest told prescribing physicians a half-truth and thereby prevented them and the public from having all potentially available information when making decisions about how to treat a serious medical condition in pediatric patients.

64. Forest's conduct regarding the Lundbeck study results was consistent with the way it handled prior negative study data on Celexa. Just a few months before the pediatric Lundbeck study was unblinded, senior executives from Forest and Lundbeck discussed whether publicly to disclose the negative results from a study of Celexa in a primary care population. The study included three groups: patients taking Lexapro, patients taking Celexa, and patients taking placebo. Although Lexapro showed efficacy versus the placebo in the study, Celexa did not. Minutes of a December 2000 meeting of senior Forest and Lundbeck executives show that Forest wanted to publicize only the Lexapro versus placebo results, while Lundbeck wanted the results from the entire study to be publicly disclosed. As Lundbeck executives noted a month earlier, "Forest made clear their concern over disclosing any data that could put Celexa in an unfavorable light." In May 2001, Lundbeck executives observed that "Forest are at the moment unwilling to release data where citalopram does not sufficiently surpass placebo." Forest ultimately prevailed over Lundbeck and, as it did later with Lundbeck's negative pediatric data, kept the negative Celexa versus placebo results confidential.

C. Forest's Fraudulent Course Of Conduct To Promote Celexa And Lexapro For Off-Label, Pediatric Use

65. To obtain FDA approval for a drug, a drug must be demonstrated to be safe and effective for each of its proposed uses. The approved uses for a drug are limited to those uses identified in the FDA-approved product label. *See* 21 U.S.C. § 355(a), (b). "Off-label" use

refers to the promotion of an approved drug for any purpose, or in any manner, other than what is described in the drug's FDA-approved labeling.

66. From 1998 through at least 2005, Forest engaged in a widespread campaign to promote Celexa and Lexapro for pediatric use, even though neither drug was approved for pediatric use and the science was, at best, inconclusive about the safety and efficacy of these drugs for pediatric use. Forest used its sales representatives to detail or target pediatric specialists; paid pediatric specialists to give promotional speeches to other physicians on pediatric use; selectively distributed publications on pediatric uses to pediatric specialists; misrepresented the safety and effectiveness of the drugs; and made extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses.

67. Forest knew that its off-label promotion for pediatric use was unlawful. Shortly before the FDA ordered the black box warning in September 2004, a Forest executive testified before Congress: "I want to emphasize that, because the FDA has not approved pediatric labeling for our products, Forest has always been scrupulous about not promoting the pediatric use of our antidepressant drugs, Celexa and Lexapro. That is the law, and we follow it." In fact, Forest had been illegally promoting the pediatric use of Celexa and Lexapro throughout the preceding six years.

68. Forest assigned its sales representatives to specific geographic regions across the United States. Within each region, sales representatives encouraged specific doctors to increase their prescriptions of Celexa and Lexapro. A specific component of this marketing scheme included the promotion of Celexa and Lexapro for pediatric indications.

69. From 1998 through the end of 2004, the lists of physicians whom Forest directed its sales representatives to target, also known as "call panels," included thousands of child psychiatrists, pediatricians, and other physicians who specialized in treating children. Forest had more than 500,000 promotional sales calls or "details" with these pediatric specialists. The sales representatives documented these details through "call notes." Forest recorded thousands of call notes evidencing pediatric promotion. Examples of such notes include the following:

- "discussed cx [Celexa] use in children . . . and results of dr. karen wagner study regarding cx use for children and adolescents."
- "went over peds use, 0 drug interactions, less ae, less compliance issues for children, he is sold on that. closed on keeping cx first choice."
- "went over Celexa children, the invitation to the winery."
- "[doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!"
- "discuss lx [Lexapro] brief and what he [is] using dosing w children . . . reinforce safety for children."
- "Let him know some child psychs are using LX for children."
- "Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat the anxiety and depression and OCD."
- "dinner program [with child psychiatrist as speaker] at amato's with yale child study center."
- "focus on Lexapro efficacy at just 10mg..great choice for child/adolescents."
- "mainly sees children but always felt comfortable with CX & children - got his commitment to give [Lexapro] a fair clinical trial."

- "went over lxp use on children and efficacy."

Call notes such as these represent only some of the instances when sales representatives memorialized their illegal off-label promotion of Celexa and Lexapro. The call notes exemplify the tip of what was a much more pervasive and widespread off-label campaign.

70. Forest's headquarters office in New York maintained a list of "approved" promotional speakers that included numerous pediatric specialists. Forest sales representatives and managers identified speakers from these lists to organize promotional lunches and dinners on Celexa and Lexapro. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on off-label pediatric use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Updates in Depression," "Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment Options in Depressive Disorders in Adolescents," "New Age Depression Treatment," "Use of Antidepressants in Adolescents," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children," "Adolescents, and Adults," "Celexa in CHP/Ped Practice," "Treating Difficult Younger Patients," "Treatment of Depression," "Assessment and Treatments of Suicidal Adolescents," and "Treating Pediatric Depression." Forest management approved each of these programs.

71. From 1999 through 2006, one pediatric specialist, Dr. Jeffrey Bostic, Medical Director of the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital, gave more than 350 Forest-sponsored talks and presentations, many of which addressed

pediatric use of Celexa and Lexapro. Dr. Bostic's programs, which took place in at least 28 states, had topics such as "Uses of Celexa in Children" and "Celexa Use in Children and Adolescents." Forest also paid Dr. Bostic to meet other physicians in their offices in order to ease their concerns about prescribing Celexa or Lexapro off-label for pediatric use.

72. Dr. Bostic became Forest's star spokesman in the promotion of Celexa and Lexapro for pediatric use. As one sales representative wrote, "DR. BOSTIC is the man when it comes to child Psych!" Between 2000 and 2006, Forest paid Bostic over $750,000 in honoraria for his presentations on Celexa and Lexapro.

D. Forest's Illegal Inducements To Physicians To Prescribe Celexa And Lexapro

73. Forest augmented its off-label promotion efforts through extensive payments and gifts to physicians to induce them to prescribe Celexa and Lexapro. Forest's marketing department directed some of the kickbacks, such as honoraria for participation in advisory boards and in a large marketing study on Lexapro. Forest's sales representatives, often acting with the knowledge and encouragement of their managers, arranged for other kickbacks, such as restaurant gift certificates for physicians, lavish entertainment of physicians and their spouses, and grants to individual physicians.

1. Advisory Boards

74. Between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro, with over 19,000 advisory board attendees that Forest called "consultants." Forest paid each "consultant" an honorarium of $500.

75. Ostensibly, Forest paid physicians to attend these advisory boards to get their

feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal company documents, Forest intended that the advisory boards induce the attendees to prescribe more Celexa and Lexapro.

76. In a May 2000 proposal for a series of 44 Celexa advisory boards, a Forest contractor, Intramed, wrote that the advisory boards, each with 20 physicians attendees, would "give Forest an opportunity to influence more physicians." Forest's marketing department approved this proposal. Later that year, Steve Closter, the Forest marketing executive who organized the advisory boards, wrote that the Celexa advisory boards begun in June 2000 had been successful and, as a result, "will become an even larger part of the promotional mix in the future." For years thereafter, Forest's marketing department included the cost of advisory boards in its annual promotional budgets for Celexa and Lexapro.

77. With the early success of the advisory board programs, the Forest sales force enthusiastically used them to drive up sales. As one Forest District Manager told his Regional Director in a November 2000 planning document, he intended to conduct a local advisory board to "target[] the highest prescribers" in several of his territories because "[t]here is no doubt that a program of this magnitude will increase Celexa market share." In approximately January 2002, a marketing strategy slide deck given to Forest's chief executive, Howard Solomon, quoted a Regional Director stating that, "[w]ell planned Advisory Board meetings will be key to our efforts of reaching hesitant physicians."

78. In June 2002, Forest's two Vice Presidents of Sales sent a memorandum to all sales managers observing that, notwithstanding new promotional guidelines for the industry,

advisory boards remained among "the wealth of activities and programs that we can conduct that will impact physicians." Similarly, in August 2002, a Forest Regional Director sent an e-mail to his District Managers stating that, "[w]ith the new guidelines in place, Ad Boards have become even a more valuable resource, thus each one needs to be a home run! With your attention and focus, we can make [*sic*] maximize this opportunity!"

79. In the fall of 2002, to coincide with the launch of Lexapro, Forest conducted a series of 200 advisory boards reaching over 4,000 potential new Lexapro prescribers.

80. Forest monitored its return on investment, or "ROI," from the advisory boards. To conduct its ROI analyses, Forest measured the increase in prescriptions written by physicians that attended the local advisory boards, and then compared the value of those prescriptions to the cost – primarily the honoraria payments – of putting on the programs. A November 2000 ROI analysis of a single advisory board program reached the following conclusion:

> Post program the Ad Board group [24 attendees] wrote an average of 19.6% Celexa as measured by a 5-week 1st Rx average. This is an increase of 3.7% in share. At first glance, the share increase might not appear substantial. However, considering the volume of SSRIs written by these physicians, 3.7% translates into almost 2000 new prescriptions on a yearly basis.

81. In May 2001, an internal ROI analysis of all of the Celexa advisory boards in 2000 found that "participants in the program prescribed nearly 14 additional prescriptions of Celexa vs. the control group over a seven-month period."

82. Three months later, in August 2001, the author of the ROI analysis reiterated to the Celexa marketing team that, "[o]ur goal is to increase the ROI on these advisory boards." That same month, a Forest Regional Director reported to the company's Vice President of Sales

that three local advisory boards had "generated close to $30K" from just a subset of the attendees and that "the scripts will continue, and continue to generate additional $$$ and ROI."

83. After 2003, Forest stopped conducting ROI analyses of advisory boards because of concerns about memorializing illegal intent, but the company continued to use the same types of advisory board programs as a means of inducing doctors to prescribe Celexa and Lexapro. As a Forest Area Business Director noted in a September 2003 memorandum to his Regional Directors, "[w]e are not able to do as many Ad Boards as we have in the past, so it [is] critical that we get the best targets to the programs." Similarly, in March 2004, a Texas-based Forest District Manager reported to her Regional Director and fellow District Managers that she had met with her sales team about "the types of doctors" they wanted to recruit for an upcoming advisory board and that they had come "up with 40 doctors that are either high Celexa writers or can be converted/persuaded to write Lexapro." In August 2004, a Massachusetts District Manager wrote to his colleagues and sales team that, for an upcoming Lexapro advisory board, "we are looking for the best ROI."

2. The EXCEED Study

84. In 1998, Forest successfully used a so-called "seeding study" – a clinical study intended to induce participating physicians to prescribe the drug under study – as part of the promotional strategy for the launch of Celexa. With the launch of Lexapro in 2002, Forest sought to replicate the success of the Celexa seeding study. Forest called the Lexapro seeding study EXCEED (EXamining Clinical Experience with Escitalopram in Depression).

85. In the planning stages for EXCEED, a senior Forest marketing executive wrote

that the purpose of the study was to ensure a "fast uptake" for Lexapro. The overall Lexapro marketing plan, which was reviewed by the company's most senior executives, stated:

> Another component of the rapid uptake of Lexapro will be to encourage trial. The experience trial for Lexapro (EXCEED) will follow approval and will be larger in scope than the Celexa experience trial (EASE). More prescribers will have the ability to trial Lexapro on several patients to gain experience. Trial leads to adoption and continued usage of a product if a prescriber has successful results.

At the conclusion of EXCEED, Forest's marketing department planned to calculate the study's "ROI," *i.e.*, the number of prescriptions generated as compared against the cost of funding the study.

86. To the extent the EXCEED trial had a scientific purpose, it was secondary to the purpose of inducing participating physicians to prescribe Lexapro. Forest conceived the study as a promotional tool and then sought out company scientists "to discuss possible endpoints/outcomes to look at for our early usage trial." Forest hired Covance, a contract research organization, to conduct the study, but, according to Covance's own study implementation plan, Covance, too, understood that "the primary goal of this trial is to provide experience to physicians." Similarly, Forest openly referred to the EXCEED trial as a "seeding" study in their internal communications.

87. Forest aimed the EXCEED study at 2,000 physicians. Under the study protocol, each participating physician could enroll up to five patients in the study, which would last eight weeks and involve three patient visits. After the first visit, the physician would fill out a one-page form with the patient's age, race, gender, and basic medical history, and Forest would pay the physician $50. After each of the next two visits, the physician would fill out an additional

page requiring the physician to write the date of the visit and to check one of seven boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference.

88. By the time the EXCEED study was completed, Forest had made study participation payments to 1,053 physicians, who in turn put 5,703 patients on Lexapro during the course of the study.

3. Preceptorships

89. Between 1999 and 2003, Forest paid millions of dollars to physicians who participated in so-called "preceptorships." Each physician who participated in a preceptorship received a "grant" of as much as $1,000 per preceptorship.

90. Ostensibly, preceptorships were a training opportunity where Forest sales representatives would spend a half-day or full day with a physician and learn about how Celexa and Lexapro were used in practice. In reality, Forest sales representatives used the preceptorships to induce physicians to prescribe Celexa and Lexapro.

91. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out "Return on Investment (R.O.I.)" forms to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a

statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify the cost to Forest. Senior Forest sales managers and headquarters staff reviewed and approved the completed preceptorship ROI forms.

92. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments, included the following:

- "Dr. ___ is the managing partner of the '____ Psychiatric Group' and is very influential among his colleagues in the ___ Hospital network. He currently averages @ 12 per week on 1st RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. ___."

- "Dr. ___ is the largest prescriber of SSRI's in a 3 state area. . . . We are currently her first line SSRI. We must, however, continue to support her monetarily or this will not continue to be the case. . . . We have to keep the pressure on to continue to receive the growth we are getting with Dr. ___."

- "Dr. ___ is my largest prescribing Celexa physician. He is a high maintenance target and doing round tables and preceptorships will help me to keep his business and to continue to grow his business."

- "2 different preceptorhsips. Doc is 3rd ranked phys. in SSRI potential + bus had dropped. Needed his full attention."

- "Dr. ___ is my fourth largest SSRI writer. . . . A preceptorship will provide opportunity for rapport and for future detail time and sales."

- "# 1 physician in Territory. . . . Dr. ___ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship."

- "This full day preceptorship will give me the opportunity to sell Celexa as a first-line choice in doctor ___'s practice."

- "To influence doctor to Rx Celexa."

Forest approved all of these preceptorship payment justifications.

4. Lavish Entertainment And Gifts

93. During the period from 1998 through at least 2005, each Forest sales representative typically had a quarterly marketing budget of thousands of dollars to spend on physicians. As a Forest Regional Director put it in an April 2006 memo to his sales team, "we have a ton of promotional money." Forest sales managers put pressure on their sales representatives to spend their entire marketing budgets.

94. Prior to 2003, Forest sales representatives commonly spent their marketing money on fishing, golf, and spa outings for physicians, and on buying tickets to sporting events and the theater for physicians. Both prior to and after 2003, Forest sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."

- In September 2002, a sales representative gave a high-prescribing

child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.

- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.

- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.

- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.

- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."

- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.

- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would "always rxlex [*i.e.*, prescribe Lexapro] #1 aslong [*sic*] as we have fun and take care of him."

95. All of this spending was intended to induce physicians to prescribe Celexa or Lexapro.

VII. FALSE CLAIMS

96. As a result of Forest's fraudulent course of conduct, Forest caused the submission of false or fraudulent claims for Celexa and Lexapro to federal health care programs. These claims were not reimbursable because they were not covered for off-label pediatric use and/or

were ineligible for payment as a result of illegal kickbacks.

97. The chart set forth below identifies examples of false or fraudulent claims caused by Forest's off-label promotion. The chart includes: (a) the prescribing physician; (b) the number of promotional sales calls by Forest to each physician; (c) the number of pediatric Medicaid claims resulting from that physician; and (d) the amount paid for those pediatric claims by Medicaid.

CELEXA			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. A.	58	1927	$110,865
Dr. B.	70	977	$70,311
Dr. C.	133	871	$85,980
Dr. D.	58	777	$42,568
Dr. E.	33	586	$44,280
Dr. F.	50	589	$39,807
LEXAPRO			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. G.	257	1769	$197,052
Dr. H.	118	7790	$428,627
Dr. I.	76	4565	$251,378
Dr. J.	192	3219	$229,469
Dr. K.	296	2441	$252,879

98. The chart set forth below provides examples of false or fraudulent claims caused by Forest's illegal kickbacks to a physician, Dr. L. The chart identifies: (a) the year; (b) the type

of meeting or event Dr. L attended; (c) the amount paid to Dr. L; (d) the number of claims resulting from Dr. L; and (e) the amount paid for those claims by Medicaid.

Year	Type of Meeting or Event	Amount Paid	Claims	Medicaid Payment
2000	Advisory Boards	$500	197	$12,867
2001	Advisory Boards/Speaker Programs	$1,250	221	$14,646
2002	Advisory Boards/Speaker Programs/ Sponsorships	$2,500	367	$25,570
2003	Advisory Boards/Speaker Programs/Sponsorships	$10,250	302	$21,175
2004	Sponsorships	$500	272	$20,402

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

99. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

100. Forest knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use, and/or were ineligible for payment as a result of illegal kickbacks.

101. By virtue of the false or fraudulent claims that Forest caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION
(Unjust Enrichment)

102. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

103. The United States claims the recovery of all monies by which Forest has been unjustly enriched.

104. As a consequence of the acts set forth above, Forest was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Forest as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the damages sustained and/or amounts by which Forest was unjustly enriched or by which Forest retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

MICHAEL F. HERTZ
ACTING ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

Dated: February 13, 2009 By: 

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FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. JAMES WETTA,	)	
Plaintiff,	)	C.A. No. 04-3479
v.	)	Filed Under Seal
ASTRAZENECA CORPORATION,	)	
Defendant.	)	

UNITED STATES' NOTICE OF INTERVENTION FOR PURPOSES OF SETTLEMENT

The United States of America, by and through its undersigned attorneys, provides this written notice to the Court that it is intervening in the above-captioned action pursuant to 31 U.S.C. §3730(b) for the purposes of settlement and dismissal.

The United States, relator James Wetta and defendant AstraZeneca have reached an amicable resolution of these matters. A copy of the Settlement Agreement is attached as Exhibit A. The parties agree that, upon receipt of the Settlement Amount as defined in the Settlement Agreement, the United States and relator will file a Stipulation of Dismissal in accordance with

the terms of the Settlement Agreement.

Respectfully submitted,

MICHAEL L. LEVY
United States Attorney

VIRGINIA A. GIBSON
First Assistant United States Attorney

COLIN M. CHERICO
Assistant United States Attorney

EXHIBIT A

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity ("TMA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"); James Wetta ("Wetta"); Stephan Kruszewski, M.D. ("Kruszewski"); and Astra Zeneca LP and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. AstraZeneca LP and AstraZeneca Pharmaceuticals LP are Delaware limited partnerships with their principal places of business in Wilmington, Delaware. At all relevant times herein, AstraZeneca distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Seroquel.

B. On July 24, 2004, Wetta filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. James Wetta v. AstraZeneca Corporation, Civil Action No. 04-3479 (hereinafter "Civil Action I").

C. On September 8, 2006, Kruszewski filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. Stephan Kruszewski v. AstraZeneca Pharmaceuticals LP, Civil Action No. 06-4004

(hereinafter "Civil Action II"). Civil Action I and Civil Action II hereinafter may be referred to collectively as the "Civil Actions."

D. AstraZeneca has entered or will be entering into separate settlement agreements, described in Paragraph 1(b), below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct. States with which AstraZeneca executes a Medicaid State Settlement Agreement in the form to which AstraZeneca and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by AstraZeneca and an individual State, shall be defined as "Medicaid Participating States."

E. The United States and the Medicaid Participating States allege that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid Program).

F. The United States further alleges that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395hhh; the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 et seq; and caused purchases of Seroquel by the Department of Veterans' Affairs ("DVA"), Department of Defense, and the Bureau of Prisons ("BOP") (collectively, the "other Federal Health Care Programs").

G. The United States contends that it has certain civil claims, as specified in Paragraph 2, below, against AstraZeneca for engaging in the following conduct during the period January 1, 2001 through December 31, 2006 (hereinafter referred to as the "Covered Conduct"):

(1) AstraZeneca promoted the sale and use of Seroquel to psychiatrists, other physicians (including primary care physicians) and other health care professionals in pediatric and primary care physician offices, in long-term care facilities and hospitals and in prisons for certain uses that were not approved by the Food and Drug Administration as safe and effective for those uses (including aggression, Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness) ("unapproved uses"). AstraZeneca also promoted the unapproved uses by engaging in the following conduct: AstraZeneca improperly and unduly influenced the content of and speakers in company-sponsored Continuing Medical Education programs; engaged doctors to give promotional speaker programs it controlled on unapproved uses for Seroquel; engaged doctors to conduct studies on unapproved uses of Seroquel; recruited doctors to serve as authors of articles largely prepared by medical literature companies about studies they did not conduct on unapproved uses of Seroquel; and, used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel. These unapproved uses were not medically accepted indications for which the United States and the state Medicaid programs provided coverage for Seroquel.

(2) AstraZeneca offered and paid illegal remuneration to doctors: (a) it recruited to conduct studies for unapproved uses, (b) it recruited to serve as authors of articles written by AstraZeneca and its agents about these unapproved uses of Seroquel, (c) to travel to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses of Seroquel, and (d) it recruited to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel. The United States contends that these payments were intended to induce the doctors to promote and/or prescribe Seroquel for unapproved uses in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b).

As a result of the foregoing conduct, the United States contends that AstraZeneca knowingly caused false or fraudulent claims for Seroquel to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

H. The United States also contends that it has certain administrative claims against AstraZeneca, as set forth in Paragraphs 4 through 6, below, for engaging in the Covered Conduct.

I. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by AstraZeneca nor a concession by the United States that its claims are not well founded. AstraZeneca expressly denies the allegations of the United States, the Medicaid Participating States, Wetta and Kruszewski as set forth herein and in Civil Action I and Civil Action II and denies that it has engaged in any wrongful conduct. Neither this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, are intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by AstraZeneca.

J. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. AstraZeneca agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of Five Hundred and Twenty Million Dollars ($520,000,000), plus

accrued interest at the rate of 3% per annum from December 1, 2009, and continuing until and including the date of payment (the "Settlement Amount"). Payments shall be made as follows:

(a) AstraZeneca shall pay to the United States the sum of $301,907,007, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than ten (10) business days after the Effective Date of this Agreement.

(b) AstraZeneca shall pay to the Medicaid Participating States the sum of $218,092,993, plus accrued interest as set forth above ("Medicaid State Settlement Amount") pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that AstraZeneca will enter into with the Medicaid Participating States.

(c) Contingent upon the United States receiving the Federal Settlement Amount from AstraZeneca, the United States agrees to pay, as soon as feasible after receipt, to Wetta $45,286,051, plus a pro rata share of the actual accrued interest paid to the United States by AstraZeneca, as set forth in Paragraph 1(a), above, ("Relator's Share") as relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d). No other relator payments of any sort shall be made by the United States to Wetta and/or Kruszewski with respect to the matters covered by this Agreement.

(d) Wetta and Kruszewski have entered into a separate agreement under which Kruszewski will receive a portion of the Relator's Share.

2. Subject to the exceptions in Paragraph 7, below, in consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of

the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release AstraZeneca, together with AstraZeneca's predecessors, current and former parents, affiliates, direct and indirect subsidiaries, brother or sister entities, divisions, transferees, successors and assigns, and all of their current or former directors, officers and employees (hereinafter, collectively "AstraZeneca Releasees") from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, Section 0.45(D); or the common law theories of payment by mistake, unjust enrichment, fraud, disgorgement of illegal profits, and, if applicable, breach of contract.

3. In consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, Wetta and Kruszewski, for themselves and for their heirs, successors, attorneys, agents, and assigns, fully and finally release the AstraZeneca Releasees from any claim the United States has, may have or could have asserted related to the Covered Conduct, and from all liability, claims, demands, actions or causes of action whatsoever existing as of the Effective Date of this Agreement, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation or that they or their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including any liability arising from the filing of the Civil Actions, except for any claims they may have under 31 U.S.C. § 3730(d) and/or 31 U.S.C.

§ 3730(h).

4. In consideration of the obligations of AstraZeneca in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and AstraZeneca, conditioned upon AstraZeneca's full payment of the Settlement Amount, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), against AstraZeneca under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude AstraZeneca from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

5. In consideration of the obligations of AstraZeneca set forth in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program, against AstraZeneca under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7, below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude AstraZeneca under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph

precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action, against AstraZeneca under 5 U.S.C. § 8902a or 5 C.F.R. Part 919 or Part 970 for the Covered Conduct, except as reserved in Paragraph 7, below and except as required by 5 U.S.C. §8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding any term of this Agreement, the following claims of the United States are specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including AstraZeneca, Wetta and/or Kruszewski):

(a) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any criminal liability;

(c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

(d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

(e) Any liability based upon such obligations as are created by this Agreement;

(f) Any liability for express or implied warranty claims or other claims for

defective or deficient products or services, including quality of goods and services;

(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and

(h) Any liability for failure to deliver goods or services due.

8. Wetta and Kruszewski and their heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and, conditioned upon the United States' payment of the Relator's Share, as set forth in Paragraph 1(c), above, Wetta and Kruszewski, for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge the United States, and its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of Civil Action I and/or Civil Action II; and from any other claims for a share of the Settlement Amount or payment of any sort from the United States relating to the Settlement Agreement or the filing of Civil Action I and/or Civil Action II; and in full settlement of any claims Wetta and/or Kruszewski may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against Wetta and/or Kruszewki arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. AstraZeneca waives and shall not assert any defenses AstraZeneca may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth

Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. AstraZeneca fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that AstraZeneca has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. Conditioned upon Wetta and Kruszewski's compliance with their obligations under this Agreement, AstraZeneca fully and finally releases Wetta and Kruszewski from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that AstraZeneca has asserted, could have asserted, or may assert in the future against Wetta and/or Kruszewksi, related to the Covered Conduct and Wetta and/or Kruszewski's investigation and prosecution thereof, except to the extent related to claims Wetta or Kruszewski may have under 31 U.S.C. § 3730(d) and/or 31 U.S.C. § 3730(h).

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any other state or Federal payer, related to the Covered Conduct; and AstraZeneca agrees not to resubmit to any Medicare carrier or intermediary or any other state or Federal payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such

denials of claims.

13. AstraZeneca agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of AstraZeneca, its present or former officers, directors, employees, shareholders and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP:

(i) the matters covered by this Agreement;

(ii) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(iii) AstraZeneca's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(iv) the negotiation and performance of this Agreement;

(v) the payment AstraZeneca makes to the United States pursuant to this Agreement and any payments that AstraZeneca may make to Wetta and/or Kruszewski, including costs and attorneys fees; and

(vi) the negotiation of, and obligations undertaken pursuant to the CIA to:

(a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(b) prepare and submit reports to the OIG-HHS.

However, nothing in this paragraph 13(a)(vi) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to AstraZeneca. (All costs described or set forth in this Paragraph 13(a) are hereafter "Unallowable Costs.")

(b) Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately determined and accounted for by AstraZeneca, and AstraZeneca shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by AstraZeneca or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, AstraZeneca further agrees that within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by AstraZeneca or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the

effect of the inclusion of the unallowable costs. AstraZeneca agrees that the United States, at a minimum, shall be entitled to recoup from AstraZeneca any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by AstraZeneca or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on AstraZeneca or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine AstraZeneca's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for above or in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. AstraZeneca agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. AstraZeneca warrants that it has reviewed its financial situation and that it

currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to AstraZeneca, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which AstraZeneca was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

17. Upon receipt of the payments described in Paragraph 1, above, the United States and Wetta shall promptly sign and file in Civil Action I a Notice of Intervention and Joint Stipulation of Dismissal with prejudice as to all federal counts in Civil Action I pursuant to the terms and conditions of the Agreement. Upon receipt of the payments described in Paragraph 1, above, Kruszewski shall promptly sign and file in Civil Action II a Notice of Dismissal with prejudice as to all federal counts in Civil Action II pursuant to the terms and conditions of the Agreement.

18. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. AstraZeneca represents that this Agreement is freely and voluntarily entered into

without any degree of duress or compulsion whatsoever.

20. Wetta and Kruszewski represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the Eastern District of Pennsylvania, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

22. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

24. The individuals signing this Agreement on behalf of AstraZeneca represent and warrant that they are authorized by AstraZeneca to execute this Agreement. The individual(s) signing this Agreement on behalf of Wetta and Kruszewski represent and warrant that they are authorized by Wetta and Kruszewski to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on AstraZeneca's successors, transferees, heirs, and

assigns.

27. This Agreement is binding on Wetta and Kruszewski's successors, transferees, heirs, and assigns.

28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4-27-10 BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: _____ BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

THE UNITED STATES OF AMERICA

DATED:_____ BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4/27/10 BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 4/27/10 BY: 

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED:_____ BY: _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED:_____ BY: _____

DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: April 23, 2010 BY: Rhonda L. Bershok, Acting Deputy General Counsel
For: LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED:_____ BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED:_____ BY: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 4/26/10 BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED: 4/26/2010 BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

ASTRAZENECA

DATED: 4/27/10 BY: _____

Glenn M. Engelmann
Vice President and General Counsel
AstraZeneca LP
AstraZeneca Pharmaceuticals LP

DATED: 4/27/10 BY: _____

JOHN C. DODDS, ESQ.
Morgan, Lewis and Bockius, LLP

RELATOR JAMES WETTA

DATED:_____ BY: _____
JAMES WETTA

DATED:_____ BY: _____
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

RELATOR JAMES WETTA

DATED: 4/23/10

BY: James Wetta by Michael Mustokoff
JAMES WETTA

DATED: 4/23/10

BY: Stephen A. Sheller
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

BY: Michael Mustokoff
MICHAEL MUSTOKOFF
MARK LIPOWICZ
TERESA CAVENAGH
DUANE MORRIS, LLP

BY: Gary M. Farmer by Michael Mustokoff
GARY M. FARMER JR.
FARMER JAFFE WEISSING EDWARDS FISTOS and LEHRMAN

[redacted]

RELATOR STEPHAN KRUSZEWSKI

DATED: 4/23/2010 BY: _____
STEFAN KRUSZEWSKI

DATED: _____ BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)

RELATOR STEPHAN KRUSZEWSKI

DATED:_____ BY: _____
STEFAN KRUSZEWSKI

DATED: 4/23/10 BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)