UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v. Case No. 11-CV-236-JPS

JENNIFER KING VASSEL,

Defendant.

***RELATOR'S* RESPONSE TO DOCUMENT NUMBERS:**

159- Motion *in Limine* to Preclude any Reference that the Prescription of Off-Label Use of FDA Approved Prescription Medication was Medicaid Fraud;

161- Motion *in Limine* to Preclude Reference that this Lawsuit Provided Notice that Dr. King Should Have Changed Her Practice;

163- *Amicus Brief* by Wisconsin Medical Society;

165- Motion *in Limine* to Preclude Certain Witnesses of the Plaintiff from Testifying about Liability, Causation, or Damages;

169- Motion *in Limine* to Permit Reference to Other Physicians that Treated N.B. Prior to Dr. King;

170- Motion *in Limine* to Exclude Evidence of Geodon Prescriptions; and

Relator Dr. Toby Tyler Watson (Dr. Watson) hereby responds to Document Numbers 159, 161, 163, 165, 169, 170 and 174, all filed on November 25 or 26, 2013.

I. Document Number 159 -- Motion *in Limine* to Preclude any Reference that the Prescription of Off-Label Use of FDA Approved Prescription Medication was Medicaid Fraud

In Document Number 159, Dr. King's Motion *in Limine* to Preclude any Reference that the Prescription of Off-Label Use of FDA Approved Prescription Medication was Medicaid Fraud, she continues to misstate Dr. Watson's position in a number of ways. First, as has been

repeatedly pointed out, Dr. Watson has never asserted, nor is he asserting now, that all off-label use of drugs when presented to Medicaid are false claims. It is only off-label prescriptions that do not have "support" in any of the statutorily incorporated compendia that are false claims.[1]

A. That Off-Label Use Occurs is Not Relevant In This Case

All of Section A of Document Number 159 is irrelevant. As the Court of Appeals held:

> Once a drug has been approved for one use . . . the FDA cannot prevent physicians from prescribing the drug for other uses. Indeed, off-label prescriptions by physicians are quite common. . . . The legality of the prescription, however, does not answer questions such as . . . whether the government is obligated to pay for a Medicaid patient's off-label prescriptions.

U.S. v. King-Vassel, 728 F. 3d 707, 709, citations omitted.

The Court of Appeals, then went on to hold:

> Medicaid can only provide reimbursement for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r–8(a)(3). Covered drugs do not include any drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r–8(k)(3). . . . Helpfully, "medically accepted indication" is a statutorily-defined term that refers to a prescription purpose approved by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or "supported by" any of several identified "compendia," 42 U.S.C. § 1396r–8(k)(6), § 1396r–8(g)(1)(B)(i).

U.S. v. King-Vassel, 728 F.3d 707, 715 (7th Cir. 2013).

The question in this case is did Dr. King write prescriptions that were not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), § 1396r–8(g)(1)(B)(i) that were presented to Medicaid.[2]

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[1] "An 'off-label' prescription is one written for a purpose that has not been approved by the Food and Drug Administration ('FDA')." *United States v. King-Vassel*, 728 F.3d 707, 709 (7th Cir. 2013).

[2] The Court of Appeals held that writing a prescription to a Medicaid patient "causes" a claim for such prescription absent some affirmative evidence to the contrary. *U.S. v. King-Vassel*, 728 F.3d 707, 715 (7th Cir. 2013). However, in this case, Dr. Watson need not rely on this presumption because he has evidence of actual payment of the claims by Medicaid. Trial Exhibits 8, 10, 11, 12, 15 & 16.

B. The Question Is Not the Regulation of the Practice of Medicine, But Instead Medicaid Coverage for Outpatient Drugs

In the first Section B of Dr. King's Motion *in Limine* to Preclude any Reference that the Prescription of Off-Label Use of FDA Approved Prescription Medication was Medicaid Fraud, Document Number 159, Dr. King cites to House Report No. 88 1[3] for the proposition that in enacting the original version of 42 U.S.C. § 1396r-8(d)(1)(B), the bill would not alter the current relationships between Medicaid beneficiaries and their physicians or their pharmacists.

However, resort to legislative history is only allowed when there is ambiguity in the text of the statute.

> Ambiguity sometimes justifies resort to legislative history, but it is used to decipher the ambiguous language, not to replace it. The text is what it is and must be applied whether or not the result seems equitable.

Peterson v. Somers Dublin Ltd., 729 F.3d 741, 749 (2013). As this Court held in its October 2, 2012, Order, Document No. 116, p. 3:

> In other words, walking this statutory scheme backwards to a logical conclusion,
>
> > *if* King Vassel prescribed a medication to N.B. for a use that is neither approved by the FDCA nor supported by a medical compendia,
> >
> > *then* such a prescription was not for a medically accepted indication,
> >
> > *further meaning* that the prescription is not for a covered outpatient drug, and
> >
> > *accordingly establishing* that the prescription written by King-Vassel was a false claim if submitted to Medicaid for reimbursement.
>
> That is the plain reading of the statutory scheme . . .

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[3] H. Rep. No. 881, 101st Congress, 2d Session at 98, reprinted in U.S. Congress and Administrative News, p. 2110.

Moreover, if one were to engage in an archeological dig through the legislative history, it does not support Dr. King's contention. First, House Report 88-1, upon which Dr. King relies refers to a bill that was rejected by the Senate as set forth in the House Conference Report, relevant, pages of which are attached as Exhibit 1.[4]

In the legislation that passed, as set forth in the Conference Report,[5] Section 4401 Reimbursement for Prescribed Drugs, subsection (a)(2)(C) provides,

> (C) by inserting after paragraph (53) the following new paragraph:
>
> "(54)(A) provide that, any formulary or similar restriction (except as provided in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under section 1927(a), *which are prescribed for a medically accepted indication (as defined in subsection 1927(k)(6))*, and

(emphasis added Exhibit 1, p. 2.) The familiar language restricting coverage to medically accepted indications is at page 4 of Exhibit 2.

In the Joint Explanatory Statement of the Conference Committee,[6] the Conference Committee first discusses the House bill provisions:

> House bill
>
> (a) In General.–Denies Federal matching funds for prescription drugs unless rebate agreements are in effect and States implement drug use review by January 1, 1993. Requires drug manufacturers to comply with rebate requirements in all States and the District of Columbia. Provides that, in the case of a manufacturer which has entered into and complies with an agreement, States will cover the manufacturer's covered outpatient drugs *which are prescribed* on or after April 1,

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[4] H.R. CONF. REP. 101-964, H.R. Conf. Rep. No. 964, 101ST Cong., 2ND Sess. 1990, 1990 WL 201626, 1990 U.S.C.C.A.N. 2374 (Leg.Hist.)

[5] The citation for the bill, as passed is Omnibus Budget Reconciliation Act Of 1990, PL 101-508, November 5, 1990, 104 Stat 1388.

[6] See p. 5 of Exhibit 1.

1991, *for a medically accepted indication*.[7]

. . .

(D) Limitations on Coverage of Drugs.–States are required to cover a manufacturer's covered outpatient drugs *prescribed for a medically accepted indication* when the manufacturer which has entered into and complies with a rebate agreement.. . .[8]

. . .

Medically Accepted Indication *A medically accepted indication means any use for a covered outpatient drug which is approved by the FDA or which is accepted by one of the following compendia*: American Hospital Formulary Service–Drug Information, American Medical Association Drug Evaluations, and United States Pharmacopeia–Drug Information.[9]

(emphasis added).

Then, the Conference Committee discusses the Senate Amendment to the House Bill, the relevant section of which is:

Senate Amendment[10]

(D) Limitations on Coverage of Drugs.–Except in the first year following approval of a new drug, States are permitted to subject any covered outpatient drug to prior authorization. States may limit quantities of drugs, provided the limitations are necessary to discourage waste. *States may exclude* or restrict coverage of a drug if the prescribed use is *not for a medically accepted indication*, the drug is subject to an agreement between the manufacturer and the State that is authorized by the Secretary, or the drug is in the list below.[11]

(emphasis added). Then, the Conference Report states in comparing the two versions:

Covered Outpatient Drug Similar provision.

. . .

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[7] See, p. 6 of Exhibit 1.

[8] See, page 7 of Exhibit 1.

[9] See, page 8 of Exhibit 1.

[10] See, page 9 of Exhibit 1.

[11] See, page 10 of Exhibit 1.

> Medically Accepted Indication.–Similar provision.[12]

Finally, the Conference Report states that the Conference Agreement as relevant was that:

> States are permitted to impose prior authorization controls *on all covered drugs*, except new drugs within 6 months of FDA approval, and to exclude from coverage certain categories of drugs.[13]

(emphasis added).

One explanation for the universal restriction to medically accepted indications contained in 42 U.S.C. §§ 1396b(i)(10), 1396r–8(a)(3), § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), and the state option to restrict coverage to medically accepted indications in 42 U.S.C. §1396r–8(d)(1)(B)(i) both being enacted is that it was simply a mistake. The Westlaw version of OBRA 1990 runs 490 pages and it is possible the drafters simply missed that both versions stayed in. Another possible explanation is that the negotiators just never agreed on which one should be included and both were. Neither of these may be what happened, but statutory construction rules mandate that the universal restriction is applicable because it does not conflict with the state option. It merely makes the state option surplusage.

As the Supreme Court held in *Chickasaw Nation v. United States*, 534 U.S. 84, 94, 122 S.Ct. 528, 151 L.Ed.2d 474 (2001):

> 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 ...."

In this case, both provisions can be effective, it is just that the state option is a subset of the universal provision.

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[12] See, page 11 of Exhibit 1.

[13] See, page 12 of Exhibit 1.

The balance of Section B relates to doctors having the right to prescribe drugs for purposes not approved by the FDA and that such uses are often beneficial. This has been addressed by the Court of Appeals

> Once a drug has been approved for one use . . . the FDA cannot prevent physicians from prescribing the drug for other uses. Indeed, off-label prescriptions by physicians are quite common. . . . The legality of the prescription, however, does not answer questions such as . . . whether the government is obligated to pay for a Medicaid patient's off-label prescriptions.

U.S. v. King-Vassel, 728 F. 3d 707, 709 (7th Cir. 2013), citations omitted. The question in this case is Medicaid insurance coverage, not whether the prescriptions were illegal. The United States government has the right to determine what drug prescriptions it will cover under Medicaid, and it has chosen to limit such coverage to uses approved by the FDA or supported by what it determined to be reliable arbiters of appropriate off-label uses, the compendia.

If Dr. King loses at trial, she can appeal this back to the Court of Appeals and make her arguments about why *U.S. v. King-Vassel* was wrongly decided, but it is respectfully suggested this court should follow it.[14]

C. That Off-Label Prescriptions Are Not Illegal Is Irrelevant

The second B Section of Dr. King's Motion *in Limine* to Preclude any Reference that the Prescription of Off-Label Use of FDA Approved Prescription Medication was Medicaid Fraud, Document Number 159 argues that off-label prescriptions are allowed. This is not disputed, but that is not the question in this case. This is addressed in the previous section.

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[14] Dr. King also makes the argument that enforcing Congress' restriction of coverage to medically accepted indications will harm children. This will be address in Section IV below in Dr. Watson's response to the Wisconsin Medical Society's *Amicus* Brief, Document Number 163)

II. Document Number 161 -- Motion *in Limine* to Preclude Reference that this Lawsuit Provided Notice that Dr. King Should Have Changed Her Practice

Through Document Number 161, Dr. King's Motion *in Limine* to Preclude Reference that this Lawsuit Provided Notice that Dr. King Should Have Changed Her Practice, she argues that this Court's Order of October 23, 2012, Document No. 59 holding that prescriptions presented to Medicaid not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), and the Court of Appeals' affirmance on August 28, 2013, should not be allowed to establish the "knowingly" or *scienter* element under the False Claims Act on the grounds that there has been no final adjudication.

In support of this argument, she cites *U.S. v. King-Vassel*, 728 F. 3d at 717 as follows:

> "The district court may very well be correct that Watson requires an expert to explain some number of the prescriptions he charges constitute false claims. For instance, if N.B. was prescribed a specific drug to treat 'anxiety,' and there is support in one of the compendia for prescribing the drug to treat 'depression,' Watson would need to present expert testimony to prove that those two diagnoses are not co-extensive."

This is a different question than whether Dr. King knew within the meaning of the False Claims Act, 31 U.S.C. §3729(b) that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) were false.[15]

It is true that the Seventh Circuit did not hold that any particular prescriptions constituted false claims, but it did hold that prescriptions not for a medically accepted indication as defined

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[15] One must distinguish between false *claims* cases under 31 U.S.C. §3729(a)(1)(A) from false *statement* cases under 31 U.S.C. §3729(a)(1)(B). As the Seventh Circuit said in *Hindo v. University of Health Services*, 65 F.3d 608 (7th Cir. 1995), with respect to false *claims* cases.

> "[W]hat constitutes the offense is not intent to deceive but knowing presentation of a claim that is either fraudulent or *simply false*. The requisite intent is the knowing presentation of what is known to be false."

(emphasis added).

under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) are false. Dr. King had to know this within the meaning of 31 U.S.C. 3729(b) after this Court issued its order to this effect on October 23, 2012.

The same is true with respect to this Court not having ruled that any particular prescriptions constitute false claims because they were not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). That is a different question than knowing that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) are false.

Dr. Watson understands and is prepared to present evidence regarding particular prescriptions that were not written for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). Dr. King can attempt to contest this.

Dr. King complains that Dr. Watson has not moved for a preliminary injunction or any other kind of order preventing Dr. King from prescribing drugs to Medicaid patients that are not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). Leaving aside the availability of such relief in a False Claims Act case, it is not up to Dr. Watson to prevent her from continuing this practice, This is a False Claims Act case to recover money for the federal government. Dr. King continued to write prescriptions constituting false claims at her peril. The question is whether this Court's decision, which was later affirmed on appeal, means that Dr. King "knew" the claims were false within the meaning of 31 U.S.C. §3729(b)(1)(A).

In its opinion, the Court of Appeals held the reckless disregard standard is met when the person "failed 'to make such inquiry as would be reasonable and prudent to conduct under the circumstances,' " or "when the actor knows or has reason to know of facts that would lead a

reasonable person to realize." 785 F.3d at713. Dr. King certainly knew or had reason to know of facts that would lead her to realize prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) cause false claims once this Court so held on October 23, 2012.

It is also respectfully suggested that the facts in this case support that she was deliberately ignorant of the fact that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) cause false claims. Under *U.S. v. Carrillo*, 435 F.3d 767, 779 (7th Cir. 2006), in the criminal context, deliberate ignorance is shown if Dr. King "shut her eyes" to this Court's and the Court of Appeals' decisions that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) cause false claims. In her Deposition Dr. King testified:

(1) that she doesn't recall if she read this Court's October 23, 2012, decision that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) presented to Medicaid constitute false claims, Document No. 145-4, pp 46 & 48; and

(2) even if she had read the Court of Appeal's Opinion in this case where it affirmed that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) presented to Medicaid constitute false claims she wouldn't have changed her practice because she doesn't base her prescribing habits on statutes, Document No. 145-4, p. 48.

It is respectfully suggested this constituted deliberate ignorance. It certainly constitutes reckless disregard.

III. Document Number 163 -- Amicus Brief by Wisconsin Medical Society

The Wisconsin Medical Society has filed an *Amicus* Brief, Document Number 163, which this Court accepted at Document Number 173, to the effect that Doctors are allowed to prescribe for uses not approved by the FDA, i.e., "off-label," and that harm to patients will occur if this Court enforces Congress' restriction of Medicaid outpatient drug coverage to medically accepted indications as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i).

A. The Use of These Drugs on Little Children Is Very Harmful and Lack Efficacy

The Wisconsin Medical Society states at page 2 of its *Amicus* Brief, that "Dr. King prescribed drugs here that were warranted . . ." There is absolutely no basis for this statement and there is no way the Wisconsin Medical Society can knowledgeably make this statement.

Dr. King and the Wisconsin Medical Society assert that this Court holding prescriptions of these powerful neuroleptics, designed to treat adults diagnosed with schizophrenia[16] written for use on little children as young as three are not properly reimbursable by Medicaid will harm children. Nothing is further from the truth. It will reduce the great harm that is occurring through this practice.

Exhibit 2, is the chapter, Weighing the Evidence: What Science Has to Say about Prescribing Atypical Antipsychotics to Children, in Drugging Our Children How Profiteers Are Pushing Anti psychotics on Our Youngest, and What We Can Do to Stop It, Praeger, 2012, Sharna Olfman and Brent Dean Robbins, Eds., is the best summary to date of what the research

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[16] The FDA approval of the use of Risperdal on children was based on the fraudulent work of Dr. Joseph Biederman, and others, but Dr. Watson is not challenging that approval here. Dr. Watson concedes that if a prescription is written for a use approved by the FDA, it is covered by Medicaid. There are three specific uses approved for Risperdal, but none for Geodon, the two drugs which Dr. Watson intends to pursue. See, Document Number 172-I, Section B, and the documents referred to therein. Both of these are neuroleptics, which are marketed as "antipsychotics."

really shows about these drugs. In particular, it describes the extreme harm they cause and the very limited efficacy. It also describes how doctors such as Dr. King were induced to write prescriptions for neuroleptics to little children in spite of the great harm they cause and very limited efficacy.

B. The "Peer-Reviewed" Literature has Been Corrupted by the Pharmaceutical Industry.

For over a decade, the alarm has been raised that "peer-reviewed" medical articles in even the most prestigious medical journals have been corrupted by the big-money influence of the pharmaceutical industry:

- Is Academic Medicine For Sale, Marcia Angell, M.D., *The New England Journal of Medicine*, (May 18, 2000)
- Editorial: Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence, by Catherine D. DeAngelis, MD, MPH and Phil B. Fontanarosa, MD, MBA, *Journal of the American Medical Association (JAMA)*, 2008;299(15):1833-1835.
- Lies, Damned Lies, and Medical Science, by David H. Freedman, *The Atlantic*, November, 2010.
- Conflicts of Interest at Medical Journals: The Influence of Industry-Supported Randomised Trials on Journal Impact Factors and Revenue – Cohort Study, by Andreas Lundh, Marija Barbateskovic, Asbjørn Hrobjartsson, and Peter C. Gøtzsche, *Plos Medicine*, Volume 7,| Issue 10 , October, 2010.
- Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry, Thomas Bodenheimer, M.D., *Health Policy Report* in the *New England Journal of Medicine* (May 18, 2000, Vol. 342, No. 20, 1539-1544.
- Data based medicine and clinical judgement, by David Healy, Derelie Mangin, and David Antonuccio, International Journal of Risk & Safety in Medicine 25 (2013) 111–121
- Pharmaceutical research and development: what do we get for all that money? by Donald W Light and Joel R Lexchin, *British Medical Journal*, BMJ 2012;344:e4348 doi: 10.1136/bmj.e4348 (Published 7 August 2012)
- How Industry Uses the ICMJE Guidelines to Manipulate Authorship—And How They Should Be Revised, by Alastair Matheson, *Public Library of Science-Medicine*, Vol 8:8 (2011).
- Being the Ghost in the Machine: A Medical Ghostwriter's Personal View, by Linda Logdberg, *Public Library of Science-Medicine*, Vol 8:8 (2011).

- Why Does Academic Medicine Allow Ghostwriting? A Prescription for Reform, by Jonathan Leo & Jeffrey R. Lacasse & Andrea N. Cimino, *Springer*, DOI 10.1007/s12115-011-9455-2 (2011)
- Reporting of Conflicts of Interest in Meta-analyses of Trials of Pharmacological Treatments, by Michelle Roseman, BA; Katherine Milette, BS; Lisa A. Bero, PhD; James C. Coyne, PhD; Joel Lexchin, MD; Erick H. Turner, MD; and Brett D. Thombs, PhD, *Journal of the American Medical Association*, Vol 305, No. 10 (2011).
- Complaint of Scientific Misconduct against Dwight L. Evans, Laszlo Gyulai; Charles Nemeroff, Gary S. Sachs and Charles L. Bowden, to the United States Office of Research Integrity, July 8, 2011.
- Med Schools Flunk at Keeping Faculty Off Pharma Speaking Circuit, by Tracy Weber and Charles Orsntein, *Pro Publica*, December 19, 2010.
- Drug Maker Wrote Book Under 2 Doctors' Names, Documents Say, by Duff Wilson, *The New York Times*, November 29, 2010.
    - POGO Letter to NIH, November 29,2010.
- Missing clinical trial data: setting the record straight, by Fiona Godlee, editor, Elizabeth Loder, associate editor, *British Medical Journal*, October 12, 2010.
- Commentary: Ghostwriting and Academic Medicine, by Jonathan Leo and JeffreyLacasse, *The Chronicle of Higher Education*, July 19, 2010.
- Ghostwriting in Medical Literature, Minority Staff Report, U.S. Senate Committee on Finance, Sen. Charles Grassley, Ranking Member, June 24, 2010.
- Ghostwriting at Elite Academic Medical Centers in the United States, by Jeffrey R. Lacasse, Jonathan Leo, *Public Library of Science* (PLoS), Vol 7, Iss 2 (2010).
- From Evidence-based Medicine to Marketing-based Medicine: Evidence from Internal Industry Documents, Glen I. Spielmans & Peter I. Parry, *Bioethical Inquiry*, DOI 10.1007/s11673-010-9208-8 (2010).
- Ghostwriting: The Dirty Little Secret of Medical Publishing That Just Got Bigger; Editorial from the PLoS Medicine Editors, September 2009 | Volume 6 | Issue 9 | e1000156.
- The Neurontin Legacy -- Marketing throuh Misinformation and Manipulation, by C. Seth Landefeld, M.D., and Michael A. Steinman, M.D., *New England Journal of Medicine*, 360;2, 103-106 (2009).
- Side Effects | Are Doctors' Loyalties Divided? Drug Firms' Cash Skews Doctor Classes: Company-funded UW Courses Often Favor Medicine, Leave Out Side Effects, by Susanne Rust and John Fauber, *Journal Sentinel* (Wis),March 29, 2009.
- Clinical trials and drug promotion: Selective reporting of study 329, by Jon N. Jureidini, Leemon B. McHenry, and Peter R. Mansfield, International Journal of Risk & Safety in Medicine 20 (2008) 73–81.

- Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation, Kristin Rising, Peter Bacchetti, Lisa Bero, PLoS Medicine, Vol. 5:11 1561-1570 (November 2008).
- Publication of Clinical Trials Supporting Successful New Drug Applications: A Literature Analysis, by Kirby Lee, Peter Bacchetti, and Ida Sim, *Plos Medicine*, September 2008, Vol.5, Issue 9, e191.
- Our Censored Journals, by David Healy, in *Medicine, Mental Health, Science, Religion and Well-being* (A.R.Singh and S.A. Singh eds), *MSM*, 6 Jan - Dec 2008, p244-256.
- Contract Research Organisations: Truly independent research? by Jeanne Lenzer, medical investigative journalist, *British Medical Journal*, August 18, 2008.
- Is There and (Unbiased) Doctor in the House? by Jeanne Lenzer and Shannon Brownlee, *British Medical Journal*, 2008;337:a930, July 23, 2008.
- Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry? by Sergio Sismondo, *PLOS*, September 2007, Volume 4, Issue 9, e286.
- Influence of Drug Company Authorship and Sponsorship on Drug Trial Outcomes, Tongeji Tunaraza and Rob Poole, *British Journal of Psychiatry*, 191, 82-83 (2007).
- The Growth of Psychopharmacology in the 1990s: Evidence-based practice or irrational exuberance, by Robert Rosenheck, *International Journal of Law and Psychiatry*, 2005, Vol. 28, 467-483.
- Forum: Financial Conflicts of Interest in Psychiatry, *The Journal of the World Psychiatry Association*, February, 2007.
- Manufacturing Consensus, by David Healy, *Culture, Medicine and Psychiatry*, (2006) 30: 135-56.
- Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic review, by Anders W Jørgensen, Jørgen Hilden, Peter C Gøtzsche, *British Medical Journal* (*BMJ*), BMJ, doi:10.1136/bmj.38973.444699.0B (published 6 October 2006).
- Can We Tame the Monster, *British Medical Journal*, July 8, 2006.
- Commercial bias in medical journals: Commercial influence and the content of medical journals, by Joel Lexchin, Donald W Light, *British Medical Journal*, 2006; 332:1444-7.
- Psychiatry and the pharmaceutical industry: Who pays the piper?, by Moncrieff J, Hopker S, Thomas P., *Psychiatric Bull*. 2005;29:84-5.
- Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies, by Richard Smith, PLoS Med. 2005 May; 2(5): e138, Published online 2005 May 17. doi: 10.1371/journal.pmed.0020138.
- How Tightly Do Ties Between Doctor and Drug Company Bind?, by By Abigail Zuger, M.D., *New York Times*, July 27,2004.

- Clinical Trials Controversy Spotlights Flawed System, by Jim Rosack, Psychiatric News July 16, 2004, Volume 39 Number 14.
- Revealed: how drug firms 'hoodwink' medical journals. Pharmaceutical giants hire ghostwriters to produce articles - then put doctors' names on them. Antony Barnett, public affairs editor, Sunday December 7, 2003, The Observer
- Stealth Merger: Drug Companies and Government Medical Research. Some of the National Institutes of Health's top scientists are also collecting paychecks and stock options from biomedical firms. Increasingly, such deals are kept secret. By David Willman. LA Times Staff Writer. December 7, 2003
- Scandal of scientists who take money for papers ghostwritten by drug companies: Doctors named as authors may not have seen raw data, Sarah Boseley, health editor, Thursday February 7, 2002, The Guardian
- Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry, Niteesh K. Choudhry, M.D.; Henry Thomas Stelfox, M.D.: and Allan S. Detsky M.D., *Journal of the American Medical Association*, (February 6, 2002) V. 287, No.56, 102-617
- Drug firms accused of distorting research, by Sarah Boseley, *UK Guardian*, September 10, 2001.
- Accuracy of Data in Abstracts of Published Research Articles, by Roy M. Pitkin, MD, Mary Ann Branagan, Leon Fe. Burmeister, PhD, *Journal of the American Medical Association*, Vol 281, No. 12, 1110-1111 (1999).

Dr. King and the Wisconsin Medical Society have chosen to close their eyes to this corruption of the practice of medicine and self-righteously assert that no one should interfere with the harmful, ineffective, treatments they are providing.

Dr. Watson can engage on that topic, although he would need more time to marshall his witnesses, but it is not relevant to this lawsuit.

C. Congress Limited Outpatient Drug Coverage to the Objective Standard of Medically Accepted Indication As Defined Under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i)

Congress made the decision that with respect to Medicaid *coverage*, the United States will not pay for uses that are not approved by the FDA or supported by at least one of the compendia. This makes perfect sense, both in protecting the public fisc and public health. Unlike the "peer-reviewed literature," which has become corrupted by pharmaceutical company

machinations (see, below), the compendia at least attempt to objectively review the studies. DRUGDEX, in particular, is very well organized and provides Recommendation, Evidence and Efficacy Ratings.[17] The Strength of Recommendation Ratings are as follows:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminate	Evidence Inconclusive	

This provides an objective basis for determining coverage for prescriptions that are not for a use approved by the FDA. Congress has the right to determine Medicaid *coverage* in this manner and has done so.

> Dr. Watson's view of this case, with which the Court of Appeals agrees, is:
>
> Medicaid can only provide reimbursement for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r–8(a)(3). Covered drugs do not include any drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r–8(k)(3). . . . Helpfully, "medically accepted indication" is a statutorily-defined term that refers to a prescription purpose approved by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or "supported by" any of several identified "compendia," 42 U.S.C. § 1396r–8(k)(6), § 1396r–8(g)(1)(B)(i).

U.S. v. King-Vassel, 728 F.3d 707, 715 (7th Cir. 2013).

That Doctors can prescribe for uses not approved by the FDA and are relying on fraudulent drug company representations in forming their clinical judgments is irrelevant to this case. This case is about whether Dr. King wrote specific drug prescriptions to Medicaid patients

[17] See, Exhibit 3.

that were not for a medically accepted indication under 42 U.S.C. §§ 1396b(i)(10), 1396r–8(a)(3).

IV. Document Number 165 -- Motion *in Limine* to Preclude Certain Witnesses of the Plaintiff from Testifying about Liability, Causation, or Damages

Dr. King's Motion *in Limine* to Preclude Certain Witnesses of the Plaintiff from Testifying about Liability, Causation, or Damages, Document Number 165, seeks to preclude the plaintiff/*relator* Dr. Toby Watson, Kimberly Smithers, Monica Yeazel, and Matt Joy from testifying at trial about liability, causation, or damages. Dr. Watson will go through each in turn.

A. Dr. Toby Tyler Watson

The grounds for the request to exclude Dr. Watson are that (1) he never treated N.B., (2) he is not a psychiatrist or physician, (3) he has no experience with Medicaid billing and reimbursement, (4) he agrees that off-label prescribing is common, and (5) he did not have any involvement in creating PsychRights Chart.

None of these are grounds to exclude Dr. Watson's testimony. This case is about whether Dr. King prescribed drugs that were not for medically accepted indications as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). None of the asserted grounds are relevant to this determination. Dr. Watson should be allowed to testify as to what he knows about prescriptions prescribed to N.B., that were not for medically accepted indications as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i)

B. Kimberly Smithers

Kimberly Smithers was identified to potentially testify about whether Wisconsin had determined to pay for drugs that were not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). This issue has fallen out of the case because the

State has indicated it doesn't consider such prescriptions to be false claims and Dr. Watson is not pursuing the claims on behalf of the State of Wisconsin. Therefore, Dr. Watson no longer intends to call her for that purpose.

However, Ms. Smithers later certified the electronic records produced by the State of Wisconsin, Trial Exhibit 11, and it might be desirable to have her testify as to their contents should there be a dispute over them.

C. Monica Yeazel

Ms. Yeazel was identified to potentially testify about whether Wisconsin had determined to pay for drugs that were not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). This issue has fallen out of the case because the State has indicated it doesn't consider such prescriptions to be false claims and Dr. Watson is not pursuing the claims on behalf of the State of Wisconsin. Therefore, Dr. Watson no longer intends to call her.

D. Matt Joy

Matt Joy has been listed to testify about the contents of the State of Wisconsin electronic discovery production. He produced compilations of the contents of those files with respect to (1) Risperdal prescriptions written since this Court held on October 23, 2012, Document No. 59, that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) and presented to Medicaid are false claims and (2) Geodon prescriptions for the entire period within the statute of limitations. Trial Exhibits 15 & 16. The same reports calculate the statutory damages and he should be allowed to testify as to both the contents of Wisconsin's electronic discovery and the calculation of damages.

V. Document Number 169- Motion *in Limine* to Permit Reference to Other Physicians that Treated N.B. Prior to Dr. King

Dr. King's Motion *in Limine* to Permit Reference to Other Physicians that Treated N.B. Prior to Dr. King, Document 169, essentially seeks this court reverse its Order, Document No. 137, pp 1-2, that such information is not relevant. Dr. Watson respectfully suggests Dr. King has presented no reason for the Court to reverse itself on this question.

VI. Document Number 170- Motion in Limine to Exclude Evidence of Geodon Prescriptions

Dr. King's Motion *in Limine* to Exclude Evidence of Geodon Prescriptions, Document Number 170, is based on the Geodon prescriptions not being identified until after the State of Wisconsin responded to Dr. Watson's Request for Production allowed under this Court's October 2, 2012, Orders, Document Numbers 116 & 117. This electronic discovery was provided on November 5, 2013, and Dr. Watson sent a listing of the Geodon prescriptions the very next day through a secure Internet large file sending website, YouSendIt.Com. Exhibit 4. The next day, November 7, 2013, Dr. Watson's counsel e-mailed counsel for Dr. King expressing concern that they had not downloaded these documents. Exhibit 5. The next day, October 8, 2013, Dr. King's counsel sent a fax refusing to download the documents and requesting that it be faxed or e-mailed. Exhibit 6. That same day, counsel for Dr. Watson did so. Exhibit 7 (redacted to remove birth dates of minors as required under Fed. R. Civ. Proc. 5.2(a)).

The short timing from the identification of the prescriptions to the date of the Final Pretrial Report was implicit when this Court granted Dr. Watson's Renewed Motion for HIPAA Qualified Protective Order, Document Number 102, in its October 2, 2013, Order, Document Number 116.

Dr. King is correct in *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003:

> the following factors should guide the district court's discretion: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date.

In *Caterpiller*, the Court of Appeals, upheld the preclusion denial, noting that Caterpillar had not requested a continuance.

Dr. King asserts at page 3:

> In order to assess the Geodon prescriptions, Dr. King would need to be provided access to records, including her own treatment records, of the patients the plaintiff is now claiming to be part of the case. The plaintiff's new assertion of Geodon, less than two weeks before trial, prohibits this from occurring. This review would include, as noted above, assuming that Geodon was in fact prescribed as listed in the State records and was not incorrectly placed in the list because of an error, the age of the patient, the history and presenting symptoms in order for her to be provided an opportunity comment of the allegations. The total number of Geodon claims, based on the records provided by the State and alleged by the plaintiff, is approximately 139. Joint Pretrial Report. Only on rare occasions is the diagnosis even provided in the State records.

First, it will be noted that the diagnoses are provided on Trial Exhibit 15, but also that the diagnosis is not relevant to a determination that the Geodon prescriptions constituted false claims because there is no medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) for anyone under 18.

In Dr. Watson's view, there is no real question about these prescriptions having been written by Dr. King and not only presented to Medicaid for payment, but actually paid. However, Dr. King is entitled to challenge it and if she asks for a continuance to do so, Dr. Watson believes it should be granted.[18] Otherwise, it is respectfully suggested the grounds for preclusion do not exist.

[18] This is not the thrust of Dr. King's defense, however. Dr. King has been defending on the grounds that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) are not false claims.

VII. Conclusion

For the foregoing reasons, Dr. Watson respectfully suggests that his, November 18, Renewed Motion *In Limine* Re: False Claims, **Document No. 144, be GRANTED**, and with respect to the motions addressed above, that the following be **DENIED:**

159- Motion *in Limine* to Preclude any Reference that the Prescription of Off-Label Use of FDA Approved Prescription Medication was Medicaid Fraud;

161- Motion *in Limine* to Preclude Reference that this Lawsuit Provided Notice that Dr. King Should Have Changed Her Practice;

169- Motion *in Limine* to Permit Reference to Other Physicians that Treated N.B. Prior to Dr. King; and.

170- Motion *in Limine* to Exclude Evidence of Geodon Prescriptions.

Finally, Dr. Watson respectfully suggests that Dr. King's Motion *in Limine* to Preclude Certain Witnesses of the Plaintiff from Testifying about Liability, Causation, or Damages, Document Number 165, should be denied except with respect to Monica Yeazel and that Matt Joy's testimony be restricted to the contents of the State of Wisconsin's electronic discovery and damages calculations.

Dated: November 29, 2013

s/ James B. Gottstein
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406 G Street, Suite 206, Anchorage, AK 99501
(907) 274-7686
jim.gottstein@psychrights.org

Attorney for *Relator*, Dr. Toby Tyler Watson

Exhibits

1. Relevant pages of House Conference Report No. 101-964, Omnibus Budget Reconciliation Act of 1990.

2. Chapter, Weighing the Evidence: What Science Has to Say about Prescribing Atypical Antipsychotics to Children, in Drugging Our Children How Profiteers Are Pushing Anti psychotics on Our Youngest, and What We Can Do to Stop It, Praeger, 2012, Sharna Olfman and Brent Dean Robbins, Eds.

3. DRUGDEX Recommendation Ratings

4. November 6, 2013, e-mailed notice from YouSendIt.Com of Geodon prescriptions summaries being available for download.

5. November 7, 2013, e-mail from James B. Gottstein to Mark Larson and Brad Foley.

6. November 8, Fax from Brad Foley.

7. November 8, 2013, e-mail transmittal of Geodon prescriptions to Brad Foley.

H.R. CONF. REP. 101-964, H.R. Conf. Rep. No. 964, 101ST Cong., 2ND Sess. 1990, 1990 WL 201626, 1990 U.S.C.C.A.N. 2374 (Leg.Hist.)

P.L. 101-508, OMNIBUS BUDGET RECONCILIATION ACT OF 1990

HOUSE CONFERENCE REPORT NO. 101–964
October 27, 1990
[To accompany H.R. 5835]

***0** The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 5835) to provide for reconciliation pursuant to section 4 of the concurrent resolution on the budget for fiscal year 1991, have met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Omnibus Budget Reconciliation Act of 1990".

SEC. 2. TABLE OF TITLES.

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

TITLE I–AGRICULTURE AND RELATED PROGRAMS

SEC. 1001. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.–This title may be cited as the "Agricultural Reconciliation Act of 1990".
(b) Table of Contents.–The table of contents of this title is as follows:
TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

Subtitle A–Commodity Programs

SEC. 1101. TRIPLE BASE FOR DEFICIENCY PAYMENTS.

(a) Wheat.–Section 107B(c)(1)(C)(ii) of the Agricultural Act of 1949 (as added by section 301 of the Food, Agriculture, Conservation, and Trade Act of 1990) is amended by striking "100 percent" and inserting "85 percent".
(b) Feed Grains.–Section 105B(c)(1)(C)(ii) of the Agricultural Act of 1949 (as added by section 401 of the Food, Agriculture, Conservation, and Trade Act of 1990) is amended by striking "100 percent" and inserting "85 percent".
(c) Upland Cotton.–Section 103B(c)(1)(C)(ii) of the Agricultural Act of 1949 (as added by section 501 of the Food, Agriculture, Conservation, and Trade Act of 1990) is amended by striking "100 percent" and inserting "85 percent".

Exhibit 1

(3) outlines the problems that eligible individuals encounter in procuring adequate and appropriate health care coverage;
(4) makes recommendations that the Secretary determines to be appropriate to address the problems described in paragraph (3); and
(5) in the case of the report issued 2 years after the date of enactment of this section, evaluates the effectiveness of counseling programs established under this program, and makes recommendations regarding continued authorization of funds for these purposes.
(f) Authorization of Appropriations for Grants.–There are authorized to be appropriated, in equal parts from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, $10,000,000 for each of fiscal years 1991, 1992, and 1993, to fund the grant programs described in this section.

SEC. 4361. MEDICARE AND MEDIGAP INFORMATION BY TELEPHONE.

(a) In General.–Title XVIII (42 U.S.C. 1395 et seq.) is amended by inserting after section 1888 the following:

"MEDICARE AND MEDIGAP INFORMATION BY TELEPHONE

"Sec. 1889. The Secretary shall provide information via a toll-free telephone number on the programs under this title and on medicare supplemental policies as defined in section 1882(g)(1) (including the relationship of State programs under title XIX to such policies).".
(b) Demonstration Projects.–The Secretary of Health and Human Services is authorized to conduct demonstration projects in up to 5 States for the purpose of establishing statewide toll-free telephone numbers for providing information on medicare benefits, medicare supplemental policies available in the State, and benefits under the State medicaid program.
TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

PART 1–REDUCTIONS IN SPENDING

SEC. 4401. REIMBURSEMENT FOR PRESCRIBED DRUGS.

(a) In General.–
(1) Denial of federal financial participation unless rebate agreements and drug use review in effect.–Section 1903(i) (42 U.S.C. 1396b(i)) is amended–
(A) by striking the period at the end of paragraph (9) and inserting "; or", and
(B) by inserting after paragraph (9) the following new paragraph:
"(10) with respect to covered outpatient drugs of a manufacturer dispensed in any State unless, (A) except as provided in section 1927(a)(3), the manufacturer complies with the rebate requirements of section 1927(a) with respect to the drugs so dispensed in all States, and (B) effective January 1, 1993, the State provides for drug use review in accordance with section 1927(g).".
(2) Prohibiting state plan drug access limitations for drugs covered under a rebate agreement.–Section 1902(a) of such Act (42 U.S.C. 1396a(a)) is amended–
(A) by striking "and" at the end of paragraph (52),
(B) by striking the period at the end of paragraph (53) and inserting "; and", and
(C) by inserting after paragraph (53) the following new paragraph:
"(54)(A) provide that, any formulary or similar restriction (except as provided in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under section 1927(a), which are prescribed for a medically accepted indication (as defined in subsection 1927(k)(6)), and
"(B) comply with the reporting requirements of section 1927(b)(2)(A) and the requirements of subsections (d) and (g) of section 1927.".

Exhibit 1

(3) Rebate agreements for covered outpatient drugs, drug use review, and related provisions.–Title XIX of the Social Security Act is amended by redesignating section 1927 as section 1928 and by inserting after section 1926 the following new section:

"PAYMENT FOR COVERED OUTPATIENT DRUGS

"Sec. 1927. (a) Requirement for Rebate Agreement.–
"(1) In general.–In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.
"(2) Effective date.–Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.
"(3) Authorizing payment for drugs not covered under rebate agreements.–Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug 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), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.
"(4) Effect on existing agreements.–In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.
"(b) Terms of Rebate Agreement.–
"(1) Periodic rebates.–
"(A) In general.–A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate each calendar quarter (or periodically in accordance with a schedule specified by the Secretary) in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the quarter (or such other period as the Secretary may specify). Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.
"(B) Offset against medical assistance.–Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).
"(2) State provision of information.–
"(A) State responsibility.–Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each calendar quarter and in a form consistent with a standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under

Exhibit 1

"(2) Covered outpatient drug.–Subject to the exceptions in paragraph (3), the term 'covered outpatient drug' means–
"(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and–
"(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;
"(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or
"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and
"(B) a biological product, other than a vaccine which–
"(i) may only be dispensed upon prescription,
"(ii) is licensed under section 351 of the Public Health Service Act, and
"(iii) is produced at an establishment licensed under such section to produce such product; and
"(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.
"(3) Limiting definition.–The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):
"(A) Inpatient hospital services.
"(B) Hospice services.
"(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.
"(D) Physicians'services.
"(E) Outpatient hospital services ****emergency room visits.
"(F) Nursing facility sevices.
"(G) Other laboratory and x-ray services.
"(H) Renal dialysis.
Such term also does not include any such drug or product which is used for a medical indication which is not a medically accepted indication.
"(4) Nonprescription drugs.–If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as 'over-the-counter' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.
"(5) Manufacturer.–The term 'manufacturer' means any entity which is engaged in–
"(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or
"(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.
Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.
"(6) Medically accepted indication.–The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, which appears in peer-reviewed medical literature or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States

Exhibit 1

Pete V. Domenici,
From the Committee on Environment and Public Works:
Quentin N. Burdick,
Daniel Patrick Moynihan,
George Mitchell,
Max Baucus,
Bob Graham,
John H. Chafee,
From the Committee on Finance:
Lloyd Bentsen,
Daniel Patrick Moynihan,
D.L. Boren,
George Mitchell,
David Pryor,
John D. Rockefeller IV,
Bob Packwood,
Bob Dole,
John C. Danforth,
John H. Chafee,
From the Committee on Governmental Affairs:
John Glenn,
Jim Sasser,
David Pryor,
From the Committee on the Judiciary:
Dennis DeConcini,
Patrick Leahy,
Orrin Hatch,
From the Committee on Labor and Human Resources for the Child Care and Development Block Grant Act:
Edward M. Kennedy,
Christopher J. Dodd,
Orrin G. Hatch,
From the Committee on Labor and Human Resources:
Edward M. Kennedy,
Claiborne Pell,
Howard M. Metzenbaum,
Christopher J. Dodd,
From the Committee on Labor and Human Resources for pension provisions (reversions and retiree health transfers):
Edward M. Kennedy,
Howard M. Metzenbaum,
From the Committee on Veterans' Affairs:
Alan Cranston,
Dennis DeConcini,
John D. Rockefeller IV,
Managers on the Part of the Senate.

***2374** JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 5835) to provide for reconciliation pursuant to section 4 of the concurrent resolution on the budget for fiscal year 1991, submit the following joint statement to the House and

Exhibit 1

3. Coinsurance for Clinical Lab Services (Section 6163 of Senate amendment)

Present law

Medicare payment for clinical diagnostic laboratory tests, other than tests performed by a hospital or other provider for its inpatients, is made according to fee schedules established by the Secretary. The laboratory or physician providing these tests must accept assignment. Payments are made at 100 percent of the fee schedule, and the deductible and coinsurance are waived.

House bill

No provision.
Effective date: No provision.

Senate amendment

Imposes the 20 percent coinsurance for clinical diagnostic laboratory tests. The beneficiary must first meet the Part B deductible before payment is made by the program for covered clinical laboratory test expenses.
Provides that payment is made at 100 percent of the fee schedule amount for tests required in connection with a mandatory second or third opinion.
Effective date: Applies to clinical diagnostic laboratory tests performed on or after January 1, 1991.

Conference agreement

The conference agreement does not include the Senate amendment.

1. Reimbursement for Prescribed Drugs (Section 4401 of the House bill, section 6201 of the Senate amendment)

Present law

Coverage of prescription drugs is an optional Medicaid service that is provided by all States and the District of Columbia. Federal regulations require that States pay for drug ingredients subject to upper payment limits established by HHS, plus a reasonable professional dispensing fee established by the State. The Health Care Financing Administration of HHS has established upper payment ***2527** limits for some multiple source drugs. For some drugs, States have established upper payment limits. States may control utilization of prescribed drugs through various means including prior authorization requirements and denial of coverage for certain drugs or groups of drug products.

House bill

(a) In General.–Denies Federal matching funds for prescription drugs unless rebate agreements are in effect and States implement drug use review by January 1, 1993. Requires drug manufacturers to comply with rebate requirements in all States and the District of Columbia. Provides that, in the case of a manufacturer which has entered into and complies with an agreement, States will cover the manufacturer's covered outpatient drugs which are prescribed on or after April 1, 1991, for a medically accepted indication.
(b) Requirement of Rebate Agreement.–
(1) To ensure availability of payment for the covered drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement with the Secretary on behalf of all the States and the District of Columbia.

Exhibit 1

Secretary will provide a manufacturer a hearing which will not delay the effective date of termination. A manufacturer may terminate an agreement for any reason; the time from date of notice to effective date is specified by the Secretary. Any termination does not affect rebates due before the effective ***2529** date of termination. If an agreement has been terminated, a new agreement may not be entered into with the manufacturer (or successor manufacturer) until one year after the date of termination unless the Secretary finds good cause for earlier reinstatement.

(d) Amount of Rebate.–

(A) In General.–The rebate for single source drugs and innovator multiple source drugs (IMSDs) is the product of:

The amount by which the average manufacturer price during the quarter exceeds the manufacturer's best price for each dosage form and strength of a covered outpatient drug; and

The number of units dispensed to Medicaid beneficiaries in the State during the quarter.

For covered outpatient drugs other than single source drugs and IMSDs, the rebate is the product of:

10 percent of the average manufacturer price to wholesalers during the quarter (after deducting customary prompt payment discounts) for each dosage form and strength; and

The number of units dispensed to Medicaid beneficiaries in the State during the quarter.

(B) Minimum and Maximum Rebates for Single Source Drugs and Innovator Multiple Source Drugs (IMSDs).–Rebates for single source drugs and IMSDs are subject to minimum and maximum limits based on the product of the average manufacturer's price and the number of units dispensed. The minimum is 10 percent. For calendar quarters beginning before April 1, 1995 the maximum is 25 percent (for each quarter during the 8 calendar quarter period beginning April 1, 1991), or 50 percent (for each quarter during the 8 calendar quarter period beginning April 1, 1993).

(C) Best Price Defined.–Best price is the lowest price available for the drug during the calendar quarter (or, if lower, the lowest price in effect September 1, 1990, indexed to the CPI) from the manufacturer to any wholesaler, retailer, provider, non-profit entity, or governmental entity in the U.S. For new drugs, the “best price” is the lower of the lowest price on the market or the initial lowest price, indexed by the CPI.

The lowest price is inclusive of cash discounts, free goods, volume discounts, and rebates and is determined regardless of special packaging labelling or identifiers on the dosage form or product or package. The lowest price does not take into account nominal prices.

(D) Limitations on Coverage of Drugs.–States are required to cover a manufacturer's covered outpatient drugs prescribed for a medically accepted indication when the manufacturer which has entered into and complies with a rebate agreement. States are not required to cover any drug for which the manufacturer or its designee has imposed certain conditions of sale.

(e) Drug Use Review.–(1) In General.–In accordance with guidelines developed by the Agency for Health Care Policy and Research, each State must have a drug use review program in effect by January 1, 1993, for covered outpatient drugs (other than psychopharmacologic drugs dispensed to residents of nursing facilities) in order to assure that prescriptions are appropriate and medically ***2530** necessary. Each drug use review program is to comply with the requirements for prospective drug review, retrospective drug review, and education.

(2) Description of Program.–Prospective review involves review of drug therapy before a prescription is filled, typically at the point of sale or distribution. Pharmacists are required to use published compendia as the source of standards for review.

Retrospective review requires the periodic examination of claims data and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

The State drug use review program must educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs. The program is also to identify potential and actual severe adverse reactions to drugs.

(f) Miscellaneous.–(1) States are not prevented from restricting the amount, duration, and scope of coverage of covered outpatient drugs consistent with the need to safeguard against unnecessary utilization.

(2) This bill does not affect or supersede provisions relating to maximum allowable cost limitation for covered outpatient drugs; rebates must be made without regard to whether payments by the State are subject to such limitations.

(3) States are not required to provide Medicaid coverage for covered outpatient drugs of a manufacturer which requires, as a condition for purchase, that the manufacturer be paid for associated services or tests provided only by

Exhibit 1

the manufacturer or its designee.

(g) Definitions.–

Average Manufacturer Price Average manufacturer price is the average price paid to the manufacturer by retail pharmacies or by wholesalers for drugs distributed to the retail pharmacy class of trade.

Covered Outpatient Drug A covered outpatient drug is a prescribed drug which is approved under the Food, Drug and Cosmetic Act; which was commercially used or sold in the U.S. before enactment of the Federal Food, Drug and Cosmetic Act, and which has not been the subject of a final determination by the Secretary that it is a "new drug" under the Food, Drug and Cosmetic Act; for which the Secretary has not issued a notice for an opportunity for hearing because the drug is less than effective; and for which the Secretary has determined there is compelling justification for its medical need. Also included are identical, similar or related drugs.

The term includes a biological product which may only be dispensed by prescription, is licensed, and produced by a licensed establishment. Also included is insulin.

The term excludes any drug, biological product, or insulin provided with inpatient hospital services, hospice services, dental services (except where state plan authorizes direct reimbursement to dispensing dentist), physician office visits, outpatient hospital emergency room visits, and outpatient surgical procedures.

Non-prescription ("over-the-counter") drugs prescribed by a physician, or other authorized prescriber, may be regarded as covered outpatient drugs.

***2531** Manufacturer A manufacturer is the entity that both manufactures and distributes the drugs, or if no such entity exists, the entity that distributes the drug. The term does not include a wholesale distributor of drugs or a retail pharmacy.

Medically Accepted Indication A medically accepted indication means any use for a covered outpatient drug which is approved by the FDA or which is accepted by one of the following compendia: American Hospital Formulary Service–Drug Information, American Medical Association Drug Evaluations, and United States Pharmacopeia–Drug Information.

Multiple Source Drug; Innovator Multiple Source Drug; Noninnovator Multiple Source Drug; Single Source Drug.–(A) A multiple source drug is a covered outpatient drug for which there are 2 or more drug products sold or marketed in the State, which the Food and Drug Administration has rated as therapeutically equivalent and has determined are pharmaceutically equivalent and bioequivalent.

(B) Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(C) Noninnovator multiple source drug means a multiple source drug that is not an innovator multiple source drug.

(D) Single source drug means a covered outpatient drug which is not multiple source drug.

Drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity.

Drug products are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

A drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(h) Funding.–Seventy-five percent Federal matching, over the 1991–1993 period, is available for the costs of the statewide adoption of a drug use review program meeting the requirements of the bill. Seventy-five percent Federal matching is available in FY 1991 for administrative activities related to meeting other requirements.

(i) Denial of Federal Financial Participation in Certain Cases.–No provision.

(j) Pharmacy Reimbursement.–No provision.

(k) Electronic Claims Management.–No provision.

(l) Annual Report.–No provision.

(m) Exemption of Organized Health Care Settings.–No provision.

(n) Demonstration Projects.–No provision.

(o) Studies.–No provision.

***2532** Senate amendment

(a) In General.–Similar, but does not include a date after which States must permit coverage of the drugs of a manufacturer which has entered into an agreement.

Prohibits the Secretary or a State from making any changes, prior to April 1, 1993, to the formula used to determine the reimbursement limits in effect as of Aug. 1, 1990, if those changes would result in reductions to the ingredient cost or dispensing fee for covered outpatient drugs.

Requires the Health Care Financing Administration to establish upper limits for all multiple source drugs for which the Food and Drug Administration has rated 3 or more therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such.

(b) Requirement of Rebate Agreement.–

(1) Similar provision, except permits the Secretary to authorize a State to enter directly in agreements with manufacturers, and requires that manufacturers enter into agreements by Jan. 1, 1991.

(2) For a rebate agreement in effect between a State and a manufacturer on the date of enactment of this bill, the agreement is considered to be in compliance for the initial agreement period if the State agrees to report to the Secretary any rebates paid under the agreement. The agreement is considered to be in compliance for renewal periods of the agreement if the State agrees to report any rebates to the Secretary, and the State establishes to the satisfaction of the Secretary that the agreement can reasonably be expected to provide rebates at least as large as the rebates otherwise required under this bill.

(3) No provision.

(4) Payment is authorized for single source drugs or innovator multiple source drugs not covered under rebate agreements if the State has made a determination that the availability of the drug is essential to the health of Medicaid beneficiaries; and the physician has received prior authorization for use of the drug, or the Secretary has approved the State's determination.

(c) Terms of Rebate Agreement.–(1) Quarterly rebates. Similar provision, but provides for periodicity other than quarterly, as specified by the Secretary. Does not include special payment rule.

(2) State Provision of Information.–States are required to report to each manufacturer within the same time period and copy each report to the Secretary. Places no limitations on audits by manufacturers. Otherwise similar provision.

(3) Manufacturer Provision of Price Information.–(A) In General.–Each manufacturer with a rebate agreement in effect is required to report to the Secretary the average manufacturer price within 30 days after each quarter beginning on or after January 1, 1991. The manufacturer's best price for single source drugs and innovator multiple source drugs is to be reported effective for quarters beginning on or after January 1, 1994. Within 30 days of entering into a rebate agreement, each manufacturer must report to the Secretary on the average manufacturer price for each of the manufacturer's drugs as of Oct. 1, 1990.

***2533** (B) Verification surveys of average manufacturer price.–Similar, but penalty applies whether request is written or not.

(C) Penalties.–Similar provision, except the rebate is increased by $10,000 for each day information is not provided.

(D) Confidentiality of information.–Similar provision.

(4) Length of Agreement.–Similar provision.

(d) Amount of Rebate.–

(A) In General.–The basic rebate for single source drugs and innovator multiple source drugs (IMSDs) is the product of:

For quarters beginning after Dec. 31, 1990 and before Jan. 1, 1994, 15 percent of the average manufacturer price for each dosage form and strength (after deducting customary prompt payment discounts);

For quarters beginning after Dec. 31, 1993, the greater of

The difference between the average manufacturer price for a drug and 85 percent of the price, or

The difference between the average manufacturer price for a drug and the best price; and

The number of units of such form and dosage dispensed to Medicaid beneficiaries.

The Secretary is required to establish a method for ensuring that a manufacturer's prices, determined on an aggregate weighted average basis, using the average manufacturer price for each drug, do not increase by a percentage greater than the increase in the Consumer Price Index for all urban consumers (CPI–U) from Oct. 1, 1990.

Exhibit 1

For covered outpatient drugs other than single source drugs and IMSDs, the rebate is the product of:

12 percent of the average manufacturer price for each dosage form and strength (after deducting customary prompt payment discounts) and

The number of units dispensed.

In 1994 and beyond, rebates on single source drugs and IMSDs would be the greater of a 12 percent discount from the average manufacturer's price on Sept. 1, 1990, or the "best price". Rebates on drugs other than single source drugs and IMSDs would be discounts of 12 percent from the current average manufacturer's price.

The 12 percent minimum discount would be indexed annually by the CPI–U. A maximum discount of 20 percent would apply only in fiscal years 1991–1995.

(B) Minimum and Maximum Rebates for Single Source Drugs and Innovator Multiple Source Drugs (IMSDs).–No provision.

(C) Best Price Defined.–Best price is the lowest price available from the manufacturer excluding depot prices of any agency of the Federal Government. There is no provision for the best price of new drugs. Otherwise similar provision.

(D) Limitations on Coverage of Drugs.–Except in the first year following approval of a new drug, States are permitted to subject any covered outpatient drug to prior authorization. States may limit quantities of drugs, provided the limitations are necessary to discourage waste. States may exclude or restrict coverage of a drug if the prescribed use is not for a medically accepted indication, the drug is subject to an agreement between the manufacturer and the ***2534** State that is authorized by the Secretary, or the drug is in the list below.

The following drug products are subject to restriction:

Agents used for anorexia or weight gain that are not approved by the FDA;

Agents used to promote fertility;

Agents used for cosmetic purposes or hair growth;

Cough and cold relief agents;

Smoking cessation agents;

Prescription vitamins and minerals, except prenatal preparations;

Nonprescription drugs;

Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee;

Drugs determined by the Secretary to be less than effective; and

Barbiturates.

By regulation, the Secretary is required to periodically update the list.

Innovator multiple source drugs are to be treated as under otherwise applicable law and regulation.

States are prohibited from imposing prior authorization requirements unless its approval system is available at least 10 hours each weekday and provides for obtaining approval during other times, provides for response within 24 hours of a request, and provides for dispensing at least a 72 hour supply of a covered drug in an emergency situation.

(e) Drug Use Review.–(1) In General.–Similar provision, but requires the assessment of data on drug use against explicit predetermined standards consistent with certain compendia.

(2) Description of Program.–Similar provision specifies that prospective review shall include screening for certain drug therapy problems. Requires that State programs include standards established under State law for counseling of Medicaid recipients or caregivers by pharmacists. Counseling is to include at least a reasonable effort by the pharmacist to provide face-to-face counseling to discuss matters concerning the medication. The pharmacist is required to make a reasonable effort to obtain, record, and maintain certain information about the recipient. The pharmacist is not required to provide consultation when a recipient or caregiver refuses.

Similar provision for retrospective review.

Requires each State to establish a drug use review board (DUR board), either directly or through contract with a private organization, to provide for education outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices. Specifies the membership of the board and specifies activities including intervention programs which include the following, as appropriate: information dissemination, reminders containing specific information and suggested changes in practices, discussions between health care professionals and prescribers and pharmacists targeted for educational intervention, ***2535** and intensified review of selected prescribers or dispensers. The board is required to evaluate interventions periodically.

Annually, each State is required to submit to the Secretary a report prepared by the DUR board. The report must include a description of the board's activities, a summary of the interventions, an assessment of their impact, and an estimate of the cost savings generated by the program.

(f) Miscellaneous.–Provisions similar to (1) and (3). No provision comparable to (2).

(g) Definitions.–Average Manufacturer Price Similar provision.

Covered Outpatient Drug Similar provision.

Manufacturer.–A manufacturer is any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term does not include a wholesale distributor of drugs or a retail pharmacy.

Medically Accepted Indication.–Similar provision.

Multiple Source Drug; Innovator Multiple Source Drug; Noninnovator Multiple Source Drug; Single Source Drug.–Similar provision.

(h) Funding.–Similar provision.

(i) Denial of Federal Financial Participation in Certain Cases.–Denies Federal matching funds for an innovator multiple source drug dispensed on or after July 1, 1991, if a less expensive noninnovator multiple source drug could have been dispensed under State law.

(j) Pharmacy Reimbursement.–Within 60 days after the end of each fiscal year, beginning FY1991 and ending Sept. 30, 1993, each State Medicaid program is required to make a lump-sum payment, to pharmacies dispensing covered outpatient drugs under Medicaid during the fiscal year. The amount of payment is to bear the same ratio to 5 percent of the total rebates received by the State in the year, as the ratio of the number of prescriptions filled by a pharmacy bear to the total number of prescriptions filled by all pharmacies in the State in the fiscal year.

(k) Electronic Claims Management.–The Secretary must encourage each State to establish, as its principal means of processing claims for covered outpatient drugs under Medicaid, a point-of-sale electronic claims management system, for the purpose of performing eligibility verifications, capturing claims data, adjudicating claims, and assisting pharmacists to apply for and receive payment. During fiscal years 1991 and 1992, States may receive 90 percent Federal matching funds for the development of a system if the State acquires the most cost-effective services and equipment. The Secretary may permit States to substitute their requests for proposal for such systems in place of advance planning and implementation documents.

(l) Annual Report.–By May 1, of each year, the Secretary is required to submit a report to the appropriate committees of Congress. The report is to include information on ingredient costs paid ***2536** under Medicaid, the total value of rebates received and the number of manufacturers providing such rebates; comparison of these rebates with rebates offered to other purchasers; effect of inflation on the value of rebates; and trends in prices paid for drugs by Medicaid.

(m) Exemption of Organized Health Care Settings.–Health maintenance organizations are exempt from these requirements. States are required to exempt hospitals from these requirements provided the hospitals bill Medicaid no more than the hospital's acquisition costs for covered outpatient drugs. Amounts that health maintenance organizations and hospitals pay for covered outpatient drugs may be taken into account to determine the “best price”.

(n) Demonstration Projects.–The Secretary is required to establish 10 statewide demonstration projects by January 1, 1992, to evaluate the efficiency and cost-effectiveness of prospective drug utilization review as a component of on-line, real-time electronic point-of-sales claims management. A report is due to Congress by January 1, 1994.

The Secretary is to conduct a demonstration project at no fewer than five sites to evaluate the impact on quality of care and cost-effectiveness of paying pharmacists, whether or not a drug is dispensed, for drug use review services. The Secretary is to report the results of the projects to Congress by January 1, 1995.

(o) Studies.–The Comptroller General is required to conduct a study, and submit a report to the Secretary and to Congress by May 1, 1991, of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the Medicaid program.

The Comptroller General is required to submit an annual report to the Secretary and to Congress by May 1, of each year, on changes in prices charged by manufacturers for prescription drugs sold to the Department of Veterans Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

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In consultation with the Comptroller General, the Secretary is required to study prior approval procedures used in State Medicaid programs, including appeals provisions and the effects of the procedures on access to medications. By December 31, 1991, the Secretary and Comptroller General must report the results of the study to Congress and make recommendations as to which procedures are appropriate for Medicaid.

By December 31, 1991, the Secretary is required to report to Congress on the results of a study on the adequacy of current reimbursement rates to pharmacists under each State Medicaid programs, and the extent to which the reimbursement rates affect beneficiary access to covered medications and to pharmacy services.

The Secretary is required to study the relationship between State Medicaid programs and governmental acquisition and reimbursement policies for vaccines, and the accessibility of vaccinations to children. The Secretary is required to report to Congress on the study within one year after the date of enactment of this Act.

The Comptroller General is required to conduct a study examining methods to encourage Medicare providers to negotiate discounts ***2537** with suppliers of prescription drugs. A report to Congress is due within one year after enactment of this section.

Conference agreement

1. Reimbursement for Prescribed Drugs.–

(a) In General.–The conference agreement includes the House bill with amendments to prohibit the Secretary and the States from reducing drug product reimbursement levels and dispensing fees for pharmacists from the levels in effect August 1, 1990, through March 30, 1995.

(b) Requirement of Rebate Agreement.–The conference agreement includes the House bill with the modification that rebate requirements would not apply to drugs of manufacturers with existing rebate contracts, through the minimum term of the contract, provided the amount of the rebate under the contract totals at least 10 percent of the manufacturer's sales to Medicaid in the State. States are permitted to impose prior authorization controls on all covered drugs, except new drugs within 6 months of FDA approval, and to exclude from coverage certain categories of drugs. States are permitted to cover non-rebated drugs with an FDA “A” rating if the State make a finding that the drug is essential to beneficiaries' health and the Secretary concurs, or if the State requires prior approval.

(c) Terms of Rebate Agreement.–The conference agreement includes the House bill.

(d) Amount of Rebate.–The conference agreement includes the House bill with the following amendments in calculation of the rebate amount for drugs prescribed on or after January 1, 1991. In the first year, the rebate amount is calculated on a drug-by-drug basis and is the greater of the difference between the average manufacturer price (AMP) and a specified percentage of the AMP, or the difference between the AMP and the best price, for sole source and innovator multiple source drugs. The rebate is subject to a maximum. In subsequent years, the rebate is to be calculated on an aggregate basis. The AMP is indexed according to the Consumers Price Index for all urban consumers. Rebates for multiple source (non-innovator) drugs are 10 percent of the AMP in years 1 through 3 and 11 percent in years 4 and 5 and thereafter with no adjustment for inflation. The rebate mechanism does not preclude imposition of current upper payment limits on multiple source drugs. The best price excludes depot prices of certain Federal agencies.

(e) Drug Use Review.–The conference agreement includes the House bill.

(f) Miscellaneous.–The conference agreement includes the House bill.

(g) Definitions.–The conference agreement includes the House bill.

(h) Funding.–The conference agreement includes the House bill with amendments that add 90 percent Federal matching funds in fiscal years 1991 and 1992 for electronic point of sale mechanisms.

(i) Denial of Federal Financial Participation in Certain Cases.–The Senate amendment is not included in the conference agreement.

***2538** (j) Pharmacy Reimbursement.–The Senate amendment is not included in the conference agreement.

(k) Electronic Claims Management.–The conference agreement includes the Senate amendment.

The conference agreement does not include provisions on annual report, exemption of organized health care settings, or demonstration projects.

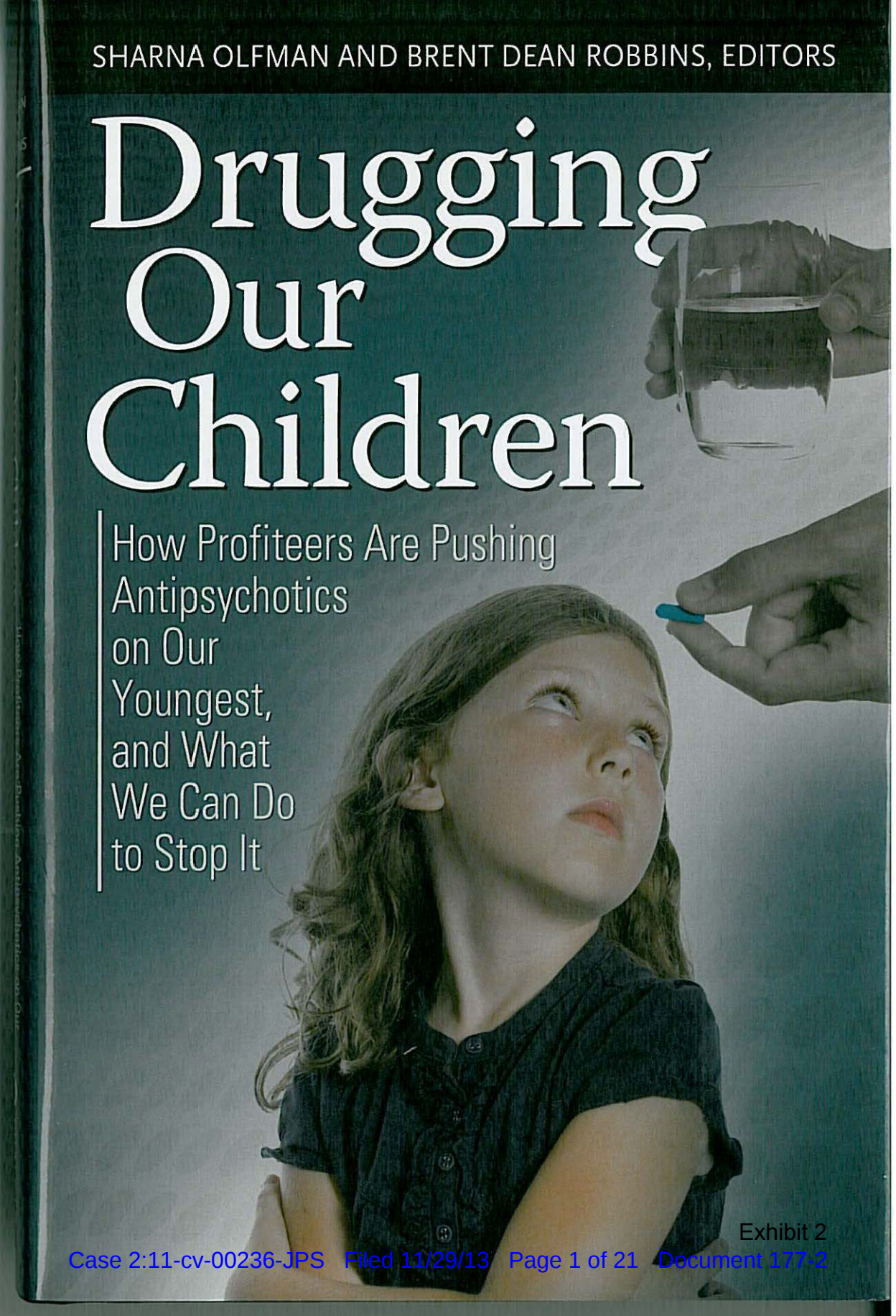
2. Requiring Medicaid Payment of Premiums and Cost-Sharing for Enrollment under Group Health Plans Where

Exhibit 1

SHARNA OLFMAN AND BRENT DEAN ROBBINS, EDITORS

Drugging Our Children

How Profiteers Are Pushing Antipsychotics on Our Youngest, and What We Can Do to Stop It



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Childhood in America
Sharna Olfman, Series Editor

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Medical disclaimer: This book discusses treatments (including types of medication and mental health therapies), diagnostic tests for various symptoms and mental health disorders, and organizations. The authors have made every effort to present accurate and up-to-date information. However, the information in this book is not intended to recommend or endorse particular treatments or organizations, or substitute for the care or medical advice of a qualified health professional, or used to alter any medical therapy without a medical doctor's advice. Specific situations may require specific therapeutic approaches not included in this book. For those reasons, we recommend that readers follow the advice of qualified health care professionals directly involved in their care. Readers who suspect they may have specific medical problems should consult a physician about any suggestions made in this book.

1

Weighing the Evidence: What Science Has to Say about Prescribing Atypical Antipsychotics to Children

Robert Whitaker

Today, prescribing antipsychotics to children and adolescents in the United States has become commonplace. More than 1 percent of American youth are on these medications for diagnoses that indicate long-term use. There is now enough scientific research describing how these drugs affect children and adolescents, both in terms of their safety and efficacy, and so we can now ask the key question: Are antipsychotics helping them to grow up and thrive as adults, or is it doing great harm?

THE RISE OF ANTIPSYCHOTIC PRESCRIPTIONS FOR CHILDREN

Prior to the early 1990s, it was uncommon to treat children with antipsychotics. Physicians understood that Thorazine, Haldol, and other neuroleptics were very problematic medications, and therefore prescribed them primarily to adults with schizophrenia or behavioral problems. For example, in 1987, among youth 6 to 17 years old covered by private insurance, only 1 in every 2,500 was prescribed an antipsychotic (0.04%). The prescribing rate for youth of that age covered by Medicaid was higher, and yet still uncommon (1 in 300).[1] There was virtually no prescribing of antipsychotics to children less than 6 years of age at that time. All told, there were fewer than 50,000 U.S. youth under 18 years old who were prescribed an antipsychotic in 1987.[2]

The first *atypical* antipsychotic to come to market in the United States was Clozaril in 1990. It was said to be an atypical antipsychotic because it didn't cause the motor dysfunction—known as extrapyramidal symptoms—that Thorazine and the other *standard* antipsychotics did. However, because Clozaril can cause agranulocytosis, a potentially fatal depletion of white blood cells, its use was reserved for refractory schizophrenia patients. Then Risperdal arrived on the market in 1993, an atypical touted as being much safer than the older antipsychotics and Clozaril. Other atypicals followed—Zyprexa, Seroquel, and so forth—said to be much safer as well.

It was this belief on the part of clinicians, that atypicals were safe, that made it possible for pharmaceutical companies to push their off-label use in pediatric populations. The drug companies worked closely with academic child psychiatrists in the United States to build this market. The manufacturers provided academic psychiatrists with research grants and paid them to serve as advisors, consultants, and speakers. Pharmaceutical companies refer to the academic doctors they hire as *thought leaders*, and in this instance, their thought leaders promoted the prescribing of atypicals for psychotic disorders, for juvenile bipolar disorder (which was rarely diagnosed prior to the arrival of the atypicals), and for controlling aggression and other behavioral problems.

The rise of juvenile bipolar illness is the best example of this market-building process. Up until the late 1970s, there was consensus among researchers that manic-depressive illness virtually never occurred in prepubertal children. But then physicians began to prescribe stimulants to children diagnosed with attention deficit disorder, a treatment that occasionally triggered manic (or psychotic) symptoms, and suddenly researchers began publishing case reports of younger children with manic-depressive illness (the researchers generally ignored the possibility that the stimulants had caused the mania). After Prozac and other SSRIs came to market in the late 1980s, the frequency of this diagnosis rose, as those drugs produce mania in children with some regularity. Together, prescriptions of stimulants and antidepressants to children and adolescents helped to create a new group of juvenile bipolar patients in the United States. However, when Risperdal came to market in 1993, there were still only 20,000 youth under age 20 so diagnosed.[3] Then, in 1996, Joseph Biederman, a child psychiatrist at Harvard-affiliated Massachusetts General Hospital, provided a new and greatly expanded diagnostic framework for juvenile bipolar disorder, and the juvenile bipolar boom was on.

In 2009, while giving a deposition in a legal case, Biederman acknowledged that there was no scientific discovery that led to his creation of this new diagnostic framework. Instead, he said, all psychiatric

diagnoses "are subjective in children and in adults." As such, he and his colleagues had decided in 1996 that children with pronounced behavioral problems should be diagnosed with juvenile bipolar illness. "The conditions that we see in front of us are reconceptualized," he testified. "These children have been called in the past conduct disorder, oppositional-defiant disorder. It's not that these children did not exist, they were just under different names."[4] Biederman and his collaborators decided that "severe irritability" or "affective storms" would be the telltale sign of juvenile bipolar disorder. Having invented these new diagnostic criteria, they then announced that many children diagnosed with attention deficit/hyperactivity disorder (ADHD) were in fact "bipolar" or else "comorbid" for both illnesses.[5] The illness, Biederman told the public in the 1990s, was a "much more common condition than was previously thought," often appearing when children were only 4 or 5 years old.[6]

Biederman quickly became one of the pharmaceutical industry's favorite thought leaders. From 2000 to 2007, pharmaceutical companies paid him $1.6 million for his various services.[7] In addition, Janssen pharmaceutical company, the division of Johnson & Johnson that sells Risperdal, gave Biederman $2 million to create the Johnson & Johnson Center for Pediatric Psychopathology at Massachusetts General Hospital.[8] The center, Biederman wrote in a 2002 report, was a "strategic collaboration" that would "move forward the commercial goals of J&J." He and his colleagues promised to develop "screening tests" for juvenile bipolar illness, and to conduct continuing medical education courses to train pediatricians and psychiatrists to use their new diagnostic tool. Their work, Biederman wrote, would "alert physicians to the existence of a large group of children who might benefit from treatment with Risperdal." In addition, the center would promote the understanding that "pediatric mania evolves into what some have called mixed or atypical mania in adulthood, [which] will provide further support for the chronic use of Risperdal from childhood through adulthood."[9]

Thanks in large part to Biederman's efforts, the number of U.S. children under age 20 diagnosed with bipolar disorder soared from 20,000 in 1994 to 800,000 in 2003, a 40-fold increase.[10] It has continued to rise since then. The number of atypical antipsychotic prescriptions to children under age 18 in the United States doubled from about 2.2 million in 2003 to 4.4 million in 2006. "The expanded use of bipolar disorder as a pediatric diagnosis has made children the fastest-growing part of the $11.5 billion U.S. market for antipsychotic drugs," Bloomberg News reported in 2007.[11]

As a result of this extraordinary explosion of pediatric bipolar diagnoses, today antipsychotics are prescribed to more than 1 percent of all

U.S. youth under 18 years old, and only a small percentage of this use is to treat schizophrenia and other psychotic disorders. In a 2006 study, researchers found that 38 percent of antipsychotic prescriptions to children were for disruptive behaviors, 32 percent for mood disorders, 17 percent for developmental disorders or mental retardation, and 14 percent for psychotic disorders.[12] The drugs are now being used for an ever broadening range of conditions, including ADHD, impulsivity, insomnia, posttraumatic stress disorder, obsessive-compulsive symptoms, eating disorders, and—as one researcher put it—poor tolerance of "frustration."[13]

HOW ATYPICAL ANTIPSYCHOTICS ACT ON THE BRAIN

During the past 20 years, the public has regularly been told that psychiatric medications fix "chemical imbalances" in the brain, and therefore are like "insulin for diabetes." When the atypical antipsychotics came to market, the National Alliance on Mental Illness, in a book titled *Breakthroughs in Antipsychotic Medications*, informed readers that these new drugs "do a better job (than the old ones) of balancing all of the brain chemicals, including dopamine and serotonin."[14] As a result, much of the public has come to believe that when atypicals are prescribed for juvenile bipolar illness and for other childhood disorders, the drugs are somehow correcting something known to be amiss in the brain. But, as a review of the science shows, that isn't true.

In the 1970s, researchers discovered that Thorazine and other antipsychotics blocked dopamine receptors in the brain, and in particular a subtype known as D2 receptors. At a therapeutic dose, these drugs block 70 percent of the D2 receptors. With this understanding, researchers then hypothesized that schizophrenia was caused by too much dopamine activity in the brain. But when they investigated that hypothesis in the 1970s and 1980s, they did not find that schizophrenia patients had, as a matter of course, *hyperactive* dopamine systems. As Harvard University neuroscientist Steven Hyman explained in a 2002 textbook, *Molecular Neuropharmacology*, "there is no compelling evidence that a lesion in the dopamine system is a primary cause of schizophrenia."[15]

However, these investigations did not consider how the brain reacts to an antipsychotic. Nerve cells or neurons communicate in this way: A presynaptic neuron releases a chemical messenger (such as dopamine) into the tiny gap between neurons known as the synaptic cleft, and this molecule then binds with receptors on the surface of the postsynaptic neuron. The neurotransmitter is said to fit into the receptor like a key into a lock. Thorazine and other standard antipsychotics gum

up the D2 locks, so to speak, and in this manner inhibit the firing of the postsynaptic neurons. This blockade thwarts the transmission of messages along dopaminergic pathways in the brain, which are essential to the functioning of the basal ganglia, the limbic system, and the frontal lobes. In response, the brain goes through a series of compensatory adaptations. For a time, the presynaptic neurons release more dopamine than normal, while the postsynaptic neurons increase the density of their D2 receptors by 30 percent or more. These adaptations are designed to keep the dopaminergic pathways at least somewhat functional. The first compensatory adaptation appears to break down after a while, but the increase in D2 receptors remains and can be detected at autopsy.

While risperidone (Risperdal), olanzapine (Zyprexa), quetiapine (Seroquel), and other newer antipsychotics are grouped together as atypicals, they vary considerably in their pharmacological effects, and thus are more accurately described as *second generation antipsychotics* (SGAs). They are all broad-acting agents. While they may not block D2 receptors quite as potently as Thorazine and the other first-generation antipsychotics (FGAs), they may also bind with serotonergic, histaminergic, adrenergic, and muscarinic receptors.[16] For the most part, atypicals thwart the passage of messages along these various neuronal pathways, triggering an avalanche of compensatory adaptations in the brain.

The drugs' disruption of normal functioning along these various neuronal pathways causes many predictable adverse events. Since dopaminergic pathways are involved in the control of motor movements, drugs that block dopamine receptors can cause Parkinsonian symptoms, muscle dystonias, akathisia, prolactin increase, and sexual dysfunction. Blocking serotonergic receptors can cause an increase in appetite, weight gain, and metabolic changes associated with an increased risk of diabetes. Blocking muscarinic M1 receptors can cause memory and cognition problems. And so on . . . each neurotransmitter has its own side effect profile.[17]

Moreover, these are the *predictable* side effects. Any drug that blocks multiple types of receptors can be expected to cause many unexpected adverse events too.

There are also distinct withdrawal effects associated with the different neuronal pathways. For instance, if a drug blocks D2 receptors, the withdrawal of that drug may lead to psychosis, mania, agitation, and akathisia. If a drug blocks muscarinic M1 receptors, its withdrawal may cause agitation, confusion, anxiety, and insomnia. And so on . . . withdrawal effects from a psychiatric drug may vary according to which neuronal pathways have been altered by it.[18] (See Table 1.1.)

TABLE 1.1. Expected Effects from a Drug's Blockade of Receptors

Receptor Type	Adverse Events	Withdrawal Effects
Dopamine	EPS, weight gain, endocrine effects, akathisia, tardive dyskinesia, increased prolactin, sexual or reproductive system dysfunction	Psychosis, mania, agitation, akathisia, dyskinesia
Serotonin	Weight gain, diabetes, increased appetite	EPS, akathisia, psychosis, decreased appetite
Histamine	Weight gain, diabetes, sedation	Agitation, insomnia, anxiety, EPS
Muscarinic	Dry mouth, blurred vision, constipation, urinary retention, diabetes, memory problems cognitive problems, tachycardia, hypertension	Agitation, confusion, psychosis, anxiety, insomnia, sialorrhea, EPS, akathisia, diarrhea, nausea, vomiting, bradycardia, hypotension, syncope
Adrenergic	Postural hypotension, dizziness, syncope	Tachycardia, hypertension, hypotension, dizziness

EPS = extrapyramidal symptoms.
Source: C Correll, "Assessing and maximizing the safety and tolerability of antipsychotics used in the treatment of children and adolescents." *J Clin Psychiatry* 69, suppl. 4 (2008): 26–36. Also see C. Correll, "Antipsychotic use in children and adolescents." *J Am Acad Child Adolesc Psychiatry* 47 (2008):9–20.

Thus, once a child or youth begins taking an antipsychotic, the child can be expected to experience many adverse events while on the drug, and to experience many distressing symptoms when trying to go off it.

THE EFFICACY OF SECOND GENERATION ANTIPSYCHOTICS IN CHILDREN AND ADOLESCENTS

The hope with any drug is that its benefit will outweigh the risks associated with its use. Because Risperdal and the other SGAs are so broad acting, they are bound to cause many adverse effects. As such, they should produce a marked therapeutic benefit of some type in children so that their use—when the risks and benefits are tallied up—can be assessed as helpful.

Short-Term Use

The FDA approved Risperdal and the other SGAs based on the results from industry-funded, short-term studies with adult schizophrenia

patients. The pharmaceutical companies then promoted their off-label use in pediatric populations. Eventually, the pharmaceutical companies funded trials of their SGAs in children and adolescents, and the results from those studies led the FDA to approve Risperdal, Zyprexa, Seroquel, and Abilify for schizophrenia, bipolar disorder, and irritability in autism.[19]

In a 2010 review of the published literature, Spanish investigators found reports of nine "placebo-controlled, randomized studies" of those four SGAs in children with psychotic and bipolar spectrum disorders. The industry-funded trials lasted from three to eight weeks. While the placebo patients in the trials saw their symptoms improve, the patients treated with one of the atypicals improved to a greater extent. As such, those industry-funded trials were seen as proving the efficacy of the four drugs for youth under 18 years old.[20]

However, when the National Institute of Mental Health (NIMH) conducted its TEOSS study of antipsychotics for early onset schizophrenia in youth 8 to 19 years old, the efficacy of the two SGAs that were tested was much more muted. The 116 youth enrolled in the trial were randomized to molindone (an FGA), Risperdal, or Zyprexa, and at the end of eight weeks, the response rate was 50 percent for those treated with molindone, 46 percent for those treated with Risperdal, and 34 percent for Zyprexa. Only 31 of the 76 youth treated with a SGA "responded" to the drug.[21]

Unfortunately, the TEOSS trial was not placebo controlled, and so it is impossible to know how those response rates would compare to outcomes in nonmedicated youth. Furthermore, in this trial, many of the patients were on other psychiatric medications (in addition to the antipsychotic), which obviously confounded the efficacy results. Those who were on antidepressants and mood stabilizers prior to the study were allowed to continue on those drugs, and during the eight-week trial, many of the children were prescribed drugs—anticholinergic agents, propranolol, and benzodiazepines—to counter the side effects of the antipsychotic agents. Given the lack of a placebo control and the use of these other psychotropic agents, this one government-funded trial of the SGAs provides no evidence that they are an effective short-term treatment for early onset schizophrenia.

Additional evidence for the short-term use of SGAs in pediatric populations consists of a handful of randomized studies that showed several of the drugs to be effective for controlling aggression and other disruptive behaviors (studies often conducted in children with autism).[22] Since antipsychotics are often sedating and may curb both motor movement and emotional engagement, the finding that SGAs are effective in curbing aggressive behavior over the short term was to be expected. The FGAs have long been used in zoos for such purposes.

Although the FDA has approved four SGAs for pediatric use, European and Canadian regulatory authorities have been much more cautious about giving their regulatory blessing for use of these agents in children. As of 2010, the only SGA licensed in Europe as an *antipsychotic* for pediatric use was Abilify (for schizophrenia patients 15 to 17 years old).[23] In several European countries, Risperdal is licensed for treating children with severe disruptive disorders (but not as an antipsychotic).[24] As of 2009, Health Canada had not approved any SGA for pediatric use.[25]

Long-Term Use

In the TEOSS study, those who initially responded to the drug (54 of 116 patients) were then followed for an additional 44 weeks. As the TEOSS investigators noted, theirs was the first well-designed study that sought to assess the effectiveness and safety of SGAs in juveniles for as long as one year. Unfortunately, the antipsychotics failed this test. In the 44-week drug-maintenance study, 40 of the 54 youth dropped out, mostly because of "adverse effects" or "inadequate response." Moreover, during this 44-week follow-up, those treated with Risperdal worsened *significantly* in their functional capacities, while those treated with Zyprexa worsened slightly in this regard. (There was no change in functioning in the molindone group.) In addition, the psychotic symptoms of the children treated with Risperdal or Zyprexa worsened to a small extent during the follow-up.[26]

Here, then, are the bottom-line results from the TEOSS study. Only 14 of the original cohort of 116 patients (12%) responded to an antipsychotic and then stayed on the drug and in the trial throughout the 44-week maintenance study. The remaining 102 children (88%) either failed to respond to an antipsychotic or dropped out during the maintenance period, mostly because of adverse effects or because they worsened on the drug. The NIMH researchers drew the obvious bottom-line conclusion: "Few youths with early onset schizophrenia who are treated with antipsychotic medications for up to a year appear to benefit from their initial treatment choice over the long-term."[27]

Unfortunately, since this longer-term trial wasn't placebo controlled, it doesn't provide any insight into how unmedicated patients might have fared at the end of one year. But in the industry-funded trials, the children treated with placebo did improve over the short term, and it is reasonable to think that such children might continue to improve if given some type of nondrug care for a longer period of time. Yet—and this shows the utter deficiency of the evidence base for prescribing SGAs to children—there has not been any study that has looked at that possibility.

As this review of the literature shows, there is no evidence that SGAs provide a benefit—in terms of symptom reduction and improvement in functioning compared to placebo—for *any* disorder at the end of one year. As such, in the risk-benefit analysis for long-term use, there is no positive finding that can be chalked up on the benefit side of the ledger. What remains then is to look at the harm these agents can cause.

EVIDENCE OF HARM DONE

Because the SGAs may act on a number of different neurotransmitter pathways, and may do so with varying degrees of potency, the adverse effects that the individual drugs cause can vary widely. But as a class of drugs, the SGAs cause a dizzying array of physical, emotional, and cognitive problems.

Movement Disorders

Although the SGAs may be less likely than the older antipsychotics to cause motor problems (extrapyramidal symptoms, or EPS), they still cause these problems with considerable frequency. In the one double-blind, randomized study that directly compared EPS rates with an FGA and SGAs in youth under 18 years old, 67 percent of the haloperidol group experienced "substantial EPS," versus 56 percent of those given Zyprexa and 53 percent of the Risperdal group.[28] While there have been a number of published studies reporting very low EPS rates in children treated with SGAs, those findings often have come from industry-funded studies of children with autism, with the autistic children having to "spontaneously report" that they were experiencing motor problems.[29]

The SGAs may also cause akathisia, a painful inner agitation associated with an increased risk of suicide and homicide. Five percent to 20 percent of pediatric patients may experience this side effect in a short trial.[30]

The published rates of tardive dyskinesia (TD) in children and adolescents treated with SGAs vary widely. TD is characterized by rhythmic involuntary motor movements, such as a constant licking of the lips, and often the abnormal movements don't go away even if the antipsychotic is withdrawn, which is evidence that the basal ganglia has been permanently damaged. In short industry-funded studies, researchers have reported seeing almost no cases of TD in their pediatric patients. However, TD is a condition that usually develops with longer exposure to antipsychotics, and two studies that looked at longer-term SGA use in children reported TD rates similar to what is seen in adult patients taking FGAs. Researchers at the University of Maryland

School of Medicine reported that 3 percent of the 116 pediatric patients they studied developed TD within 6 to 12 months on an SGA, and that 10 percent did so after being on the drugs for one to two years.[31] Spanish investigators reported an even higher rate: They determined that 38 percent of children and adolescents on antipsychotics for longer than one year showed signs of mild TD.[32] Fortunately, it appears that TD is more likely to disappear in pediatric patients than in adult patients if the offending antipsychotic is withdrawn, and thus, in this age group, the initial appearance of TD symptoms may not mean that the damage to the basal ganglia is beyond repair.

Metabolic Dysfunction

All SGAs can cause weight gain, with Zyprexa the worst offender in this regard. In a 6-month study of first-episode psychotic patients, the Zyprexa-treated youth gained an average of 34 pounds.[33] Israeli physicians reported that 90 percent of youth taking Zyprexa and 43 percent of those on Risperdal gained more than 7 percent of their baseline weight within 12 weeks.[34] When investigators at Cincinnati Children's Hospital and British Columbia Children's Hospital in Vancouver surveyed their juvenile patients with exposure to SGAs, they found that more than 50 percent were overweight or obese.[35] This weight gain, which is obviously problematic from a physical standpoint, may also cause pediatric patients to become depressed and suffer from low-esteem.[36]

The SGAs can also cause diabetes, which is one of the reasons that Eli Lilly and other SGA makers have been successfully sued for their off-label marketing of these agents to children. In 2010, Canadian investigators reported that 22 percent of pediatric patients treated with SGAs at a children's hospital in British Columbia had "impaired fasting glucose and or type 2 diabetes."[37] Since fat tissue can increase insulin resistance and glucose intolerance, this diabetes risk may be secondary to the weight gain. However, it appears that SGAs may also directly impair pancreatic beta-cell function and promote insulin resistance in that way.[38]

SGAs commonly cause a significant increase in triglycerides and LDL-cholesterol (dyslipidemia). In a survey of 95 juvenile inpatients at Cincinnati Children's Hospital who had been treated with an SGA for longer than 1 month, 51 percent had developed dyslipidemia.[39]

The weight gain, glucose intolerance, and dyslipidemia are all evidence that an SGA may profoundly impair the body's metabolic system. If a pediatric patient becomes obese and develops two other signs of metabolic dysfunction (high blood pressure, dyslipidemia, or high fasting glucose), the patient is said to have developed a "metabolic

syndrome." In their 2010 study, Canadian investigators determined that 27 percent of juvenile patients treated with an SGA on average for 12 months suffered from this broader level of metabolic dysfunction.[40]

The weight gain and metabolic impairment puts the pediatric patient on a path toward poor long-term physical health and ultimately early death. "Because drug-induced metabolic changes can persist over time and may not be fully reversible upon drug discontinuation, the implications for distal health outcomes can be profound," wrote the NIMH's Benedetto Vitiello in 2009. "Age-inappropriate weight gain and obesity increase the risk for a variety of negative outcomes, such as diabetes, hyperlipidemia, and hypertension, which are major risk factors for cardiovascular diseases and reduced quality of life and life expectancy."[41]

Endocrine Dysfunction

Several news stories reported on teenage boys prescribed Risperdal who have grown breasts and even begun lactating. This is because Risperdal may dramatically increase prolactin levels (and thus cause hyperolactinemia). While Risperdal is more likely than the other SGAs to cause this hormonal disruption, Spanish investigators reported in 2007 that 49 percent of youth treated with an SGA for longer than a year had hyperolactinemia.[42] This can cause breast enlargement and hypogonadism in males, and galactorrhea, amenorrhea, and hirsutism in females. Elevated prolactin levels may also cause a decrease in libido, sexual dysfunction, and decreased bone density. The bone density deficiency "may not be recovered later in life," and thus the SGA-treated child may end up with a lifelong increased risk of bone fractures.[43]

Other Adverse Effects

Researchers have reported that SGAs can occasionally cause elevated levels of liver enzymes in pediatric patients.[44] The cardiovascular risks associated with SGAs include cardiomegaly, tachycardia, arrhythmia, QTc prolongation, heart disease not otherwise specified, and high blood pressure.[45] In industry-funded trials, the reported adverse events included dizziness, facial flushing, dry mucous membranes, decreased sweating, constipation, urinary retention, headaches, blurred vision, and tinnitus.[46] Cases of neuroleptic malignant syndrome and pancreatitis, both of which can be fatal, have been reported in pediatric patients.[47]

SGAs can also cause an array of emotional and cognitive problems. In the TEOSS study, 26 percent of the patients reported being anxious.[48]

Other common side effects include irritability, depression, emotional lethargy, and decreased concentration.[49] SGAs are also sedating drugs, with more than half of the pediatric patients in some trials complaining of this effect, which is associated with "cognitive impairment and decreased mental activity."[50]

Poor Global Health

As can be seen from this review of adverse effects, the SGAs profoundly impair a child's physical, cognitive, and emotional well-being. While the percentage of children and adolescents who suffer any particular adverse effect may vary, nearly all children treated with an SGA will suffer an adverse effect of some type. The TEOSS investigators reported that 83 percent of the patients in the follow-up study suffered an "adverse" event.[51] Similarly, in a survey of 4,140 Medicaid youth treated with SGAs for longer periods of time, University of South Carolina researchers found that 47 percent suffered from digestive or urogenital problems; 36 percent had skin, musculoskeletal, or respiratory conditions; 9 percent had cardiovascular disorders; and 3 percent had diabetes. "The treated cohort exhibits a high incidence and diverse array of treatment-related adverse events," they concluded.[52]

LONG-TERM BRAIN DAMAGE

Although it may be that tardive dyskinesia is largely reversible when it first develops in children and adolescents, that return to health is likely to happen only if the offending SGA is withdrawn. But once youth are on SGAs, withdrawing from the drugs can be difficult, and often when youth experience problems on an SGA, they are then prescribed other psychiatric medications to go along with the antipsychotic, and thus they end up on drug cocktails. Given this common practice, it is reasonable to think that when researchers—at some point in the future—assess how children are doing after five years or more on an SGA, they will find high rates of TD, and that it will be much less reversible than it is in youth who have been on an SGA for only a few months.

In adults, the fact that TD often doesn't go away after the offending neuroleptic is withdrawn is evidence that the basal ganglia, which is the area of the brain that controls motor movement, has been permanently damaged. Adults who develop TD also show signs of a global decline in brain function. Researchers have determined that TD is associated with emotional disengagement, psychosocial impairment, and a decline in memory, visual retention, and the capacity to learn.[53] People with severe TD, one investigator concluded, lose their "road map to consciousness."[54]

In addition, there is now good evidence that both FGAs and SGAs shrink the brain, and that this shrinkage is associated with functional impairment and cognitive decline. In 1989, Nancy Andreasen, who was editor-in-chief of the *American Journal of Psychiatry* from 1993 to 2005, began a long-term study of more than 500 schizophrenia patients. She periodically measured their brain volumes with magnetic resonance scans, and in articles published in 2003 and 2005, she reported "progressive brain volume reductions" in her patients. This brain shrinkage, she found, was associated with increased emotional disengagement, functional impairment, and cognitive decline.[55]

In those 2003 and 2005 reports, Andreasen attributed the brain shrinkage to the disease, a pathological process that antipsychotics couldn't arrest. "The medications currently used cannot modify an injurious process occurring in the brain, which is the underlying basis of symptoms," she wrote in her 2003 paper. However, even as she was publishing those findings, other research—in animals and schizophrenia patients—indicated that the drugs might exacerbate this brain shrinkage (or be the primary cause of it). For instance, in a 2005 study of macaque monkeys, a daily dose of haloperidol or Zyprexa for 18 months led to an 8 percent to 11 percent reduction "in mean fresh brain weight" compared to controls.[56]

In 2011, Andreasen reported that the brain shrinkage in her schizophrenia patients was indeed drug related. She found that long-term use of FGAs, SGAs, and Clozaril was "associated with smaller brain tissue volumes," and that this shrinkage is dose related. The more of a drug a person is given, she wrote, the greater the "association with smaller grey matter volumes." Similarly, the "progressive decrement in white matter volume was most evident among patients who received more antipsychotic treatment." Finally, she determined that this shrinkage "occurs independent of illness severity and substance abuse." Those two factors—illness severity and substance abuse—had "minimal or no effects" on brain volumes.[57]

Andreasen's published articles convincingly tell of an iatrogenic process. Long-term use of an antipsychotic causes the brain to shrink, and as this occurs, the person's ability to think and function in the world declines. When children are placed on SGAs, this brain shrinkage will begin at an early age.

EARLY DEATH

Since the introduction of the SGAs, the mortality rate for schizophrenia patients has notably worsened.[58] In addition, a 2006 study found that the seriously mentally ill are now dying 15 to 25 years earlier than normal.[59] They are dying from cardiovascular ailments, respiratory problems,

metabolic illness, diabetes, kidney failure, and so forth—the physical ailments pile up as people stay on antipsychotics for years on end.

This early death is showing up in adults who were first treated with psychiatric medications when they were in their 20s or 30s. However, the children and adolescents being put on SGAs today will have years of exposure to these drugs by the time they reach their early 20s, which raises an obvious question: How much longer will they live on these agents? Will many die in their 30s? Early 40s? Fifteen to 20 years from now, reports in the scientific literature will provide us with the answer, and given what is known about these drugs, we can expect that the news will be grim.

WEIGHING ALL THE EVIDENCE

Such is the story that science tells about prescribing atypical antipsychotics to children and adolescents. In industry-funded trials, four SGAs were found to be effective over the short term in curbing the symptoms of schizophrenia and mania, and for curbing aggression and other disruptive behaviors in certain pediatric populations. However, in the one study funded by the NIMH, fewer than half of the patients responded to an antipsychotic in the short term, and at the end of 12 months, only 12 percent of the children were still on the initial antipsychotic, either because of side effects or because the drug didn't work.

The SGAs work by interfering with the normal functioning of multiple neurotransmitters, which is why they cause so many adverse effects. These drugs may impair metabolic, hormonal, muscular, and cardiovascular functions. Yet, once on an atypical, a younger person may have difficulty getting off the drug because of withdrawal effects, and so initial use often leads to long-term use, with the young patient ending up on a drug cocktail.

Those that stay on SGAs long term, into adulthood, can expect their lives to be diminished in multiple ways. They likely will suffer from poor physical health, and over time, as their brains shrink, their ability to function in society—their capacity to emotionally engage with others and to think—will diminish. They can expect to die quite early.

We can now return to the question raised at the beginning of this chapter. Does prescribing atypicals to children and adolescents help them to grow up and thrive as adults? Or is it doing great harm? Science provides a clear—and tragic—answer to that question.

11. Ibid.
12. Ibid., p. 281.
13. Olfson et al., Trends in Antipsychotic Drug Use.
14. Sheller, S. (2009, October). *Keynote Address.* ISPP Annual Conference, Syracuse, NY.
15. Ibid.
16. Olfson et al., Trends in Antipsychotic Drug Use.
17. Healy, D. (2007). Bipolar Syndrome by Proxy? The Case of Pediatric Bipolar Disorder. In Sharna Olfman, Ed., *Bipolar Children: Cutting Edge Controversy, Insight, and Research.* Praeger Press, Westport, CT; Healy, D. (2003). *Let Them Eat Prozac.* Toronto: James Lorimer & Company, pp. 12–13; Whitaker, *Mad in America.*
18. Diller, L. (2007). But Don't Call It Science. In Sharna Olfman, Ed., *Bipolar Children: Cutting Controversy, Insight, and Research* (pp. 28–45). Westport, CT: Praeger Publishers; Harris, G. (2009, March 19). Drug Maker Told Studies Would Aid It, Papers Say. *New York Times.* Retrieved from http://www.nytimes.com/2009/03/22/us/20psych.html; Kowalczyk, L. (2009, March 21). Senator broadens inquiry into psychiatrist. *Boston Globe,* p. B.1, Metro.
19. Whitaker, *Mad in America,* p. 281.
20. Healy, D., & Le Noury, J. (2007). Bipolar Syndrome by Proxy? The Case of Pediatric Bipolar Disorder. In Sharna Olfman, Ed., *Bipolar Children: Cutting Controversy, Insight, and Research, Praeger Publishers.* Westport, CT: Praeger Publishers.
21. Olfson et al., Trends in Antipsychotic Drug Use.
22. Olfman, S. (Ed.). (2006). *No Child Left Different.* Westport, CT: Praeger Publishers.
23. Olfman, S. (Ed.). (2005). *Childhood Lost.* Westport, CT: Praeger Publishers.
24. Carey, B. (2010, February 10). Revising Book on Disorders of the Mind. *New York Times.* Retrieved from http://www.nytimes.com/2010/02/10/health/10psych.html.

CHAPTER 1

1. J. Zito, "Psychotropic practice patterns for youth," *Arch Pediatr Adolesc Med* 157 (2003): 17–25.
2. This number is based upon the prescribing rates cited for the two populations, children under age 18 with private insurance and children covered by Medicaid. I assumed that children who didn't have health insurance were prescribed antipsychotics at the same rate as those covered by health insurance.
3. C. Moreno, "National trends in the outpatient diagnosis and treatment of bipolar disorder in youth," *Arch Gen Psychiatry* 64 (2007): 1032–39.
4. Deposition of Joseph Biederman in legal case of *Avila v. Johnson & Johnson Co.,* Feb. 26, 2009, pp. 139, 231, 232, 237.
5. J. Biederman, "Attention-deficit hyperactivity disorder and juvenile mania," *J Am Acad Child & Adolesc Psychiatry* 35 (1996): 997–1008.
6. Deposition of Joseph Biederman, p. 158.
7. G. Harris, "Researchers fail to reveal full drug pay," *New York Times,* June 8, 2008.
8. Deposition of Joseph Biederman, p. 119.
9. J. Biederman, *Annual Report 2002: The Johnson & Johnson Center for Pediatric Psychopathology at the Massachusetts General Hospital.*

10. C. Moreno, "National trends."
11. R. Waters, "J&J, Pfizer Profit on 'Juvenile Bipolar Juggernaut,'" *Bloomberg News*, Sept. 5, 2007.
12. M. Olfson, "National trends in the outpatient treatment of children and adolescents with antipsychotic drugs," *Arch Gen Psychiatry* 63 (2006): 679–85.
13. B. Vitiello, "Antipsychotics in children and adolescents," *Eur Neuropsychopharmacol* 19 (2009): 629–35; C. Panagiotopoulos, "First do no harm," *J Can Acad Child Adolesc Psychiatry* 19 (2010): 124–37.
14. P. Weiden, *Breakthroughs in Antipsychotic Medications* (New York: W.W. Norton, 1999), p. 26.
15. E. Nestler and S. Hyman, *Molecular Neuropharmacology* (New York: McGraw Hill, 2002), p. 392.
16. H. Nasrallah, "Atypical antipsychotic-induced metabolic side effects," *Mol Psychiatry* 13 (2008): 27–35.
17. Ibid. Also see M. DeHert, "Metabolic and endocrine adverse effects of second-generation antipsychotics in children and adolescents," *Eur Psychiatry* (2011), doi:10.1016.
18. C. Correll, "Antipsychotic use in children and adolescents," *J Am Acad Child Adolesc Psychiatry* 47 (2008): 9–20.
19. DeHert, "Metabolic and endocrine adverse effects"; Nasrallah, "Atypical antipsychotic-induced metabolic side effects."
20. D. Fraguas, "Efficacy and safety of second-generation antipsychotics in children and adolescents with psychotic and bipolar spectrum disorders," *Eur Neuropsychopharmacol* (2010), doi:10.1016.
21. L. Sikich, "Double-blind comparison of first-and second-generation antipsychotics in early-onset schizophrenia and schizoaffective disorder," *Am J Psychiatry* 165 (2008): 1420–31.
22. Vitiello, "Antipsychotics in children and adolescents."
23. DeHert, "Metabolic and endocrine adverse effects."
24. Vitiello, "Antipsychotics in children and adolescents."
25. Panagiotopoulos, "First do no harm."
26. R. Findling, "Double-blind maintenance safety and effectiveness findings from the treatment of early-onset schizophrenia spectrum (TEOSS) study," *J Am Acad Child & Adolesc Psychiatry* 49 (2010): 583–94.
27. NIMH press release, May 17, 2010, "Effectiveness of long-term use of antipsychotic medication to treat childhood schizophrenia is limited."
28. L. Sikich, "A pilot study of risperidone, olanzapine, and haloperidol in psychotic youth," *Neuropsychopharmacology* 29 (2004): 133–45.
29. Correll, "Antipsychotic use in children and adolescents."
30. Ibid. Also, C. Correll, "Assessing and maximizing the safety and tolerability of antipsychotics used in the treatment of children and adolescents," *J Clin Psychiatry* 69, suppl. 4 (2008): 26–36.
31. I. Wonodi, "Tardive dyskinesia in children treated with atypical antipsychotic medications," *Mov Disord* 22 (2007): 1777–82.
32. P. Laita, "Antipsychotic-related abnormal involuntary movements and metabolic and endocrine side effects in children and adolescents," *J Child Adolesc Psychopharmacol* 17 (2007): 487–502.
33. C. Arango, "Olanzapine compared to quetiapine in adolescents with a first psychotic episode," *Eur Child & Adolesc Psychiatry* 18 (2009): 418–28.

34. G. Ratzoni, "Weight gain associated with olanzapine and risperidone in adolescent patients," *J Am Acad Child Adolesc Psychiatry* 41 (2002): 337–43.

35. C. Pangiotopoulos, "Increased prevalence of obesity and glucose intolerance in youth treated with second-generation antipsychotic medications," *Can J Psychiatry* 54 (2009): 743–49; N. Patel. "Body mass indexes and lipid profiles in hospitalized children and adolescents exposed to atypical antipsychotics," *J Child & Adolesc Psychopharmacol* 17 (2007): 303–11.

36. Fraguas, "Efficacy and safety of second-generation antipsychotics"; DeHert, "Metabolic and endocrine adverse effects."

37. Panagiotopoulos, "First do no harm."

38. Ibid.

39. Patel, "Body mass indexes and lipid profiles."

40. Panagiotopoulos, "First do no harm."

41. Vitiello, "Antipsychotics in children and adolescents."

42. Laita, "Antipsychotic-related abnormal involuntary movements."

43. See DeHert, "Metabolic and endocrine adverse effects"; Vitiello, "Antipsychotics in children and adolescents"; Laita, "Antipsychotic-related abnormal involuntary movements"; Panagiotopoulos, "First do no harm"; and C. Correll, "Endocrine and metabolic adverse effects of psychotropic medications in children and adolescents," *J Acad Child Adolesc Psychiatry Am* 45 (2006): 771–90.

44. See De Hert, "Metabolic and endocrine adverse effects"; Panagiotopoulos, "First do no harm."

45. R. McIntyre, "Metabolic and cardiovascular adverse events associated with antipsychotic treatment in children and adolescents," *Arch Pediatr Adolesc Med* 162 (2008): 929–35. Also see De Hert, "Metabolic and endocrine adverse effects"; Panagiotopoulos, "First do no harm."

46. See Laita, "Antipsychotic-related abnormal involuntary movements"; De Hert, "Metabolic and endocrine adverse effects."

47. Correll, "Antipsychotic use in children and adolescents." Also see De Hert, "Metabolic and endocrine adverse effects."

48. Findling, "Double-blind maintenance safety and effectiveness findings."

49. Ibid.

50. L. Sikich, "Double-blind comparison of first-and second-generation antipsychotics." Also see Correll, "Assessing and maximizing the safety and tolerability of antipsychotics"; J. Jerrell, "Neurological adverse events associated with antipsychotic treatment in children and adolescents," *J Child Neurol* 23 (2008): 1392–99.

51. Findling, "Double-blind maintenance safety and effectiveness findings."

52. J. Jerrell, "Adverse events in children and adolescents treated with antipsychotic medications," *Hum Psychopharmacol* 23 (2008): 283–90.

53. J. Wade, "Tardive dyskinesia and cognitive impairment," *Biol Psychiatry* 22 (1987): 393–95.

54. M. Myslobodsky, "Central determinants of attention and mood disorder in tardive dyskinesia," *Brain Cognition* 23 (1993): 56–70.

55. B. Ho, "Progressive structural brain abnormalities and their relationship to clinical outcome," *Arch Gen Psychiatry* 60 (2003): 585–94. N; Andreasen, "Longitudinal changes in neurocognition during the first decade of schizophrenia illness," *Int Cong Schiz Res* (2005): 348.

56. K. Dorph-Petersen, "The influence of chronic exposure to antipsychotic medications on brain size before and after tissue fixation," *Neuropsychopharmacology* 30 (2005): 1649–61.

57. B. Ho, "Long-term antipsychotic treatment and brain volume," *Arch Gen Psychiatry* 68 (2011): 128–37.

58. M. Morgan, "Prospective analysis of premature mortality in schizophrenia in relation to health service engagement," *Psychiatry Res* 117 (2003): 127–35; S. Saha, "A systematic review of mortality in schizophrenia," *Arch Gen Psychiatry* 64 (2007): 1123–31; M. Joukamaa, "Schizophrenia, neuroleptic medication, and mortality," *Br J Psychiatry* 188 (2006): 122–27.

59. C. Colton, "Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states," *Prev Chronic Dis* 3 (April 2006).

CHAPTER 2

1. McIntyre, D. A. (2010, May 19). Big pharma makes more money on kids, use of medications among the young rises. 247wallst.com, n.p. Retrieved from http://247wallst.com/2010/05/19/big-pharma-makes-more-money-on-kids-use-of-medications-among-the-young-rises/.

2. Kozel, M. (2011, February 5). Little pharma: The medication of U.S. children. Huffington Post.com, n.p. Retrieved from http://www.huffingtonpost.com/maggie-kozel-md/childrens-health-care_b_803167.html.

3. Olson, J. (2011, June 23). Bipolar label soars among kids. *StarTribune*, n.p. Retrieved from http://www.startribune.com/lifestyle/wellness/124136764.html.

4. Donaldson, L. (2010, May 3). Psychiatric drugging of American children is cause for alarm. *Portland Press Herald*, n.p. http://www.pressherald.com/opinion/psychiatric-drugging-of-american-children-is-cause-for-alarm_2010-05-03.html.

5. Olfson, M., Blanco, C., Liu, L., Moreno, C., & Laje, G. (2006). National trends in the outpatient treatment of children and adolescents with antipsychotic drugs. *Archives of General Psychiatry, 63*(6), 679–685.

6. Szalavitz, M. (2011, May 26). Drugging the vulnerable: Atypical antipsychotics in children and the elderly. *Time*, n.p. Retrieved from http://healthland.time.com/2011/05/26/why-children-and-the-elderly-are-so-drugged-up-on-antipsychotics/print/; Kaplan, A. (2011, May 23). Nearly half of kids in inpatient psychiatric program receive antipsychotics. *Psychiatric Times*, n.p. Retrieved from http://www.psychiatrictimes.com/conference-reports/apa2011/content/article/10168/1865851.

7. Llorente, M. D., & Urrutia, V. (2006). Diabetes, psychiatry disorders, and the metabolic effects of antipsychotic medications. *Clinical Diabetes, 24*(1), 18–24.

8. Barnes, T.R.E., & Braude, W. M. (1985). Akathisia variants and tardive dyskinesia. *Archives of General Psychiatry, 42*(9), 874–878.

9. Ho, B. C., Andreason, N. C., Zieball, S., Pierson, R., & Magnota, V. (2011). Long-term antipsychotic treatment and brain volume: A longitudinal study of first-episode schizophrenia. *Archives of General Psychiatry, 28*(2), 128–137.

10. Whitaker, R. (2010). *Anatomy of an epidemic: Magic bullets, psychiatry drugs, and the astonishing rise of mental illness in America.* New York: Crown Publishers.

DRUGDEX-CON 3198

MICROMEDEX
DRUGDEX® Consults
Database updated September 2013

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

The Micromedex Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminate	Evidence Inconclusive	

Table 2. Strength Of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.
No Evidence	

Exhibit 3

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.

DRUGDEX-CON 3198

END OF DOCUMENT

Exhibit 3

Jim Gottstein

From: YouSendIt <delivery@yousendit.com>
Sent: Wednesday, November 06, 2013 2:07 PM
To: jim.gottstein@psychrights.org
Subject: File Delivered: Geodon Prescriptions Constituting False Claims

To: bradley.foley@gebsc.com,
mark.larson@gebsc.com,
tobywatson@abcmedsfree.com,
gietmanlaw@gmail.com,
jim.gottstein@psychrights.org

Subject: Geodon Prescriptions Constituting False Claims

Message:

Dear Messrs. Larson and Foley,

Because of the confidential nature of the information, I am using this secure, encrypted and password protected method of transferring files subject to the HIPAA Qualified Protective Orders. I will call Brad with the Password.

As you know, yesterday, we received the electronic discovery from the State of Wisconsin. Because Geodon has no medically accepted indications for anyone under 18 years of age, it was the easiest to work with and we have extracted such prescriptions in the files uploaded here. One document is the table with the relevant information and the other is a report that includes damages calculations.

If you have not received the electronic discovery from the State of Wisconsin, let me know and I will also upload it.

Sincerely

James B. Gottstein

131106Geodon_Summary.pdf
Size: 75.73 KB **Expires:** November 20, 2013 15:07 PST

View File

131106GeodonTable.pdf

Size: 64.08 KB **Expires:** November 20, 2013 15:07 PST

View File

Here's the link to this file:
http://www.hightail.com/download/OGhjeFlRUzhBNkgwZXNUQw

Options:

Password protect your file

These files are password protected. You must notify your recipient(s) of the password to access the file.

Learn More

Verify recipient identity

You requested verification of recipient identity for this transaction. The recipient(s) will be required to verify their identity by logging into Hightail.

Learn More

Get a return receipt

You requested a Return Receipt for this transaction.

Learn More

Jim Gottstein

From: Jim Gottstein <jim.gottstein@psychrights.org>
Sent: Thursday, November 07, 2013 6:04 PM
To: Mark Larson; Brad Foley (bradley.foley@gebsc.com)
Cc: Dr. Toby Watson (tobywatson@abcmedsfree.com); Rebecca Gietman (gietmanlaw@gmail.com)
Subject: New Settlement Offer
Attachments: 131107Last2PagesFrom131106Geodon_Summary-2_Redacted.pdf

Hi Mark and Brad,

It does not appear to me that you have downloaded the materials I sent you yesterday with just the Geodon prescriptions pulled out. I have therefore (hopefully) attached redacted two last pages of the summary report which include the Geodon prescriptions to L.H., and the total damages calculation for just the Geodon prescriptions (it does not include a half dozen or so additional prescriptions for the generic version, ziprasidone, which will add to the total).

If you have reviewed the electronic data, you will notice there are just over 30,000 prescriptions. As I have repeatedly informed you, if we got additional prescriptions, the damages get extremely large. We got them.

There are probably at least 10,000 prescriptions that are not for a medically accepted indication as defined in the Medicaid Statute. That would make the federal minimum penalty $55 million. However, we are probably going to stop at 1,000, making the federal minimum penalty $5.5 million. If they are also false claims for Wisconsin, the minimum penalty is $10.5 million.

[redacted]

James B. (Jim) Gottstein, Esq.
President/CEO

Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501 USA
Phone: (907) 274-7686 Fax: (907) 274-9493
jim.gottstein@psychrights.org

http://psychrights.org/

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging and electroshock. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions. Extensive information about all of this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

Initials L H DOB

RECIPIENT_ID	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS	14	1-May-08	4008122082647	175.91
GEODON 20 MG CAPS	14	29-Sep-08	4008273065736	176.41
GEODON 20 MG CAPS	15	5-Jan-09	2509005032997	172.99
GEODON 20 MG CAPS	15	12-Mar-09	2509071049096	187.41

Summary for L H Geodon Prescriptions

9405209396 (4 prescriptions)

Total Paid	$712.72
Treble Damages	$2,138.16
Federal Min. Penalty	$22,000.00
Wisconsin Min. Penalty	$20,000.00
Total Min. Penalty	$44,138.16

Geodon Summary

Total Prescription Count

134

Treble Damages	$89,731.89
Federal Min. Penalty	$737,000.00
Wisconsin Min. Penalty	$670,000.00
Total Min. Penalty	$1,496,731.89

Gutglass
Erickson
Bonville&Larson S.C.
A LIMITED LIABILITY ORGANIZATION

BRADLEY S. FOLEY
bradley.foley@gebsc.com

writer's direct: 414-908-0240

November 8, 2013

Via facsimile only
Attorney James B. Gottstein
Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, AK 99501

Re: Watson v. King-Vassel
Case No: 11-CV-236
Our File No: 911.19

Dear Mr. Gottstein:

We are in receipt of your email providing electronic access to Geodon prescriptions. We do not believe that we should be required to sign up for a commercial web site in order to receive protected health information that is already covered pursuant to a court order. Moreover, we should not be permitted to sign into a web site that is monitored by the plaintiff or his attorneys, and that will not be available for download after November 20, 2013. Pursuant to Fed. R. Civ. P. 26(b)(2), this mandate is an undue burden and is cumbersome.

Please provide copies of the documents you reference by facsimile or email. Thank you.

Very truly yours,

Bradley S. Foley

Bradley S. Foley

BSF\cgw

cc: (via facsimile): Attorney Rebecca L. Gietman

Exhibit 6

Jim Gottstein

From: Jim Gottstein <jim.gottstein@psychrights.org>
Sent: Friday, November 08, 2013 1:51 PM
To: Brad Foley (bradley.foley@gebsc.com)
Cc: Mark Larson; tobywatson@gmail.com; Rebecca Gietman (gietmanlaw@gmail.com); jim.gottstein@psychrights.org; tobywatson@gmail.com
Subject: Fax
Attachments: 131105Geodon_Summary.pdf; Geodon.xlsx

Hi Brad,

I received your fax and have (hopefully) attached the two documents you requested I e-mail or fax. Since one is an Excel spreadsheet, it seems e-mail or snail mailing a disk is the only way to do it since YouSendIt is unacceptable to you.

I didn't think you had to sign up to receive the documents from YouSendIt. Maybe it was because I required it to verify identity identities.

Also, I mailed the *Relator's* Third Supplement to Initial Disclosures yesterday and it identified 26 megabytes of documents at YouSendIt. Since these didn't have any HIPAA protected information, I didn't password protect it. Maybe it won't make you sign up to retrieve them. I suppose I could post them on PsychRights' website like the last one if you want. Or snail mail a disk.

Speaking of *Relator's* Third Supplement to Initial Disclosures, after agreeing to serve as a rebuttal expert yesterday, today, Dr. Irwin realized the short timeframe and schedule just wouldn't work for him and he won't be able to do it. So, that part of the supplemental disclosure is no longer applicable.

James B. (Jim) Gottstein, Esq.
President/CEO

Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501 USA
Phone: (907) 274-7686 Fax: (907) 274-9493
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body damaging interventions against their will. Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions. Extensive information about all of this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

Geodon Summary

Initials	C S	DOB				
RECIPIENT_ID	400462109	[redacted]90	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS			16	17-Aug-07	4007229033370	161.74
GEODON 40 MG CAPS			16	17-Aug-07	4007229033364	161.74

Summary for C S Geodon Prescriptions

400462109 (2 prescriptions)

Total Paid	$323.48
Treble Damages	$970.44
Federal Min. Penalty	$11,000.00
Wisconsin Min. Penalty	$10,000.00
Total Penalty	$21,970.44

Initials	J H	DOB				
RECIPIENT_ID	405122501	[redacted]89	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 60 MG CAPS			15	19-Mar-05	108505078111080	296.27

Summary for J H Geodon Prescriptions

405122501 (1 prescription)

Total Paid	$296.27
Treble Damages	$888.81
Federal Min. Penalty	$5,500.00
Wisconsin Min. Penalty	$5,000.00
Total Penalty	$11,388.81

Initials	C D	DOB				
RECIPIENT_ID	1403314811	[redacted]96	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS			11	27-Mar-08	4008087058085	347.43

Summary for C D Geodon Prescriptions

1403314811 (1 prescription)

Total Paid	$347.43
Treble Damages	$1,042.29
Federal Min. Penalty	$5,500.00
Wisconsin Min. Penalty	$5,000.00
Total Penalty	$11,542.29

Initials	A S	DOB				
RECIPIENT_ID	1403950318	[redacted]92	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS			14	12-Jul-06	4006193049064	7.85
GEODON 40 MG CAPS			14	6-Aug-06	4006218002937	62.73
GEODON 40 MG CAPS			14	2-Sep-06	4006245008176	62.73
GEODON 40 MG CAPS			14	28-Sep-06	4006271052865	62.73
GEODON 40 MG CAPS			14	7-Mar-07	4007066047575	63.22
GEODON 40 MG CAPS			15	7-Apr-07	4007097009539	63.22

Summary for A S Geodon Prescriptions

1403950318 (6 prescriptions)

Total Paid	$322.48
Treble Damages	$967.44
Federal Min. Penalty	$33,000.00
Wisconsin Min. Penalty	$30,000.00
Total Penalty	$63,967.44

Initials	Y A	DOB				
RECIPIENT_ID	1411704711	[redacted]-93	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS			16	7-Apr-09	2509097023795	371.37

Summary for Y A Geodon Prescriptions

1411704711 (1 prescription)

Total Paid	$371.37
Treble Damages	$1,114.11
Federal Min. Penalty	$5,500.00
Wisconsin Min. Penalty	$5,000.00
Total Penalty	$11,614.11

Initials	C B	DOB				
RECIPIENT_ID	1413467814	[redacted]-02	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS			9	18-May-11	2511138046676	435.99
GEODON 20 MG CAPS			9	5-Aug-11	2511217052111	474.91

Summary for C B Geodon Prescriptions

1413467814 (2 prescriptions)

Total Paid	$910.90
Treble Damages	$2,732.70
Federal Min. Penalty	$11,000.00
Wisconsin Min. Penalty	$10,000.00
Total Penalty	$23,732.70

Initials K M DOB [redacted]92

RECIPIENT_ID 1425230016

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 80 MG CAPS	16	28-Aug-08	4008241052168	50.07
GEODON 80 MG CAPS	16	3-Sep-08	4008247084599	418.18

Summary for K M Geodon Prescriptions

1425230016 (2 prescriptions)

Total Paid	$468.25
Treble Damages	$1,404.75
Federal Min. Penalty	$11,000.00
Wisconsin Min. Penalty	$10,000.00
Total Penalty	$22,404.75

Initials N S DOB [redacted]95

RECIPIENT_ID 2407794621

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 80 MG CAPS	15	5-Apr-10	2510095084200	503.36
GEODON 80 MG CAPS	15	29-Apr-10	2510119048554	503.36
GEODON 60 MG CAPS	15	18-Jun-10	2510169071389	120.09
GEODON 80 MG CAPS	15	18-Jun-10	2510169071398	120.09
GEODON 60 MG CAPS	15	3-Aug-10	2510215022584	253.4
GEODON 80 MG CAPS	15	3-Aug-10	2510215022605	253.4
GEODON 80 MG CAPS	15	31-Aug-10	2510243034452	253.4
GEODON 60 MG CAPS	15	31-Aug-10	2510243034421	253.4
GEODON 60 MG CAPS	15	1-Oct-10	2510274047447	253.4

Summary for N S Geodon Prescriptions

2407794621 (9 prescriptions)

Total Paid	$2,513.90
Treble Damages	$7,541.70
Federal Min. Penalty	$49,500.00
Wisconsin Min. Penalty	$45,000.00
Total Penalty	$102,041.70

Initials C D DOB

RECIPIENT_ID 2409497322 [redacted]91

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS	14	24-Aug-06	4006236001768	284.96
GEODON 20 MG CAPS	15	2-Apr-07	4007094041076	304.12
GEODON 20 MG CAPS	15	2-Aug-07	4007214038215	166.99
GEODON 40 MG CAPS	15	2-Aug-07	4007214038235	166.99
GEODON 40 MG CAPS	15	5-Sep-07	4007248052076	140.76
GEODON 20 MG CAPS	15	5-Sep-07	4007248052007	140.76
GEODON 40 MG CAPS	15	29-Sep-07	4007272007191	166.99
GEODON 20 MG CAPS	15	29-Sep-07	4007272007175	166.99
GEODON 40 MG CAPS	16	31-Oct-07	4007304044508	166.99
GEODON 20 MG CAPS	16	31-Oct-07	4007304044500	166.99
GEODON 40 MG CAPS	16	30-Nov-07	4007334023090	166.99
GEODON 20 MG CAPS	16	30-Nov-07	4007334023104	166.99
GEODON 40 MG CAPS	16	3-Jan-08	4008003018741	166.99
GEODON 20 MG CAPS	16	3-Jan-08	4008003018736	166.99
GEODON 60 MG CAPS	16	30-Jan-08	4008030010792	212.53
GEODON 60 MG CAPS	16	1-Mar-08	4008061006563	212.53
GEODON 60 MG CAPS	16	2-Apr-08	4008093022712	212.53
GEODON 60 MG CAPS	16	2-May-08	4008123028089	212.53

GEODON 60 MG CAPS	16	31-May-08	4008152011141	212.53
GEODON 80 MG CAPS	16	24-Jun-08	4008176086130	212.53
GEODON 80 MG CAPS	16	26-Jul-08	4008208002783	212.53
GEODON 80 MG CAPS	16	2-Sep-08	4008246129088	213.03
GEODON 80 MG CAPS	16	19-Sep-08	4008263034842	213.03
GEODON 80 MG CAPS	17	3-Nov-08	4008308070284	213.03
GEODON 80 MG CAPS	17	26-Nov-08	2508331032942	209.2
GEODON 80 MG CAPS	17	30-Dec-08	2508365058812	209.2
GEODON 20 MG CAPS	17	3-Feb-09	2509034064213	187.41
GEODON 80 MG CAPS	17	3-Feb-09	2509034064239	226.69
GEODON 80 MG CAPS	17	4-Mar-09	2509063054209	226.69
GEODON 20 MG CAPS	17	4-Mar-09	2509063054231	187.41
GEODON 20 MG CAPS	17	1-May-09	2509121063564	187.41
GEODON 80 MG CAPS	17	1-May-09	2509121063498	226.69
GEODON 20 MG CAPS	17	8-Jun-09	2509159063976	187.41
GEODON 80 MG CAPS	17	8-Jun-09	2509159063943	226.69
GEODON 80 MG CAPS	17	31-Jul-09	2509212027879	226.69
GEODON 20 MG CAPS	17	31-Jul-09	2509212027900	187.41
GEODON 20 MG CAPS	17	31-Aug-09	2509243071004	203.96
GEODON 80 MG CAPS	17	31-Aug-09	2509243070950	246.78
GEODON 20 MG CAPS	17	6-Oct-09	2509279044911	195.94
GEODON 80 MG CAPS	17	6-Oct-09	2509279044946	237.05

Summary for C D Geodon Prescriptions

2409497322 (40 prescriptions)

Total Paid	$8,039.93
Treble Damages	$24,119.79
Federal Min. Penalty	$220,000.00
Wisconsin Min. Penalty	$200,000.00
Total Penalty	$444,119.79

Initials N J DOB [redacted]94

RECIPIENT_ID 2412420424

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS	12	7-Aug-07	4007219019388	161.74
GEODON 80 MG CAPS	12	17-Aug-07	4007229011121	195.35
GEODON 80 MG CAPS	12	31-Aug-07	4007243058870	195.35
GEODON 20 MG CAPS	12	31-Aug-07	4007243007441	161.74

Summary for N J Geodon Prescriptions

2412420424 (4 prescriptions)

Total Paid	$714.18
Treble Damages	$2,142.54
Federal Min. Penalty	$22,000.00
Wisconsin Min. Penalty	$20,000.00
Total Penalty	$44,142.54

Initials S P DOB [redacted]89

RECIPIENT_ID 2416557726

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS	15	11-May-05	108505131389470	272.42
GEODON 20 MG CAPS	15	14-Jun-05	108505165519700	272.42
GEODON 20 MG CAPS	15	10-Jul-05	108505191112350	272.42

Summary for S P Geodon Prescriptions

2416557726 (3 prescriptions)

Total Paid	$817.26
Treble Damages	$2,451.78
Federal Min. Penalty	$16,500.00
Wisconsin Min. Penalty	$15,000.00
Total Penalty	$33,951.78

Initials	C M	DOB				
RECIPIENT_ID	3424275433	13-Apr-92	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS			14	27-Dec-06	4006361073492	42.73
GEODON 20 MG CAPS			14	21-Jan-07	4007021001551	43.22
GEODON 20 MG CAPS			14	12-Feb-07	4007043057259	35.47
GEODON 20 MG CAPS			14	15-Feb-07	4007046059114	45.81
GEODON 20 MG CAPS			14	10-Apr-07	4007100040234	48.39
GEODON 20 MG CAPS			15	15-May-07	4007135084384	48.39
GEODON 20 MG CAPS			15	15-Jun-07	4007166005834	48.39
GEODON 20 MG CAPS			15	22-Jul-07	4007203003692	26.69
GEODON 20 MG CAPS			15	22-Aug-07	4007234043357	49.16
GEODON 20 MG CAPS			15	21-Sep-07	4007264046533	49.16
GEODON 20 MG CAPS			15	21-Oct-07	4007294001586	49.16
GEODON 20 MG CAPS			15	19-Nov-07	4007323013486	49.16
GEODON 20 MG CAPS			15	23-Dec-07	4007357002102	49.16
GEODON 20 MG CAPS			15	20-Jan-08	4008020001367	50.63
GEODON 20 MG CAPS			15	24-Feb-08	4008055007654	50.63
GEODON 20 MG CAPS			15	22-Mar-08	4008082013911	50.63
GEODON 20 MG CAPS			16	26-Apr-08	4008117013169	50.63
GEODON 40 MG CAPS			16	16-May-08	4008137004048	44.71
GEODON 40 MG CAPS			16	23-Jun-08	4008175074567	44.71
GEODON 40 MG CAPS			16	27-Jul-08	4008209000593	44.71
GEODON 80 MG CAPS			16	20-Sep-08	4008264008584	40.56
GEODON 80 MG CAPS			16	20-Oct-08	4008294048472	40.56

GEODON 80 MG CAPS	16	17-Jan-09	2509017024455	39.72
GEODON 80 MG CAPS	17	2-May-09	2509122027494	39.72

Summary for C M Geodon Prescriptions

3424275433 (24 prescriptions)

Total Paid	$1,082.10
Treble Damages	$3,246.30
Federal Min. Penalty	$132,000.00
Wisconsin Min. Penalty	$120,000.00
Total Penalty	$255,246.30

Initials J N DOB

RECIPIENT_ID 4425482441 [redacted]92

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS	14	1-May-07	4007121061815	304.12
GEODON 20 MG CAPS	14	1-Jun-07	4007152054335	453.99
GEODON 20 MG CAPS	14	5-Jul-07	4007186009763	48.39
GEODON 20 MG CAPS	15	27-Jul-07	4007208036497	49.16
GEODON 20 MG CAPS	15	2-Sep-07	4007245002720	49.16
GEODON 20 MG CAPS	15	2-Oct-07	4007275012747	49.16
GEODON 20 MG CAPS	15	1-Nov-07	4007305052329	48.73
GEODON 20 MG CAPS	15	2-Dec-07	4007336005073	476.46
GEODON 20 MG CAPS	15	3-Jan-08	4008003060546	476.46
GEODON 20 MG CAPS	15	3-Feb-08	4008034006007	518.96
GEODON 20 MG CAPS	15	29-Mar-08	4008089001614	518.96
GEODON 20 MG CAPS	15	28-Apr-08	4008119073666	518.96
GEODON 20 MG CAPS	15	3-Jun-08	4008155036581	518.96
GEODON 20 MG CAPS	15	3-Jul-08	4008186002537	518.96
GEODON 20 MG CAPS	17	1-Sep-09	2509244073872	605.01
GEODON 20 MG CAPS	17	30-Sep-09	2509273068527	580.93

GEODON 20 MG CAPS	17	28-Oct-09	2509301003611	580.93
GEODON 20 MG CAPS	17	17-Dec-09	2509351083173	580.93
GEODON 20 MG CAPS	17	22-Feb-10	2510053050670	621.35
GEODON 20 MG CAPS	17	26-Mar-10	2510085040058	621.35
GEODON 20 MG CAPS	17	24-Apr-10	2510114014698	621.35
GEODON 20 MG CAPS	17	23-May-10	2510143023057	621.35
GEODON 20 MG CAPS	17	28-Jun-10	2510179068572	621.35

Summary for J N Geodon Prescriptions

4425482441 (23 prescriptions)

Total Paid	$10,004.98
Treble Damages	$30,014.94
Federal Min. Penalty	$126,500.00
Wisconsin Min. Penalty	$115,000.00
Total Penalty	$271,514.94

Initials J W DOB

RECIPIENT_ID 6403559168 ######### Age

	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS	1-Apr-11	2511091050735	219.71

Summary for J W Geodon Prescriptions

6403559168 (1 prescription)

Total Paid	$219.71
Treble Damages	$659.13
Federal Min. Penalty	$5,500.00
Wisconsin Min. Penalty	$5,000.00
Total Penalty	$11,159.13

Initials B M DOB

RECIPIENT_ID 6412307362 [redacted]-93 Age

	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS	9-Jul-09	2509190048755	371.37
GEODON 40 MG CAPS	4-Aug-09	2509216049823	371.37

Summary for B M Geodon Prescriptions

6412307362 (2 prescriptions)

Total Paid	$742.74
Treble Damages	$2,228.22
Federal Min. Penalty	$11,000.00
Wisconsin Min. Penalty	$10,000.00
Total Penalty	$23,228.22

Initials J C DOB

RECIPIENT_ID 6412585362 [redacted]-95

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 80 MG CAPS	10	30-Aug-06	4006242087947	315.24
GEODON 80 MG CAPS	11	5-Oct-06	4006278056659	315.24
GEODON 80 MG CAPS	11	2-Nov-06	4006306061067	315.24
GEODON 80 MG CAPS	11	3-Dec-06	4006337005726	315.24
GEODON 80 MG CAPS	11	13-Jan-07	4007013005751	344.47

Summary for J C Geodon Prescriptions

6412585362 (5 prescriptions)

Total Paid	$1,605.43
Treble Damages	$4,816.29
Federal Min. Penalty	$27,500.00
Wisconsin Min. Penalty	$25,000.00
Total Penalty	$57,316.29

Initials W L DOB

RECIPIENT_ID 7407833974 #########

	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS	13	1-Dec-08	2508336062071	172.99

Summary for W L Geodon Prescriptions

7407833974 (1 prescription)

Total Paid	$172.99
Treble Damages	$518.97
Federal Min. Penalty	$5,500.00
Wisconsin Min. Penalty	$5,000.00
Total Penalty	$11,018.97

Initials	A K	DOB				
RECIPIENT_ID	8410078384	[redacted]94	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS			15	23-Jun-10	2510174008966	45.13
GEODON 40 MG CAPS			15	17-Jul-10	2510198009735	45.13

Summary for A K Geodon Prescriptions

8410078384 (2 prescriptions)

Total Paid	$90.26
Treble Damages	$270.78
Federal Min. Penalty	$11,000.00
Wisconsin Min. Penalty	$10,000.00
Total Penalty	$21,270.78

Initials	B B	DOB				
RECIPIENT_ID	8426691382	[redacted]-94	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 40 MG CAPS			13	8-Mar-07	4007067044611	154.25

Summary for B B Geodon Prescriptions

8426691382 (1 prescription)

Total Paid	$154.25
Treble Damages	$462.75
Federal Min. Penalty	$5,500.00
Wisconsin Min. Penalty	$5,000.00
Total Penalty	$10,962.75

Initials	L H	DOB				
RECIPIENT_ID	9405209396	[redacted]-93	Age	First date of service on the claim	Claim No.(ICN)	TOTAL_PAID_AMT
GEODON 20 MG CAPS			14	1-May-08	4008122082647	175.91
GEODON 20 MG CAPS			14	29-Sep-08	4008273065736	176.41
GEODON 20 MG CAPS			15	5-Jan-09	2509005032997	172.99
GEODON 20 MG CAPS			15	12-Mar-09	2509071049096	187.41

Summary for L H Geodon Prescriptions

9405209396 (4 prescriptions)

Total Paid	$712.72
Treble Damages	$2,138.16
Federal Min. Penalty	$22,000.00
Wisconsin Min. Penalty	$20,000.00
Total Penalty	$44,138.16

Grand Total $29,910.63

Geodon Summary

Total Prescription Count 134

Treble Damages	$89,731.89
Federal Min. Penalty	$737,000.00
Wisconsin Min. Penalty	$670,000.00
Total Penalty	$1,496,731.89

LABEL_NAME_DESC	MEMBER_NAME	ICN	RECIPIENT_ID	FIRST_DATE_OF_SERVICE	PAID_DATE
GEODON 20 MG CAPSULE	C S	4007229033370	400462109	17-Aug-07	19-Aug-07
GEODON 40 MG CAPSULE	C S	4007229033364	400462109	17-Aug-07	19-Aug-07
GEODON 60 MG CAPSULE	J H	108505078111080	405122501	19-Mar-05	25-Mar-05
GEODON 40 MG CAPSULE	C D	4008087058085	1403314811	27-Mar-08	28-Mar-08
GEODON 40 MG CAPSULE	A S	4006193049064	1403950318	12-Jul-06	16-Jul-06
GEODON 40 MG CAPSULE	A S	4006218002937	1403950318	6-Aug-06	13-Aug-06
GEODON 40 MG CAPSULE	A S	4006245008176	1403950318	2-Sep-06	10-Sep-06
GEODON 40 MG CAPSULE	A S	4006271052865	1403950318	28-Sep-06	29-Sep-06
GEODON 40 MG CAPSULE	A S	4007066047575	1403950318	7-Mar-07	11-Mar-07
GEODON 40 MG CAPSULE	A S	4007097009539	1403950318	7-Apr-07	15-Apr-07
GEODON 20 MG CAPSULE	Y A	2509097023795	1411704711	7-Apr-09	13-Apr-09
GEODON 20 MG CAPSULE	C B	2511138046676	1413467814	18-May-11	23-May-11
GEODON 20 MG CAPSULE	C B	2511217052111	1413467814	5-Aug-11	8-Aug-11
GEODON 80 MG CAPSULE	K M	4008241052168	1425230016	28-Aug-08	29-Aug-08
GEODON 80 MG CAPSULE	K M	4008247084599	1425230016	3-Sep-08	7-Sep-08
GEODON 80 MG CAPSULE	N S	2510095084200	2407794621	5-Apr-10	12-Apr-10
GEODON 80 MG CAPSULE	N S	2510119048554	2407794621	29-Apr-10	3-May-10
GEODON 60 MG CAPSULE	N S	2510169071389	2407794621	18-Jun-10	28-Jun-10
GEODON 80 MG CAPSULE	N S	2510169071398	2407794621	18-Jun-10	28-Jun-10
GEODON 60 MG CAPSULE	N S	2510215022584	2407794621	3-Aug-10	9-Aug-10
GEODON 80 MG CAPSULE	N S	2510215022605	2407794621	3-Aug-10	9-Aug-10
GEODON 80 MG CAPSULE	N S	2510243034452	2407794621	31-Aug-10	7-Sep-10
GEODON 60 MG CAPSULE	N S	2510243034421	2407794621	31-Aug-10	7-Sep-10
GEODON 60 MG CAPSULE	N S	2510274047447	2407794621	1-Oct-10	4-Oct-10
GEODON 20 MG CAPSULE	C D	4006236001768	2409497322	24-Aug-06	25-Aug-06
GEODON 20 MG CAPSULE	C D	4007094041076	2409497322	2-Apr-07	8-Apr-07
GEODON 20 MG CAPSULE	C D	4007214038215	2409497322	2-Aug-07	5-Aug-07
GEODON 40 MG CAPSULE	C D	4007214038235	2409497322	2-Aug-07	5-Aug-07
GEODON 40 MG CAPSULE	C D	4007248052076	2409497322	5-Sep-07	9-Sep-07
GEODON 20 MG CAPSULE	C D	4007248052007	2409497322	5-Sep-07	9-Sep-07
GEODON 40 MG CAPSULE	C D	4007272007191	2409497322	29-Sep-07	7-Oct-07
GEODON 20 MG CAPSULE	C D	4007272007175	2409497322	29-Sep-07	7-Oct-07
GEODON 40 MG CAPSULE	C D	4007304044508	2409497322	31-Oct-07	4-Nov-07
GEODON 20 MG CAPSULE	C D	4007304044500	2409497322	31-Oct-07	4-Nov-07

GEODON 40 MG CAPSULE	C D	4007334023090	2409497322	30-Nov-07	30-Nov-07
GEODON 20 MG CAPSULE	C D	4007334023104	2409497322	30-Nov-07	30-Nov-07
GEODON 40 MG CAPSULE	C D	4008003018741	2409497322	3-Jan-08	6-Jan-08
GEODON 20 MG CAPSULE	C D	4008003018736	2409497322	3-Jan-08	6-Jan-08
GEODON 60 MG CAPSULE	C D	4008030010792	2409497322	30-Jan-08	3-Feb-08
GEODON 60 MG CAPSULE	C D	4008061006563	2409497322	1-Mar-08	9-Mar-08
GEODON 60 MG CAPSULE	C D	4008093022712	2409497322	2-Apr-08	6-Apr-08
GEODON 60 MG CAPSULE	C D	4008123028089	2409497322	2-May-08	4-May-08
GEODON 60 MG CAPSULE	C D	4008152011141	2409497322	31-May-08	8-Jun-08
GEODON 80 MG CAPSULE	C D	4008176086130	2409497322	24-Jun-08	27-Jun-08
GEODON 80 MG CAPSULE	C D	4008208002783	2409497322	26-Jul-08	3-Aug-08
GEODON 80 MG CAPSULE	C D	4008246129088	2409497322	2-Sep-08	7-Sep-08
GEODON 80 MG CAPSULE	C D	4008263034842	2409497322	19-Sep-08	21-Sep-08
GEODON 80 MG CAPSULE	C D	4008308070284	2409497322	3-Nov-08	9-Nov-08
GEODON 80 MG CAPSULE	C D	2508331032942	2409497322	26-Nov-08	1-Dec-08
GEODON 80 MG CAPSULE	C D	2508365058812	2409497322	30-Dec-08	5-Jan-09
GEODON 20 MG CAPSULE	C D	2509034064213	2409497322	3-Feb-09	9-Feb-09
GEODON 80 MG CAPSULE	C D	2509034064239	2409497322	3-Feb-09	9-Feb-09
GEODON 80 MG CAPSULE	C D	2509063054209	2409497322	4-Mar-09	9-Mar-09
GEODON 20 MG CAPSULE	C D	2509063054231	2409497322	4-Mar-09	9-Mar-09
GEODON 20 MG CAPSULE	C D	2509121063564	2409497322	1-May-09	4-May-09
GEODON 80 MG CAPSULE	C D	2509121063498	2409497322	1-May-09	4-May-09
GEODON 20 MG CAPSULE	C D	2509159063976	2409497322	8-Jun-09	15-Jun-09
GEODON 80 MG CAPSULE	C D	2509159063943	2409497322	8-Jun-09	15-Jun-09
GEODON 80 MG CAPSULE	C D	2509212027879	2409497322	31-Jul-09	3-Aug-09
GEODON 20 MG CAPSULE	C D	2509212027900	2409497322	31-Jul-09	3-Aug-09
GEODON 20 MG CAPSULE	C D	2509243071004	2409497322	31-Aug-09	8-Sep-09
GEODON 80 MG CAPSULE	C D	2509243070950	2409497322	31-Aug-09	8-Sep-09
GEODON 20 MG CAPSULE	C D	2509279044911	2409497322	6-Oct-09	13-Oct-09
GEODON 80 MG CAPSULE	C D	2509279044946	2409497322	6-Oct-09	13-Oct-09
GEODON 20 MG CAPSULE	N J	4007219019388	2412420424	7-Aug-07	12-Aug-07
GEODON 80 MG CAPSULE	N J	4007229011121	2412420424	17-Aug-07	19-Aug-07
GEODON 80 MG CAPSULE	N J	4007243058870	2412420424	31-Aug-07	31-Aug-07
GEODON 20 MG CAPSULE	N J	4007243007441	2412420424	31-Aug-07	31-Aug-07
GEODON 20 MG CAPSULE	S P	108505131389470	2416557726	11-May-05	15-May-05

GEODON 20 MG CAPSULE	S P	108505165519700	2416557726	14-Jun-05	19-Jun-05
GEODON 20 MG CAPSULE	S P	108505191112350	2416557726	10-Jul-05	17-Jul-05
GEODON 20 MG CAPSULE	C M	4006361073492	3424275433	27-Dec-06	29-Dec-06
GEODON 20 MG CAPSULE	C M	4007021001551	3424275433	21-Jan-07	26-Jan-07
GEODON 20 MG CAPSULE	C M	4007043057259	3424275433	12-Feb-07	18-Feb-07
GEODON 20 MG CAPSULE	C M	4007046059114	3424275433	15-Feb-07	18-Feb-07
GEODON 20 MG CAPSULE	C M	4007100040234	3424275433	10-Apr-07	15-Apr-07
GEODON 20 MG CAPSULE	C M	4007135084384	3424275433	15-May-07	20-May-07
GEODON 20 MG CAPSULE	C M	4007166005834	3424275433	15-Jun-07	17-Jun-07
GEODON 20 MG CAPSULE	C M	4007203003692	3424275433	22-Jul-07	27-Jul-07
GEODON 20 MG CAPSULE	C M	4007234043357	3424275433	22-Aug-07	26-Aug-07
GEODON 20 MG CAPSULE	C M	4007264046533	3424275433	21-Sep-07	23-Sep-07
GEODON 20 MG CAPSULE	C M	4007294001586	3424275433	21-Oct-07	26-Oct-07
GEODON 20 MG CAPSULE	C M	4007323013486	3424275433	19-Nov-07	25-Nov-07
GEODON 20 MG CAPSULE	C M	4007357002102	3424275433	23-Dec-07	28-Dec-07
GEODON 20 MG CAPSULE	C M	4008020001367	3424275433	20-Jan-08	25-Jan-08
GEODON 20 MG CAPSULE	C M	4008055007654	3424275433	24-Feb-08	29-Feb-08
GEODON 20 MG CAPSULE	C M	4008082013911	3424275433	22-Mar-08	28-Mar-08
GEODON 20 MG CAPSULE	C M	4008117013169	3424275433	26-Apr-08	4-May-08
GEODON 40 MG CAPSULE	C M	4008137004048	3424275433	16-May-08	18-May-08
GEODON 40 MG CAPSULE	C M	4008175074567	3424275433	23-Jun-08	27-Jun-08
GEODON 40 MG CAPSULE	C M	4008209000593	3424275433	27-Jul-08	3-Aug-08
GEODON 80 MG CAPSULE	C M	4008264008584	3424275433	20-Sep-08	26-Sep-08
GEODON 80 MG CAPSULE	C M	4008294048472	3424275433	20-Oct-08	26-Oct-08
GEODON 80 MG CAPSULE	C M	2509017024455	3424275433	17-Jan-09	27-Jan-09
GEODON 80 MG CAPSULE	C M	2509122027494	3424275433	2-May-09	11-May-09
GEODON 20 MG CAPSULE	J N	4007121061815	4425482441	1-May-07	6-May-07
GEODON 20 MG CAPSULE	J N	4007152054335	4425482441	1-Jun-07	3-Jun-07
GEODON 20 MG CAPSULE	J N	4007186009763	4425482441	5-Jul-07	8-Jul-07
GEODON 20 MG CAPSULE	J N	4007208036497	4425482441	27-Jul-07	27-Jul-07
GEODON 20 MG CAPSULE	J N	4007245002720	4425482441	2-Sep-07	9-Sep-07
GEODON 20 MG CAPSULE	J N	4007275012747	4425482441	2-Oct-07	7-Oct-07
GEODON 20 MG CAPSULE	J N	4007305052329	4425482441	1-Nov-07	4-Nov-07
GEODON 20 MG CAPSULE	J N	4007336005073	4425482441	2-Dec-07	9-Dec-07
GEODON 20 MG CAPSULE	J N	4008003060546	4425482441	3-Jan-08	6-Jan-08

GEODON 20 MG CAPSULE	J N	4008034006007	4425482441	3-Feb-08	10-Feb-08
GEODON 20 MG CAPSULE	J N	4008089001614	4425482441	29-Mar-08	6-Apr-08
GEODON 20 MG CAPSULE	J N	4008119073666	4425482441	28-Apr-08	4-May-08
GEODON 20 MG CAPSULE	J N	4008155036581	4425482441	3-Jun-08	8-Jun-08
GEODON 20 MG CAPSULE	J N	4008186002537	4425482441	3-Jul-08	13-Jul-08
GEODON 20 MG CAPSULE	J N	2509244073872	4425482441	1-Sep-09	8-Sep-09
GEODON 20 MG CAPSULE	J N	2509273068527	4425482441	30-Sep-09	5-Oct-09
GEODON 20 MG CAPSULE	J N	2509301003611	4425482441	28-Oct-09	2-Nov-09
GEODON 20 MG CAPSULE	J N	2509351083173	4425482441	17-Dec-09	21-Dec-09
GEODON 20 MG CAPSULE	J N	2510053050670	4425482441	22-Feb-10	1-Mar-10
GEODON 20 MG CAPSULE	J N	2510085040058	4425482441	26-Mar-10	29-Mar-10
GEODON 20 MG CAPSULE	J N	2510114014698	4425482441	24-Apr-10	3-May-10
GEODON 20 MG CAPSULE	J N	2510143023057	4425482441	23-May-10	1-Jun-10
GEODON 20 MG CAPSULE	J N	2510179068572	4425482441	28-Jun-10	6-Jul-10
GEODON 40 MG CAPSULE	J W	2511091050735	6403559168	1-Apr-11	4-Apr-11
GEODON 40 MG CAPSULE	B M	2509190048755	6412307362	9-Jul-09	13-Jul-09
GEODON 40 MG CAPSULE	B M	2509216049823	6412307362	4-Aug-09	10-Aug-09
GEODON 80 MG CAPSULE	J C	4006242087947	6412585362	30-Aug-06	3-Sep-06
GEODON 80 MG CAPSULE	J C	4006278056659	6412585362	5-Oct-06	8-Oct-06
GEODON 80 MG CAPSULE	J C	4006306061067	6412585362	2-Nov-06	5-Nov-06
GEODON 80 MG CAPSULE	J C	4006337005726	6412585362	3-Dec-06	10-Dec-06
GEODON 80 MG CAPSULE	J C	4007013005751	6412585362	13-Jan-07	21-Jan-07
GEODON 40 MG CAPSULE	W L	2508336062071	7407833974	1-Dec-08	8-Dec-08
GEODON 40 MG CAPSULE	A K	2510174008966	8410078384	23-Jun-10	28-Jun-10
GEODON 40 MG CAPSULE	A K	2510198009735	8410078384	17-Jul-10	26-Jul-10
GEODON 40 MG CAPSULE	B B	4007067044611	8426691382	8-Mar-07	11-Mar-07
GEODON 20 MG CAPSULE	L H	4008122082647	9405209396	1-May-08	4-May-08
GEODON 20 MG CAPSULE	L H	4008273065736	9405209396	29-Sep-08	5-Oct-08
GEODON 20 MG CAPSULE	L H	2509005032997	9405209396	5-Jan-09	12-Jan-09
GEODON 20 MG CAPSULE	L H	2509071049096	9405209396	12-Mar-09	16-Mar-09

BIRTH_DATE	Calculated Age atFirstDateofService	CLAIM_LINE_PAID_AMT	TOTAL_PAID_AMT
[redacted]	16	161.74	161.74
[redacted]	16	161.74	161.74
[redacted]	15	296.27	296.27
[redacted]	11	347.43	347.43
[redacted]	14	7.85	7.85
[redacted]	14	62.73	62.73
[redacted]	14	62.73	62.73
[redacted]	14	62.73	62.73
[redacted]	14	63.22	63.22
[redacted]	15	63.22	63.22
[redacted]	16	371.37	371.37
[redacted]	9	435.99	435.99
[redacted]	9	474.91	474.91
[redacted]	16	50.07	50.07
[redacted]	16	418.18	418.18
[redacted]	15	503.36	503.36
[redacted]	15	503.36	503.36
[redacted]	15	120.09	120.09
[redacted]	15	120.09	120.09
[redacted]	15	253.4	253.4
[redacted]	15	253.4	253.4
[redacted]	15	253.4	253.4
[redacted]	15	253.4	253.4
[redacted]	15	253.4	253.4
[redacted]	14	284.96	284.96
[redacted]	15	304.12	304.12
[redacted]	15	166.99	166.99
[redacted]	15	166.99	166.99
[redacted]	15	140.76	140.76
[redacted]	15	140.76	140.76
[redacted]	15	166.99	166.99
[redacted]	15	166.99	166.99
[redacted]	16	166.99	166.99
[redacted]	16	166.99	166.99

Exhibit 7

[redacted]	16	166.99	166.99
[redacted]	16	166.99	166.99
[redacted]	16	166.99	166.99
[redacted]	16	166.99	166.99
[redacted]	16	212.53	212.53
[redacted]	16	212.53	212.53
[redacted]	16	212.53	212.53
[redacted]	16	212.53	212.53
[redacted]	16	212.53	212.53
[redacted]	16	212.53	212.53
[redacted]	16	212.53	212.53
[redacted]	16	213.03	213.03
[redacted]	16	213.03	213.03
[redacted]	17	213.03	213.03
[redacted]	17	209.2	209.2
[redacted]	17	209.2	209.2
[redacted]	17	187.41	187.41
[redacted]	17	226.69	226.69
[redacted]	17	226.69	226.69
[redacted]	17	187.41	187.41
[redacted]	17	187.41	187.41
[redacted]	17	226.69	226.69
[redacted]	17	187.41	187.41
[redacted]	17	226.69	226.69
[redacted]	17	226.69	226.69
[redacted]	17	187.41	187.41
[redacted]	17	203.96	203.96
[redacted]	17	246.78	246.78
[redacted]	17	195.94	195.94
[redacted]	17	237.05	237.05
[redacted]	12	161.74	161.74
[redacted]	12	195.35	195.35
[redacted]	12	195.35	195.35
[redacted]	12	161.74	161.74
[redacted]	15	272.42	272.42

[redacted]	15	272.42	272.42
[redacted]	15	272.42	272.42
[redacted]	14	42.73	42.73
[redacted]	14	43.22	43.22
[redacted]	14	35.47	35.47
[redacted]	14	45.81	45.81
[redacted]	14	48.39	48.39
[redacted]	15	48.39	48.39
[redacted]	15	48.39	48.39
[redacted]	15	26.69	26.69
[redacted]	15	49.16	49.16
[redacted]	15	49.16	49.16
[redacted]	15	49.16	49.16
[redacted]	15	49.16	49.16
[redacted]	15	49.16	49.16
[redacted]	15	50.63	50.63
[redacted]	15	50.63	50.63
[redacted]	15	50.63	50.63
[redacted]	16	50.63	50.63
[redacted]	16	44.71	44.71
[redacted]	16	44.71	44.71
[redacted]	16	44.71	44.71
[redacted]	16	40.56	40.56
[redacted]	16	40.56	40.56
[redacted]	16	39.72	39.72
[redacted]	17	39.72	39.72
[redacted]	14	304.12	304.12
[redacted]	14	453.99	453.99
[redacted]	14	48.39	48.39
[redacted]	15	49.16	49.16
[redacted]	15	49.16	49.16
[redacted]	15	49.16	49.16
[redacted]	15	48.73	48.73
[redacted]	15	476.46	476.46
[redacted]	15	476.46	476.46

[redacted]	15	518.96	518.96
[redacted]	15	518.96	518.96
[redacted]	15	518.96	518.96
[redacted]	15	518.96	518.96
[redacted]	15	518.96	518.96
[redacted]	17	605.01	605.01
[redacted]	17	580.93	580.93
[redacted]	17	580.93	580.93
[redacted]	17	580.93	580.93
[redacted]	17	621.35	621.35
[redacted]	17	621.35	621.35
[redacted]	17	621.35	621.35
[redacted]	17	621.35	621.35
[redacted]	17	621.35	621.35
[redacted]	12	219.71	219.71
[redacted]	15	371.37	371.37
[redacted]	15	371.37	371.37
[redacted]	10	315.24	315.24
[redacted]	11	315.24	315.24
[redacted]	11	315.24	315.24
[redacted]	11	315.24	315.24
[redacted]	11	344.47	344.47
[redacted]	13	172.99	172.99
[redacted]	15	45.13	45.13
[redacted]	15	45.13	45.13
[redacted]	13	154.25	154.25
[redacted]	14	175.91	175.91
[redacted]	14	176.41	176.41
[redacted]	15	172.99	172.99
[redacted]	15	187.41	187.41