PsychRights®
Law Project for
Psychiatric Rights, Inc.

November 9, 2010

Senator Tom Carper
United States Senate
513 Hart Building
Washington, DC 20510

Re: Pediatric Psychopharmacology Medicaid Fraud

Dear Senator Carper:

It is our understanding you have asked the Government Accountability Office (GAO) to investigate the psychiatric drugging of children and youth in foster care and this is to bring to your attention certain information we think is important and germane to this investigation. In particular, two letters from the Centers for Medicare and Medicaid Services, both of which were signed "for" someone else, appear to endorse Medicaid Fraud. Secondarily, the Department of Justice apparently recognizes the fraudulent conduct, but as a matter of prosecutorial discretion is only ineffectively pursuing enforcement against the drug companies. This allows the tens of billions of dollars in annual fraudulent Medicaid billings to continue.

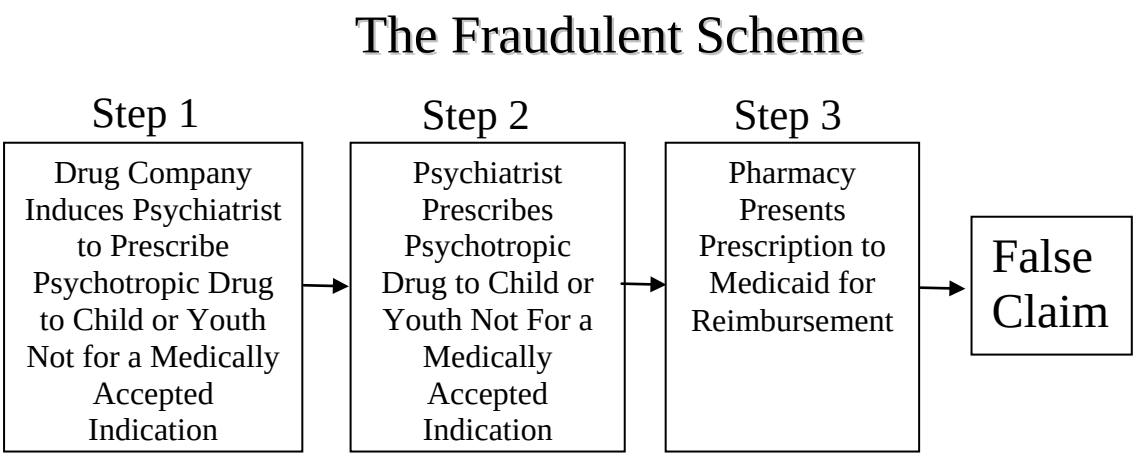
Covered Outpatient Drugs Limited to Medically Accepted Indication

By way of background, in 42 USC 1396R-8(k)(3), Congress generally prohibited reimbursement under Medicaid for any outpatient drugs "used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) then 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.

As succinctly stated by the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass. 2008):

> 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).



The Department of Justice concurs that prescriptions not for a medically accepted indication presented to Medicaid are false claims and has negotiated a couple of billion dollars in settlements with drug companies for causing such false claims.[1] However, the Department of Justice is declining to enforce the law against the non-drug company participants, i.e., at Steps 2 and 3 of the Fraudulent Scheme. When I queried a US Attorney about this I was told that even though these other participants were indeed committing Medicaid Fraud, the government would not proceed against them as a matter of prosecutorial discretion.

The result is the drug companies cap their liability while their profits from the Fraudulent Scheme continue. In other words, the drug companies have gotten certain psychiatrists to prescribe psychotropic drugs to children that are not for a medically accepted indication and the fraudulent practice is continuing apace in spite of enforcement actions against the drug companies. And, of course, a tremendous amount of harm is being done to children and youth given these very dangerous psychiatric drugs of dubious, at best, benefit. To prevent this kind of harm was presumably one of the prime reasons Congress limited Medicaid coverage to those prescribed for a medically accepted indication.

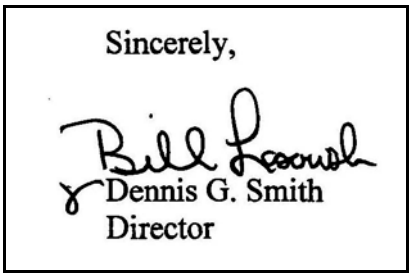
The CMS Correspondence

Added into this mix is a curious 2007 exchange of correspondence between the Utah Attorney General's Office and the Centers for Medicare and Medicaid Services (CMS). The correspondence was initiated by the Utah Attorney General's Office asking whether CMS interpreted the Medicaid statute as prohibiting Medicaid coverage of outpatient drugs that are not for a medically accepted indication.[2] A letter on CMS letterhead responding to this question states, "(the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal

[1] Department of Justice News Release regarding settlement agreement in *United States of America ex rel Stefan Kruszewski et al., v. Pfizer, Inc.*, Case No. 07-CV-4106, USDC EDPA, Attachment 1; Settlement Agreement in *United States ex rel Wetta v. Atrazenaca*, USDC EDPA, Case No. 04-3479, Attachment 2; United States Complaint in Intervention and Settlement Agreement and Release in *United States ex rel Gobble v. Forest Laboratories*, USDC Mass, Case No. 03-10395-NMG, Attachments 3 & 4, respectively.

[2] Attachment 5.

regulations." [3] The letter is signed for the Director of the Centers for Medicaid and State Operations by someone else, as follows: [4]



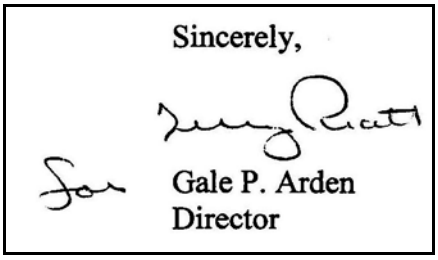
Incredulous with this response, the Utah Attorney General's Office wrote back:

> With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) **does not include "a drug or biological used for a medical indication which is not a medically accepted indication."**[5]

and:

> I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.[6]

In response, without addressing the legal issues involved and without any indication CMS had consulted counsel, a letter was sent back re-affirming the previous letter. This letter was signed for the Director of the Center for Medicaid and State Operations, Disabled and Elderly Health Program Group as follows:[7]



Thus, all four persons whose name appears on these two letters from CMS can claim the letter over their name was not written by him or her. This in itself doesn't prove any misconduct by

[3] Attachment 6.
[4] *Id*.
[5] Attachment 7, emphasis in original.
[6] *Id*.
[7] Attachment 8.

any or all of the four people whose names are associated with this CMS correspondence, but it certainly raises a serious question.

U.S. ex rel PsychRights v. Matsutani et al.

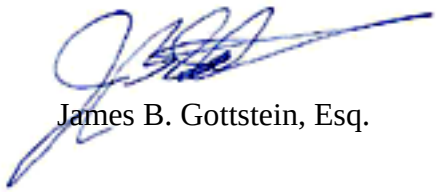
In the interest of full disclosure, last April we filed a False Claims Act case in the US District Court in Alaska against a number of defendants, including psychiatrists and pharmacies for causing and presenting claims for outpatient prescriptions of psychotropic drugs to children and youth not for a medically accepted indication and therefore false claims.[8] On September 24, 2010, the District Court dismissed this False Claims Act case under what is known as the "Public Disclosure Bar," 31 U.S.C. §3730(e)(4)(A), on the grounds government officials already know about the industry-wide fraud and are allowing it to continue:

> [T]he Government already "has pursued False Claims Act cases and achieved extremely large recoveries against drug companies for causing the presentment of claims to Medicaid for prescriptions of psychotropic drugs that are not for medically accepted indications. . . ." Thus, . . . the Government already knows about the conduct . . . .[9]

We have appealed this decision because we think it is contrary to directly controlling 9th Circuit precedent and the intent of Congress. However the appeal turns out, we wanted to direct your attention to the facts outlined in this letter for your possible action.

We will be pleased to provide whatever other assistance we can that you might request.

Yours truly,



James B. Gottstein, Esq.

Cc: Kathleen Sebelius, Secretary of Health & Human Services
Eric Holder, Attorney General

[8] *United States ex rel Law Project for Psychiatric Rights v. Matsutani, et al.*, USDCAK Case No. 3:09-cv-80-TMB. All of the significant filings on this case are at http://psychrights.org/States/Alaska/Matsutani/Matsutani.htm.

[9] Page 21 in Docket No. 163, *United States ex rel Law Project for Psychiatric Rights v. Matsutani et.al*, No. 3:09-cv-80, and Docket No. 26 in *U.S. ex rel Griffin v. Martino, Family Centered Services and Safeway*, No. 3:09-cv-246.

Department of Justice

FOR IMMEDIATE RELEASE
Wednesday, September 2, 2009
WWW.USDOJ.GOV

AAG
(202) 514-2007
TDD (202) 514-1888

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."

###

09-900

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.

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
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)

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release (the "Settlement Agreement") is entered into by and among: the United States of America, acting through the United States Department of Justice on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), the Veterans' Affairs Administration ("VA"), and the United States Office of Personnel Management ("OPM") (collectively, the "United States"); Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc. (collectively, "Forest"); and Christopher Gobble, Joseph Piacentile, Constance Conrad, and Jim Conrad (collectively, the "Relators"). Collectively, all of the above will be referred to as the "Parties."

II. PREAMBLE

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

A. At all relevant times, Forest Laboratories, Inc., was a Delaware corporation headquartered in New York, New York, and Forest Pharmaceuticals, Inc., a Delaware corporation headquartered in St. Louis, Missouri, was a wholly owned subsidiary of Forest Laboratories, Inc.

B. At all relevant times, Forest distributed, marketed, and sold pharmaceutical products in the United States, including the drugs sold under the trade names Celexa (generic name citalopram hydrobromide), Lexapro (generic name escitalopram oxalate), and Levothroid (generic name levothyroxine sodium tablets, USP).

C. The Relators listed herein have filed the following *qui tam* actions against Forest (collectively the "Civil Actions"):

1. *United States ex rel. Christopher R. Gobble, et al. v. Forest Laboratories, Inc. & Forest Pharmaceuticals, Inc.*, Civil Action No. 03–10395–NMG (D. Mass.) (the "Gobble *qui tam* action");

2. *United States ex rel. Joseph Piacentile, et al. v. Forest Laboratories, Inc.*, Civil Action No. 05–10201–NMG (D. Mass.) (the "Piacentile *qui tam* action");

3. *United States ex rel. Constance Conrad v. Forest Pharmaceuticals, Inc., et al.*, Civil Action No. 02–11738–NG (D. Mass.) (the "Conrad *qui tam* action"); and

4. [redacted]

D. The United States intervened in the Gobble *qui tam* action and the Piacentile *qui tam* action on November 14, 2008. The District of Columbia and the states of California, Delaware, Florida, Illinois, Massachusetts, Michigan, New York, Oklahoma, Texas, Virginia, and Wisconsin filed notices of intervention in those actions on February 13, 2009. The United

States filed its Complaint in Intervention in those actions (the "United States Complaint in Intervention") on February 13, 2009.

E. On such date as may be determined by the Court, Forest Pharmaceuticals, Inc. ("FPI") will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information, attached as Exhibit A to a plea agreement into which FPI is entering simultaneously with the execution of this Settlement Agreement, to be filed in *United States of America v. Forest Pharmaceuticals, Inc.*, Criminal Action No. [to be assigned] (D. Mass.) (the "Criminal Action").

F. The United States alleges that Forest caused claims for payment for the drugs Celexa, Lexapro, and Levothroid to be submitted to the Medicaid program, 42 U.S.C. §§ 1396–1396w–5, the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services), 10 U.S.C. §§ 1071–1110a, and the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901–8914, and that Forest caused the VA to purchase those drugs (collectively "the Federal Health Care Programs").

G. The United States contends that it and the Medicaid Participating States (as defined below) have certain civil claims against Forest, as specified below, for engaging in the following alleged conduct (hereinafter referred to as the "Covered Conduct"):

1. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs by promoting the sale and use of Celexa and Lexapro to physicians for pediatric uses (including by disseminating false and misleading information about the safety and efficacy of Celexa and Lexapro in treating pediatric patients), as set forth in the

United States Complaint in Intervention, when those uses were not approved by the Food and Drug Administration ("FDA"), were not medically accepted indications (as defined by 42 U.S.C. § 1396r–8(k)(6)), and were not covered by Federal Health Care Programs.

2. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs and caused the VA to purchase those drugs by offering and paying illegal remuneration to physicians as set forth in the United States Complaint in Intervention to induce the physicians to promote and to prescribe Celexa and Lexapro, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a–7b(b)(2).

3. During the period August 2001 through December 2005, Forest knowingly caused false or fraudulent claims to be submitted to the Federal Health Care Programs and caused purchases by the VA through its distribution of a drug, Levothroid, that did not qualify as a covered outpatient drug (as defined in 42 U.S.C. § 1396r–8(k)(2)). In 1997, FDA determined that oral levothyroxine sodium products, including Levothroid, were "new drugs." FDA later announced that it would exercise its discretion not to take enforcement action against a manufacturer for distribution of an unapproved oral levothyroxine sodium product if, among other things, the manufacturer phased down distribution of its unapproved oral levothyroxine sodium product over a two-year period following August 14, 2001. Notwithstanding FDA's announcement, Forest increased distribution of its unapproved oral levothyroxine sodium product, Levothroid, after August 14, 2001, and failed to advise CMS that unapproved Levothroid no longer qualified as a covered outpatient drug under 42 U.S.C. § 1396r–8(k)(2).

they are authorized by Relators to execute this Settlement Agreement. The United States signatories represent that they are signing this Settlement Agreement in their official capacities and that they are authorized to execute this Settlement Agreement.

28. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Settlement Agreement. Facsimiles of signatures and/or electronic signatures in portable document format (.pdf) shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

29. This Settlement Agreement is binding on Forest's successors, transferees, heirs, and assigns.

30. This Settlement Agreement is binding on Relators' successors, transferees, heirs, and assigns.

31. All parties consent to the disclosure of this Settlement Agreement, and information about this Settlement Agreement, to the public on or after the Effective Date.

32. As used in this Settlement Agreement, the "Effective Date" shall mean the date of the signature of the last signatory to the Settlement Agreement.

THE UNITED STATES OF AMERICA

DATED:_____ **BY:** _____

JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/15/10 **BY:** _____

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

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

THE UNITED STATES OF AMERICA

DATED: 9/15/2010 **BY:** _____

JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____ **BY:** _____

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

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

THE UNITED STATES OF AMERICA

DATED:_____ **BY:** _____
JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_____ **BY:** _____
GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

DATED: 9/15/10 **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: 14 Sep 2010 **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
United States Office of Personnel Management

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ **BY:** _____

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

DATED: 9/14/10 **BY:** Shirley R. Patterson

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
United States Office of Personnel Management

9/15/10

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

FOREST LABORATORIES, INC. & FOREST PHARMACEUTICALS, INC. - DEFENDANTS

DATED: 9/14/2010 **BY:** _____

HERSCHEL S. WEINSTEIN
Vice President - General Counsel
Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022

DATED: 9/14/2010 **BY:** _____

MARY JO WHITE
CHRISTOPHER K. TAHBAZ
ANDREW J. CERESNEY
KRISTIN D. KIEHN
Debevoise & Plimpton LLP
919 Third Avenue
New York, NY 10022

CHRISTOPHER R. GOBBLE - RELATOR

DATED: 9/14/10 **BY:** Marlan B. Wilbanks /SEO

MARLAN B. WILBANKS
Wilbanks & Bridges LLP
3414 Peachtree Rd., NE, Suite 1075
Atlanta, GA 30326

DATED: 9/14/10 **BY:** Philip S. Marstiller /SEO

PHILIP S. MARSTILLER
Philip S. Marstiller, P.C.
16 Second Street
Richmond, VA 23219

DATED: 9/14/10 **BY:** Suzanne E. Durrell

SUZANNE E. DURRELL
Durrell Law Office
180 Williams Ave.
Milton, MA 02186

DR. JOSEPH PIACENTILE - RELATOR

DATED:_____ **BY:** _____

DAVID S. STONE
Stone & Magnanini, LLP
150 John F. Kennedy Parkway, 4th Floor
Short Hills, NJ 07078

CHRISTOPHER R. GOBBLE - RELATOR

DATED:_____ **BY:** _____

MARLAN B. WILBANKS
Wilbanks & Bridges LLP
3414 Peachtree Rd., NE, Suite 1075
Atlanta, GA 30326

DATED:_____ **BY:** _____

PHILIP S. MARSTILLER
Philip S. Marstiller, P.C.
16 Second Street
Richmond, VA 23219

DATED:_____ **BY:** _____

SUZANNE E. DURRELL
Durrell Law Office
180 Williams Ave.
Milton, MA 02186

DR. JOSEPH PIACENTILE - RELATOR

DATED: 9/14/2010 **BY:** _____

DAVID S. STONE
Stone & Magnanini, LLP
150 John F. Kennedy Parkway, 4th Floor
Short Hills, NJ 07078

CONSTANCE CONRAD AND JIM CONRAD - RELATORS

DATED: 9/14/10 **BY:** _____

KENNETH J. NOLAN
MARCELLA AUERBACH
Nolan & Auerbach, P.A.
435 North Andrews Avenue
Suite 401
Ft. Lauderdale, FL 33301

DATED: _____ **BY:** _____

JOHN RODDY
Roddy, Klein & Ryan
727 Atlantic Ave., 2d Floor
Boston, MA 02111

CONSTANCE CONRAD AND JIM CONRAD - RELATORS

DATED:_____ **BY:** _____

KENNETH J. NOLAN
MARCELLA AUERBACH
Nolan & Auerbach, P.A.
435 North Andrews Avenue
Suite 401
Ft. Lauderdale, FL 33301

DATED: 9/14/10 **BY:** _____

JOHN RODDY
Roddy, Klein & Ryan
727 Atlantic Ave., 2d Floor
Boston, MA 02111

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

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

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

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: 

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3366

JOYCE R. BRANDA
JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 305-0546

STATE OF UTAH
OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

October 22, 2007

Steve E. Phurrough, M.D., MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for clarification regarding Medicaid "covered outpatient drugs"

Dear Dr. Phurrough:

In working on state actions recently against various pharmaceutical manufacturers for off-label promotion causing the filing of false Medicaid claims, it has come to our attention that many state Medicaid programs are liberally reimbursing -- and presumably receiving Federal Financial Participation ("FFP") -- for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia. Clarification on the permissible scope of FFP-eligible reimbursement by state Medicaid programs for covered outpatient drugs is critically important.

More specifically, §1927 of the Social Security Act (42 U.S. Code §1396r-8, often referred to as OBRA '90) provides:

- in subsection (k)(3) that the term "covered outpatient drug" excludes "a drug or biological used for a medical indication which is not a medically accepted indication."
- in subsection (k)(6) that the term "medically accepted indication" means any use approved by the FDA or "supported" in one or more specified compendia
- in subsection (g)(1)(B)(i) that the specified compendia are American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications) and the DRUGDEX Information System

ISSUE #1: ***Does CMS interpret federal law to restrict FFP for state Medicaid programs to uses of otherwise "covered outpatient drugs" that are either FDA-approved or supported in the specified compendia?***

ISSUE #2: ***If the answer to question #1 is yes, has the federal government delegated to the states any authority to approve exceptions, i.e., to expand FFP-eligible Medicaid prescription drug coverage?*** *(e.g., May a state grant its Drug Utilization Review Board the authority to approve FFP-eligible Medicaid reimbursement for off-label indications not supported in the specified compendia?)*

ATTORNEY GENERAL'S OFFICE • MEDICAID FRAUD CONTROL UNIT • 5272 SO. COLLEGE DRIVE, #200 • MURRAY, UTAH 84123 • TEL: (801) 281-1259 • FAX: (801) 281-1250

Your clarification regarding these Medicaid drug coverage issues is respectfully requested.

Very truly yours,

David R. Stallard

David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov

/DRS

cc: David Frank, Director, Medicaid Integrity Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

DEC 6 2007

David R. Stallard, CPA
Assistant Attorney General
Office of the Attorney General
5272 S. College Drive, #200
Murray, Utah 84123

Dear Mr. Stallard:

Thank you for your recent letter to Dr. Steve E. Phurrough regarding clarification of reimbursement by Medicaid for covered outpatient drugs. Your letter has been forwarded to me for response.

Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations. Section 1927(d) of the Act authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act), however, it does not explicitly require them to do so. States are responsible for defining this coverage in their approved Medicaid State plan and implementing policies. To determine the indications for the coverage of a drug, you would need to review the State's approved plan and policies on the specific coverage of that drug.

I appreciate your concern regarding the necessity for proper reimbursement under the Medicaid drug program.

Sincerely,

Bill Pharrough

Dennis G. Smith
Director

Attachment 6

STATE OF UTAH
OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

December 17, 2007

Dennis G. Smith, Director
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Re: Improper Off-Label Indications - definition of "covered outpatient drugs"

Dear Mr. Smith:

Thank you for your reply dated December 6, 2007, in which you stated that "the Social Security Act does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter," namely for uses other than "medically accepted indications" (i.e., for uses not FDA-approved or "supported" in the specified compendia).

With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) **does not include "a drug or biological used for a medical indication which is not a medically accepted indication.**"

This federal statute defining the term "covered outpatient drug" clearly delineates that Medicaid drugs are covered only so long as they are used for "medically accepted indications." Congress apparently intended that Medicaid not be so restrictive as to prohibit all off-label use, but that it not be so expansive as to cover experimental uses not yet medically accepted. The criterion Congress chose for permissible off-label use was that the particular use be "supported" in at least one of the specified compendia [(k)(6)].

Frankly, I do not see how CMS can ignore this unambiguous statutory definition of "covered outpatient drug." I conclude from your letter that CMS, while ignoring the clear statutory definition, is focusing on the Limitations subsection (d) that lists permissible restrictions, including prescribed uses not for a medically accepted indication at subsection (d)(1)(B)(i).

ATTORNEY GENERAL'S OFFICE • MEDICAID FRAUD CONTROL UNIT • 5272 SO. COLLEGE DRIVE, #200 • MURRAY, UTAH 84123 • TEL: (801) 281-1259 • FAX: (801) 281-1250

Apparently an inference is being drawn from this subsection that, since a State may exclude coverage for a prescribed use that is not a medically accepted indication, it is not required to do so. But for the clear, unambiguous definition of "covered outpatient drug," it would appear to be reasonable to draw such an inference; however, as a principle of statutory construction, a mere negative inference from a Limitations section (the purpose of which is to identify restrictions to coverage, not to expand coverage) does not trump a clear delineation of coverage in the definitional section.

I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.

A "poster child" example of exactly why this issue is important not only for cost considerations, but also for patient safety, is the atypical antipsychotic drug Zyprexa manufactured by Eli Lilly. For about 10 years it has been at or near the highest dollar volume drug reimbursed by Medicaid nationwide. It is only approved for schizophrenia and bipolar disorder in adults, a very narrow segment of the population. It has been widely reported that approximately 50% of utilization is off-label, including for infants and toddlers. Based on recent lawsuit settlements totaling over a billion dollars and involving thousands of Zyprexa users, the drug causes substantial weight gain and diabetes in a significant percentage of cases. In other words, Medicaid is not only paying for a very expensive drug for uses that are not "medically accepted indications," but its reimbursement of this drug is resulting in many Medicaid recipients developing diabetes, a life-threatening condition with many adverse health complications for the individuals and a significant cost burden on taxpayers for treating these complications.

I implore you to look into this drug coverage issue resulting in substantial overpayments and jeopardizing the health and safety of hundreds of thousands of Medicaid recipients.

Very truly yours,

David R. Stallard

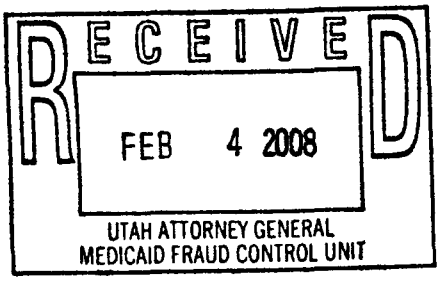
David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov
/DRS
cc: Steven E. Phurrough, M.D., MPA, Director, Coverage and Analysis Group
David Frank, Director, Medicaid Integrity Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations
Disabled and Elderly Health Programs Group (DEHPG)

JAN 30 2008



David R. Stallard, CPA
Office of the Attorney General
Medicaid Fraud Control Unit
5272 S. College Drive, #200
Murray, UT 84123

Dear Mr. Stallard:

Thank you for your letter expressing further concerns regarding the Utah Medicaid Program's coverage of outpatient drugs. I've been asked to respond to you directly since this program area is the responsibility of my group.

I wish to confirm that our previous response to you is correct. As we noted in that response, the State may limit coverage for drugs to medically accepted indications. To verify what Utah has chosen to do for coverage of a particular drug, we again suggest you contact State personnel and review the State's approved State plan and policies on the specific coverage of drugs, including Zyprexa.

I hope this information adequately addresses your concerns.

Sincerely,

for Gale P. Arden
Director

Attachment 8