UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* McCoyd, Plaintiffs, v. ABBOTT LABORATORIES, *et al.*, Defendants.	)	Civil Action No. 1:07-cv-00081 **LEAD CASE**
UNITED STATES OF AMERICA, *et al.*, *ex rel.* Spetter, Plaintiffs, v. ABBOTT LABORATORIES, INC., *et al.* Defendants.	)	Civil Action No. 1:10-cv-00006

COMPLAINT OF THE UNITED STATES

For more than a decade, Defendant Omnicare, Inc. ("Omnicare") – the nation's largest provider of pharmacy services to nursing homes – solicited and received kickbacks from drug manufacturer Abbott Laboratories ("Abbott") to promote the use of the prescription drug Depakote to control the behavior of elderly nursing home residents with dementia. Through its consultant pharmacists, Omnicare wielded enormous influence over the drugs administered to the residents of Omnicare-serviced nursing homes. In exchange for millions of dollars in kickbacks disguised as rebates, educational grants, and other corporate financial support,

Omnicare used its consultant pharmacists to tout Depakote as a tool to control agitation, aggression, and other behavioral disturbances and to avoid federal regulations designed to prevent the use of chemical restraints on the elderly. By knowingly and actively soliciting kickbacks to promote Depakote, Omnicare enhanced its profits at the expense of the elderly nursing home residents it purported to protect and caused the Medicaid and Medicare programs to pay hundreds of millions of dollars for claims that should not have been paid.

Nature of the Action

1. This is an action against defendant Omnicare to recover treble damages, restitution, and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA"), and the common law for the submission of false claims to Medicare and Medicaid as a result of kickbacks that Omnicare solicited and received from Abbott in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). During the period from 1998 through 2008, Omnicare solicited and received from Abbott tens of millions of dollars in kickbacks in exchange for promoting and recommending Depakote for use in the elderly residents of the nursing homes that Omnicare serviced. These kickback payments took various forms, including market share rebate payments conditioned on Omnicare's active involvement in Depakote promotion and intervention programs, payments for market data and management conferences, and various grants and other payments, all of which Omnicare solicited and received for purchasing and recommending Depakote.

2. Nursing homes relied on Omnicare's consultant pharmacists to review their residents' drug regimens on a monthly basis and ensure that nursing home residents' prescriptions were appropriate and that unnecessary drugs were not administered. However, in exchange for Abbott's kickbacks, Omnicare engaged in intensive efforts to convince nursing

home physicians to prescribe Depakote, and its claims to federal healthcare programs for prescriptions of Depakote increased from less than $3 million in 1998 to over $92 million in 2008.

Jurisdiction and Venue

3. The Court has subject matter jurisdiction to hear this action under 28 U.S.C. § 1345. This Court has supplemental jurisdiction to hear the common law cause of action under 28 U.S.C. § 1367(a). The Court has personal jurisdiction over Defendant Omnicare and venue is appropriate in this Court under 31 U.S.C. § 3732(a) because Omnicare transacts business and submitted or conspired to submit false claims in this District.

The Parties

4. The United States of America, 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"), and administers the prescription drug program for Medicare.

5. Relator Meredith McCoyd ("McCoyd") is a resident of Georgia. On October 31, 2007, Ms. McCoyd filed an action in this Court against Abbott alleging violations of the FCA on behalf of herself, the United States, and various states pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1). On June 14, 2010, Ms. McCoyd filed an amended complaint which, *inter alia,* named Omnicare as a defendant.

6. Relator Thomas J. Spetter ("Spetter") is a resident of California. On January 21, 2010, Mr. Spetter filed an action in this Court against Abbott and others, including Omnicare, alleging violations of the FCA on behalf of himself, the United States, and various states pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1).

7. Defendant Omnicare is the nation's largest provider of pharmacy dispensing services to nursing homes. Through contracts with nursing homes and other long-term care facilities, Omnicare dispenses drugs to approximately 1.4 million residents in 47 states, including Virginia. During the relevant time period, Omnicare also provided many of the nursing homes it serviced with consultant pharmacists, who had significant influence over the drugs prescribed to nursing home residents.

Legal Background

8. The FCA provides, 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 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 to get a false or fraudulent claim paid or approved by the Government;
>
> [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 FCA,

> 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.

[1] On May 20, 2009, the FCA was amended pursuant to the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Public Law 111-21. 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 3729(a)(1) and (a)(3) of the statute prior to FERA, and as amended in 1986, remain applicable here.

31 U.S.C. § 3729(b).

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

10. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), 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.

11. The AKS 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).

The Medicaid Federal-State Healthcare Program

12. Omnicare delivers drugs to patients in nursing homes and other long term care facilities, and submits reimbursement claims on behalf of those patients to their insurers, including Medicaid. Omnicare understood that a substantial portion of its claims for nursing home residents were to Medicaid.

13. Medicaid is a joint federal-state program that provides health care benefits primarily to the poor and disabled. The federal share of each state's Medicaid payments is between 50 and 83 percent, depending on the state's per capita income. 42 U.S.C § 1396d(b).

14. The Medicaid programs of all states reimburse for prescription drugs. Most states contract with private companies to evaluate and process claims for payment. Typically, after processing the claims, these companies request funding from the state Medicaid programs. Before 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, determines the federal funding needs for the quarter, and determines the 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 Omnicare and other pharmacy providers, are presented for payment. After 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.

15. Omnicare is a party to provider agreements with each of the state Medicaid programs to which it submits drug reimbursement claims.

16. In Virginia, for example, Omnicare has a provider agreement with the Department of Medical Assistance Services ("DMAS"), which provides, in part, that "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]."

The Medicare Program

17. Medicare is a federally funded and administered health insurance program, primarily for elderly and disabled persons. CMS is also responsible for the administration and supervision of the Medicare program.

18. The Medicare program has several parts, including Medicare Part D, a voluntary prescription drug benefit program for Medicare enrollees that became effective January 1, 2006. Medicare Part D coverage is offered through private companies, known as Part D sponsors, that contract with CMS to administer prescription drug plans. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.329.

19. Throughout the payment year, each time a Medicare beneficiary has a prescription filled under Part D, the sponsor notifies CMS of the event, known as a "prescription drug event"

or "PDE," including the cost it has incurred. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred based on the PDEs it has submitted. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs per beneficiary exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

20. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM") and receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. As discussed above, the Part D sponsor then notifies CMS of the drug dispensing event, including the amount it has paid to the pharmacy. CMS uses that information at the end of the payment year when it reconciles its advance payments to the sponsor with the costs that sponsor has incurred throughout the year.

21. Part D sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, the AKS. 42 C.F.R. § 423.505(h)(1).

22. CMS regulations require that all subcontracts between Part D sponsors and pharmacies contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv). Omnicare has entered into subcontracts with the vast majority of Medicare Part D sponsors.

Omnicare's Consultant Pharmacists

23. In the Omnibus Budget Reconciliation Act of 1987 ("OBRA"), Pub. L. 100-203, Congress enacted the Nursing Home Reform Act, which reflected Congress' concern about the treatment of elderly nursing home residents and particularly the use of chemical restraints in nursing homes. In OBRA, Congress mandated that nursing homes protect the rights of each of their residents, including the right "to be free from . . . chemical restraints." 42 U.S.C. § 1396r(c)(1)(A). OBRA required that psychopharmacological drugs only be administered upon a physician's orders and only as part of a written plan of care "designed to eliminate or modify the symptoms for which the drugs are prescribed."

24. To implement OBRA, CMS issued regulations requiring nursing homes to ensure that residents were "free from unnecessary drugs," including drugs used in excessive amounts, for excessive duration, without adequate monitoring, or in the presence of adverse consequences indicating that the dose should be reduced or discontinued. These regulations directed that, with respect to antipsychotic drugs in particular, nursing homes must ensure that the drugs are "necessary to treat a specific condition as diagnosed and documented in the clinical record" and that residents "receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated in an effort to discontinue these drugs." 42 C.F.R. § 483.60(c).

25. To comply with these requirements, nursing homes arrange for a consultant pharmacist to review the medications of each resident at least once a month. During the course

of these reviews, the consultant pharmacists make recommendations – which are ostensibly independent and objective – to remove, change, or add medications to the nursing home residents' drug regimens.

26. During the period 1998 until at least 2008, Omnicare employed hundreds of consultant pharmacists to make recommendations to physicians about the drugs they should prescribe for nursing home residents. Omnicare entered into agreements with some drug manufacturers, including Abbott, to recommend that manufacturer's products over competitor drugs in exchange for "rebates" and other payments and remuneration. These payments undermined the independence of the consulting pharmacists and subverted their role of ensuring that nursing homes complied with OBRA regulations such that they, in fact, became an extension of the drug manufacturers' sales forces.

Omnicare's Relationship to Abbott

27. In June 1997, Abbott developed a Strategic Marketing Plan to promote the use of Depakote to control agitation and aggression in nursing home residents with dementia, a use that FDA had never approved as safe and effective. One of the objectives of Abbott's plan was to contract with nursing home pharmacy providers to drive Depakote growth. Abbott recognized that nursing home pharmacy providers, such as Omnicare, had the ability to influence therapy for the treatment of aggression and agitation in the elderly through formulary control and treatment protocols, and that Abbott could expand the market share of Depakote by establishing relationships and agreements with such pharmacy providers. (A copy of Abbott's 1998 Strategic Marketing Plan is attached hereto as Exhibit 1.)

28. Beginning as early as 1998 and continuing until at least 2008, Abbott implemented its strategy to promote the use of Depakote to control agitation, aggression, and

other behavioral issues in nursing home residents with dementia by entering into arrangements to pay Omnicare millions of dollars in various forms such as rebates, data purchases, educational grants, and sponsorships in exchange for Omnicare's active promotional efforts to increase the use of Depakote.

Omnicare's Solicitations to Abbott for Kickback Payments

29. Omnicare began soliciting kickbacks from Abbott as early as 1998. In approximately March 1998, Omnicare's Director of Clinical Services, Mark E. Lehman ("Lehman"), solicited a substantial payment from Abbott. The subsequent discussions between Omnicare and Abbott focused on what amount of payments "would suffice" and how the parties would explain the payments.

30. Initially, Lehman requested an "unrestricted educational grant" of $15,000 from Abbott's National Manager for Long Term Care ("LTC Manager"). (A copy of Lehman's March 18, 1998 letter is attached hereto as Exhibit 2.) Abbott's LTC Manager responded to Omnicare's Senior Vice President for Purchasing and Professional Services, Timothy Bien ("Bien"), that in order to justify such expenditures, Abbott needed Omnicare to provide data on Depakote utilization in nursing homes serviced by Omnicare in a format compatible with sales data that Abbott obtained from other sources. In a follow-up phone call to Omnicare's Director of Purchasing, Daniel J. Maloney ("Maloney"), Abbott's LTC Manager offered that Abbott would pay Omnicare $12,500 per year for Depakote sales data, $16,000 to support Omnicare's Management Meeting, and additional funding of an "assay methodology" for Depakote and K-tabs (an extended release potassium chloride tablet marketed by Abbott). In a handwritten memorandum from Maloney to Bien describing the conversation, Maloney relayed that Abbott's

LTC Manager "wants to know will this suffice?" (A copy of Maloney's June 9, 1998 handwritten memorandum is attached hereto as Exhibit 3.)

31. On June 16, 1998, Abbott's LTC Manager and Maloney again discussed the proposed payments. Later that day, Abbott's LTC Manager summarized the discussions stating that Abbott would pay $12,500 for monthly data for the next calendar year and pay a $15,000 "unrestricted educational grant" to "support ongoing educational programs." Abbott's LTC Manager concluded by requesting a summary report of all Depakote and Depakene unit and dollar sales by month for 1998, to be followed by a data disc. (A copy of the June 16, 1998 letter from Abbott's LTC Manager is attached hereto as Exhibit 4.)

Omnicare Hosts "Industry Day"

32. On January 6, 2000, Bien solicited Abbott for a payment described as "an educational grant in the amount of $50,000" to support the development and implementation of "a new health management . . . program, called 'Re*View: Another look. A new focus,'" specifically aimed at "the geriatric population we serve." (A copy of Bien's January 6, 2000 letter is attached hereto as Exhibit 5.)

33. While Omnicare senior managers described Re*View as an educational program involved in "identifying those conditions/diseases that are under-treated, under-diagnosed or potentially inappropriately treated," no such program existed. In fact, Re*View was simply a means by which Omnicare solicited kickbacks from pharmaceutical manufacturers in exchange for promoting their drugs in elderly nursing home residents. In internal communications, Omnicare employees referred to the Re*View program as the "one extra script per patient (Re*View) program."

34. On May 24, 2000, Abbott paid Omnicare $50,000, which the companies characterized as a "Re*View grant."

35. In approximately February 2001, Omnicare invited Abbott and over a dozen other pharmaceutical manufacturers to a meeting that Omnicare referred to internally as "Industry Day." During Industry Day, Omnicare presented materials about the Re*View program and other opportunities for manufacturers to provide remuneration to Omnicare. The presentation included a solicitation for an additional $50,000 payment to support the "Re*View program."

36. Following Industry Day, Omnicare maintained an internal score sheet to track each pharmaceutical manufacturer's willingness to pay kickbacks to Omnicare in various forms, including increased discounts for drug purchases, contracts for sample packaging, "good faith discussion of microchip projects," "good faith discussion on contract research for [Omnicare]," and "commit[ment] to 'Review' grant request." (A copy of the score sheet is attached hereto as Exhibit 6.) Bien received reports about the status of these solicitations.

37. On the score sheet, Omnicare noted that Abbott would participate in microchip projects, good faith discussion on contract research, and "'Review' grant request," but that Abbott would provide a "[v]erbal agreement only due to Tap litigation." TAP Pharmacueticals was a joint venture between Abbott and another drug manufacturer. In October 2001, the United States completed a global criminal and civil resolution with TAP resolving, among other things, allegations that TAP paid illegal kickbacks to doctors.

38. On March 14, 2001, Maloney sent a letter to Abbott confirming its agreement to purchase sales data. Although Abbott paid $12,500 for data in 2000, the letter stated that "[t]he agreed upon price to continue receiving Depakote and Oxandrin sales data at the pharmacy level

will be $32,000 for 2001." Maloney forwarded a copy of the letter to Bien with a handwritten note asking "What bucket do you want this applied to?"

39. After Abbott confirmed the $32,000 payment, Omnicare promptly took additional steps to promote the use of Depakote in the nursing homes it serviced. On April 2, 2001, Omnicare issued a memorandum informing its Consultant Coordinators that Abbott had commissioned "Behavior Management Wall Charts." In the memorandum, Omnicare's Chief Clinical Officer instructed the Coordinators that "[w]hile distributing these reference charts, the consultant should be reinforcing the appropriate place of Depakote in treating behaviors in the long-term care facility with nursing staff and nursing supervisors."

40. In an April 3, 2001, memorandum from Bien to Omnicare chief executive officer Joel Gemunder, Bien stated that he raised almost $1,000,000 from the drug industry in 2000 through Re*View, and that as of April 2001 Omnicare still had a balance of over $925,000. Bien noted that with the $1.1 million he expected to be raised in 2001 through the program, Omnicare would have more than $2 million in a "war chest." (A copy of Bien's April 3, 2001 memorandum is attached hereto as Exhibit 7.)

41. On March 6, 2002, Bien acknowledged receiving a check from Abbott for the Re*View program in the amount of $50,000. (A copy of Bien's March 6, 2002 letter is attached hereto as Exhibit 8.)

Omnicare Disguises Kickback Payments as "Rebates"

42. Omnicare began receiving kickback payments from Abbott as early as approximately October 1999, which it described as "rebates," even before the two had a written "rebate agreement."

43. In approximately May 2000, Abbott sought a written agreement with Omnicare, and executives of both companies met on June 1, 2000, to "structure a program of value for both Omnicare and Abbott." Before the meeting, Abbott's Director of National Accounts wrote to Bien to state the objectives of the meeting, including an "*extreme commitment*" from Omnicare to Abbott:

> The objectives and agenda I recommend for the meeting are:
>
> *General* A corporate agreement between Abbott and Omnicare should require *extreme commitment*, including all divisions of Abbott (HPD, RPD, PPD, and MediSense). That commitment should be formally acknowledged from the executive offices of each organization, and should provide for rewards and business gains beyond those covered by Abbott Divisions' current product agreements.

44. On approximately June 30, 2000, Omnicare received a payment from Abbott that it identified as a rebate in the amount of $43,218.64.

45. On approximately July 21, 2000, Omnicare executed a "Pharmaceutical Rebate Agreement" effective July 1, 2000 through June 30, 2002. The agreement provided that Abbott would make quarterly payments to Omnicare in exchange for Omnicare's help in increasing the use of Depakote in the nursing homes it serviced. According to the agreement, Omnicare would increase the use of Depakote through its "control of Formulary" and "willingness to engage in and develop numerous product programs and promotional activities designed to encourage the cost-effective, medically appropriate therapeutic and market share management of pharmaceutical products." The agreement provided that the amount of the payments to Omnicare would be based on its increasing Depakote use in the nursing home residents it serviced by certain threshold amounts compared to the same quarter in the previous year, adjusted yearly based on changes in the number of nursing home residents serviced by Omnicare. Thus, Omnicare could only receive kickback payments by increasing Depakote use

per nursing home resident. In a Power Point presentation describing the contract terms, Abbott emphasized that these payments were contingent on meeting the threshold increases: "Rebates paid on total Depakote sales ONLY after achieving growth tiers."

46. For the first six months of the agreement (through December 31, 2000), Omnicare was not entitled to any payments unless it increased the Depakote use by its nursing home patients by at least 12.5 percent over the previous year (adjusted for any changes in the number of patients Omnicare serviced). The agreement provided that after January 1, 2001, the threshold would rise to 15 percent. The agreement also required Omnicare to provide Abbott with quarterly reports of Depakote use by drug formulation, dispensing facility, and date for the purpose of determining the quarterly payment amounts.

47. On approximately July 27, 2000 – less than a month after the rebate agreement became effective and just six days after Omnicare executed it – Omnicare received a $54,237.78 kickback payment from Abbott.

48. On September 8, 2000, Omnicare signed a superseding agreement that added a kickback payment to Omnicare for increasing the use of Depakote ER for its nursing home patients by certain thresholds compared to total Depakote sales. Under this new agreement, if Omnicare increased the use of Depakote ER in its nursing home patients to 10 percent of the total Depakote use, it was entitled to a kickback of 2 percent of the total price of its Depakote ER purchases for the quarter.

49. On September 11, 2000, Abbott informed Omnicare that based on the July sales figures "[w]e're not going to hit the first rebate tier at this rate."

50. On May 11, 2001, Omnicare sent a letter to Abbott demanding additional kickbacks to compensate it for revenue losses caused by changes in Abbott Hospital Products

Division's wholesale acquisition costs. Omnicare stated that it "expect[ed] Abbott to make [Omnicare] whole in the form of discounts on Abbott's portfolio of products." Omnicare also noted that Abbott representatives had attended Omnicare's Industry Day where they had discussed "the pressures on Omnicare's top line as a direct result of newer, more expensive products sold by the pharmaceutical industry." Omnicare concluded by requesting a response "on what will be done by Abbott to alleviate this Abbott-caused loss to Omnicare."

51. On June 15, 2001, Abbott and Omnicare retroactively amended the "rebate agreement" to extend the 12.5 percent threshold growth requirement from the original December 31, 2000 expiration to the June 30, 2002 contract ending date.

52. Omnicare failed to achieve the 12.5 percent threshold increase in any quarter in 2000 and 2001 and, therefore, under the terms of the agreement, failed to earn any payments for the six quarters covered by the agreement and amended agreement. Nonetheless, on December 20, 2001, Abbott paid Omnicare six checks totaling more than $175,000. Omnicare described these kickback payments as Depakote rebates.

53. Although Omnicare again failed to achieve the 12.5 percent threshold required by the "rebate agreement," Abbott paid Omnicare kickbacks of $394,185.42 and $435,744.61 for the first and second quarters of 2002. Omnicare described these payments as "rebates."

54. Although the July 1, 2000 "rebate agreement" expired on June 30, 2002, Omnicare signed an amendment that was effective January 1, 2003 and which lowered the threshold increase in Depakote use from 12.5 percent to 5 percent. In addition, the agreement stated:

> Abbott and [Omnicare] shall work together cooperatively to achieve success in the business relationship contemplated by this Agreement. Abbott and [Omnicare] shall develop and implement a mutually agreeable strategic plan to support the appropriate use of [Depakote]. Abbott shall

provide consultative expertise and assistance in implementing this appropriate use plan. The parties shall meet quarterly to ensure successful execution of agreed upon strategies and projects. The parties shall consider adjustments to the strategic plan in good faith when presented by a party.

55. On March 24, 2003, Omnicare received a $508,544.33 kickback payment from Abbott, which was disguised as a "rebate" for the fourth quarter of 2002, when there was no rebate agreement in effect. On approximately the following dates, Omnicare received kickback payments from Abbott in the stated amounts that Omnicare disguised as "rebates:"

Date	Amount
August 1, 2003	$558,755.33
September 15, 2003	$838,537.75
December 15, 2003	$971,325.00
March 29, 2004	$699,328.45
May 7, 2004	$101,997.41

56. On December 3, 2003, Abbott provided Omnicare with an amended "rebate agreement" effective for Depakote purchased January 1, 2004 through December 31, 2004. The amended agreement included a new two-tiered formula for calculating kickback payments. Under the first tier, Omnicare was entitled to a kickback of 2 percent of the price of the base utilization (the amount of Depakote used the previous year) and 20 percent of the price of the increased use of Depakote by its nursing home patients, but only if Omnicare increased Depakote utilization by at least 2.5 percent over the previous year. Under the second tier, it could receive a 4 percent rebate of the base amount used and a 40 percent rebate on the increased amount used, but only if Omnicare increased the use by at least 5 percent.

57. On approximately the following dates, Omnicare received kickback payments in the stated amounts for Depakote sales, which Omnicare disguised as rebates:

Date	Amount
June 23, 2004	$1,248,291.50
September 30, 2004	$1,318,663.19
December 16, 2004	$1,422,669.18

58. In December 2004, Abbott executed a new rebate agreement with Omnicare effective the fourth quarter of 2004 through December 31, 2005, and a nearly identical agreement with Omnicare's subsidiary, Neighborcare, Inc. The agreements changed the formula for calculating the kickback payments by reducing the importance of increasing the overall use of Depakote, and emphasizing the increase in the market share of Depakote ER compared to all Depakote.

59. On approximately the following dates, Omnicare received kickback payments in the stated amounts for Depakote sales, which Omnicare disguised as rebates:

Date	Amount
March 1, 2005	$1,967,240.62
May 16, 2005	$ 629,306.31
October 27, 2005	$2,115,134.04

60. In 2005, Abbott sought an agreement that would measure Depakote sales against sales of other manufacturers' drugs that competed with Depakote in the control of behaviors in nursing home residents. The competitor drugs, which included atypical antipsychotics, would constitute a "market basket" against which Depakote sales would be measured. To facilitate such an agreement, Omnicare provided Abbott with prescription data for atypical antipsychotic drugs. Omnicare initially rejected Abbott's "market basket" proposal for a 2 percent kickback on Depakote DR, stating that it "need[ed] a blended average of a minimum of 8% discount between Depakote ER and Depakote DR to be competitive with other drugs in the market basket such as Risperdal, Seroquel, Zyprexa and Keppra to name a few." On approximately January 31, 2006, Omnicare executed an amended agreement, purported to be effective

October 1, 2005 through March 31, 2006, which required Omnicare to provide Abbott with quarterly reports, with specific dispensing data, of the use of Depakote and the competitor products by Omnicare's patients.

61. On approximately March 31, 2006, Omnicare received a $1,601,897.21 kickback for Depakote sales, which Omnicare disguised as a rebate.

62. In April 2006, Abbott and Omnicare extended the rebate agreement for the period April 1, 2006 through June 30, 2006. A September 2006 email from Abbott to Omnicare indicated that "Abbott is extending our current agreement until 10/1/06 and then the new agreement takes effect as we discussed . . . ." An Abbott presentation described the new 2006 agreement and included a discussion about "optimizing contract performance." One slide focused on the highest volume pharmacies for ER conversions with support from the Omnicare Clinical Intervention Center and consultant pharmacists. The slide described the "Depakote Market Share Growth Strategy" to include "Consultant drug regimen review."

63. In September 2006, Abbott and Omnicare entered into a new "Pharmaceutical Rebate Agreement" effective July 1, 2006 through June 30, 2008. This agreement included modified Market Share and Compensation paragraphs, which stated:

> Abbott provides rebates in consideration of [Omnicare]'s control of Market Share (as such term is defined below) and offers performance rebates in consideration of [Omnicare]'s ability to control Market Share, and its willingness to engage in and develop numerous product programs and other promotional activities designed to encourage the cost-effective, medically appropriate therapeutic management of pharmaceutical products.
>
> This Agreement sets forth the terms and conditions upon which [Omnicare] will not place any Product [defined as Depakote and Depakote ER] in a disadvantaged position relative to other Formulary products regarding promotional efforts in favor of any Competitive Product and Abbott will sell such Products to [Omnicare] and will compensate [Omnicare] based on the actual dispensing of Products to patients who are

> residents of a Facility under such Formulary, all in accordance with this Agreement.

The agreement also required Omnicare to provide Abbott with detailed reports for the use of Depakote and a dozen "competitor" products by Omnicare's nursing home patients.

64. In January 2007, Abbott and Omnicare executed an amendment to the July 1, 2006 agreement to change the method of calculating and paying rebates. In February and April 2008, the companies executed two additional amendments. The amendments extended the contract term and changed the baseline period for computing rebates and the listing of competitive products, but left all other terms and conditions unchanged.

65. On approximately the following dates, Omnicare received kickback payments in the stated amounts for Depakote sales, which Omnicare has disguised as rebates:

Date	Amount
6/22/2007	$991,461.56
9/24/2007	$1,021,161.18

<u>Kickbacks Disguised as Grants for the Omnicare Management Conference</u>

66. Beginning as early as 1999, Omnicare annually solicited kickbacks from pharmaceutical manufacturers purportedly to fund an annual management conference on Amelia Island, Florida. As described above, Abbott's LTC Manager asked Omnicare executives if $16,000 for the management conference and various other payments "would suffice." Thereafter, on August 13, 1999, and September 24, 1999, Omnicare received $8,000 kickback checks from Abbott, purportedly for the management conference.

67. In February 2000, Omnicare received a $27,000 kickback payment from Abbott. Omnicare and Abbott both attempted to disguise this payment, first as a data purchase payment and, later, as a payment for Omnicare's management conference. On February 4, 2000, Abbott issued a purchase order to "Omnicare Management Conference" purportedly for the purchase of

"zip level data for sales reporting to LTC [long-term care] salesforce." On February 17, 2000, Omnicare issued an invoice billing Abbott for $27,000 for this "data." Finally, Omnicare disguised this kickback in its records as a payment to sponsor its management conference.

68. Between 2000 and 2008, Omnicare solicited and received the following kickback payments disguised as payments for its management meetings on Amelia Island:

Date	Amount
8/15/2000	$9,000
8/15/2000	$9,000
9/4/2001	$19,000
6/17/2002	$19,000
6/20/2003	$21,000
5/27/2004	$14,500
7/1/2004	$10,500
5/17/2005	$14,500
5/18/2005	$10,500
4/6/2006	$12,500
8/6/2007	$12,500
8/10/2007	$12,500
7/25/2008	$6,250
8/18/2008	$12,500
11/13/2008	$6,250

Other Kickbacks

69. As Abbott negotiated with Omnicare for the initial Depakote rebate agreement in July 2000, Abbott offered Bien, Maloney, and other Omnicare senior managers free tickets to the Ladies Professional Golf Association United States Open golf tournament, as well as a round of golf at the Kemper Lakes golf course.

70. In 2001 and 2002, Omnicare subsidiary Shore Pharmaceutical Providers ("Shore") received $36,750 and $38,500, respectively, for a variety of amenities such as parties and dinners, to include $12,000 from Abbott for a 2001 "golf outing." (A copy of Abbott's August 21, 2001 check and remittance advice is attached hereto as Exhibit 9.) In 2002, Shore used payments from several pharmaceutical manufacturers designated for parties, picnics,

seminars, and personal electronic equipment, including $5,000 from Abbott, to fund seminar and American Society of Consultant Pharmacists meeting expenses. The miscellaneous cash receipts journal indicated that $9,500 would be carried over to 2003.

71. From 1998 through 2004, Omnicare subsidiaries Jacobs Healthcare Systems and Lawrence-Weber Medical, received $120,630 from drug manufacturers for education, programs, preceptorships, and the holiday party, including $24,000 from Abbott.

72. In January 2004, Omnicare sent Abbott a letter of agreement, requesting that Abbott "produc[e] more of the Omnicare Behavior Management clipboards" at a cost of $21,500.

73. In December 2006, Abbott delivered a $2,000 check payable to Omnicare for Omnicare of Nebraska's Christmas party. Because the check was payable to "Omnicare," it could not be cashed by Omnicare of Nebraska, so it was deposited to Omnicare's central cash account and a check was issued to an Omnicare of Nebraska employee and "code[d] to employee relations." (A copy of the December 29, 2006 e-mail and check are attached hereto as Exhibit 10.)

Omnicare Promoted Depakote in Nursing Homes

74. In exchange for Abbott's kickback payments, Omnicare's corporate management directed Omnicare's pharmacists to promote Depakote to control the behavior of elderly nursing home residents suffering from dementia. In a June 26, 2000, memorandum to regional vice presidents, operations managers, and regional clinical directors, for distribution to consultant pharmacists, Lehman stated that one of Omnicare's clinical priorities was "[b]ehavior management in dementia" with a focus "on the treatment of aggression and the use of Depakote."

75. On September 26, 2002, Abbott and Omnicare executives met to discuss Omnicare's Depakote purchases in 2002. Abbott encouraged Omnicare to "focus[ ] on identifying new residents that could benefit from the addition of Depakote." Abbott suggested, among other things, giving Depakote preference on Omnicare's formulary, corresponding regularly with consulting pharmacists about the Depakote initiative, providing Abbott with physician-level utilization data for generic valproic acid and antipsychotic drugs to permit physician targeting, and targeting patients with behavioral disturbances.

76. On September 27, 2002, Abbott's national account manager wrote to Maloney to confirm that Omnicare would make increasing Depakote sales in Omnicare-serviced nursing homes a top priority and would provide Abbott with prescribing information to focus sales calls and medical education programs. The letter stated that Omnicare was focused on:

- converting patients from generic valproate prescriptions to Depakote,
- identifying new nursing home residents with behavioral disturbances not exhibiting psychotic features and recommending Depakote as first-line treatment for them,
- using Depakote to augment nursing home residents being treated with an antipsychotic, converting nursing home residents taking benzodiazepines to Depakote, and
- increasing the Depakote dosage in nursing home residents taking Depakote but still exhibiting behavioral disturbances.

77. On October 1, 2002, Abbott's national account manager issued a memorandum to Abbott managers describing Omnicare's updated behavior management initiative, which included:

- targeting nursing home residents with behavioral issues for prescriptions of Depakote;
- directing pharmacists to use Facility Quality Indicator Reports generating in nursing homes to identify residents suffering from negative outcomes where Depakote may be an appropriate consideration;

- identifying residents that are currently prescribed Depakote, but may be on a sub-therapeutic dose; and
- targeting residents receiving generic Valproic prescriptions for possible conversion to Depakote.

The memorandum also confirmed that Abbott provided Omnicare Operations Managers, Consultant Coordinators, and Regional Clinical Directors, with a "toolkit" which highlighted that use of Depakote to control behaviors in nursing home residents was not subject to the same OBRA restrictions as the use of antipsychotics; macros to be loaded onto Omnicare pharmacists' computers to encourage prescribers to approve Depakote use to control behaviors, and posters bearing the Omnicare logo that summarized symptoms and medication choices. These "toolkits" were mailed out with specific instruction for copying and distribution to all Omnicare consultant pharmacists.

78. To standardize and facilitate the company's promotion of Depakote, Omnicare developed model comments or "macros" that consulting pharmacists could import into the recommendations they sent to prescribing physicians following their monthly review of nursing home residents' drug regimens. Among other things, these comments:

(a) Advocated the use of Depakote to control behaviors in nursing homes:

> "[T]his resident was identified as having recurrent behavioral symptoms affecting others. . . . The non-medication behavioral interventions being utilized for this resident have not been fully successful at eliminating these adverse behaviors.
>
> Please consider initiating Depakote at 250 mg QHS in an attempt to control resident's behaviors. . . ."

(b) Encouraged doctors to prescribe higher doses of Depakote:

> "Depakote was initiated at 125 mg BID to control behaviors and behavioral symptoms persist. Average target doses of Depakote needed to control behaviors are 500 mg – 1000 mg daily.
>
> Please consider further titration to Depakote ER 500 mg QHS. . . ."

(c) Encouraged doctors to add Depakote when a resident's drug regimen already included an antipsychotic drug:

> Current medication regimen includes * (an antipsychotic). Despite the use of antipsychotic therapy, resident continues to display behavioral symptoms.
>
> Please consider initiating Depakote 125 mg BID. Further titration in therapy (i.e., Depakote 250 BID) can then be based upon clinical response. . . .

79. In many cases, the recommendations reflecting these macros directly resulted in the administration of Depakote to the nursing home resident and submission of claims to federal healthcare programs.

80. The following are examples of consultant pharmacist recommendations that directly resulted in claims to federal healthcare programs:

(a) On February 24, 2004, an Omnicare consultant pharmacist in Virginia provided the following comment about Patient A, an 82-year-old nursing home resident:

> This resident is exhibiting aggitative behaviors toward staff/residents, which may be harmful to themselves and/or others.

The consultant pharmacist made the following recommendation to initiate Depakote:

> Please consider initiating Depakote 125mg BID, in an attempt to further improve these behaviors. Further titration in therapy (e.g. 250mg BID) can then be based upon clinical response. Liver Function Tests (LFT's) should be drawn at baseline and at least every 6 months thereafter.

On May 12, 2004, Patient A was prescribed 125 mg of Depakote Sprinkle, a formulation of Depakote that is often added to soft food for elderly individuals who have difficulty swallowing pills. Omnicare subsequently submitted claims to the Virginia Medicaid program for Depakote prescriptions, resulting in payments totaling at least $695. Beginning in January 1, 2006, Omnicare began submitting claims to the Medicare Part D program for Depakote Sprinkle dispensed to Patient A. Omnicare submitted at least five claims to Medicare for Depakote

prescriptions dispensed to Patient A on January 1, February 1 and 23, March 28, and April 28, 2006.

(b) On September 3, 2004, an Omnicare consultant pharmacist in Arkansas provided the following comment about Patient B, an 80-year-old nursing home resident who was already being administered Risperdal, an antipsychotic drug, to control behaviors:

> This resident's current medication regimen includes* Risperdal 0.5mg pm daily. Despite use of antipsychotic therapy, resident continues to display behavioral symptoms.

The consultant pharmacist made the following recommendation to initiate Depakote:

> Please consider initiating extended-release divalproex sodium (Depakote ER) 250 mg daily (titrating to 500 mg ER daily ,if necessary). Further titration in therapy can then be based upon clinical response. If added, recommend obtaining baseline LFT's and at least every six months thereafter.

On October 13, 2004, Patient B was prescribed 125 mg of Depakote Sprinkle. Omnicare subsequently submitted at least 16 claims to the Arkansas Medicaid program for the Depakote prescriptions, resulting in payments totaling at least $657. Beginning in January 1, 2006, Omnicare began submitting claims to the Medicare Part D program for Depakote Sprinkle dispensed to Patient B. Omnicare submitted at least 8 claims to Medicare for Depakote prescriptions dispensed to Patient B on January 25, February 22, March 24, June 5 and 22, July 14,, August 7 and September 5, 2006.

(c) On December 15, 2004, an Omnicare consultant pharmacist in Arizona provided the following comment about Patient C, a 78-year-old nursing home resident who was already being administered Haldol, an antipsychotic drug, to control behaviors:

> This resident's current medication regimen includes PRN Haldol for her behaviors. A PRN antipsychotic should not be used more than 2 times in 7 days. After discussing with nursing, she has behaviors daily.

The consultant pharmacist made the following recommendation to initiate Depakote:

> Please consider initiating extended-release divalproex sodium (Depakote ER) 500 mg daily (titrating to 1000 mg ER daily ,if necessary, after 5-7 days). If added, recommend obtaining baseline LFT's and at least every six months thereafter.

On December 28, 2004, Patient C was prescribed 500 mg of Depakote ER. Omnicare subsequently submitted at least 10 claims to the Arizona Medicaid program for the Depakote prescriptions. Beginning in January 2006, Omnicare began submitting claims to the Medicare Part D program for Depakote ER 500 mg dispensed to Patient C. Omnicare submitted at least 18 claims to Medicare for Depakote prescriptions dispensed to Patient C on January 2, February 1, April 17, May 12, June 18, July 15, September 26, October 20, and November 13, 2006, January 8, February 19, March 14, April 9, May 3, and May 29, 2007, and September 25, November 18, and December 26, 2008.

False Claims

81. Compliance with the AKS is a condition of payment for reimbursement under both Medicare and Medicaid because kickbacks destroy an essential premise upon which the reimbursement of all health care claims depends: that the medical services, devices, or drugs are being furnished because they are medically necessary for the patient and not simply because they advance the financial interests of the party furnishing the services, devices or drugs.

82. As a result of Omnicare's solicitation and receipt of kickbacks from Abbott as alleged above, Omnicare submitted false claims to Medicaid and Medicare for Depakote dispensed to residents at nursing homes. Because of patient privacy concerns, the United States will provide a disc containing examples of false claims to defendant pursuant to a protective order to be negotiated by the parties and submitted to the Court.

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

83. Paragraphs 1 through 82 of this Complaint are realleged and made a part of Count One.

84. As a result of kickbacks paid by Abbott, Omnicare purchased, ordered, or recommended or arranged for the purchasing or ordering of Depakote, in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), all of the claims Omnicare presented to Medicaid and Medicare for Depakote are false or fraudulent. Accordingly, Omnicare knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

85. As a result of the false or fraudulent claims Omnicare knowingly presented or 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))

86. Paragraphs 1 through 82 of this Complaint are realleged and made a part of Count Two.

87. Omnicare knowingly made or used 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). 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.

88. As a result of the false records or statements Omnicare made or used, 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))

89. Paragraphs 1 through 82 of this Complaint are realleged and made a part of Count Three.

90. Omnicare conspired with Abbott to solicit and receive kickbacks in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), in exchange for Omnicare's purchase of Depakote from Abbott, thereby causing all of Omnicare's claims to Medicaid and Medicare for Depakote to be false or fraudulent. Accordingly, Omnicare 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).

91. As a result of the false or fraudulent claims that Omnicare 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)

92. Paragraphs 1 through 82 of this Complaint are realleged and made a part of Count Four.

93. The United States claims the recovery of all monies by which Omnicare has been unjustly enriched, including profits earned by Omnicare because of illegal inducements it received from Abbott.

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

95. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Omnicare on purchases from Abbott for Depakote, 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:

96. 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.

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

Respectfully submitted,

ANTHONY P. GIORNO
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Dated: December 22, 2014

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CERTIFICATE OF SERVICE

I 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 that a copy will be served by email on December 22, 2014, upon Defendant Omnicare, Inc., to its attorneys, set forth below, who have agreed to accept service in this manner on behalf of Defendant Omnicare, Inc.

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