UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.* BERNARD LISITZA and DAVID KAMMERER, Plaintiffs, v. JOHNSON & JOHNSON, ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., and JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC., Defendants.	Civil Action No. 07-10288-RGS Civil Action No. 05-11518-RGS

COMPLAINT OF THE UNITED STATES

This is an action against defendant pharmaceutical manufacturer Johnson & Johnson and two of its subsidiaries (collectively, "J&J") to recover treble damages, restitution, and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-33, and the common law for causing Omnicare, Inc. ("Omnicare"), the nation's largest long-term care pharmacy, to submit false claims to Medicaid as a result of numerous kickbacks that J&J paid to Omnicare in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), during the period from 1999 through 2004. At the time, Omnicare was one of J&J's largest customers, especially for Risperdal, a J&J antipsychotic drug that, at J&J's behest, Omnicare pharmacists recommended for nursing home patients who exhibited behavioral symptoms associated with Alzheimer's Disease and dementia. Over the years 1999 through 2004, J&J paid Omnicare tens of millions of dollars in kickbacks to induce Omnicare to purchase and to recommend Risperdal and other J&J drugs. As detailed below, these kickbacks took various forms, including market share rebate payments conditioned on Omnicare engaging in "active intervention programs" for J&J drugs, payments that were

ostensibly for the purchase of Omnicare data, and various "grants" and other payments, all of which J&J intended to induce Omnicare to purchase and to recommend J&J drugs.

The kickbacks achieved J&J's intended purpose. During the 1999 through 2004 period, Omnicare engaged in intensive efforts to convince physicians to prescribe J&J drugs, and Omnicare's annual purchases of J&J drugs increased from approximately $100 million to over $280 million, with annual purchases of Risperdal alone rising to over $100 million. For a substantial portion of these purchases, Omnicare then submitted reimbursement claims to Medicaid.

Jurisdiction and Venue

1. This Court has subject matter jurisdiction under 28 U.S.C. § 1345. The Court has supplemental jurisdiction to entertain the common law cause of action under 28 U.S.C. § 1367(a). The Court may exercise personal jurisdiction over J&J, and venue is appropriate in this Court, under 31 U.S.C. § 3732(a), because J&J transacts business in this District and caused to be submitted or conspired to submit false claims in this District.

The Parties

2. Plaintiff United States, acting through the Department of Health and Human Services ("HHS"), administers Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* ("Medicaid").

3. Relator Bernard Lisitza is a resident of Illinois.

4. Relator David Kammerer is a resident of Ohio.

5. Defendant Johnson & Johnson is a manufacturer and seller of pharmaceutical products and medical devices.

6. Ortho-McNeil-Janssen Pharmaceuticals, Inc., a subsidiary of Johnson & Johnson, is a manufacturer and seller of pharmaceutical products. It is the successor in interest to Janssen Pharmaceutica Products, L.P. ("Janssen"), and Ortho-McNeil Pharmaceutical Products, Inc. ("OMP"). During the period from 1999 through 2004, Janssen sold pharmaceutical products, including Risperdal, an atypical (also known as a second generation) antipsychotic drug, and OMP sold pharmaceutical products, including Levaquin, an antibiotic drug. During this period, both Janssen and OMP sold their pharmaceutical products to Omnicare.

7. Johnson & Johnson Health Care Systems, Inc., is the contracting arm of Johnson & Johnson and entered into contracts with Omnicare on behalf of Johnson & Johnson, Janssen, and OMP.

8. Omnicare was originally named as a defendant in Civil Action No. 05-11518-RGS, but was dismissed from that action by order dated November 12, 2009, pursuant to a settlement agreement. Omnicare is the nation's largest provider of pharmacy dispensing services to nursing homes and other long-term care facilities. Through contracts with nursing homes, it dispenses drugs to approximately 1.4 million long-term care residents in 47 states, including Massachusetts. Omnicare also provides consultant pharmacist services to nursing homes. As J&J was well aware, Omnicare's pharmacists and consultant pharmacists have significant influence over the drugs that nursing home residents receive.

Legal Background

9. The False Claims Act provides, in pertinent part, that any person who:

> (a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (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
>
> (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.

31 U.S.C. § 3729.[1] For purposes of the False Claims Act,

> 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(b) (1986).

10. 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

[1] On May 20, 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). 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 Sections 3279(a)(1) and 3279(a)(3) of the statute prior to FERA, and as amended in 1986, remain applicable here.

Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

11. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(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. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

12. The anti-kickback statute prohibits any person or entity from knowingly and willfully offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-reimbursable medical goods or services:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony

> and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2). Violation of the statute also can subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

Omnicare's Relationship With Medicaid

13. Omnicare delivers drugs to patients in nursing homes, and submits reimbursement claims on behalf of those patients to their insurers, including Medicaid. J&J understood that Omnicare submitted approximately 65 percent of its reimbursement claims to Medicaid.

14. 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, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent.

15. The Medicaid programs of all states reimburse for prescription drugs. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to the Centers for Medicare & Medicaid Services ("CMS") an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, 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, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

16. Omnicare is a party to provider agreements with each of the state Medicaid programs to which it submits drug reimbursement claims. In Massachusetts, for example, Omnicare has a provider agreement with MassHealth. Massachusetts regulations provide that: "All pharmacies participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to MassHealth regulations set forth in 130 CMR 406.000 and 450.000." The Massachusetts regulation at 130 CMR 450.261 in turn provides: "All members and providers must comply with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, specifically including but not limited to 42 U.S.C. 1320a-7b [the federal anti-kickback statute]."

Background on Omnicare's Consultant Pharmacists and Omnicare's Relationship with J&J

17. In 1983, at the urging of Congress, the Health Care Financing Administration, now known as CMS, contracted with the Institute of Medicine, a group chartered by the National Academy of Sciences, to conduct a study of quality of care in nursing homes. *See* Institute of Medicine, *Improving the Quality of Care in Nursing Homes* at 2 (1986). The Institute of Medicine performed the study and included among its findings that "understaffed [nursing]

facilities may make excessive use of antipsychotic drugs to substitute for inadequate numbers of nursing staff." *Id.* at 54.

18. In the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87"), Pub. L. 100-203, Congress amended the Social Security Act (the "Act") to mandate that nursing homes "protect and promote the rights of each resident, including . . . the right to be free from . . . chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." 42 U.S.C. § 1396r(c)(1)(A)(ii). Congress further amended the Act to provide as follows:

> Psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan (included in the written plan of care described in paragraph (2)) designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs.

42 U.S.C. § 1396r(c)(1)(D).

19. In order to implement the OBRA '87 amendments to the Act, HHS promulgated a regulation, now codified at 42 C.F.R. § 483.60(c), which provides that, in each nursing home:

> (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
>
> (2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

See 54 Fed. Reg. 5316, 5345 (1989) ("This provision is in accordance with the spirit of [42 U.S.C. § 1396r(c)(1)(D)], added by OBRA '87, which strongly emphasizes efforts to control the abuse of psychopharmacologic drugs as chemical restraints."). Thus, each nursing home must arrange for a consultant pharmacist to review the medications of each of its residents at least

once a month. During the course of these reviews, the consultant pharmacists make recommendations – which are ostensibly objective – to remove, change, or add medications to the nursing home residents' drug regimens.

20. During the period from 1999 and continuing at least through 2004, Omnicare employed hundreds of consultant pharmacists and relied on them to make recommendations to nursing home physicians about the drugs they should prescribe for nursing home residents. In some cases, as with J&J, Omnicare struck deals with a drug manufacturer for Omnicare's consultant pharmacists to recommend that manufacturer's products.

21. As J&J observed in an internal memorandum from 2003:

> Omnicare has over 900 consultant pharmacists who review patient charts monthly and make recommendations based on the formulary and Omnicare programs for physicians. Pharmacists' recommendations are accepted more than 80% of the time. Consultant pharmacists actively meet with physicians or correspond with them through the mail to obtain approval to make appropriate medication switches for all their applicable nursing home patients. . . . Omnicare consultant pharmacists receive monthly "report cards" showing them their success in obtaining goals for therapeutic programs."

(A copy of the 2003 J&J memorandum that includes this statement is attached hereto as Exhibit 1.)[2] In the same memorandum, J&J observed that Omnicare's "consultant pharmacists are active in having physicians sign therapeutic interchange forms that allow pharmacists to review charts and make switches without having to consult with the physician." *See id.* at JNJ 351940. J&J further understood that consultant pharmacists had a "[h]igh degree of impact on product selection" in nursing homes and that their recommendations were "highly motivated based on

[2] Where noted, personal information has been redacted from the exhibits to this Complaint.

economics," which depended "less on net costs [to payers], and more on quality of product and 'spread' (their margin)." (A copy of the 2003 J&J presentation that includes these statements is attached hereto as Exhibit 2.) A J&J National Account Manager similarly observed that, while Omnicare could effect dramatic shifts in utilization from one drug to another, "in order to have the Omnicare's of the world drive share that high, it must be financially wor[th] their while." (A copy of the J&J e-mail containing this statement is attached as Exhibit 3.)

22. J&J and Omnicare both used the term "intervention" to refer to the process in which Omnicare pharmacists and consultant pharmacists obtained physician authorization to switch nursing home patients from one drug to another. J&J viewed consultant pharmacists engaged in such intervention programs as an "Extension of [the J&J] Sales Force." (A copy of the J&J presentation that includes this statement is attached hereto as Exhibit 4.) During much of the 1999 through 2004 time period, Omnicare's primary intervention was to drive prescriptions of Risperdal, an atypical antipsychotic drug that can be used as a chemical restraint. As Tim Bien, Omnicare's Senior Vice President of Professional Services and Purchasing, wrote in a 2001 letter to J&J: "WE ARE SELLING MORE HIGH PRICED DRUGS (read Risperdal here) FOR THE PHARMACEUTICAL INDUSTRY!!" (A copy of Mr. Bien's 2001 letter to J&J is attached hereto as Exhibit 5.) Overall, Omnicare and J&J shared the goal of increasing spending by Medicaid and other federal health care programs on J&J drugs. Thus, when Omnicare and J&J were to meet on or about January 18, 2001, Omnicare wrote that one of its goals for the meeting was to obtain help from J&J in conveying to Congress that the United States "NEED[S] TO SPEND MORE ON MEDS." (A copy of the document containing this

statement is contained in Exhibit 6.)

J&J's Understanding of the Anti-Kickback Statute

23. J&J and its employees understood that it was a violation of the anti-kickback statute to offer or to pay remuneration, by whatever means, to induce a customer like Omnicare to purchase or to recommend J&J drugs. For example, J&J understood from its outside counsel that the company could violate the law through market share rebate agreements, *i.e.*, agreements where J&J agreed to pay customers rebates for switching patients from competitors' drugs to J&J drugs. (A copy of an internal J&J e-mail chain reflecting this understanding is attached hereto as Exhibit 7.) Likewise, the J&J employees responsible for handling the Omnicare account understood from the company's in-house attorneys that J&J could violate the law by using payments to customers for data as a substitute for discounts or rebates that, if disclosed, could increase J&J's financial obligations to the Medicaid program. (A copy of an internal J&J e-mail chain reflecting this understanding is attached hereto as Exhibit 8.) J&J employees also understood that it would be a kickback to pay a customer like Omnicare for the sake of fostering a relationship or for good will, where J&J's goal was always to convince Omnicare to purchase and to recommend J&J drugs.

24. As this complaint alleges, notwithstanding J&J's understanding of the anti-kickback statute, J&J repeatedly violated the statute in its relationship with Omnicare by paying Omnicare rebates to switch patients to J&J drugs, making payments to Omnicare for data (that J&J was not actually receiving) as a substitute for rebates or discounts, and paying Omnicare various grants and sponsorship fees whose purpose was to induce Omnicare to purchase and to

recommend J&J drugs. Notably, J&J recognized the problematical nature of its relationship with Omnicare. As one J&J employee described a September 2002 internal meeting, J&J's Omnicare sales team "got hammered re Healthcare Compliance." (A copy of the e-mail containing this statement is attached hereto as Exhibit 9.)

J&J's Kickbacks to Omnicare

Rebate Payments Contingent on Active Intervention by Omnicare

25. The drug supply agreement in place between J&J and Omnicare in 1999 was signed on April 8, 1997, and had an ostensible term of April 1, 1997, to March 31, 2000 (hereinafter, the "1997 Agreement"). (A copy of the 1997 Agreement is attached hereto as Exhibit 10.) The 1997 Agreement provided for J&J to sell Omnicare certain drugs, including Risperdal, Propulsid, Levaquin, Procrit, Duragesic, and Ultram, and for J&J then to pay Omnicare quarterly market share rebates, where the percentage amount of the rebate on each drug increased as market share of that drug increased, and market share was determined based on Omnicare's purchases of each drug in comparison to Omnicare's purchases of competing products. The 1997 Agreement further required J&J to pay Omnicare an "Annual Strategic Product Performance Rebate" on specific drugs that had "an Active Intervention Program (AIP) or Appropriate Use Program (AUP) applied in their favor." *Id.* at JNJ 001100. The 1997 Agreement defined AIP and AUP as follows:

> "**Active Intervention Program**" shall mean a program, applied by [Omnicare] and accepted by [J&J] in writing, which is designed to appropriately shift market share to [J&J]'s Product. Active interventions can include, but are not limited to, disease management initiatives, written correspondence to Participating Providers prescribing or dispensing pharmaceutical products, educating nursing home staff regarding [J&J]'s Products, [and] conducting clinical intervention programs

> through which consultant pharmacists recommend Supplier's Products when appropriate.
>
> "**Appropriate Utilization Program**" or "AUP" shall mean a program applied by [Omnicare], and accepted in writing by Supplier, designed to cause the appropriate use of [J&J]'s Products.

Id. at JNJ 001089.

26. In November 1998, J&J and Omnicare signed an amendment to the 1997 Agreement concerning Levaquin. (A copy of this amendment is attached hereto as Exhibit 11.) The amendment specified that:

> All Rebates are contingent upon the existence of and adherence to the following interventions:
>
> - Levaquin® will have a Selected formulary position and will be first line therapy for quinolones, when clinically appropriate and indicated. For the purpose of this Amendment, "Selected" shall mean . . . Levaquin® is favored, when clinically appropriate and indicated, over all other branded Drugs also available.
>
> * * *
>
> - [Omnicare's] appropriate personnel will actively participate in educational and promotional programs discussing Levaquin®'s clinical advantages.

Id. at 1079.

27. In J&J's words, J&J intended all of its rebates to Omnicare to be "incentives to Omnicare to advocate appropriate use of J&J products." (A copy of the J&J document containing this statement is attached hereto as Exhibit 12.) J&J calculated its return from the rebates it provided to Omnicare. In 2003, J&J determined that, "for a $3MM investment in rebates with Omnicare, [J&J] gains $9MM in sales, less costs and investments, returns $4.8MM to OMP." (A copy of the e-mail containing this statement is attached hereto as Exhibit 13.)

Another J&J manager calculated that J&J could generate the same return with just $1.44 million in rebates. *See id.* J&J also understood that "Rebates represent approximately 60%+ of [Omnicare's] net income model." (A copy of the e-mail containing this statement is attached hereto as Exhibit 14.)

28. In March 2000, J&J and Omnicare signed a new drug supply agreement with an ostensible term from April 1, 1999, to March 31, 2004 (hereinafter, the "2000 Agreement"). (A copy of the 2000 Agreement is attached hereto as Exhibit 15.) In similar fashion to the 1997 Agreement, the 2000 Agreement provided for J&J to sell certain drugs to Omnicare, and for J&J to pay Omnicare market share rebates and an additional two percent "Annual Product Performance Incentive." The 2000 Agreement further specified that J&J would not pay any rebates to Omnicare for a particular drug unless Omnicare had "an AIP/AUP, as and when specified under the Schedule of Qualifying Active Intervention Programs," for that drug. *See id.* at JNJ 001033. The 2000 Agreement's definitions of "Active Intervention Program" and "Appropriate Utilization Program" were identical to those in the 1997 Agreement. The 2000 Agreement included a "Schedule of Qualifying Intervention Programs" for specific drugs. *See id.* at JNJ 001043. This Schedule included the following provisions:

> **Duragesic and Ultram approved AUP**
> National Pain Management Initiative was jointly developed by [Omnicare] and [J&J] to enhance compliance to this Agreement and completed by June 30, 1999. The training initiative was designed to and accomplished the following:
>
> * * *
> - Train consultant pharmacists to identify residents receiving inappropriate or inadequate pain management therapy and where Duragesic and Ultram may be appropriate alternative medications.

- Equip consultant pharmacists to effectively communicate recommendations regarding pain management to prescribing physicians and other health care professionals.

Levaquin

Levaquin® will have a Selected formulary position and will be first line therapy for quinolones, when clinically appropriate and indicated. . . . "Selected" shall mean . . . Levaquin® is favored, when clinically appropriate and indicated, over all other branded Drugs also available.

* * *

- [Omnicare's] appropriate personnel will actively participate in educational and promotional programs discussing Levaquin®'s clinical advantages.

- [Omnicare] will facilitate access of [J&J] representatives to its Participating Sites.

Risperdal

Risperdal® will have a Selected formulary position and will be the first line anti-psychotic, when clinically appropriate and indicated. . . . "Selected" shall mean . . . Risperdal® is favored, when clinically appropriate and indicated, over all other branded Drugs also available. All other competitive atypical anti-psychotic products in the Defined Market are Prior Authorized for Risperdal® failure.

During the first two quarters following the effective date of this Agreement, [Omnicare] shall work with [J&J] to implement communication effort to inform attending physicians of Risperdal®'s formulary position and to enhance compliance of this Agreement.

[Omnicare]'s appropriate personnel will actively participate in educational and promotional programs discussing Risperdal®'s clinical advantages. [J&J] will organize such programs. [Omnicare] will facilitate access of [J&J] representatives to its Participating Sites.

Id. at JNJ 001043.

29. During the period from 1999 through 2004, J&J paid Omnicare tens of millions of dollars in market share rebates pursuant to the 1997 Agreement and the 2000 Agreement. In

many instances, at Omnicare's request, J&J paid quarterly rebates to Omnicare in advance, thus effectively providing Omnicare with interest-free loans of millions of dollars.

Payments for Data as Substitute for Rebate Payments that J&J Would Have Had to Disclose to Medicaid

30. Congress enacted the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, to ensure that the Medicaid program would receive the benefit of the same discounts and prices on drugs that other large public and private purchasers enjoyed. *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Under the Medicaid Drug Rebate Statute, in order for a brand name drug, such as Risperdal, to be covered and reimbursed by the Medicaid program, its manufacturer has two primary obligations. First, the manufacturer must report on a quarterly basis to the Secretary of HHS the drug's "average manufacturer price" and the "best price" offered for that drug. 42 U.S.C. § 1396r-8(b)(3)(A). Second, the manufacturer must pay each state a quarterly rebate equal to the total number of drug units (*e.g.*, pills) purchased by the state times the greater of (1) 15.1 percent of the drug's average manufacturer price, or (2) the difference between the average manufacturer price and the best price. 42 U.S.C. § 1396r-8(c)(1)(A). In other words, for a drug like Risperdal, J&J was required to pay at least a 15.1 percent rebate to each state on all of its Risperdal sales for Medicaid patients, but J&J would have to pay a higher Medicaid rebate on all of those sales if it offered any single customer, *e.g.*, Omnicare, a total discount that exceeded 15.1 percent.

31. During the late 1990s and early 2000s, J&J rarely, if ever, reported a quarterly "best price" for Risperdal that reflected total discounts in excess of the minimum 15.1 percent rebate J&J was required to pay to the state Medicaid programs. In 1999, however, J&J became

concerned that, combined with the up-front discounts on Risperdal that J&J was giving to Omnicare, the additional quarterly rebates J&J owed to Omnicare would set a new "Best Price" that J&J would have to report to the Medicaid program. In an August 1999 e-mail, a J&J employee commented that: "[t]otal rebates [on J&J's Risperdal sales to Omnicare] in both 1Q99& 4Q98 needed to be reduced because the combined front end price and performance rebate exceeded 15%." (A copy of the J&J e-mail that includes this statement is attached hereto as Exhibit 16.) As of September 1999, Omnicare was taking the position that J&J owed it approximately $700,000 in 1998-1999 rebates that J&J did not want to pay because of best price concerns. (A copy of the J&J e-mail reflecting Omnicare's position is attached hereto as Exhibit 17.) J&J also believed that Omnicare had failed to meet the contract requirements for earning the rebates. Commenting on Omnicare's insistence on receiving the money and its lack of support for the amount sought, a J&J employee wrote to a colleague, "they just know that they need money." (A copy of the J&J document containing this statement is attached hereto as Exhibit 18.)

32. In or about October 1999, J&J began discussing with Omnicare the concept of J&J paying Omnicare for data identifying physician prescribers of antipsychotics in lieu of paying Omnicare the hundreds of thousands of dollars in rebates Omnicare believed it was owed. (A copy of a J&J e-mail concerning the initiation of this discussion is attached hereto as Exhibit 19.) In seeking to justify this data purchase concept internally, J&J's Omnicare sales team noted that "Johnson & Johnson believes [Omnicare] to be the gold standard of Pharmacy Providers" and that Omnicare had "been able to switch propoxyphene prescriptions to Ultram and ha[d]

done an outstanding job in generating Risperdal market share." (A copy of the J&J document containing these statements is attached hereto as Exhibit 20.)

33. During 1999, Omnicare already was providing – free of charge – the type of physician data J&J was proposing to buy from Omnicare. In an e-mail dated October 26, 1999, a J&J employee noted to his colleagues that "[m]any of you have been collecting names of physicians from OMNICARE pharmacies." (A copy of this e-mail is attached hereto as Exhibit 21.) Similarly, in a document dated July 19, 1999, J&J noted that:

> In June of 1999, Omnicare was willing to provide a prescriber list to the J & J Group and the Janssen ElderCare Sales Force. These names were provided to the sales force in an effort to increase the call frequency on these resistant prescribers and to eventually influence them to use more Risperdal in the Elderly demented patient. As of July, 1999, over 350 names have been acquired and the representatives have begun their targeting on these prescribers.

Ex. 12 at JNJ 301390. In a "2000 Business Plan" concerning the Omnicare account, a J&J employee noted that his unit's "1999 Accomplishments" included having "Worked closely with Eldercare Sales Force in Developing Physician Call Activity Based on Omnicare Generated Lists." (A copy of the J&J document containing this statement is attached hereto as Exhibit 22.)

34. J&J was concerned about the legality of paying for data in lieu of paying a rebate. In connection with a dispute over rebates Omnicare claimed it was owed for an earlier period (from the second quarter of 1997 to the first quarter of 1998), J&J had concluded in June 1999 that paying for data in lieu of the rebate claimed by Omnicare would "put us at risk for fraud and abuse." (A copy of the J&J e-mail chain containing this statement is attached hereto as Exhibit 23.) Moreover, J&J was concerned that "[p]aying for data/analysis that Omnicare does currently for us such as the Risperdal (daily average consumption) analysis will set a precedence [*sic*] for

J&J paying Omnicare for data." *Id.* As a J&J Director of National Accounts later noted, "J&J Pharma, has previously gone on record, from corporate, that . . . [w]e will *not* pay customers for data." (A copy of the e-mail containing this statement is attached hereto as Exhibit 24.) But J&J made an exception to that policy for Omnicare.

35. In order to resolve the dispute with Omnicare over rebates allegedly owed for the fourth quarter of 1998 and the first quarter of 1999, J&J continued to pursue the concept of purchasing data from Omnicare pursuant to a "Consulting and Services Agreement." J&J viewed such an agreement as a means of "assisting [Omnicare] financially" with "some of the non market share activities that they do on our behalf," including "[c]ommunicating J&J promotions to nursing home[s] that they serve." (A copy of the e-mail chain containing these statements is attached hereto as Exhibit 25.)

36. As the process evolved, J&J began to consider having the total amount of data fee payments increased in order to serve as a substitute not only for the rebates from the fourth quarter of 1998 and the first quarter of 1999, but also for additional rebates in the form of the ongoing two percent Annual Product Performance Incentive (also referred to as a "strategic overlay") on Risperdal that J&J was required to pay under the 2000 Agreement. Thus, in a July 2000 e-mail, a senior manager in J&J's Long Term Care Group asked: "How close are we to finalizing a proposal around Omnicare consultant services revenues to replace the current 2% overlay?" (A copy of this e-mail is attached hereto as Exhibit 26.)

37. As with the rebates Omnicare was claiming for the fourth quarter of 1998 and the first quarter of 1999, J&J did not want to pay the strategic overlay in the 2000 Agreement

because J&J feared the additional two percent discount on Risperdal would set a lower best price on Risperdal, and thus would substantially increase J&J's overall Medicaid rebate liabilities to the states. J&J explained its rationale in a document prepared in or about the summer of 2000:

> **Recent developments**
> 1. Consulting and Services Agreement
> a. Risperdal rebates have been pushing towards Best Price
> b. To avoid Best Price, the Strategic Overlay for Risperdal (2% of sales) had to be eliminated
> c. In order to balance this, an agreement was established with Omnicare to purchase data, roughly at the cost of the Strategic Overlay for Risperdal
> d. Data to be sent to J&J include data which is not available via IMS or other 3rd parties
> (Quarterly physician prescribing reports, quarterly competitive market share by pharmacy site, monthly market share reports.)

(A copy of the J&J document containing this passage is attached hereto as Exhibit 27.)

38. J&J and Omnicare signed their Consulting and Services Agreement in October 2000. (A copy of the Consulting and Services Agreement is attached hereto as Exhibit 28.) The agreement had a term of July 1, 2000, to April 1, 2004, and called for J&J to pay Omnicare $450,000 for the first three-month period of the term, and then $300,000 per quarter thereafter, for a total of $4,650,000. In exchange, Omnicare was to provide the following:

A. **Physician Prescribing Report by Strategic Brand- [Quarterly]** This national report will list 200 competitive prescribing physicians for each J&J Strategic Brand (RISPERDAL® risperidone, DURAGESIC® fentanyl transdermal system, and ACIPHEX™ rabeprazole, LEVAQUIN TABS® levoflaxacin, LEVAQUIN IV® levoflaxacin, and ULTRAM® tramadol) and the preferred product of such physicians. This report will be provided by Omnicare's national clinical director.

B. **Competitive Market Share Report by Pharmacy Site- [Quarterly]** This report will list Days of Therapy (DOT) market shares at each Omnicare pharmacy site for the following J&J products and their relative competitive products as defined by their respective J&JHCS Defined Markets: Risperdal, Duragesic, Aciphex, Ultram, Levaquin, and Levaquin IV.

C. **Market Share Report by Pharmacy Site- [Monthly]** This report will list DOT market shares at each Omnicare pharmacy site for the following J&J products as defined by their respective J&JHCF Defined Markets: Risperdal, Duragesic, Aciphex, Ultram and Levaquin.

Id. at JNJ 001017.

39. At exactly the same time J&J and Omnicare signed the Consulting and Services Agreement, they also signed an amendment to the 2000 Agreement removing Risperdal from the two percent strategic overlay. (A copy of this amendment is attached hereto as Exhibit 29.)

40. To justify the legality of the Consulting and Services Agreement internally, J&J purported to conduct a "fair market value" analysis of the data it agreed to purchase. In reality, however, Omnicare never supplied much of the data J&J had agreed to purchase, and J&J never demanded it. Neither Omnicare's national clinical director nor any other Omnicare employee ever supplied J&J with any quarterly lists of "200 competitive prescribing physicians for each J&J Strategic Brand . . . and the preferred product of such physicians," as part A of the Consulting and Services Agreement required. Instead, as had been the case prior to the signing of the Consulting and Services Agreement, local Omnicare pharmacy sites occasionally supplied local J&J sales representatives with names of prescribing physicians. As a J&J National Account Director later observed, the Omnicare pharmacies did so "randomly" and "generally not . . . willingly." (Copies of e-mail chains containing these statements are attached as Exhibits 30 and 31.).

41. Even though Omnicare did not provide the data it was contractually obligated to provide in the Consulting and Services Agreement, J&J paid Omnicare as specified under the

agreement. (A copy of J&J's payment schedule pursuant to the Consulting and Services Agreement is attached hereto as Exhibit 32.) In cover letters enclosing J&J's payments to Omnicare pursuant to the Consulting and Services Agreement, J&J referred to each payment as a "marketing fee." (Copies of examples of these letters are attached hereto as Exhibit 33.) The letters also cautioned Omnicare that "some or all of this amount may be considered a Discount which Omnicare may have an obligation to reflect in any cost report or claim for reimbursement with Medicare/Medicaid," even though J&J itself did not treat the payments as discounts and did not disclose them to Medicaid. *See id.*

J&J's "Grants" and Other Miscellaneous Kickback Payments to Omnicare

42. J&J supplemented its rebate and data fee kickbacks to Omnicare by paying various other kickbacks in the form of "grants," "educational funding," and meeting sponsorship fees. In January 1999, J&J noted that it had paid Omnicare "in excess of $1,000,000 since 1997 for educational, pull-through, and social activities." (A copy of the J&J document containing this statement is attached hereto as Exhibit 34.) J&J continued to make such payments in subsequent years.

43. $300,000 "Program Fee" in lieu of Rebates Claimed for 2Q97 to 1Q98. The Consulting and Services Agreement in 2000 was not the first time J&J devised a subterfuge to avoid paying Omnicare discounts or rebates that could have affected the Medicaid best price of Risperdal. In mid-1999, J&J considered whether it could pay Omnicare approximately $300,000 to satisfy Omnicare's claim under the 1997 Agreement's one percent strategic overlay provision

for the period from the second quarter of 1997 to the first quarter of 1998. *See* Exhibit 23. J&J ultimately determined that it would be illegal to make such a payment. *See id.*

44. Instead of J&J paying $300,000 to Omnicare as a strategic overlay (which would have been reportable to Medicaid for best price purposes), J&J and Omnicare orally agreed that J&J would pay Omnicare $300,000 for "educational funding." (A copy of the e-mail describing this oral agreement is attached hereto as Exhibit 35.) J&J then sent a letter to Omnicare enclosing written agreements pursuant to which J&J would pay Omnicare $300,000 to support a "program in helping Omnicare's consultant pharmacists overcome objections from physicians. This program will be especially effective in overcoming obstacles pertaining to resistance in prescribing Risperdal." (A copy of this letter, along with an e-mail to which it was attached, is attached hereto as Exhibit 36.)

45. In mid-October 1999, J&J and Omnicare formally entered into an "Initiative Partnership Agreement" pursuant to which J&J paid Omnicare $300,000 "to partially defray the cost to Omnicare in developing and marketing mutually acceptable broad-based formulary intervention initiatives and to assist Omnicare consultant pharmacists overcome obstacles and objections they encounter in implementing intervention programs." (A copy of this agreement, along with the cover letter with which it was enclosed, is attached hereto as Exhibit 37.) The cover letter enclosing the agreement noted that it "calls for educational assistance in overcoming objections and obstacles pertaining to the Risperdal Initiative." *See id.* In other words, rather than paying Omnicare a $300,000 strategic overlay under the 1997 Agreement, J&J instead paid

Omnicare $300,000 in "educational funding" for the express purpose of inducing Omnicare to recommend that physicians prescribe Risperdal for their nursing home patients.

46. J&J's "ReView" Grants to Omnicare. During the early 2000s, Omnicare raised money from numerous drug manufacturers for its so-called "ReView" program. The ostensible purpose of the program was to develop "health management" programs that would identify nursing home patients for whom additional drugs could be prescribed. In a memorandum to Omnicare's Chief Executive Officer, Omnicare's Senior Vice President of Professional Services and Purchasing referred to the ReView program as the "one extra script per patient (ReView) program." (A copy of the memorandum containing this description is attached hereto as Exhibit 38.) One of the Omnicare ReView health management programs was "Behavior Management in Dementia – encompassing the appropriate use of antipsychotics and going from the typical to the newer and better tolerated atypical antipsychotics." (A copy of the Omnicare memorandum containing this statement is attached hereto as Exhibit 39.)

47. In January 2000, Omnicare requested that J&J make a $50,000 grant for the ReView program. (A copy of Omnicare's request is attached hereto as Exhibit 40.) In response, J&J made $251,000 in ReView grants to Omnicare during 2000. (A copy of an Omnicare spreadsheet showing these payments is attached hereto as Exhibit 41.) No other drug manufacturer paid Omnicare more than $75,000 for the ReView program in 2000. *See id.* In 2001, J&J observed that Omnicare's ReView program had "[g]enerated over 11,000 new prescriptions for antipsychotics." (A copy of the J&J presentation containing this statement is attached hereto as Exhibit 42. *See also* Exhibit 6 at OMNI-MA 040785.)

48. J&J's Sponsorship of Omnicare's Annual National Managers Meeting. During the period from 1999 through 2004, J&J paid Omnicare between $27,000 and $50,000 each year to "sponsor" Omnicare's annual national managers meeting at the Amelia Island resort in Florida. As Omnicare explained in requesting $45,000 from J&J for the 1999 meeting, Omnicare intended "to use these funds, to further advance our expertise in management activities including management of our clinical programs such as our Risperdal initiative." (A copy of the Omnicare letter containing this request is attached hereto as Exhibit 43.) In addition, J&J's sponsorship fees entitled J&J sales managers to play golf with Omnicare managers and to make presentations to Omnicare managers on why Omnicare should increase its purchases and recommendations of J&J drugs.

Omnicare's Purchases and Recommendations of J&J Drugs in Response to J&J's Kickbacks

49. As noted above, during the 1999 to 2004 period, Omnicare's annual purchases of J&J drugs nearly tripled to almost $300 million. This increase in purchases reflected increased prescribing of J&J drugs by physicians at nursing homes served by Omnicare, which in turn reflected the numerous "intervention" efforts Omnicare undertook in response to the kickbacks it received from J&J.

50. Even though Congress expressed clear concerns about the use of antipsychotics in nursing homes, and even though there is an intrinsic clinical risk in switching a stabilized patient from one antipsychotic to another, Omnicare devoted substantial effort to its intervention for Risperdal. Both Omnicare and J&J referred to this effort as Omnicare's "Risperdal Initiative." The goal of the Risperdal Initiative was to generate as many Risperdal prescriptions as possible.

51. The Risperdal Initiative began in 1997, after J&J and Omnicare entered into the 1997 Agreement. In order to implement it, Omnicare distributed to all of its pharmacists around the country a so-called Patient Specific Therapeutic Interchange Protocol for Risperdal (the "Risperdal PSTI"). Copies of the 1997 and 1998 versions of the Risperdal PSTI are attached hereto as Exhibits 44 and 45. In the 1998 version of the Risperdal PSTI, Omnicare provided its pharmacists with suggested oral statements and written comments to use to encourage physicians to prescribe Risperdal, sometimes regardless of whether a given patient was already stabilized on another antipsychotic. *See* Exhibit 45 at OMNI-MA 881954-57.

52. In a summer 2000 memorandum, a J&J employee observed that Omnicare's ongoing Risperdal Initiative "has generated an all time market share high of 55.5% throughout the 1st quarter of 2000. This market share represents Omnicare's ability to persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia." (A copy of the memorandum containing this statement is attached hereto as Exhibit 46.) By the following spring, Omnicare had driven Risperdal's share of Omnicare's antipsychotic utilization to 58.5 percent.

53. In November 2001, Omnicare's Chief Clinical Officer distributed a memorandum to all Omnicare consultant pharmacists describing a nationwide "Risperdal Fax Campaign" in which Omnicare had asked physicians "for conversion to Risperdal® therapy." (A copy of this memorandum is attached hereto as Exhibit 47.)

54. Another means by which Omnicare implemented the Risperdal Initiative was through Physician Authorization Letters, or "PALs." (A copy of such a PAL is attached hereto

as Exhibit 48.) As a J&J employee explained Omnicare's PALs, "Certain states allow for interchange letters to be sent to physicians which authorizes a substitution based on clinical data, formulary, etc…. to take place at the pharmacy level when a pharmacist[] receive[s] a prescription for a competitive medication. If the physician signs the authorization, the pharmacist will switch the medication at the pharmacy. . . . Where we have the opportunity, we are doing [this] in partnership with our external customer – Omnicare." (A copy of the e-mail containing this statement is attached hereto as Exhibit 49.) In a July 2001 internal report, J&J observed that two Omnicare pharmacies, "Jacobs Healthcare (16,000 beds) and Lawrence Weber (12,000 beds) started a PAL initiative with Risperdal in the month of May. The authorization letter requests a substitution to Risperdal from any new prescription of Zyprexa or Seroquel." (A copy of the report containing this statement is attached hereto as Exhibit 50.)

55. In 2002, J&J's Long-Term Care Group reported that, in a recent meeting, Omnicare's Director of Clinical Operations had "stressed that Risperdal is their primary intervention." (A copy of the document containing this statement is attached hereto as Exhibit 51.)

56. Omnicare ceased its Risperdal intervention activities only in or about 2003, when it became concerned about an increased risk of cerebrovascular events, including stroke, associated with Risperdal therapy in elderly patients. The Food & Drug Administration ("FDA") subsequently determined that "Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo." By August

2005, the FDA required that all atypical antipsychotic drugs carry a black box warning of this risk.

57. Beginning in 1999 and continuing well into the 2000s, Omnicare also implemented a "Levaquin Initiative" on behalf of that J&J antibiotic drug. As J&J observed in July 1999, "Omnicare has begun its first prospective intervention with Levaquin during February of 1999. The overall goal of this program was to achieve a market share of over 50% in the quinolone market. Cipro had been the main anti-biotic of choice generating over 70% of the market (UTI). At the end of June, Levaquin national share for Omnicare was 41%." *See* Exhibit 12 at JNJ 301376. Ultimately, Omnicare far exceeded J&J's market share hopes with the Levaquin Initiative.

58. In July 2001, J&J's Long-Term Care Group noted that "Omnicare agree[d] to send PAL letters as well as a universal mailing in August/September to promote Levaquin for the upcoming respiratory season." Exhibit 50 at JNJ 289773.

59. In September 2001, J&J observed that "Omnicare has grown Levaquin Share from 19.2% in 4th Quarter of '98 prior to the Levaquin Initiative to 66.4% in 2Q '01. In this same time period Cipro has gone from 80% + to the 28% range." (A copy of the document containing this statement is attached hereto as Exhibit 52.) By October 2001, Omnicare's Levaquin Initiative had generated a 71.1 percent share for the J&J drug at Omnicare pharmacies.

60. In a June 2002 e-mail concerning Omnicare's Levaquin Initiative, a J&J manager noted that Omnicare had achieved a "19% share gain in 5 months due to Omnicare pharmacist's physician calling." Exhibit 49.

61. In another June 2002 e-mail, a J&J Long Term Care Business Manager reported: "I wanted to share some great news. In January of this year I worked with Cedar Rapids, IA to do Therapeutic interchange letters for Levaquin. They implemented them in Jan while they had a share of 70%. Then in March of '02 they started calling the physicians back. They would fill one script of Cipro and then call the doctor and if they would not return the call after 2 days they would stay on Cipro but the majority of the physicians would call back and let Omnicare know it was ok to switch to Levaquin. So in May of 02 they have a share of 89% while Cipro is down to 11%." (A copy of the e-mail containing this statement is attached hereto as Exhibit 53.)

62. Omnicare also undertook "intervention" programs for other J&J drugs in response to J&J's kickbacks. In July 2001 and July 2002 contract compliance certifications to J&J pursuant to the 2000 Agreement, Omnicare represented that it was conducting "Product Specific Active Intervention Program[s]" for four J&J drugs: Risperdal, Levaquin, Procrit, and Ultram. Omnicare further represented that it was conducting "General Active Intervention Program[s]" for other J&J drugs. (Copies of these contract compliance certifications are attached hereto as Exhibit 54.)

False Claims

63. As a result of J&J's kickbacks to Omnicare, as alleged above, J&J caused Omnicare to submit false claims to Medicaid for drugs dispensed to residents at nursing homes. Examples of such false claims are attached hereto in Exhibit 55.

Count One
(False Claims Act, 31 U.S.C. § 3729(a)(1) (1986))

64. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

65. As a result of J&J's kickbacks to induce Omnicare to purchase, order, or recommend or arrange for the purchasing or ordering of J&J drugs, in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), all of the claims J&J caused Omnicare to present to Medicaid for those drugs are false or fraudulent. Accordingly, J&J knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (1986).

66. By virtue of the false or fraudulent claims J&J knowingly caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count Two
(False Claims Act: 31 U.S.C. § 3729(a)(1)(B) (2009))

67. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

68. J&J knowingly caused Omnicare to make or use false records or statements material to false or fraudulent claims paid or approved by the Government, in violation of 31 U.S.C. § 3729(a)(1) (B) (2009). The false records or statements were Omnicare's false certifications and representations of full compliance with all federal and state laws and

regulations prohibiting fraudulent acts and false reporting, including but not limited to the anti-kickback statute, 42 U.S.C. § 1320a-7b.

69. By virtue of the false records or statements J&J caused Omnicare to make or use, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count Three
(False Claims Act, 31 U.S.C. § 3729(a)(3) (1986))

70. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

71. J&J conspired with Omnicare to pay kickbacks to Omnicare in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), to induce Omnicare's purchase of drugs from J&J, thereby causing all of Omnicare's claims to Medicaid for those drugs to be false or fraudulent. Accordingly, J&J conspired to defraud the United States by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(3) (1986).

72. By virtue of the false or fraudulent claims J&J conspired to get allowed or paid, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count Four
(Unjust Enrichment)

73. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

74. The United States claims the recovery of all monies by which J&J has been unjustly enriched, including profits earned by J&J because of illegal inducements J&J paid to Omnicare.

75. By obtaining monies as a result of its violations of federal and state law, J&J was unjustly enriched, and is liable to account and pay such amounts, which are to be determined at trial, to the United States.

76. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by J&J on sales to Omnicare, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

Prayer For Relief

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

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

2. On Count Four for unjust enrichment, for the damages sustained and/or amounts by which J&J retained illegally obtained monies, plus interest, costs, and expenses, and such further relief as may be just and proper.

Respectfully submitted,

CARMEN M. ORTIZ
United States Attorney

Dated: January 15, 2010 By: /s/ Gregg Shapiro

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Certificate of Service

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on January 15, 2010.

/s/ Gregg Shapiro
Gregg Shapiro