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, *et al.*,

Defendant.

OPPOSITION TO DEFENDANT JENNIFER KING-VASSEL'S MOTION *IN LIMINE* TO PRECLUDE THE PLAINTIFF'S CLAIMS THAT DR. KING KNOWINGLY CAUSED TO BE SUBMITTED FALSE CLAIMS

Relator, Dr. Toby Tyler Watson (Dr. Watson), by his attorneys, James B. Gottstein of the Law Project for Psychiatric Rights and Rebecca L. Gietman of Gietman Law oppose Defendant Jennifer King-Vassel's Motion *In Limine* To Preclude The Plaintiff's Claims That Dr. King Knowingly Caused To Be Submitted False Claims for the reasons that follow.

A. SUMMARY

In her Motion *In Limine* Dr. King essentially is moving for an order that she cannot be held to have "knowingly" presented false claims for writing prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) because (a) they are not false claims, and (b) she relied on Wisconsin's program paying for such claims which she argues negates the knowledge requirement under the False Claims Act, 31 U.S.C. §3729.

On November 22, 2013, Dr. King filed an affidavit by an attorney for the Wisconsin Department of Health Services stating that it was Wisconsin's position to pay for such claims,

and in fact disagreeing that such claims are false. Thus, as stated in his Brief in Support of his Renewed Motion *In Limine*, Document No. 145, p. 8, Dr. Watson will dismiss the State Claims.

However, as also stated in Dr. Watson's Brief in Support of his Renewed Motion *In Limine*, Document No. 145, the claims are still false as to the federal government. Having said that, there is the legitimate question as to whether the actions of Wisconsin negated Dr. King's knowledge even as to the federal claims. On this point, while that *may*, or may not be true as to prescriptions written before this Court's decision holding such prescriptions are false claims on October 23, 2012, Document No. 59, p. 11, subsequently affirmed by the Court of Appeals, it cannot be true with respect to prescriptions written *after* this Court held such prescriptions were false claims.

Dr. King completely ignores that she was put on notice repeatedly that such prescriptions were false claims, first with her receipt of the Complaint, then with this Court's October 23, 2012 Order, Document No. 59, p. 11, and then with the Court of Appeals decision in August of 2013.

B. THE BASES FOR DR. KING'S KNOWLEDGE[1]

First, the United States Supreme Court has held government agent representations do not negate knowledge, i.e., do not create an estoppel:

> Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that *those who deal with the Government are*

[1] Because of its centrality to this case and Dr. Watson feels an incorporation by reference may not be sufficient, this section is verbatim the same as Section III.B. of Dr. Watson's Brief In Support Of Relator's Renewed Motion In Limine Re: False Claims, Document No. 145 (Renewed Motion *In Limine*), except that the first and last paragraphs are not included and the references to exhibits are to the document numbers.

> *expected to know the law and may not rely on the conduct of Government agents contrary to law*.

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

Citing to *Heckler*, in *Edgewater Hospital v. Bowen*, 857 F.2d 1123, 1138 (7th Cir. 1988), amended at 866 F.2d 228, the Seventh Circuit recognized a limited exception:

> The Supreme Court has questioned whether "*estoppel* can ever be appropriately applied against the Government." The general rule is that reliance on misinformation provided by a government employee (or agent) does not provide a basis for *estoppel*. However, various circuits have invoked the doctrine against the government in narrowly defined circumstances. This court set forth its standard for applying *estoppel* against a government agency in *Portmann v. United States*, 674 F.2d 1155 (7th Cir.1982):
>
> > First, the party to be *estopped* must know the facts. Second, this party must intend that his conduct shall be acted upon, or must so act that the party asserting *estoppel* has a right to believe it is so intended. Third, the party asserting *estoppel* must have been ignorant of the facts. Finally, the party asserting *estoppel* must reasonably rely on the other's conduct to his substantial injury.
>
> 674 F.2d at 1167. In addition to these traditional private law elements of the *estoppel* doctrine, we require that the party asserting *estoppel* establish that the government's action amounted to affirmative misconduct. Although the Supreme Court has not yet addressed the appropriateness of this additional element, many circuits have required it.
>
> The party claiming *estoppel* has the burden of demonstrating the elements.

(emphasis added, some citations and footnotes omitted).

Also citing to Heckler, in *Hagood v.Sonoma County Water Agency*, 929 F. 2d 1416 (9th Cir. 1991), the Ninth Circuit held that United States government officials' approval of a contract based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's dismissal under Fed. R. Civ. Proc. 12(b)(6).

It is upon this body of law that Dr. Watson relies to establish the knowledge element for the prescriptions written to N.B. Dr. Watson acknowledges this Court's Order of October 2,

2013, Document No. 116, casts doubt on whether this Court will apply to the facts in this case the principle that *estoppel* will not lie against the government. Even if this Court does not apply the principle that *estoppel* against the government does not apply in this case, Dr. King must still affirmatively prove the representation and that she relied upon it. General expert testimony regarding prescribing practices and the reimbursement process do not establish this.

However, even if she can establish an *estoppel* for the prescriptions identified in the Complaint, prescriptions written after

(a) Dr. King was served with the Complaint in this matter,

(b) this Court held 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) constitute false claims, Document No. 59, p. 11, and

(c) the Court of Appeals affirmed this on appeal, 728 F.3d at 715,

are a different matter.

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 was certainly put on notice 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) constituted false claims when she was served with the Complaint in this matter. By this Court's Order on October 23, 2012, Dr. King was not only put on notice, there was a judicial ruling that such prescriptions constituted false claims. And on August 28, 2013, the Court of Appeals affirmed that such prescriptions constituted false claims.

In her deposition, Dr. King testified:

(1) that she did not change her practice with respect to what prescriptions she would write to a Medicaid patient after being served with the Complaint, Document No. 145-4, pp 45-46;

(2) 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. 59, and that she did not change anything in how she prescribed medication to Medicaid patients, Document No. 145-4, pp 46 & 48; and

(3) 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.

This certainly satisfies the reckless disregard standard for "knowingly" under the False Claims Act as a matter of law, and probably the deliberate ignorance standard as well.

Thus, Dr. Watson respectfully suggests the only relevant fact inquiry with respect to prescriptions written after this Court's October 23, 2012, Decision, Document No. 59, is whether they were written for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). As a matter of law, Dr. King knowingly caused false claims within the meaning of the False Claims Act as to prescriptions written to Medicaid patients 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) after this Court's Order of October 23, 2012, Document 59. Any representations by Wisconsin state officials or anyone else cannot negate the knowingly element

in the face of court decisions in this case holding prescriptions written to Medicaid patients 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) constitute false claims.

C. DELIBERATE IGNORANCE

Dr. King asserts "the plaintiff has also not presented any evidence that Dr. King acted in deliberate ignorance of the truth" at page 2 of her brief, Document No. 151. First, Dr. Watson is not required to present evidence before trial because there is no summary judgment motion on the issue. Second, it is not true. As set forth above, with respect to prescriptions written after being served with the Complaint, in his Renewed Motion *In Limine*, Document No. 145, Dr. Watson presented Dr. King's deposition testimony:

(1) that she did not change her practice with respect to what prescriptions she would write to a Medicaid patient after being served with the Complaint, Document 145-4, pp 45-46;

(2) 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. 59, and that she did not change anything in how she prescribed medication to Medicaid patients, Document 145-4, pp 46 & 48; and

(3) 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 that (2) & (3) constitute deliberate ignorance. In fact, this case squarely presents the issue of how long a doctor can claim ignorance that writing prescriptions to Medicaid patients 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.

D. PRIOR AUTHORIZATIONS NEGATE KNOWLEDGE ONLY AS TO PRESCRIPTIONS WRITTEN BEFORE BEING SERVED WITH THE COMPLAINT

Dr. King cites *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008), for the proposition that payment by the State pursuant to its criteria eviscerates Dr. King's liability. However, the quoted portion of *Rost*, is specifically limited to situations where prior authorizations were obtained. In her deposition, Document No. 145-4, at page 45, Dr. King testified she "possibly" obtained a prior-authorization for Strattera for N.B.,[2] but then on the next page testified that she had reviewed N.B.'s records two days previously and did not see any such prior authorization forms.[3] At page 83 of her deposition, Document No. 145-4, Dr. King testifies that she obtained prior authorizations for Risperdal prescriptions to little boys and girls ages seven and under. Only if Dr. King proves prior authorizations for specific identified prescriptions that are not for a medically accepted indication does the *Rost* holding apply. However, even then, it is respectfully suggested the *Rost* rationale does not apply after being served with the complaint because reliance is no longer reasonable without some sort of inquiry. As set forth above, Dr. King conducted no such inquiry.

[2] In order to streamline the trial, Dr. Watson plans on only pursuing claims for two drugs, Risperdal, also known as risperidone, and Geodon, also known as ziprasidone.
[3] Later, at page 43, Dr. King testifies she saw at least one prior authorization form, but doesn't identify for which drug or prescription.

E. THE DRUG UTILIZATION BOARD IS NOT EMPOWERED TO EXPAND COVERAGE

As Dr. Watson explained in his Reply Re; Motion *In Limine* Re: False Claims, Document 112, pp 3-4, the function of the Drug Utilization Board is not as asserted by Dr. King. The statutory framework only allows formularies and DUR boards to further *restrict* coverage, not expand it. See 42 U.S.C. §1396r(d)(1).

This is in fact how the DUR process is utilized in practice. The Centers for Medicare and Medicaid Services (CMS), the Government agency charged with administering the Medicaid program at the federal level, describes the role of the DUR as follows:

> The Medicaid Drug Utilization Review (DUR) Program promotes patient safety through state-administered utilization management tools and systems that interface with CMS' Medicaid Management Information Systems (MMIS). Medicaid DUR is a two-phase process that is conducted by the Medicaid state agencies. In the first phase (prospective DUR) the state's Medicaid agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implements corrective action when needed.

http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Drug-Utilization-Review.html (Document 112-1)

To the same effect is the State of Wisconsin's description of it Drug Utilization Review Board. Exhibit 1

F. THE "PEER REVIEWED MEDICAL LITERATURE" WAS DELETED FROM THE DEFINITION OF MEDICALLY ACCEPTED INDICATION

As originally enacted in 1990 as part of the Omnibus Reconciliation Act of 1990, Pub.L. No. 101–508, 104 Stat. 1388–299 (OBRA), the "peer review literature" was included as part of the definition of a medically accepted indication:

> "(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 Pharmacopeia-Drug Information.[4]

There have been a number of amendments since then and the current version is:

> (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 [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 U.S.C. § 1396r–8(k)(6).

42 U.S.C. §1396r–8(g)(1)(B), which involves drug utilization review, which serves the purpose of *further restricting* drug coverage, provides:

> (B) The program shall assess data on drug use against predetermined standards, consistent with the following:
>
> (i) compendia which shall consist of the following:
>
> (I) American Hospital Formulary Service Drug Information;
>
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
>
> (III) the DRUGDEX Information System; and
>
> (IV) Repealed. Pub.L. 108-173, Title I, § 101(e)(9)(B), Dec. 8, 2003, 117 Stat. 2152.
>
> (ii) the peer-reviewed medical literature.

[4] It is hard to figure out the official citation, but this is at Subtitle B—Medicaid PART 1—REDUCTION IN SPENDING, §4401, (k)(6), which appears on page 119 of the Westlaw version downloaded on November 24, 2013, a copy of which is attached hereto as Exhibit 2, for the convenience of the Court in locating it in OBRA 1990.

The current definition of medically accepted indication, contained in §1396r–8(k)(6), explicitly excludes subsection (ii) the peer-reviewed medical literature.

Thus, Dr. King's citation to peer reviewed medical literature in 42 U.S.C. §1396r–8(g)(1)(B)(i)(II) is misplaced. As explained in previous briefing, the drug review process of 42 U.S.C. §1396r–8(g)(1) is one of the further restrictions on coverage contained in 42 U.S.C. §1396r–8(g). It cannot be used to expand coverage beyond covered outpatient drugs.

This Court has held federal Medicaid coverage of outpatient drugs is limited to what is defined as a medically accepted indication, i.e., uses approved under the Food, Drug, and Cosmetic Act (FDCA) or supported by one of the compendia. Dr. King has made the same argument about §1396r-8(d)(1)(B)(i) before and it was at least implicitly rejected by this Court. In addition, Dr. King made the same argument at oral argument before the Court of Appeals and the Court of Appeals has held coverage is limited to uses approved under the Food, Drug, and Cosmetic Act or supported by one of the compendia. This issue should be settled, at least in this case at this point.

The knowledge element under the False Claims Act is a legitimate issue, although as set forth above, Dr. King had to have at least reckless indifference knowledge after this Court's October 23, 2012, Order, holding coverage is restricted to uses approved under the FDCA or supported by a compendia. Whether the prescriptions at issue in this case were written for a use approved under the FDCA or supported by a compendia is also a legitimate issue. Dr. Watson has at least the initial burden for both of these elements. That prescriptions not written for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) are false claims, it is respectfully suggested, has been settled.

G. THE POSITION OF THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IS DUE DEFERENCE, NOT TOO SUSPICIOUS LETTERS FROM CMS EMPLOYEES

At Section II.B, of her motion, Dr. King asserts the Centers for Medicare and Medicaid Services (CMS) does not support Dr. Watson's interpretation of the statute limiting outpatient drug coverage to medically accepted indications as defined in 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), citing to two letter from CMS in late 2007 and early 2008. Document Nos. 31-7 & 31-9. First, this ignores that the Inspector General of the Department of Health and Human Services has since issued an official position, as Dr. Watson discussed inDocument No. 112, pp 8-9, that in May of 2011, in his report, titled, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, Document 112-5. The Executive Summary Background section at page i, includes the statement:

> Medicare requires that drugs be used for medically accepted indications supported by one or more of three compendia to be eligible for reimbursement.

And at page 5, it states:

> For drugs to qualify for Medicare Part D reimbursement, the Medicare Benefit Policy Manual and the Prescription Drug Benefit Manual require that drugs be used for medically accepted indications.[16]
>
> These indications include both the uses approved by FDA and those uses, including off-label, supported by one or more of three compendia: (1) the American Society of Health System Pharmacists, Inc.'s, *American Hospital Formulary Service Drug Information*; (2) the *United States Pharmacopeia-Drug Information* (or its successor publications); and (3) Thomson Reuters' DrugDEX Information System. Hereinafter these are collectively referred to as the compendia.
>
> [16] The Social Security Act (the Act) § 1927(g)(1)(B)(i). 42 U.S.C. 1396r-8(g)(1)(B)(i). The compendia described at the Act § 1927(g)(1)(B)(i) are incorporated into the Part D definition of "medically accepted indication" through the Act § 1860D-2(e)(4)(A)(ii), 42 U.S.C. 1395w-102(e)(4)(A)(ii), which refers to the Act § 1927(k)(6), which, in turn, refers to the Act § 1927(g)(1)(B)(i).

(footnotes, except 16, omitted).

In other words, Medicare Part D drug coverage incorporates the Medicaid restriction to medically accepted indications, which is limited to uses approved under the FDCA or supported by one of the compendia. This is an explicit, official statement of the coverage restriction by the Inspector General of the United States Department of Health and Human Services. [5]

This is in sharp contrast to the two suspicious letters on CMS letterhead three years prior to the Inspector General's officially stated position, in both cases signed by someone for someone else, which means all four people can deny that the letter to which his name is attached really came from him.[6] However, the suspicious nature of these letters and their unofficial status fade into the background in the face of the Inspector General's officially stated position.

Dr. King cites to *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 844 (1984) for the proposition that deference is due these letters, but in fact, deference is due the official position of the government, as stated by the Inspector General of the Department of Health and Human Services.

H. DR. KING'S INTERPRETATION OF 42 U.S.C. §1396R-8(D)(1)(B)(I) IS NONSENSICAL

In Dr. Watson's Reply regarding his original Motion *In Limine* Re: False Claims, Document No. 112, pp 4-5, he points out that Dr. King's interpretation that 42 U.S.C. §1396r-

[5] Through Document 112, pp 6-9, Dr. Watson previously demonstrated that the United States Department of Justice takes the same position that Medicaid outpatient drug coverage (at least as to federal money) is limited to uses approved under the FDCA or supported by a compendia. Just earlier this month, this position was reiterated by the United States Government in its Complaint in Intervention in *United States v. Janssen Pharmaceutica Products, L.P., et al.*, Case 2:04-cv-01529-TJS, ED Pennsylvania, Document No. 60, a highlighted copy of relevant portions of which is attached as Exhibit 3. For this case, Dr. Watson has decided to restrict his claims to prescriptions for just two drugs, one of which is Risperdal, the subject of the $2.2 Billion settlement by the manufacturer for causing false claims by inducing doctors (which includes Dr. King here) to prescribe Risperdal to children that are not for a medically accepted indication. See, United States Department of Justice November 4, 2013, News Release, Exhibit 4.

[6] Document Nos. 31-7 and 31-9.

8(d)(1)(B)(i) that states can expand coverage beyond medically accepted indications as defined in the statute is nonsensical as a strict matter of statutory construction. This Court's Order on that motion, Document 116, implicitly rejected Dr. King's argument. Dr. Watson, however, feels he must restate it here. §1396r-8(d)(1)(B)(i) provides:

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

This provision is circular, because "covered outpatient drug" is defined in 42 USC 1396R-8(k)(3) to "not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." Thus, substituting the definition of "medically accepted indication," the statutory provision relied upon by the Defendant states,

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

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

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

It is apparent there are two provisions to restrict coverage to medically accepted indications. One is universal and the other is at the option of the states, but both have been enacted, leaving superfluous the state option, at least as to federal funds. The whole structure of the statute with respect to covered outpatient drugs is that it is restricted to medically accepted indications, defined as uses approved under the FDCA or supported by at least one of the compendia. Section1396r-8(d)(1)(B)(i) cannot be read to override Congress' explicit limitation of Medicaid coverage for outpatient drugs to medically accepted indications.

A. CONCLUSION

For the foregoing reasons, Dr. Watson respectfully suggests Dr. King's Motion *In Limine*, Document No. 151 should be **DENIED.**

Dated: November 25, 2013

s/ James B. Gottstein
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Program Name: BadgerCare Plus and Medicaid Handbook Area: Pharmacy

10/04/2013

Claims : Drug Utilization Review

Exhibit 1

Topic #1978

A Comprehensive Overview

The federal OBRA '90 (Omnibus Reconciliation Act of 1990) established program requirements regarding several aspects of pharmacy practice. One of the requirements of OBRA '90 was a DUR (Drug Utilization Review) program for BadgerCare Plus, Medicaid, and SeniorCare members to improve the quality and cost-effectiveness of care.

The OBRA '90 requires that BadgerCare Plus, Medicaid, and SeniorCare DUR program includes all of the following:

- Prospective DUR.
- Retrospective DUR.
- An educational program using DUR program data on common drug therapy.

Individual pharmacies are responsible for prospective DUR, while BadgerCare Plus, Medicaid, and SeniorCare are responsible for retrospective DUR and educational programming. Additional differences between prospective and retrospective DUR can be found in the following table.

Prospective Versus Retrospective DUR	
Prospective DUR	Retrospective DUR
• Performed before a drug is dispensed • Identifies a potential problem before it occurs • Provides real-time response to a potential problem • Has preventive and corrective action	• Performed after a drug is dispensed • Warns when a potential problem has occurred • Useful for detecting patterns and designing targets for intervention • Has corrective action

The DUR Board, required by federal law, consists of three physicians, five pharmacists, and one nurse practitioner. The DUR Board and the DHS (Department of Health Services) review and approve all DUR criteria and establish a hierarchy of alerts for prospective and retrospective DUR.

Providers should refer to Phar. 7.01(1)(e) and 7.08, Wis. Admin. Code, and s. 450.01(16)(i), Wis. Stats., for additional information about DUR program requirements.

Topic #12657

Additive Toxicity

The additive toxicity DUR (Drug Utilization Review) alert is activated when a prescribed drug causes a cumulative effect with other drugs in the claims history. Points accumulate for side effects based on the severity and the frequency of the side effect. Once a defined threshold is reached, an alert is sent to the provider.

Topic #1983

Alerts and Alert Hierarchy

The DUR (Drug Utilization Review) Board established a hierarchy for the order in which multiple alerts appear if more than one alert is activated for a drug claim. Factors taken into account in determining the hierarchy include the potential for avoidance of adverse consequences, improvement of the quality of care, cost savings, likelihood of a false positive, retrospective DUR experience, and a review of alerts used by other state Medicaid programs for prospective DUR. The clinical drug tables used to establish the alerts are provided to BadgerCare Plus, Medicaid, and SeniorCare by First DataBank, Inc.

For information about overriding DUR alerts, providers may refer to the Prospective Drug Utilization Review System topic.

BadgerCare Plus, Medicaid, and SeniorCare activate alerts that identify the following problems. These alerts are listed in hierarchical order according to the following prospective DUR conflict codes:

- DD — Drug-drug interaction.
- Drug-disease contraindication.
    - MC — reported.
    - DC — inferred.
- TD — Therapeutic duplication.
- PG — Pregnancy alert.
- ER — Overuse.
- AT — Additive toxicity.
- LR — Underuse.
- NS — Insufficient Quantity.

Topic #12618

Drug-Disease Contraindication

The drug-disease contraindication DUR (Drug Utilization Review) alert is activated when a drug is prescribed for a member who has a disease for which the drug is contraindicated. Acute diseases remain in the member's medical profile for a limited period of time, while chronic diseases remain permanently. The disease may have been reported on a medical claim or inferred from a drug in claims history.

Contraindications include the following:

- Reported — The diagnosis is extracted from the member's medical profile. A medical profile includes previously reimbursed claims, including pharmacy claims, where a diagnosis is submitted.
- Inferred — Infer that the member has a disease based on a drug present in claims history. This inference is made if there is one disease indicated for a drug.

Topic #12617

Drug-Drug Interaction

The drug-drug interaction DUR (Drug Utilization Review) alert is activated when another drug in claims history interacts with the drug being filled. The system reviews not only the prescriptions at the current pharmacy, but all of the prescriptions reimbursed by BadgerCare Plus, Medicaid, and SeniorCare.

Topic #1981

Edits and Audits

The claims processing system includes certain edits and audits. Edits check the validity of data on each individual claim. For example, a claim with an invalid NDC (National Drug Code) will be denied with an edit. In contrast, audits review claim history. For example, if the same claim is filed at two different pharmacies on the same day, the claim at the second pharmacy will be denied with an audit.

Only payable claims that are not denied by an edit or audit are submitted to prospective DUR (Drug Utilization Review). Prospective DUR alerts inform providers of potential drug therapy problems. With the exception of the overuse precaution ("ER") alert, providers can override any of these alerts.

Topic #1980

Educational Programming

A number of educational programs are generated by the DUR (Drug Utilization Review) Board. One of the primary means of education is the distribution of educational newsletters to prescribers and pharmacists. Topics for newsletters include:

- Current treatment protocols.
- How to best use the information received in the intervention letter.
- New drug-drug interactions.
- Utilization and cost data for selected therapeutic classes of drugs.
- Comparison of efficacy and cost of drugs within a therapeutic class.

In addition, the intervention letters sent out generate additional calls to the DUR pharmacy staff that provide an opportunity for a one-on-one educational activity with the prescriber.

Topic #12660

High Dose

Providers receive the high dose prospective DUR (Drug Utilization Review) alert on claims for drugs listed in the table below if the dose exceeds daily limit indicated.

Drug	Daily Limit
Acetaminophen	Greater than 4,000 mg/day, for all members
Alprazolam	Greater than 2 mg/day, for members 65 or older
Amitriptyline	Greater than 150 mg/day, for all members
Cyclobenzaprine	Greater than 30 mg/day, for all members
Escitalopram	Greater than 30 mg/day, for all members
Tramadol	Greater than 300 mg/day, for members 65 or older
Zolpidem	Greater than 10 mg/day for members 65 or older

Topic #12637

Overuse Precaution

The overuse precaution DUR (Drug Utilization Review) alert is activated when a member is requesting an early refill of a prescription. The alert is sent to the provider if a claim is submitted before 80 percent of the previous claim's days' supply for the same drug, drug strength, and dosage form has been taken. The alert indicates the number of days that should remain on the prescription, not the day that the drug can be refilled without activating the alert. Drugs with up to a 10-day supply are excluded from this alert.

A comprehensive list of drug categories are monitored for the "ER" prospective DUR alert if a member requests a refill before 80 percent of a previous claim's days supply has been taken. Antibiotics, insulins, IV solutions, electrolytes (except potassium, blood components and factors), and diagnostic

drugs are excluded.

The Prospective Drug Utilization Review System topic includes more information about override policies.

Topic #12620

Pregnancy Alert

The pregnancy DUR (Drug Utilization Review) alert is activated when the prescribed drug is contraindicated in pregnancy. This alert is activated when all of the following conditions are met:

- The member is a woman between 12 and 60 years of age.
- ForwardHealth receives a medical or pharmacy claim for a member that indicates pregnancy using a diagnosis code.
- A pharmacy claim for a drug that possesses a clinical significance of D, X, or 1 (as assigned by the FDA (Food and Drug Administration) or First DataBank, Inc.) is submitted for a member.

Clinical Significance Codes	
D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans. However, potential benefits may warrant use of the drug in pregnant women despite potential risks if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective. This is a FDA-assigned value.
X	Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. This is an FDA-assigned value.
1	No FDA rating but is contraindicated or not recommended; may have animal and/or human studies or pre- or post-marketing information. This is a First DataBank, Inc.-assigned value.

The pregnancy diagnosis will be deactivated from a member's medical profile after 260 days or if an intervening diagnosis indicating delivery or other pregnancy termination is received on a claim.

Topic #1977

Prospective Drug Utilization Review System

To help individual pharmacies comply with their prospective DUR (Drug Utilization Review) responsibility, BadgerCare Plus, Medicaid, and SeniorCare developed a prospective DUR system. The system screens certain drug categories for clinically significant potential drug therapy problems before a drug is dispensed to a member. Prospective DUR enhances clinical quality and cost-effective drug use.

Prospective DUR is applied to all BadgerCare Plus, Medicaid, and SeniorCare real-time POS (Point-of-Sale) claims submitted to ForwardHealth. Prospective DUR alerts are returned to pharmacy providers as a conflict code. Providers may refer to the ForwardHealth Payer Sheet: (P-00272) NCPDP (National Council for Prescription Drug Programs) Version D.0 for more information about prospective DUR.

Although the prospective DUR system alerts pharmacy providers to a variety of potential problems, it is not intended to replace pharmacists' professional judgment. Potential drug therapy problems may exist which do not trigger the prospective DUR system. Prospective DUR remains the responsibility of the pharmacy, as required by federal and state law. The system is an additional tool to assist

pharmacists in meeting this requirement.

Claims Reviewed by the Prospective Drug Utilization Review System

Under the prospective DUR system, only reimbursable claims for BadgerCare Plus, Medicaid, and SeniorCare members submitted through the real-time pharmacy POS system are reviewed. Although paper claims and compound drug claims are not reviewed by the prospective DUR system, pharmacy providers are still required under provisions of OBRA '90 (Omnibus Budget Reconciliation Act of 1990) to perform prospective DUR independently.

Claims for Assisted Living Facility, Group Home, and Nursing Facility Members

Real-time claims for assisted living facility, group home, and nursing facility members are reviewed through the prospective DUR system; however, they do not require a response to obtain reimbursement since claims submission for these members does not always occur at the same time the drug is dispensed. The assisted living facility, group home, or nursing facility pharmacist consultant is responsible for prospective DUR. Although assisted living facility, group home, and nursing facility claims are exempt from denial, an informational alert will be received on POS claims.

Overriding Prospective Drug Utilization Review Alerts

When a claim is processed for a drug that has the potential to cause problems for a member, BadgerCare Plus, Medicaid, or SeniorCare return an alert to inform the pharmacy provider about the potential problem. The provider is then required to respond to the alert to obtain reimbursement. For certain drugs, providers may override the claim in the POS system. The provider is required to resubmit the claim and include information about the action taken and the resulting outcome.

For other drugs, pharmacy providers are required to call the DAPO (Drug Authorization and Policy Override) Center to request authorization.

If a provider receives a prospective DUR alert and subsequently receives an override through DAPO Center, the DUR alert pre-override is not required on the resubmitted claim. If multiple DUR alerts are received for a claim and an override from the DAPO Center is obtained for one DUR alert, the provider may be required to pre-override/override the additional prospective DUR alerts, as appropriate.

Providers are strongly encouraged to contact their software vendors to ensure that they have access to these necessary fields. Providers may also refer to the payer sheet for information about NCPDP transactions.

Prospective DUR allows pre-overrides if a drug in claims history will activate an alert for a drug that will dispensed from the same pharmacy. Providers may not pre-override claims for certain drugs for which the overuse precaution ("ER") DUR alert will activate.

Early Refill Prospective Drug Utilization Review Overrides

Examples of when an early refill override request may be approved through the DAPO Center include, but are not limited to, the following:

- If the member has an appropriate medical need (e.g., the member's medications were lost or stolen, the member has requested a vacation supply).
- A member has been taking too much of a medication because he or she misunderstood the directions for administration from the prescriber.
- A prescriber changed the directions for administration of the drug and did not inform the pharmacy provider.

Pharmacy providers should call prescribers to verify the directions for use or to determine whether or not the directions for use changed.

If the pharmacist determines that it is not appropriate to refill the drug early, the pharmacy may instruct the member to return to the pharmacy to pick up the refill after 80 percent of the previous claim's days supply has been taken. Providers may refer to NCPDP field 544-FY (DUR Free Text Message) to determine the date the member may pick up the refill of a drug.

When pharmacy providers submit noncompound drug claims or reversals with a response to a prospective DUR alert at a minimum, the following fields are required:

- Reason for Service Code (NCPDP field 439-E4).

- Professional Service Code (NCPDP field 440-E5).
- Result of Service Code (NCPDP field 441-E6).

The following table indicates the specific fields that providers are required to submit for prospective DUR claims. The "X" denotes a required field with a prospective DUR claim submission.

Policy Requirements	Drug Utilization Review/PPS Code Counter	Reason for Service Code	Professional Service Code	Result of Service Code
Prospective DUR Override	X	X	X	X

The following table provides additional prospective DUR claim submission examples for when providers submit responses to the prospective DUR alert services in the same transaction.

Example	Reason for Service Code	Professional Service Code	Result of Service Code	Drug Utilization Review or Pharmaceutical Care
A	AT	M0	15	DUR
B	AT	RE	1E	DUR
C	AT	RE	1E	DUR
D	AT	RE	1E	DUR
	SR	M0	1F	Not applicable
F	AT	RE	1E	DUR
	SR	M0	1F	Not applicable

Topic #1975

Retrospective Drug Utilization Review

Retrospective DURs (Drug Utilization Reviews) are performed by BadgerCare Plus, Medicaid, and SeniorCare on a monthly basis. Review of drug claims against DUR Board-approved criteria generates patient profiles that are individually reviewed for clinical significance.

Each month, all BadgerCare Plus, Medicaid, and SeniorCare pharmacy claims are examined by a software program for potential adverse drug concerns. Criteria are developed by BadgerCare Plus, Medicaid, and SeniorCare and are reviewed and approved by the DUR Board. Problems that are reviewed include drug-drug interactions, overuse (i.e., early refill), drug-disease contraindications, duplicate therapy, high dose, and drug pregnancy contraindication.

If a potential drug problem is discovered, intervention letters are sent to all prescribers who ordered a drug relevant to an identified problem. Also included with an intervention letter is a response form for the prescriber to complete, a pre-addressed return envelope, and a patient drug profile.

Topic #12619

Therapeutic Duplication

The therapeutic duplication DUR (Drug Utilization Review) alert is activated when another drug is present in claims history in the same therapeutic class as the drug being dispensed. The message sent to the provider includes the drug name in claims history that is causing the alert. The therapeutic classes for the duplication alert include:

- Anti-anxiety agents.
- Antidepressants.
- Antihistamines.
- Antihypertensives.
- Antipsychotics.
- Antithrombotics.
- Barbiturates.
- Cardiovascular agents.
- Diuretics.
- Histamine H2 receptor inhibitors.
- Hypoglycemics.
- Narcotic analgesics.
- NSAIDs (nonsteroidal anti-inflammatory drugs) (including COX-2 selective agents).
- Oral contraceptives.
- Platelet aggregation inhibitors.
- PPI (proton pump inhibitor) drugs.
- Sedatives and hypnotics.
- Skeletal muscle relaxants.

Topic #12659

Underuse Precaution

The underuse precaution DUR (Drug Utilization Review) alert is activated when a member is late in obtaining a refill of a maintenance drug. The alert is sent to the provider when a drug is refilled and exceeds 125 percent of the days' supply on the same drug in history. The number of days late is calculated as the days after the prescription should have been refilled. Drugs with up to a 10-day supply are excluded from this alert. This alert applies, but is not limited to, the following therapeutic categories:

- ACE (angiotensin converting enzyme) inhibitor drugs.
- Alpha-blockers.
- Antilipidemics.
- Angiotensin-2 receptor antagonists.
- Anti-arrhythmics.
- Anticonvulsants.
- Antidepressants.
- Antipsychotics.
- Beta-blockers.
- Calcium channel blockers.
- Digoxin.
- Diuretics.
- Oral hypoglycemics.

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(b) 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 services.

"(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 Pharmacopeia–Drug Information.

"(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug.—

"(A) Defined.—

"(i) Multiple source drug.—The term 'multiple source drug' means, with respect to a c outpatient drug (not including any drug described in paragraph (5)) for which there are 2 c

"(I) are rated as therapeutically equivalent (under the Food and Drug Administratio 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(II) except as provided in subparagraph (B), are pharmaceutically equivalent an

Exhibit 2

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

UNITED STATES OF AMERICA *ex rel.* Victoria Starr, Plaintiffs, v. JANSSEN PHARMACEUTICA PRODUCTS, L.P., Defendant.	CIVIL ACTION NO. 04-cv-1529
UNITED STATES OF AMERICA *ex rel.* Lynn Powell, Plaintiffs, v. JANSSEN PHARMACEUTICA PRODUCTS, L.P., and JOHNSON & JOHNSON, Defendants.	CIVIL ACTION NO. 04-cv-5184
UNITED STATES OF AMERICA *ex rel.* Camille McGowan and Judy Doetterl, Plaintiffs, v. JANSSEN PHARMACEUTICA, INC., JANSSEN PHARMACEUTICA PRODUCTS, L.P., and JOHNSON & JOHNSON, INC. Defendants.	CIVIL ACTION NO. 05-cv-5436

UNITED STATES OF AMERICA, *et al.*, *ex rel.* Kurtis J. Barry, Plaintiffs, v. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON, INC. Defendants.	CIVIL ACTION NO. 10-cv-0098

UNITED STATES' COMPLAINT IN INTERVENTION

From at least 1999 through 2005, Johnson & Johnson (J&J) and its subsidiary Janssen Pharmaceuticals, Inc. ("Janssen") (collectively, "defendants") promoted Risperdal, an atypical antipsychotic drug, for uses that were not approved as safe and effective by the Food and Drug Administration (FDA) ("off-label uses") and, in some cases, were not covered by Medicaid and other federal healthcare programs. Defendants established a specialized ElderCare sales force to promote Risperdal. This sales force promoted Risperdal in nursing homes to control agitation, aggression, and other behavioral disturbances in elderly dementia patients. Janssen promoted Risperdal to control behavioral disturbances and conduct disorders in children and to treat attention deficit disorder and other off-label conditions. Janssen also promoted Risperdal for use in the general population to control mood and anxiety symptoms unrelated to any psychotic disorder. Clinical trials, including those sponsored by defendants, indicated that taking Risperdal increased the risk of strokes in the elderly and diabetes in all patients. In 2005, FDA requested that Janssen change the Risperdal label to include a "Boxed Warning," commonly known as a "black-box warning" – the agency's strongest warning – about the increased risk of death in the elderly. By knowingly and actively promoting Risperdal as safe and effective for off-label and

non-covered uses, defendants caused Medicaid and other federal healthcare programs to pay hundreds of millions of dollars for uncovered claims.

I. JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345 and supplemental jurisdiction over the common law causes of action pursuant to 28 U.S.C. § 1367(a).

2. This Court may exercise personal jurisdiction over defendants pursuant to 31 U.S.C. § 3732(a), because they transact business in this District.

3. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because defendants have transacted business in this District and have committed acts proscribed by 31 U.S.C. § 3729 in this District.

II. PARTIES

4. The United States brings this action on behalf of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) (formerly known as the Health Care Financing Administration), which administers the Medicaid program in conjunction with the states; the TRICARE Management Activity (TMA); the United States Office of Personnel Management (OPM); the United States Department of Veterans Affairs (VA); and the Office of Workers' Compensation Programs of the United States Department of Labor (DOL-OWCP).

5. Relator Victoria Starr resides in Oregon. In April 2004, Ms. Starr filed an action alleging violations of the False Claims Act (FCA), 31 U.S.C. §§ 3729-33, on behalf of herself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1) (2008).

6. Relator Lynn Powell resides in North Carolina. In November 2004, Ms. Powell filed an action alleging violations of the FCA on behalf of herself and the United States Government pursuant to *qui tam* provisions of the FCA.

7. Relators Camille McGowan and Judy Doetterl reside in New York. In December 2004, these relators filed an action alleging violations of the FCA on behalf of themselves and the United States Government pursuant to *qui tam* provisions of the FCA.

8. Relator Kurtis Barry resides in Colorado. In January 2010, Mr. Barry filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to *qui tam* provisions of the FCA.

9. Defendant J&J is a New Jersey corporation with its principal place of business in New Jersey. J&J manufactures, markets, and sells a wide range of pharmaceutical, medical, and related products. J&J is qualified to do business in Pennsylvania and does business in Pennsylvania.

10. Defendant Janssen is a Pennsylvania corporation with its principal place of business in New Jersey. Janssen is a wholly owned subsidiary of J&J and the successor in interest to Janssen Pharmaceutical Products, L.P., Janssen Pharmaceutica, Inc., and Ortho-McNeil-Janssen Pharmaceutical Products, Inc. From 1999 through 2005, and at all times relevant to the complaint, Janssen marketed and sold Risperdal. Janssen is qualified to do business in Pennsylvania and does business in Pennsylvania.

11. During the relevant time period, J&J was Janssen's sole owner. Janssen's President and Chief Executive Officer (CEO) reported directly to a J&J Company Group Chairman, who in turn reported to J&J's Executive Committee and Board of Directors. J&J and Janssen executives were also members of a Pharmaceutical Global Operating Committee and a Pharmaceutical Global Strategic Marketing Committee, through which J&J set overall corporate

goals that guided Janssen's strategic and tactical plans for Risperdal. J&J established Janssen's business objectives and sales goals and regularly reviewed and approved Janssen's sales numbers and projections. During the relevant time period, J&J supervised and controlled corporate sales goals; drug research, development, and manufacturing; medical affairs; regulatory affairs and compliance; legal affairs; and public relations. Defendants worked together to achieve the common business purpose of selling Risperdal.

III. STATUTORY AND REGULATORY FRAMEWORK

A. The False Claims Act

12. The False Claims Act (FCA), 31 U.S.C. §§ 3729–3733, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States, knowingly using a false record or statement material to a false claim, or conspiring to get a false claim paid. Specifically, the FCA provided, in part, that any person who:

> (a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or][1]
>
> (a)(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .
>
> * * *

[1] The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to this case by virtue of Section 4(f) of FERA, while Section 3279(a)(1) of the statute prior to FERA, and as amended in 1986, remains applicable here.

> For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information, (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(a)(1) (2008), (a)(1)(B) (2009), and (a)(3) (2008).

13. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 per false claim for violations occurring on or after September 29, 1999.

B. The Anti-Kickback Statute

14. The federal anti-kickback statute, 42 U.S.C. § 1320a7b(b), arose out of Congressional concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the Medicare and Medicaid programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

15. The anti-kickback statute prohibits drug companies from knowingly and willfully offering, paying, soliciting, or receiving remuneration, in cash or in kind, directly or indirectly to induce physicians or others to prescribe drugs for which payment may be made by federal health care programs.

C. The Federal Healthcare Programs

1. Medicaid Federal-State Health Care Program

16. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid

payments varies by state and is generally between 50 and 83 percent, depending on the state's per capita income. 42 U.S.C. § 1396d(b).

17. Although prescription drug coverage is an optional benefit for states under Medicaid, all states and the District of Columbia have opted to cover prescription drugs under their Medicaid state plan. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, determines the amount of federal funding needs for the quarter, and determines the amount of federal funding each state will be permitted to draw down as it actually incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims are presented for payment. At the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

18. The Medicaid Drug Rebate Program ("Rebate Program") is a partnership between CMS, State Medicaid Agencies, and participating drug manufacturers that helps to offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients. The Rebate Program requires, among other things, that a drug manufacturer enter into, and have in effect, a national rebate agreement ("Rebate Agreement") with the Secretary of HHS in exchange for State Medicaid coverage of most of the manufacturer's outpatient prescription drugs. Manufacturers are then responsible for paying rebates to states for those drugs based in part on the part on utilization by Medicaid patients. These rebates are paid by drug manufacturers on a quarterly basis and are generally shared between the States and the Federal government to offset the overall cost of the prescription drugs under the Medicaid program.

19. Under the Rebate Program, all states are generally required to provide coverage for drugs that meet the definition of a covered outpatient drug, as defined in the federal Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8(k)(2). Once the manufacturer enters into a Rebate Agreement, a state is generally required to cover that manufacturer's covered outpatient drugs under the state plan (with certain limited exceptions) unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(I).

20. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for inclusion in any of the compendia" set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

21. A drug does not generally meet the definition of a "covered outpatient drug" if it is prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. § 1396r-8 (k)(3). CMS has stated that the statutory definition of medically accepted indication "requires coverage of off-label uses of FDA-approved drugs for indications that are **supported** (as opposed to listed) in the compendia." Medicaid State Rebate Release No. 141 (May 4, 2006) (emphasis added). Thus, even if a drug is FDA-approved for one indication, Medicaid ordinarily does not cover other uses that do not qualify as medically accepted indications.

2. The TRICARE Program

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

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

24. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. § 199.4(g)(15)(i)(A)(Note).

3. The Federal Employee Health Benefits Program

25. The Federal Employee Health Benefits Program ("FEHBP") is a federally-funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. §§ 8901 *et seq.*

26. OPM administers this program and contracts with various health insurance carriers to provide services to FEHBP members. *Id.* at §§ 8902, 8909(a).

27. Monies for the FEHBP are maintained in the Employees Benefits Fund ("Treasury Fund"), which OPM administers. *Id.* at § 8909(a). The Treasury Fund — which the United States Treasury holds and invests — is the source of all relevant payments to the insurance carriers for services rendered to members. *Id.* at § 8909.

4. The Veterans Administration

28. The VA maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are purchased directly or indirectly by the VA and dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

5. The Labor Department

29. DOL-OWCP administers the following programs: the Federal Employees' Compensation Act, 5 U.S.C. § 8101 *et seq.*, which provides medical benefits to federal employees injured in the performance of duty; the Energy Employees Occupational Illness Compensation Program Act, 42 U.S.C. § 7384 *et seq.*, which provides medical benefits to eligible Department of Energy nuclear weapons workers; and the Black Lung Benefits Act,

30 U.S.C. § 901 *et seq.*, which provides medical benefits to coal miners who are totally disabled by pneumoconiosis arising out of coal mine employment.

IV. THE RISPERDAL LABEL

30. Risperdal is an atypical antipsychotic drug. On December 29, 1993, FDA approved Risperdal for "management of the manifestations of psychotic disorders" in adults. The approved label explained that "[t]he antipsychotic efficacy of RISPERDAL was established in short-term (6 to 8-weeks) controlled trials of schizophrenic inpatients."

31. The approved Risperdal label included a statement in the Precautions section that "[c]linical studies of Risperdal did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients." The label also provided special dosing instructions for the elderly, stating that "[i]n general, a lower starting dose is recommended for an elderly patient, reflecting a decreased pharmacokinetic clearance in the elderly, as well as a greater frequency of decreased hepatic, renal or cardiac function, and therapy greater tendency to postural hypotension." Janssen later sought FDA approval for 0.5 mg and 0.25 mg Risperdal tablets to address special dosing requirements of certain patient populations, including the elderly. In 1999, FDA approved the lower-dose Risperdal tablets.

32. On March 3, 2002, FDA approved revised labeling for Risperdal to state that Risperdal is indicated for "the treatment of schizophrenia."

33. On December 4, 2003, FDA approved Risperdal for the short-term treatment of acute manic or mixed episodes associated with Bipolar I disorder in adults.

34. Between 1999 and 2005, Risperdal was not approved by FDA for any other conditions in adults or for use in children for any purpose.

35. In 2006 and 2007, FDA approved Risperdal for the treatment of irritability associated with autistic disorder in children and adolescents, schizophrenia in adolescents, and Bipolar I disorder in children and adolescents.

V. PROMOTION OF RISPERDAL

A. Janssen Promoted Risperdal for Elderly Nursing Home Residents

36. From the time Risperdal was first approved in 1993, FDA repeatedly advised Janssen not to market the drug as safe and effective for the elderly. In addition, clinical studies, including those sponsored by defendants, indicated health risks in elderly dementia patients taking Risperdal, including the risk of strokes. In 2005, FDA requested that Janssen add a black-box warning to the Risperdal label about the risk of death in elderly patients taking the drug. Janssen promoted Risperdal to control behavioral disturbances in the elderly until at least 2005.

1. FDA Warned Janssen Against Promoting Risperdal as Safe and Effective in the Elderly.

37. When Janssen asked FDA to review certain marketing materials in August 1994, FDA advised Janssen "it would be misleading to suggest that the safety and efficacy of Risperdal has been established in the elderly." (Exhibit 1).

38. Janssen subsequently informed FDA that it was conducting a clinical trial (RIS-USA-63) aimed at determining the effectiveness of Risperdal in treating "behavioral disturbances in demented patients." In a letter dated April 28, 1995, FDA responded that the proposed label expansion would improperly suggest that Risperdal was effective for "all the various signs and symptoms that fall under such an umbrella, e.g., anxiety, depression, phobic fears, panic attacks, diurnal rhythm disturbances, etc. We would consider such a claim misleading in that sense. . . ." FDA also cautioned that behavioral disturbances in dementia patients were not necessarily psychotic manifestations and "might even be construed by some as

69. In addition to nursing homes, the long-term care pharmacy providers also serviced mental health facilities. In its 2002 business plan, Janssen identified mental retardation and developmental disability (MRDD) as a target market and encouraged sales representatives to market Risperdal as "the first choice for psychotic and behavioral disorder, including MRDD." Janssen trained speakers and consultant pharmacists and sponsored advisory boards or round table discussions to promote Risperdal for behavioral and conduct symptoms in MRDD patients.

B. Janssen Promoted Risperdal for Use in Children

70. Until late 2006, Risperdal was not approved for use in children for any purpose. The Risperdal label stated that "[t]he safety and effectiveness in children have not been established." Nonetheless, from at least 1999 through 2005, Janssen promoted Risperdal to treat children for a variety of unapproved uses, including conduct disorders, attention-deficit-hyperactivity disorder (ADHD), and bipolar disorder.

71. On August 15, 1996, Janssen asked FDA to approve an addition of language to the Risperdal label regarding pediatric use. FDA rejected Janssen's request, stating:

> [Y]ou have not identified any pediatric indications for which you believe Risperdal could be approved and you have provided no data from adequate and well controlled trials to support any such approvals. . . To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and the nonspecific cautionary advice about how to prescribe Risperdal for the unspecified target indication would only serve to promote the use of this drug in pediatric patients without any justification.

(Exhibit 13).

72. On March 3, 2000, Janssen met with FDA to discuss a clinical development plan for an indication for "conduct disorder" in children. Although FDA recognized that "conduct disorder" is a diagnosis listed in the Diagnostic and Statistical Manual of Mental Disorders, the agency questioned whether it could approve Risperdal for "conduct disorder," explaining that its

"main concern is that RISPERDAL or any other product would be used as a chemical straight jacket." In addition, FDA expressed concern that conduct disorder was "synonymous with aggression" and that Janssen was "trying to get approval of aggression under the guise of CD [conduct disorder]." (Exhibit 14).

73. Defendants knew that Risperdal could cause elevated levels of prolactin, a hormone released by the pituitary gland that stimulates breast development and milk production. Since launch, the FDA-approved label stated that Risperdal, like other antipsychotics, "elevates prolactin levels." The Risperdal label further stated that "the clinical significance of elevated serum prolactin levels is unknown for most patients."

74. One of Janssen's Key Base Business Goals was to grow and protect share in the child/adolescent market, which Janssen defined to include patients 19 years and under. Janssen's 2001 Base Business Plan stated that the fastest-growing market for Risperdal was pediatrics, with the use of Risperdal "exploding" at a growth rate of 17 percent, for a total market share of $340 million per year. Janssen recognized that Risperdal was used in children primarily for non-psychotic diagnoses: bipolar disorder (21%), autism (18%), ADHD (15%). Janssen also noted that Risperdal was typically prescribed in children "to control aggressive/impulsive behavior."

75. Janssen instructed its sales representatives to call on child psychiatrists as well as on mental health facilities that primarily treated children and to market Risperdal as effective to treat symptoms associated with various childhood disorders such as ADHD, OCD, and autism. The company sponsored numerous advisory boards with child psychiatrists and speakers programs concerning "Risperdal in Children and Adolescents with Severe and Disruptive Behaviors and Below-Average IQ."

76. Janssen prepared two plans for addressing the child and adolescent market in 2002: a business plan ("Risperdal Child and Adolescent Market Segment: 2002 Business Plan

Summary") and a tactical plan ("2002 Tactical Plan RISPERDAL Child and Adolescent Segment: Reach New Heights with Risperdal in 2002"). Janssen identified four key business strategies:

- Understand the level of awareness of RISPERDAL in the child and adolescent market segment;
- Educate health care providers on therapeutic options for treating mental illness in children;
- Develop a child and adolescent public relations and media management plan; and
- Clarify FDA requirements and accelerate JRF program to obtain child and adolescent labeling.

77. In 2002, Janssen created a "C&A Educational Initiative" to promote the use of Risperdal in children and adolescents ("C&A"). As part of this Initiative, Janssen developed advisory boards and CME programs and utilized national and regional opinion thought leaders in child psychiatry. For example, in March 2002, Janssen sponsored a meeting attended by 1,000 physicians, which Janssen executives later described as "[a] great way to get the word out to a big part of the child and adolescent prescribing community." Similarly, at an "Advisory Summit" in February 2003, Janssen presented data promoting Risperdal to treat conduct disorders in children with disruptive behavior disorders.

78. When FDA approved M-Tabs in April 2003, Janssen district managers encouraged contests and other incentives to promote this quick-dissolving Risperdal formulation in children:

> In the San Antonio District, district managers encouraged "Risperdal 'Back to School' Bashing" and proposed ice-cream parties, snacks and lunches as an effective way to deliver an efficacy message of fast onset of M-Tabs and use in the pediatric population.
>
> Notes from a District Managers' Conference Call on August 11, 2003 state: "'There is a very large market for the M-TABs* for children/adolescents!"

> In an August 20, 2003 Field Conference Report, a district manager praised the sales representative, stating " You have a great idea for M-Tab starter kits by including lollipops or small toys to be included in the kit along with a coupon and a 1 box of sample. These will be great to use on any child & adolescent psychiatrists that you have....Plan to have these made for our next work session." (Exhibit 15).

79. From at least 1997 through 2004, call notes by Janssen sales representatives and field conference reports from their managers reflect promotion of Risperdal as safe and effective in controlling behavioral disturbances in children and adolescents. For example:

Examples from 1997 & 1998 Call Notes

Maryland: "remind her [doctor] that risperdal is very effective and safe because she sees lots of children and aldolescence [sic]."

Michigan: "sold him on efficacy and safety in children."

Examples from 2000 Field Conference Reports

New York: "I observed that prolactin was a concern with several of your customers. [Y]ou have a good understanding of prolactin and how to handle this objection with your customers. For example, Dr. H[] stated that she sees prolactin related side effects quite often with Risperdal . . . You did a nice job of discussing how rare prolactin related side effects occur, how to manage it i.e. lowering the dose, and brought the discussion back to side effects that are not easily managed, i.e. diabetes."

Examples from 2001 Call Notes

Texas: "Discussed . . . proper dosing in children. Warned him about competition putting side effects out of centext [sic] regarding R[isperdal] in children. Asked for starts/switches in aggression"

Virginia: "INSERVICE FOR THE GROUP, WENT OVER RISPERDAL USE IN ADULTS AND CHILDREN, THE SYMPTOMS IT COVERS . . ."

Examples from 2002 Call Notes

Washington: "Dr. has not received information on conduct disorder and recent published articles. We reviewed efficacy of risperdone on aggression and hostility in special populations and doses."

New York: "[D]oesn't see adhd but will rx [prescribe] when sees."

Examples from 2002 Field Conference Reports

Minnesota: "[The doctor] then told you a story about a young woman who developed some prolactin related side effects on Risperdal. Based on his comments it was clear prolactin was an issue of his. You handled his objection and issue perfectly by explaining that any drug that blocks D2 [dopamine] can have an effect on prolactin however the incidence of seeing side effects is very low. You then went onto explain that he may be able to decrease the dose and maintain the great efficacy that he is seeing with Risperdal and at the same time hopefully the side effect will subside. He agreed that this was a good idea and would give it a try."

Examples from 2003 Call Notes

North Carolina: "Sees 30% kids, 40% adolescents, 30% adults . . . With kids – discussed serotonin profile page – lower doses equate to efficacy in treatment of agitation, aggression – symptoms with behavioral problems."

Indiana: "Next call remind him of the type of syms [symptoms] he can treat with Ris[perdal]. [P]aint the picture of a younger patient suffering from these sym [symptoms] and what ris can do for them."

Examples from 2004 Call Notes

South Carolina: "[B]rief follow up on use of Risperdal and moa [mechanism of action] that will treat anxiety and depressive symptoms. [E]mphasized the importance of dosing and how if dosed appropriately will treat odd [Oppositional Defiant Disorder] symptoms that present with adhd."

Maryland: "Goal: aggitated [sic]/aggression in children. Response: must rule out ADHD in children before rx [prescribing] atypical – Risperdal effectively treat[s] resistant depression at lower doses."

C. Off-Label Promotion in the General Population

80. In addition to marketing Risperdal for use in the elderly, children, and the mentally disabled, Janssen used many of the same tactics to promote Risperdal for off-label use in the general population. Janssen's business and tactical plans aimed at expanding the use of Risperdal to any patient who exhibited mood and anxiety symptoms.

81. At a National Meeting in 2001, Janssen directed sales representatives to emphasize that Risperdal was effective in treating a broad range of symptoms. Janssen's Mood and Anxiety Positioning statement for 2001 was:

Notes 1 through 8 referred to a list of all eight published, peer-reviewed epidemiological studies addressing atypical antipsychotics and diabetes risk.

99. On April 19, 2004, FDA sent a Warning Letter to Janssen that identified several concerns regarding the way Janssen characterized the diabetes risk of Risperdal in its November 10, 2003 letter (Exhibit 16).

100. Janssen sent a second letter to doctors on July 21, 2004, which reported the concerns that FDA had identified in its Warning Letter.

VII. PAYMENTS TO HEALTHCARE PROVIDERS

101. Janssen paid doctors who participated in the speakers program and other programs related to Risperdal to influence the doctors to write more prescriptions for Risperdal, and certain of the prescriptions written by these doctors were reimbursed by Medicaid and other public healthcare programs.

102. Sales representatives identified local doctors to be trained as speakers based on their potential for writing Risperdal prescriptions. Sales representatives told doctors that if they wanted to speak, they had to increase their Risperdal prescriptions. For example, in an October 7, 2003, e-mail, one sales representative told her district manager that a doctor in her district wanted to be a speaker for Janssen, but only 16 percent of his antipsychotic prescriptions were for Risperdal. The representative discussed plans to tell the doctor that he could qualify to speak the following year if he wrote 50 percent of his prescriptions for Risperdal. The doctor subsequently increased his Risperdal prescriptions and became a paid speaker in 2004.

103. Like local speakers, attendees at advisory boards were chosen by sales representatives based on their ability to write prescriptions for Risperdal. Attendees were paid an honorarium of approximately $1,500 to $2,000. Janssen intended to induce these attendees to

write prescriptions for Risperdal and tracked their prescriptions before and after their attendance at advisory boards to measure whether they increased their prescriptions.

VIII. SUBMISSION OF FALSE CLAIMS TO FEDERAL HEALTHCARE PROGRAMS

104. Defendants' fraudulent conduct resulted in the submission of false claims to federal healthcare programs. From 1999 through 2005, domestic sales of Risperdal increased from $892 million to $2 billion per year. Defendants targeted patient populations that they knew included large numbers of Medicaid beneficiaries, such as nursing home residents. As a result, during the same time period, defendants caused the Medicaid reimbursements for Risperdal to more than double from $500 million to over $1 billion annually. Defendants also closely tracked the effect of their sales and marketing on both on-label and off-label utilization. According to defendants' own market research, in 2002 as much as 70 to 75 percent of the prescriptions for Risperdal were for off-label uses, some of which were not medically accepted indications for which the United States and state Medicaid programs provided coverage.

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1) (2008))

105. The United States re-alleges the preceding paragraphs as if fully set forth herein.

106. Defendants knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for Risperdal prescriptions that were not covered by Medicaid and/or were ineligible for payment as a result of illegal kickbacks.

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

SECOND CAUSE OF ACTION
(False Claims Act: False Statements)
(31 U.S.C. § 3729(a)(1)(B) (2009))

108. The United States re-alleges the preceding paragraphs as if fully set forth herein.

109. Defendants knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim.

110. By virtue of the false records or statements that defendants made, used, or caused to be made or used, the United States is entitled to treble damages and civil penalties of not less than $5,500 or more than $11,000 for each such false record or statement.

THIRD CAUSE OF ACTION
(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(3) (2008))

111. The United States re-alleges the preceding paragraphs as if fully set forth herein.

112. Defendants and others conspired to defraud the Government by getting false or fraudulent claims allowed.

113. By virtue of the conspiracy, defendants and others got false or fraudulent claims paid and the United States is entitled to treble damages and civil penalties of not less than $5,500 or more than $11,000 for each such false or fraudulent claim.

FOURTH CAUSE OF ACTION
(Unjust Enrichment)

114. The United States re-alleges the preceding paragraphs as if fully set forth herein.

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

116. The United States claims the recovery of all monies by which defendants have been unjustly enriched.

PRAYER FOR RELIEF

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

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law.

2. On the Second Count under the False Claims Act, for the amount the United States was damaged, trebled as required by law, and such civil penalties as are required by law.

3. On the Third Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law.

4. On the Fourth Count for unjust enrichment, for the amounts by which defendants were unjustly enriched, plus interest, costs, and expenses.

5. On all Counts, such further relief as the Court deems just and proper.

Respectfully submitted,

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Civil Division

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United States Attorney
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Dated: November 4, 2013

EXHIBIT 13

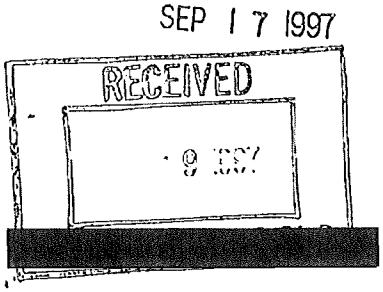
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-272 / SLR-006
NDA 20-588 / SLR-001

Janssen Research Foundation
Attention: [redacted]
1125 Trenton-Harbourton Road
Post Office Box 200
Titusville, NJ 08560-0200



Dear [redacted]

Please refer to your supplemental new drug applications dated August 15, 1996, received August 21, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Risperdal (risperidone) 1mg, 2mg, 3mg, 4mg tablets and Risperdal (risperidone) 1mg/mL oral solution.

These supplemental applications provide for a change in the labeling with the addition of a new section for pediatric use.

We have completed our review and find the information presented is inadequate, and the supplemental applications are not approvable under section 505(d) of the Act and 21 CFR 314.125(b).

Your supplement proposes the expansion of Risperdal use into pediatric patients, however, you never state for what child or adolescent psychiatric disorders Risperdal would be intended. Indeed, you acknowledge that you have not provided substantial evidence from adequate and well-controlled trials to support any pediatric indications nor developed a rationale to extend the results of studies conducted in adults to children. Your rationale for proposing this supplement appears to be simply that, since Risperdal is being used in pediatric patients, this use should be acknowledged in some way in labeling.

We note that labeling changes proposed are nonspecific:

1. Under the Pharmacokinetic subsection of Clinical Pharmacology, you propose acknowledging that no systematically collected PK data are available, but you refer nevertheless to the Dosage and Administration section.

2. Under the Pediatric Use subsection of Precautions, you refer to "limited evidence regarding the safety and effectiveness of risperidone in the pediatric population," and again refer to the Dosage and Administration section.

3. Finally, in the Dosage and Administration section, you again suggest that there is limited evidence of safety and effectiveness from "small clinical studies, literature reports, and spontaneously reported adverse events." As noted, you never state in this language what indications are supported by these data. Regarding safety, you simply suggest that the safety profile for Risperdal appears to be similar in pediatric patients to that observed in adults. Nevertheless, you advise caution, i.e., avoidance of prescribing in neonates and infants, and cautious titration, beginning with 0.25 mg/day in children and adolescents.

You have provided very little information to support these proposed labeling changes. You acknowledge that the supplements provide no i nterpretable efficacy data. The safety data submitted were also very limited, including data for n=14 pediatric patients exposed to Risperdal in Janssen-sponsored studies, n=29 pediatric patients exposed to Risperdal in studies reported in the published literature, and n=186 spontaneous reports involving pediatric patients exposed to Risperdal. None of these data were suggestive of any unusual or unexpected adverse events occurring specifically in association with the use of Risperdal in the pediatric age group.

Accordingly, we must conclude that there is inadequate support for the changes sought. As noted, you have not identified any pediatric indications for which you believe Risperdal could be approved and you have provided no data from adequate and well controlled trials to support any such approvals. There were no specific safety findings of sufficient concern among the meager safety data submitted to justify adding any information to labeling about the safety experience with this drug in the pediatric age group. To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and the nonspecific cautionary advice about how to prescribe Risperdal for the unspecified target indications would serve only to promote the use of this drug in pediatric patients without any justification. Consequently, this supplement is not approved.

Within 10 days after the date of this letter, you are required to amend the supplemental applications, notify us of your intent to file amendments, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may proceed to withdraw these supplemental applications. Any amendments should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

If you have any questions, please contact Steven D. Hardeman, R.Ph., Project Manager, at (301) 594-5533.

Sincerely yours,

Paul Leber, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

EXHIBIT 14

JANSSEN · PHARMACEUTICA · RESEARCH FOUNDATION ·

RECORD OF FDA CONTACT

PRODUCT IDENTIFICATION: RISPERDAL® (risperidone) tablets and oral solution	
ORIGINATOR/SIGNATURE: [redacted]	DATE: 03 March 2000
NDA NUMBER: IND NUMBER: 31,931	INITIATED BY: JANSSEN X BY TELEPHONE FDA IN PERSON X
FDA PERSONNEL: See below	DIVISION: Neuropharmacological Drug Products TELEPHONE: (301) 594-5533
SUBJECT: Minutes of March 3rd Meeting to Discuss RISPERDAL Pediatric Exclusivity and Development Program for Conduct Disorder	

Meeting Attendees:

FDA *Janssen Research Foundation (JRF)*

[redacted]

Summary: The objectives of this meeting were to discuss the requirements to obtain an additional six months market exclusivity as permitted under the FDA Modernization Act of 1997 and to discuss the clinical development plan for an indication in conduct disorder. The key issues discussed were:

Pediatric Exclusivity

- Pediatric exclusivity is not possible based on safety and PK alone (as proposed). Exclusivity must be based on the approved indication.
- FDA will issue a written request that contains a controlled trial in schizophrenia. JRF will submit a proposal for this controlled trial in adolescents (>13 years old); younger children will not need to be studied.
- The proposed PK trial was acceptable and if needed, JRF could enroll a mixed diagnosis (conduct disorder, schizophrenia) population.

Conduct Disorder (CD) as an Indication

- FDA questioned the validity of CD as a diagnosis and even the concept of CD as a disorder.
- They stated that even though CD is in DSM-IV that does not mean it is a disorder warranting an indication in the label.
- FDA feels a public hearing is needed to define how to look at CD. Their main concern is that RISPERDAL or any other product would be used as a chemical straight jacket. This is the reason the issue needs to be publicly debated.
- FDA believes aggression is synonymous with CD.
- We could proceed with the two trials proposed (RIS-USA-161, RIS-USA-222). However, even if these trials are positive, they would want a consensus advisory committee meeting to confirm the disorder exists. This advisory committee meeting would be triggered by the review of our supplemental application.
- The Division is willing to work with us to define scales for CD and would like to see our data to show their validity and reliability.

Details: A briefing package was submitted on February 10, 2000 (Serial No. 237) in which background information was provided to address questions proposed by Janssen. The questions were divided into two sections, pediatric exclusivity and registration strategy for conduct disorder, and served as the agenda for the meeting. Although we did not discuss each question individually, the issues raised in the questions were discussed in general. The questions and associated discussion points are provided below.

Pediatric Exclusivity

- *Is RIS-USA-160 adequately designed to provide sufficient pK/safety data for inclusion in the labeling for a pediatric population?*
- *Will a written request be issued based on the pharmacokinetic data from the proposed trial RIS-USA-160, as well as the safety data from trials RIS-USA-93, RIS-CAN-19, RIS-USA-97, RIS-CAN-20 and RIS-INT-41?*

[redacted] indicated that they want to see at least 1 controlled trial in the indication we already have approved in order to obtain pediatric exclusivity. They don't believe that submitting only PK and safety data is in the spirit of the pediatric exclusivity provision, unless we can prove schizophrenia is the same in pediatric and adults. So far they have not seen a credible argument that the two populations are the same and did not think it was a worth while endeavor for us to try to prove. Because the safety data proposed is not from a schizophrenic population, it can not be handled appropriately in the label since it would be considered an implied claim. The safety and PK data for pediatrics may be useful, but there are other ways to convey this information to physicians.

For the controlled trial, FDA thought the appropriate pediatric subgroup to study in schizophrenia would be adolescents 13 to 16 years old. Although there are some schizophrenic patients as young as 10 years old, they did not think it would be possible to enroll enough patients in this younger age group. FDA felt they had enough information to issue a written request, however, we suggested that we submit a proposal for the study for them to base the written request on. FDA agreed this would be helpful.

In regards to the proposed PK trial, FDA did not have any specific comments and believed it would provide useful information. They did not have any concerns that the age groups being proposed were younger (5-16 years old), as long as this information was being generated to support an indication in younger patients. FDA also indicated that it is acceptable to study a mixed diagnosis (conduct disorder, schizophrenia) population in the PK trial.

Registration Strategy for Conduct Spectrum Disorder

- *Does the Division support the use of the term "conduct spectrum disorder" to describe conduct disorder, oppositional defiant disorder and disruptive behavior disorder not otherwise specified, in children?*
- *As a follow-up to the letter from the Division on January 22, 1997, does the Division agree with our proposed clinical development plan to support the indication of Conduct Spectrum Disorder, including Conduct Disorder (312.8), Oppositional Defiant Disorder (313.81) and Disruptive Behavior Disorder Not Otherwise Specified (312.9), in children ages 5-16 without mental retardation?*
- *In studies RIS-USA-161 and RIS-USA-222, the Nisonger Child Behavior Rating Form - modified version (N-CBRF), will be used to assess efficacy. The Conduct Problem subscale of the N-CBRF will be the primary outcome variable of these trials. Secondary efficacy parameters will be based on the Conners Parent Rating Scale (CPRS) and Clinical Global Impression (CGI). Does the Division agree that these are the appropriate parameters for evaluating non-mentally retarded children with conduct spectrum disorder?*

- *Are the proposed studies RIS-USA-161 and RIS-USA-222 adequately designed to evaluate the safety and efficacy of risperidone in non-mentally retarded children with conduct spectrum disorder?*
- *Are the available data and data from the proposed trials adequate to support a new indication for risperidone for the treatment of conduct spectrum disorder in pediatric patients (ages 5-16) without mental retardation?*

FDA questioned the validity of conduct disorder (CD) as a diagnosis and even the concept of CD as a disorder. They don't believe it is well accepted outside the child psychiatrist community. FDA acknowledged CD as a valid clinical entity as it is included in DSM-IV, however elevation of a disorder to permanent status in DSM does not make it a disorder warranting an indication in the label.

FDA believes CD is synonymous with aggression and thinks we are trying to get approval of aggression under the guise of CD. Although we strongly disagreed, FDA indicated that they feel the problem is in the nature of the diagnosis because it is just a "list of behaviors", mainly aggressive behaviors that annoy others. If CD is just a form of aggressive behavior, they recommended that we study this from a symptom approach and look at aggression straight on. If the symptom approach were taken, FDA would expect us to look at the effects of RISPERDAL in three models. The suggested populations to examine were dementia, mental retardation, and conduct disorder. However, the first step in looking at aggression would be to get agreement publicly (e.g., an advisory committee meeting) on how to define aggression and the best way to measure it. FDA acknowledged it would take time to get public agreement and that this approach may not be the easiest way to get approval.

FDA commented that they do not often question a diagnosis, but in the case of CD they are. They feel a public hearing is needed to define how to look at CD and if it is an indication that society is willing to treat. Their main concern is that RISPERDAL or any other product would be used as a chemical straight jacket. Although CD has been discussed publicly at several conferences, the conference audiences have been only child psychiatrists. FDA would require this type of issue to be discussed by a wider scope of psychiatrists, so that the entire psychiatric community can weigh in on the decision, similar to discussions regarding behavioral disturbances in dementia at the March 9, 2000 Psychopharmacological Drug Advisory Committee meeting.

In the absence of a public hearing, either on aggression or CD itself, FDA could not assure us that we would be able to get an indication in the label, even with two positive trials. They emphasized again that they are uncertain whether CD is a diagnosis that merits treatment.

In regards to the two trials proposed (RIS-USA-161, RIS-USA-222), the FDA commented that they have no experience with the scale selected (Nisonger Behavior Rating Form). Based on the information we provided, (Attachment 1), they did not feel the subscale of the Nisonger mapped well to CD, and it was more of a combination of Oppositional Defiant Disorder and CD. This is based on the questions "talks back to teacher, parents, or other adults," "stubborn, has to do things own way," and "disobedient". We commented that we have experience with the Nisonger scale and believe it has a better CD subscale than the Conners rating scale does.

FDA asked about the validity and reliability of the Nisonger scale. We provided an article by Aman, et al (Attachment 2) to demonstrate validation in a mental retardation (MR) population. FDA indicated that they would not extrapolate from the MR population to the non-MR, and that we would have to validate the use of the scale in the non-MR population as well. We informed them we are in the process of doing the validation in the non-MR population. To address reliability, we offered to send the available clinical data we have generated along with any literature references. FDA requested that the clinical data provided include an item analysis.

Until FDA reviews the validation and reliability data, they can not accept the use of the Nisonger scale as the primary endpoint. We asked if they preferred us to use another scale (i.e., Conners), but they

indicated they did not have an alternative scale for us to use. The subscales of the Conners rating scale was provided to FDA for their review as well (Attachment 3).

We talked briefly about the length of the proposed trials. Although 6 weeks is short, they thought it is an acceptable duration for the trials. In chronic conditions, they would like to see that the drug effect persists, and that may not be accomplished in a 6 week trial. If we decide to do 6 week trials, they requested that we provide a rationale as to why trials of longer duration are not possible (e.g., because of a high drop out rate).

With regards to safety, we pointed out that our long-term data in pediatrics would be in a MR population. FDA did not think this would taint the non-MR safety data, but we would need to address how the MR data is relevant in any application. The number of pediatric patients with long-term exposure to RISPERDAL (>300) is not robust, but is generally the exposure numbers the Division is used to seeing. FDA commented on the high rate of somnolence (50%) presented in the background package for RIS-USA-93 and pointed out that this will be a problem if it is a chronic effect. We explained that additional analyses of the data have been performed which showed that this effect was not tied into efficacy.

It was emphasized in conclusion, that if we choose to proceed with the two proposed trials, even if they are positive, FDA would want a consensus advisory committee meeting to confirm that CD is a disorder worthy of treatment and requires a separate indication in the label.

Action Item: Submit available clinical data on the reliability of Nisonger scale.

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Exhibit 4

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, November 4, 2013

Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations

Allegations Include Off-label Marketing and Kickbacks to Doctors and Pharmacists

WASHINGTON - Global health care giant Johnson & Johnson (J&J) and its subsidiaries will pay more than $2.2 billion to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal, Invega and Natrecor, including promotion for uses not approved as safe and effective by the Food and Drug Administration (FDA) and payment of kickbacks to physicians and to the nation's largest long-term care pharmacy provider. The global resolution is one of the largest health care fraud settlements in U.S. history, including criminal fines and forfeiture totaling $485 million and civil settlements with the federal government and states totaling $1.72 billion.

"The conduct at issue in this case jeopardized the health and safety of patients and damaged the public trust," said Attorney General Eric Holder. "This multibillion-dollar resolution demonstrates the Justice Department's firm commitment to preventing and combating all forms of health care fraud. And it proves our determination to hold accountable any corporation that breaks the law and enriches its bottom line at the expense of the American people."

The resolution includes criminal fines and forfeiture for violations of the law and civil settlements based on the False Claims Act arising out of multiple investigations of the company and its subsidiaries.

"When companies put profit over patients' health and misuse taxpayer dollars, we demand accountability," said Associate Attorney General Tony West. "In addition to significant monetary sanctions, we will ensure that non-monetary measures are in place to facilitate change in corporate behavior and help ensure the playing field is level for all market participants."

In addition to imposing substantial monetary sanctions, the resolution will subject J&J to stringent requirements under a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). This agreement is designed to increase accountability and transparency and prevent future fraud and abuse.

"As patients and consumers, we have a right to rely upon the claims drug companies make about their products," said Assistant Attorney General for the Justice Department's Civil Division Stuart F. Delery. "And, as taxpayers, we have a right to ensure that federal health care dollars are spent appropriately. That is why this Administration has continued to pursue aggressively – with all of our available law enforcement tools -- those companies that corrupt our health care system."

J&J Subsidiary Janssen Pleads Guilty to Misbranding Antipsychotic Drug

In a criminal information filed today in the Eastern District of Pennsylvania, the government charged that, from March 3, 2002, through Dec. 31, 2003, Janssen Pharmaceuticals Inc., a J&J subsidiary, introduced the antipsychotic drug Risperdal into interstate commerce for an unapproved use, rendering the product misbranded. For most of this time period, Risperdal was approved only to treat schizophrenia. The information alleges that Janssen's sales representatives promoted Risperdal to physicians and other prescribers who treated elderly dementia patients by urging the prescribers to use Risperdal to treat symptoms such as anxiety, agitation, depression, hostility and confusion. The information alleges that the company created written sales aids for use by Janssen's ElderCare sales force that emphasized symptoms and minimized any mention of the FDA-approved use, treatment of schizophrenia. The company also provided incentives for off-label promotion and intended use by basing sales representatives' bonuses on total sales of Risperdal in their sales areas, not just sales for FDA-approved uses.

In a plea agreement resolving these charges, Janssen admitted that it promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly, non-schizophrenic dementia patients. Under the terms of the plea agreement, Janssen will pay a total of $400 million, including a criminal fine of $334 million and forfeiture of $66 million. Janssen's guilty plea will not be final until accepted by the U.S. District Court.

The Federal Food, Drug, and Cosmetic Act (FDCA) protects the health and safety of the public by ensuring, among other things, that drugs intended for use in humans are safe and effective for their intended uses and that the labeling of such drugs bear true, complete and accurate information. Under the FDCA, a pharmaceutical company must specify the intended uses of a drug in its new drug application to the FDA. Before approval, the FDA must determine that the drug is safe and effective for those specified uses. Once the drug is approved, if the company intends a different use and then introduces the drug into interstate commerce for that new, unapproved use, the drug becomes misbranded. The unapproved use is also known as an "off-label" use because it is not included in the drug's FDA-approved labeling.

"When pharmaceutical companies interfere with the FDA's mission of ensuring that drugs are safe and effective for the American public, they undermine the doctor-patient relationship and put the health and safety of patients at risk," said Director of the FDA's Office of Criminal Investigations John Roth. "Today's settlement demonstrates the government's continued focus on pharmaceutical companies that put profits ahead of the public's health. The FDA will continue to devote resources to criminal investigations targeting pharmaceutical companies that disregard the drug approval process and recklessly promote drugs for uses that have not been proven to be safe and effective."

J&J and Janssen Settle Civil Allegations of Targeting Vulnerable Patients with the Drugs Risperdal and Invega for Off-Label Uses

In a related civil complaint filed today in the Eastern District of Pennsylvania, the United States alleges that Janssen marketed Risperdal to control the behaviors and conduct of the nation's most vulnerable patients: elderly nursing home residents, children and individuals with mental disabilities. The government alleges that J&J and Janssen caused false claims to be submitted to federal health care programs by promoting Risperdal for off-label uses that federal health care programs did not cover, making false and misleading statements about the safety and efficacy of Risperdal and paying kickbacks to physicians to prescribe Risperdal.

"J&J's promotion of Risperdal for unapproved uses threatened the most vulnerable populations of our

society – children, the elderly and those with developmental disabilities," said U.S. Attorney for the Eastern District of Pennsylvania Zane Memeger. "This historic settlement sends the message that drug manufacturers who place profits over patient care will face severe criminal and civil penalties."

In its complaint, the government alleges that the FDA repeatedly advised Janssen that marketing Risperdal as safe and effective for the elderly would be "misleading." The FDA cautioned Janssen that behavioral disturbances in elderly dementia patients were not necessarily manifestations of psychotic disorders and might even be "appropriate responses to the deplorable conditions under which some demented patients are housed, thus raising an ethical question regarding the use of an antipsychotic medication for inappropriate behavioral control."

The complaint further alleges that J&J and Janssen were aware that Risperdal posed serious health risks for the elderly, including an increased risk of strokes, but that the companies downplayed these risks. For example, when a J&J study of Risperdal showed a significant risk of strokes and other adverse events in elderly dementia patients, the complaint alleges that Janssen combined the study data with other studies to make it appear that there was a lower overall risk of adverse events. A year after J&J had received the results of a second study confirming the increased safety risk for elderly patients taking Risperdal, but had not published the data, one physician who worked on the study cautioned Janssen that "[a]t this point, so long after [the study] has been completed ... we must be concerned that this gives the strong appearance that Janssen is purposely withholding the findings."

The complaint also alleges that Janssen knew that patients taking Risperdal had an increased risk of developing diabetes, but nonetheless promoted Risperdal as "uncompromised by safety concerns (does not cause diabetes)." When Janssen received the initial results of studies indicating that Risperdal posed the same diabetes risk as other antipsychotics, the complaint alleges that the company retained outside consultants to re-analyze the study results and ultimately published articles stating that Risperdal was actually associated with a lower risk of developing diabetes.

The complaint alleges that, despite the FDA warnings and increased health risks, from 1999 through 2005, Janssen aggressively marketed Risperdal to control behavioral disturbances in dementia patients through an "ElderCare sales force" designed to target nursing homes and doctors who treated the elderly. In business plans, Janssen's goal was to "[m]aximize and grow RISPERDAL's market leadership in geriatrics and long term care." The company touted Risperdal as having "proven efficacy" and "an excellent safety and tolerability profile" in geriatric patients.

In addition to promoting Risperdal for elderly dementia patients, from 1999 through 2005, Janssen allegedly promoted the antipsychotic drug for use in children and individuals with mental disabilities. The complaint alleges that J&J and Janssen knew that Risperdal posed certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production. Nonetheless, one of Janssen's Key Base Business Goals was to grow and protect the drug's market share with child/adolescent patients. Janssen instructed its sales representatives to call on child psychiatrists, as well as mental health facilities that primarily treated children, and to market Risperdal as safe and effective for symptoms of various childhood disorders, such as attention deficit hyperactivity disorder, oppositional defiant disorder, obsessive-compulsive disorder and autism. Until late 2006, Risperdal was not approved for use in children for any purpose, and the FDA repeatedly warned the company against promoting it for use in children.

The government's complaint also contains allegations that Janssen paid speaker fees to doctors to influence them to write prescriptions for Risperdal. Sales representatives allegedly told these doctors that if they wanted to receive payments for speaking, they needed to increase their Risperdal prescriptions.

In addition to allegations relating to Risperdal, today's settlement also resolves allegations relating to

Invega, a newer antipsychotic drug also sold by Janssen. Although Invega was approved only for the treatment of schizophrenia and schizoaffective disorder, the government alleges that, from 2006 through 2009, J&J and Janssen marketed the drug for off-label indications and made false and misleading statements about its safety and efficacy.

As part of the global resolution, J&J and Janssen have agreed to pay a total of $1.391 billion to resolve the false claims allegedly resulting from their off-label marketing and kickbacks for Risperdal and Invega. This total includes $1.273 billion to be paid as part of the resolution announced today, as well as $118 million that J&J and Janssen paid to the state of Texas in March 2012 to resolve similar allegations relating to Risperdal. Because Medicaid is a joint federal-state program, J&J's conduct caused losses to both the federal and state governments. The additional payment made by J&J as part of today's settlement will be shared between the federal and state governments, with the federal government recovering $749 million, and the states recovering $524 million. The federal government and Texas each received $59 million from the Texas settlement.

Kickbacks to Nursing Home Pharmacies

The civil settlement also resolves allegations that, in furtherance of their efforts to target elderly dementia patients in nursing homes, J&J and Janssen paid kickbacks to Omnicare Inc., the nation's largest pharmacy specializing in dispensing drugs to nursing home patients. In a complaint filed in the District of Massachusetts in January 2010, the United States alleged that J&J paid millions of dollars in kickbacks to Omnicare under the guise of market share rebate payments, data-purchase agreements, "grants" and "educational funding." These kickbacks were intended to induce Omnicare and its hundreds of consultant pharmacists to engage in "active intervention programs" to promote the use of Risperdal and other J&J drugs in nursing homes. Omnicare's consultant pharmacists regularly reviewed nursing home patients' medical charts and made recommendations to physicians on what drugs should be prescribed for those patients. Although consultant pharmacists purported to provide "independent" recommendations based on their clinical judgment, J&J viewed the pharmacists as an "extension of [J&J's] sales force."

J&J and Janssen have agreed to pay $149 million to resolve the government's contention that these kickbacks caused Omnicare to submit false claims to federal health care programs. The federal share of this settlement is $132 million, and the five participating states' total share is $17 million. In 2009, Omnicare paid $98 million to resolve its civil liability for claims that it accepted kickbacks from J&J and Janssen, along with certain other conduct.

"Consultant pharmacists can play an important role in protecting nursing home residents from the use of antipsychotic drugs as chemical restraints," said U.S. Attorney for the District of Massachusetts Carmen Ortiz. "This settlement is a reminder that the recommendations of consultant pharmacists should be based on their independent clinical judgment and should not be the product of money paid by drug companies."

Off-Label Promotion of the Heart Failure Drug Natrecor

The civil settlement announced today also resolves allegations that J&J and another of its subsidiaries, Scios Inc., caused false and fraudulent claims to be submitted to federal health care programs for the heart failure drug Natrecor. In August 2001, the FDA approved Natrecor to treat patients with acutely decompensated congestive heart failure who have shortness of breath at rest or with minimal activity. This approval was based on a study involving hospitalized patients experiencing severe heart failure who received infusions of Natrecor over an average 36-hour period.

In a civil complaint filed in 2009 in the Northern District of California, the government alleged that, shortly after Natrecor was approved, Scios launched an aggressive campaign to market the drug for scheduled, serial outpatient infusions for patients with less severe heart failure – a use not included in the FDA-approved label and not covered by federal health care programs. These infusions generally involved visits

to an outpatient clinic or doctor's office for four- to six-hour infusions one or two times per week for several weeks or months.

The government's complaint alleged that Scios had no sound scientific evidence supporting the medical necessity of these outpatient infusions and misleadingly used a small pilot study to encourage the serial outpatient use of the drug. Among other things, Scios sponsored an extensive speaker program through which doctors were paid to tout the purported benefits of serial outpatient use of Natrecor. Scios also urged doctors and hospitals to set up outpatient clinics specifically to administer the serial outpatient infusions, in some cases providing funds to defray the costs of setting up the clinics, and supplied providers with extensive resources and support for billing Medicare for the outpatient infusions.

As part of today's resolution, J&J and Scios have agreed to pay the federal government $184 million to resolve their civil liability for the alleged false claims to federal health care programs resulting from their off-label marketing of Natrecor. In October 2011, Scios pleaded guilty to a misdemeanor FDCA violation and paid a criminal fine of $85 million for introducing Natrecor into interstate commerce for an off-label use.

"This case is an example of a drug company encouraging doctors to use a drug in a way that was unsupported by valid scientific evidence," said First Assistant U.S. Attorney for the Northern District of California Brian Stretch. "We are committed to ensuring that federal health care programs do not pay for such inappropriate uses, and that pharmaceutical companies market their drugs only for uses that have been proven safe and effective."

Non-Monetary Provisions of the Global Resolution and Corporate Integrity Agreement

In addition to the criminal and civil resolutions, J&J has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA includes provisions requiring J&J to implement major changes to the way its pharmaceutical affiliates do business. Among other things, the CIA requires J&J to change its executive compensation program to permit the company to recoup annual bonuses and other long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. J&J may recoup monies from executives who are current employees and from those who have left the company. The CIA also requires J&J's pharmaceutical businesses to implement and maintain transparency regarding their research practices, publication policies and payments to physicians. On an annual basis, management employees, including senior executives and certain members of J&J's independent board of directors, must certify compliance with provisions of the CIA. J&J must submit detailed annual reports to HHS-OIG about its compliance program and its business operations.

"OIG will work aggressively with our law enforcement partners to hold companies accountable for marketing and promotion that violate laws intended to protect the public," said Inspector General of the U.S. Department of Health and Human Services Daniel R. Levinson. "Our compliance agreement with Johnson & Johnson increases individual accountability for board members, sales representatives, company executives and management. The agreement also contains strong monitoring and reporting provisions to help ensure that the public is protected from future unlawful and potentially harmful off-label marketing."

Coordinated Investigative Effort Spans Federal and State Law Enforcement

This resolution marks the culmination of an extensive, coordinated investigation by federal and state law enforcement partners that is the hallmark of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaborations to fight fraud. Announced in May 2009 by Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius, the HEAT initiative has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation.

The criminal cases against Janssen and Scios were handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania and the Northern District of California and the Civil Division's Consumer Protection Branch. The civil settlements were handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania, the Northern District of California and the District of Massachusetts and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division, the FDA's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

This matter was investigated by HHS-OIG, the Department of Defense's Defense Criminal Investigative Service, the FDA's Office of Criminal Investigations, the Office of Personnel Management's Office of Inspector General, the Department of Veterans Affairs, the Department of Labor, TRICARE Program Integrity, the U.S. Postal Inspection Service's Office of the Inspector General and the FBI.

One of the most powerful tools in the fight against Medicare and Medicaid financial fraud is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $16.7 billion through False Claims Act cases, with more than $11.9 billion of that amount recovered in cases involving fraud against federal health care programs.

The department enforces the FDCA by prosecuting those who illegally distribute unapproved, misbranded and adulterated drugs and medical devices in violation of the Act. Since 2009, fines, penalties and forfeitures that have been imposed in connection with such FDCA violations have totaled more than $6 billion.

The civil settlements described above resolve multiple lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the government and to share in any recovery. From the federal government's share of the civil settlements announced today, the whistleblowers in the Eastern District of Pennsylvania will receive $112 million, the whistleblowers in the District of Massachusetts will receive $27.7 million and the whistleblower in the Northern District of California will receive $28 million. Except to the extent that J&J subsidiaries have pleaded guilty or agreed to plead guilty to the criminal charges discussed above, the claims settled by the civil settlements are allegations only, and there has been no determination of liability.
Court documents related to today's settlement can be viewed online at www.justice.gov/opa/jj-pc-docs.html.

13-1170 Attorney General