

United States of America
ex rel. Quinn v. Omnicare, Inc.:
The Loophole Has Been Closed

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I. INTRODUCTION

Since its enactment during the Civil War in 1863, the False Claims Act ("FCA")² has been a potent weapon in our country's seemingly endless fight against fraudulent activity aimed at the United States government. In recent years, the statute's *qui tam* provisions,³ which permit private individuals to commence a civil action on behalf of the United States for monetary damages in exchange for a percentage of the recovery,⁴ have been quite effective in routing out the corrupt practices of unscrupulous profiteers; practices—such as providing the federal government with shoddy, defective and/or worthless goods—which have cost taxpayers millions of dollars. According to statistics recently released by the U.S. Department of Justice, during fiscal year 2005 alone, the United States obtained over \$1.4 billion from FCA litigation.⁵ The FCA has been particularly effective in curbing fraudulent practices targeting the Medicaid and health care systems.⁶

Unfortunately, the FCA is a weapon with some severe limitations. No judicial decision reveals these limitations better than the Third Circuit's decision in *U.S. ex rel. Quinn v. Omnicare, Inc., et al.*, 382 F.3d 432 (3d Cir. 2004)⁷, a case in which a federal appeals court held that the Medicaid law did not explicitly prevent pharmacies from repeatedly billing Medicaid for returned pharmaceutical products and that this practice, known as restocking, was not in violation of the FCA. Even the panel who decided *Omnicare* was disturbed by the outcome of this case and noted in their opin-

1. Harvey S. Mars, Esq., Law Office of Harvey S. Mars LLC, was co-counsel to Relator Thomas Quinn. Many thanks to Richard Hedeman, Esq., Summer C. Smith, and Jacob Heyman Kantor for their assistance in the preparation of this article.

2. 31 U.S.C. §§ 3729–3732 (1988 & Supp. 1993). The False Claims Act was enacted at the urging of President Abraham Lincoln during the Civil War to curb rampant corruption among government contractors who were engaged in fraudulent practices such as selling the Union Army boxes of "gunpowder" filled with sand. The complete history of the False Claims Act is contained in the legislative history of the False Claims Amendments Act of 1986, S. Rep. No. 99-345, 99th Cong., 2d Sess., reprinted in 1986 U.S.C.C.A.N. 5226.

3. The *qui tam* provisions of the False Claims Act are contained in 31 U.S.C. § 3730. The term "*qui tam*" is derived from the Latin phrase "*qui tam domino rege quam pro se ipso in hac parte sequitur*" meaning "he who brings the action for the king as well as for himself." William Blackstone, COMMENTARIES ON THE LAW OF ENGLAND, Book III, 160 (1768).

4. The percentage of the recovery an individual *qui tam* plaintiff (also known as a Relator under the statute) is entitled to varies from 15 to 30 percent depending upon whether the United States actually intervenes in the action. 31 U.S.C. § 3730 (d)(1).

5. 2005 U.S. Newswire 202-347-2770

6. See David J. Ryan, *The False Claims Act: An Old Weapon With New Firepower Is Aimed At Health Care Fraud*, 4 ANNALS HEALTH L. 127 (1995); John M. Parisi, *The Gun's Loaded: Using The False Claims Act To Prevent Nursing Home Fraud And Patient Abuse*, 1 ANN. 2002 ATLA_CLE 1195 (2002).

7. See 2003 WL 24296532 (Slip Copy marked "Not for Publication") for the U.S. District Court for the District of New Jersey's unpublished decision in this litigation.

ion that "[w]e find the lack of legal authority, requiring Medicaid-provider pharmacies to credit Medicaid when a medication is returned for resale, is disturbing and [w]e believe that Congress and/or the New Jersey legislature might serve Medicaid well if this lack of regulation were corrected."⁸ This lack of regulation continued unabated until Congress finally took action and enacted the Deficit Reduction Act in 2006.

The purpose of this article is to analyze in depth the various defects in the FCA as well as the Medicaid statute, as revealed by the *Omnicare* decision, and to highlight the legislative response that finally closed the loophole.⁹

II. THE STATUTORY FRAMEWORK OF THE FALSE CLAIMS ACT

The FCA imposes liability upon any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
- (2) 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;
- (3) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.¹⁰

Under the statute, a person acts "knowingly" when he or she (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. No proof of specific intent to defraud (*scienter*) is required.¹¹

Under the FCA, a "claim" is defined as any request for money or property made to the government, as well as any non-governmental third party, if the United States government provides any portion of the money or property that is requested, or if the government will reimburse the third party.¹²

Penalties under the FCA are harsh: a civil penalty may be imposed of between \$5,500.00 to \$11,000.00 for each false claim proven, plus three times the amount of proven monetary damage to the United States, plus costs and fees. An exception exists

8. *Id.*; see also *3d Circuit Calls Medicaid Drug Return Procedure "Disturbing,"* ANDREWS HEALTH LAW LITIGATION REPORTER, (September 22, 2004). In fact, during oral argument of the appeal, Third Circuit Judge McKee stated that he was "shocked" by the restocking practices engaged in by *Omnicare*.

9. Section 6033 of the Deficit Reduction Omnibus Reconciliation Act of 2005 contains curative language eliminating the industry-wide practice among long-term care provider pharmacies of multiple billing for returned medications. See S. 1932, 109th Cong. § 6033. This statute was signed into law by President Bush in February 2006 and became effective April 2006.

10. 31 U.S.C. § 3729(a)(1), (2) & (7). While there are other sections to the FCA, the sections listed above are the only provisions of the statute which are pertinent to the *Quinn* decision.

11. 31 U.S.C. § 3729(b). The 1986 amendments to the FCA made it clear that no specific proof of fraudulent intent to defraud is required to support an action under the FCA. This amendment cured a blatant ambiguity in the law concerning the meaning of the word "intent". S. Rep. No. 345, 99th Cong., 2d Sess. 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286.

12. 31 U.S.C. § 3729(c).

when a person who has submitted a false claim brings this fact to the federal government within thirty days of the government's discovery of the violation. In that case, the penalty may be reduced to two times the actual damages plus costs.¹³

III. THE RELEVANT FACTS

(A) Quinn

In February 1996, Relator Thomas Quinn ("Quinn") was hired by Pompton Nursing Home Supplier ("Pompton"), a pharmaceutical provider for long term care facilities (i.e. nursing homes), as its Regional Controller. Pompton was a subscriber and participant in New Jersey's Medicaid program.¹⁴

Quinn was directed by Alan Traster ("Traster"), Pompton's then CEO, to issue monthly reimbursement checks to New Jersey Medicaid¹⁵ for only 50% of the acquisition cost of unused (restocked) medicines returned by the nursing homes that Pompton had supplied. Quinn ascertained the value of these returned pharmaceuticals by referring to Pompton's computer-generated weekly returns reports.¹⁶

Quinn subsequently learned that the price of the pharmaceutical products on the returns report was already listed at 50% of their actual value. This meant, for a period of time, that the monthly reimbursement checks being submitted to Medicaid were only 25% of the value of the returned pharmaceuticals. Quinn verified this analysis with a Price-Waterhouse accountant employed by Omnicare who agreed that Pompton was only repaying Medicaid 25% of the value of returned pharmaceuticals.¹⁷

Quinn became alarmed about Pompton's Medicaid returns policy and sought guidance from Pompton's Special Program and Compliance Officer ("SPOC"). This individual advised Quinn that it was her belief that Pompton was obligated to pay Medicaid back the full value of returned pharmaceuticals and that its failure to do so possibly constituted fraud.¹⁸

Quinn also discussed with the SPOC Pompton's policy regarding redispensing opened pharmaceutical products. He had witnessed individuals working in the pharmacy's returns department removing pills from their original sealed packages by pushing them through the wrapping and then placing them into large bins. He witnessed other individuals in the pharmacy's returns department creating new packages for these loose pills.¹⁹

13. 31 U.S.C. § 3729(a).

14. See Brief for Appellant ("BA"), p. 5, which may be obtained through Westlaw Court/Express, 1-877 DOC-RETR, or by contacting TAF at 202-296-4826 ext. 28.

15. See BA, pp. 5-6. The federal Medicaid program ("Medicaid") is a voluntary program operated by participating states. States which are allowed to participate in the program must have adopted all regulations that the federal government deems necessary for its administration, including regulations concerning distribution of and payment for prescription medications and regulations mandating that participating States prevent unreasonable costs. 42 U.S.C. § 1396(a)(30)(A).

16. See BA, p. 5-6.

17. See BA, p. 6.

18. See BA, pp. 6-7.

19. See BA, p. 7.

Based on Quinn's unabated fears concerning Pompton's returns policy, Quinn reported them in an August 1997 memorandum to Traster. Quinn was discharged from his employment approximately one week later.

Troubled by Pompton's conduct, Quinn initiated a *qui tam* suit against Pompton and its parent corporation, Omnicare, in 1998 in The United States District Court for the District of New Jersey.

(B) Omnicare

Omnicare, a publicly traded corporation, is the nation's largest provider of pharmacy related services to long term care facilities, such as nursing homes and assisted living communities, and at the time of the litigation, conducted business within 45 of the United States.²⁰ Pompton was purchased by Omnicare in 1997.

In or about April 1998, Omnicare entered into a Settlement Agreement and Release with the United States and the State of Illinois ("Agreement") for claims Illinois had brought against Omnicare under the FCA. Those claims arose out of the failure of another Omnicare acquisition, Home Pharmacy Services, Inc. ("HPS") to credit the State of Illinois' Medicaid program for recycled returned pharmaceuticals. In addition to paying a substantial sum of money, Omnicare was required to implement a formal compliance program to assure its future compliance with Medicaid and other federally funded programs.²¹

Though no formal compliance program was yet in place, Omnicare, through its counsel, had previously conducted two surveys of state Medicaid regulations, one in June 1996 and the other in October 1997. Both surveys contained a review of New Jersey's Medicaid regulations concerning crediting for returned medications.

The June 1996 survey indicated that "unit dose medications that are returned to the pharmacy if unused can be placed back into stock. . . . **the pharmacy must return, to Medicaid, a check representing the total returned drugs**" (emphasis supplied). The October 1997 updated survey was more detailed. This survey stated that "**if pharmacies accept and redispense returned medications, they must credit the Medicaid Program by sending a check for the unused drugs to the Treasury Department**" (emphasis supplied). It went on to state that New Jersey Medicaid relied upon the pharmacist to properly credit for returned reuseable pharmaceuticals and that the crediting process worked on the "honor system."²²

As part of a formal compliance program required by the Agreement, Omnicare also submitted questionnaires to all of its pharmacy Unit Managers in May 1998 to inquire about their Medicaid returns policy. Cherry Hill, another Omnicare subsidiary operating in New Jersey, stated in its response to the questionnaire's inquiry about crediting the New Jersey Medicaid Program for returned drugs: "**the law states that the facility must have a system in place in the LTC facilities for the crediting of medications. Medicaid does expect credits but does not have any policy regard-**

20. See BA, p. 7.

21. See BA, pp. 7-8.

22. See BA, pp. 8-9.

ing crediting of meds [sic].” Pompton responded that “credit must be given where applicable as per regulation. An administrative restocking charge is taken and the remainder is credited.”²³

(C) Pompton

Prior to Omnicare’s purchase of Pompton in 1997, both financial and operational due diligence reports were prepared. The operational due diligence reports indicated that 65% of Pompton’s income came from Medicaid.²⁴

With respect to Pompton’s processing and repackaging of returned medications, the operational due diligence report noted “the actual recycling process is to push out the individual tablets and capsules and place them in separately labeled containers for subsequent use.” Another section of the report indicated “[i]f bulk pre-packed card and can find bottle with same lot number will punch product back into bulk bottle. If can’t find then destroy. Looked like they were punching everything back into bottles.”²⁵

The financial due diligence report also found that net New Jersey Medicaid sales represented roughly 60% of Pompton’s total sales prior to Omnicare’s purchase of Pompton.²⁶

Pompton is a signatory to a standard provider agreement required by the New Jersey Department of Human Services, Division of Medical Assistance and Health Services (“DMAHS”), the agency that administers the New Jersey Medicaid program. The provider agreement contains the following certification: “I understand that the maximum charge to the State of New Jersey for all Medicaid and PAAD prescriptions for covered drugs and related pharmaceutical products/devices may not exceed the pricing policies of the state as described in N.J.A.C. §10:51-1.5 and N.J.A.C. §10:51-4.5” (emphasis supplied). The provider agreement also prohibits any false statement or representation of material fact made in order to receive any benefit or payment under the Medical Assistance Program.²⁷

(D) Medicaid Returns—Defendants’ Crediting Policies

(1) Omnicare

Omnicare’s corporate returns procedure is contained within its Standard Operating Procedures manual (“SOP”). The SOP indicates “in those states that permit the return and re-use of noncontrolled substances: [e]stablish a detailed tracking system to enable the pharmacy to account for all returns, re-use and/or disposal and **full credit** has been issued.” (emphasis supplied).²⁸

23. See BA, p. 9.

24. See BA, pp. 9–10.

25. See BA, pp. 9–10.

26. See BA, p. 10.

27. See BA, p. 10.

28. See BA, p. 11.

(2) Pompton

In a memorandum produced during the litigation, Pompton noted that "since Medicaid does not spell out the financial terms for determining reimbursement, we have been following the concept that was already in place prior to Omnicare purchasing this unit. Although it is not in writing, this unit credits Medicaid at the rate of (average wholesale price) AWP-50%."²⁹

The actual amount which Pompton credited to Medicaid was determined by its accounts payable staff who totaled the billing (remittance) reports for returned medications and then requisitioned checks based upon 50% of the amount billed. However, there was no effort by Pompton to trace or keep track of returned medications to ascertain where and to whom they had been initially dispensed. For a period of time the payment amounts contained within the billing statements were automatically reduced by 50% by Pompton's computer system.³⁰

(D) The DOJ Investigation and the Price Waterhouse Analysis

During its investigation of this suit's allegations, the DOJ requested that Omnicare produce a copy of a February 1998 report prepared by Price Waterhouse concerning Pompton's Medicaid returns policy for the period August 1996 through December 1998. Omnicare's counsel prepared a written synopsis of the reports' factual findings and submitted that in place of the actual report.³¹ The synopsis indicated "the actual percentage calculated by the Returns Entry process for drugs returned to New Jersey Medicaid is approximately 50% of AWP." It further verified that Pompton credited New Jersey Medicaid 25% of AWP from November 1996 through at least September 1997.³²

The District Court held that the defendants, by producing a synopsis of the report, had waived the work product privilege concerning its factual contents and ordered them to turn over portions of that document and certain attachments to a July 1999 follow-up report. The 1998 report confirmed that the returns reports generated from Pompton's Medicaid initial billing statements were not actually sent to Medicaid with the credit payments and that Medicaid only received Pompton's credit checks without any supporting documentation.³³

According to the report, Traster acknowledged that the computer system's field for returns automatically computed the returns at 50% of their value and admitted that he had designed this field. Traster acknowledged that Quinn "was not familiar

29. See BA, p. 11.

30. See BA, pp. 11-12.

31. See BA, pp. 12-13.

32. See BA, pp. 12-13.

33. The State of New Jersey provided plaintiff with copies of all monthly credit payments made by Pompton for the period October 1996 through October 2000. Each of the checks except one issued in December 1996, indicated that the credit payments were simply for returns. The December 1996 payment contains several ambiguous notations in its descriptive remarks section, which originally were not discovered by Medicaid representatives because the check had been poorly reproduced.

with anything that was going on with the computer." Price Waterhouse concluded that "it could not be determined if the change from 50% to 25% credit was an intentional change or a misrepresentation of the data generated by the computer."

Price Waterhouse was advised by Pompton's accounts payable staff that the returns report for each month were totaled and the resulting value was then reduced by 50%. Because of the 50% reduction automatically calculated by the computer, the net returns percentage for the New Jersey returns program was actually 25%.³⁴

(F) New Jersey Regulations and Administrative Code Provisions

(1) Medicaid Claims—Payment and Adjustment

The procedure for Medicaid claims is set forth in a Fiscal Agent Billing Supplement ("FABS"). The FABS instructs provider pharmacies that **all Medicaid pharmacy claims** are to be submitted on the MC-6 claim form. The MC-6 form contains the following certification:

PROVIDER CERTIFICATION: I certify that the services covered by this claim were personally rendered by me or under my direct supervision (as defined by Program regulations); that the foregoing information is true accurate and complete; and I agree to keep such records as are necessary to disclose fully the extent of services provided, and to furnish information for such services as the State Agency may request; and that the services covered by this claim and the amount charged thereof are in accordance with the regulations of the New Jersey Health Services Program; and that no part of the net amount payable under this claim has been paid; and that payment of such amount will be accepted as payment in full without additional charge to the patient or to others on his behalf. I also certify that the services have been furnished in full compliance with the non-discrimination requirements of Title VI of the Federal Civil Rights Act and Section 504 of the Rehabilitation Act of 1973. I understand that payment and satisfaction of this claim will be from Federal and State funds and that any false claims, statements or documents, or concealment of a material fact, may be prosecuted under applicable federal or State laws, or both.³⁵

If New Jersey Medicaid pays a claim in error, the pharmacy provider is required to submit a "MMIS Adjustment Request Form." The FD-999 form itself specifically indicates that a claim must be voided when services are not provided. No reimbursement payment accompanies the FD-999 when a previously submitted claim is voided. Medicaid deducts

34. See BA, p. 13.

35. See BA, pp. 14-15.

the voided amount from the current Medicaid payment owed to the provider.³⁶

Medicaid regulations are maintained by DMAHS. According to N.J.A.C. §10:49-8.3(b), when a claim is paid by New Jersey Medicaid in error, the provider is required to void the initial claim utilizing the proper Adjustment Form (FD-999(9/91)). Similarly, Medicaid regulations require that for electronically submitted claims, "pharmacies are required to initiate claim reversals for those services in which a claim was generated and adjudicated to payment by the fiscal agents' POS computer and the service was not provided to a Medicaid . . . beneficiary" N.J.A.C. §10:51-1.25(j)(2).³⁷

Additionally, N.J.A.C. §10:49-14.5 prohibits a provider from charging Medicaid an "administrative charge or service fee for services for which reimbursement is included as part of the Medicaid fee." Medicaid also pays long term care provider pharmacies a "capitation" fee for each patient (bed) receiving Medicaid reimbursed pharmacy services. See N.J.A.C. §10:51-2.7. The amount of the capitation payment is dependent upon the method by which the medication is dispensed. The capitation fee is paid in order to reimburse the pharmacy provider for costs related to dispensing medications. A representative of New Jersey Medicaid verified that the capitation payment includes the costs associated with recycling medications because those costs are related to the dispensing of medication.³⁸

(G) N.J. Regulations—Returns, Recycling and Credits

In New Jersey, long term care provider pharmacies may resell unused pharmaceuticals returned from long-term care institutions if certain conditions are satisfied. Pharmaceuticals may only be recycled if they are in unit (single) dose packaging, have been stored in a medication room or secure area, and have their seal and control number intact.³⁹ Unit dose medications may not be recycled if their expiration date is missing from the medication's label or has passed.⁴⁰

Regulations governing the crediting of returned reusable medications were promulgated by the New Jersey Department of Health and Senior Services ("DHSS"). N.J.A.C. §8:39-29.4(j) states in its entirety: "Where allowable by law, the facility shall generate a **crediting mechanism** for medications dispensed in a unit-of-use drug distribution system, or other system which allows for re-use of medications. The **crediting system shall be monitored by the provider pharmacist and a facility representative**" (emphasis supplied).⁴¹

At the time of its enactment, New Jersey included the following assessment of the economic impact of this regulation in the New Jersey Register:

[S]ignificant cost savings will accrue as a result of N.J.A.C. §8:39-29.4(j), which requires facilities utilizing unit of use medication ad-

36. See BA, p. 15.

37. See BA, pp. 15-16.

38. See BA, p. 16.

39. N.J.A.C. § 13:39-9.5.

40. N.J.A.C. §§ 13:39-5.9 and 13:39-9.15(a)(1).

41. See BA, pp. 17.

ministration systems to establish a crediting system for return of unused pharmaceuticals. The rule discontinues the current requirement to destroy all unused medications within 30 days. When dispensed in single-use packages (for example, "bingo cards"), the product is returnable and can be dispensed again by the retail pharmacy. Although no statewide dollar impact is available, literally thousands of dollars of medications are destroyed by many facilities monthly. Both private pay consumers and the State Medicaid program will benefit from this proposed rule.⁴²

The crediting requirement was again addressed by the state when it considered the economic impact of a 1997 amendment to the long term care regulations increasing the time unit dose medications could be retained in a pharmacy's inventory. It was projected that:

The economic impact of this amendment should result in savings to residents and families and third party payors such as Medicaid. **These savings will occur as a result of drugs which will be returned to the pharmacy for credit. Drugs which have been discontinued for a particular resident and returned to the pharmacy will be credited to that resident.** The returned drugs which have some time remaining before they reach the expiration date will then be dispensed to another resident, rather than being disposed of in the pharmacy after six months regardless of the date listed on the label. The pharmacy will not dispense repackaged unit dose drugs with less than a thirty day expiration date. The overall savings to residents, families and Medicaid may exceed \$200,000. There will also be savings to all long term care pharmacies, as they will not have to pay for waste removal of these products. (emphasis supplied).⁴³

Further a January 13, 1998 letter from former DHSS Deputy Commissioner Susan C. Reinhard to a consultant pharmacist employed by a long term care provider pharmacy, indicated that "there is a requirement that the facility employ a crediting mechanism for medications dispensed in a unit-of-use drug distribution system which allows for the re-use of medications." Deputy Commissioner Reinhard further stated that "whoever supplies the medication must of course comply with the applicable requirements."⁴⁴

Finally, a 1985 audit report concerning "credits to Medicaid for return of reusable drugs" prepared by the United States Department of Health and Human Services' Office of the Inspector General indicates that the State of New Jersey does require crediting for returned reusable pharmaceuticals.⁴⁵

42. 26 N.J.R. 1776 (Monday May 2, 1994).

43. 29 N.J.R. 4415(a) (Monday, October 20, 1997).

44. See BA, p. 18.

45. See BA, p. 18.

(H) Deposition Testimony

Edward J. Vaccaro ("Vaccaro"), Assistant Director of the DMAHS Office of Health Service Administration, was deposed in this litigation. During his testimony, Vaccaro explained the contents of a December 4, 1998 letter he had written to Deputy Attorney General Krayniak regarding this suit—a letter which ultimately convinced the DOJ not to intervene in the suit.⁴⁶ Vaccaro stated that because DMAHS (N.J. Medicaid) did not have separate regulations pertaining to medication recycling, DMAHS had considered it a voluntary program. Vaccaro further testified that the DHSS had actually regulated this area. Medicaid relied upon pharmacists to comply with all relevant DHSS regulations. Vaccaro explained the genesis of this dichotomy. In 1998, former New Jersey Governor Christie Whitman issued an Executive Order which split the services provided under the Medicaid program between two Departments within state government. The responsibilities concerning seniors, including services performed by long term care providers, were transferred from DMAHS to the DHSS.⁴⁷

When he reviewed N.J.A.C. § 8:39-29.4(j), Vaccaro said that its second sentence required the provider pharmacist to set up a crediting mechanism within its own facility and to support whatever credits are sent in to the state with adequate documentation. He verified that the long term care provider pharmacy is responsible for submitting credits to Medicaid for returned reusable pharmaceuticals.

Concerning the amount of credit, Vaccaro testified that the provider was required to pay back the full amount which Medicaid had originally paid. Vaccaro stated: "Whenever Medicaid makes a purchase and then there's any return of that money that was expended, it's a hundred percent, it's never a portion of it. Its state tax dollars. This is not a private commercial entity we're dealing with here. That's not just my expectation, it's also the expectation of my administrators, my supervisors, the director of the division." Vaccaro also stated that based upon his experience, it was understood that "if a product we purchased returns back at the inventory, that we get back our full credit for the purchase."⁴⁸

IV. AN OVERVIEW OF THE THIRD CIRCUIT'S DECISION

The Third Circuit's decision,⁴⁹ issued on September 1, 2004, affirmed the United States District Court of New Jersey's unreported decision⁵⁰ granting Omnicare's motion for summary judgment dismissing Quinn's complaint in its entirety.⁵¹

46. See BA, pp. 18–19.

47. See BA, p. 19.

48. See BA, pp. 19–20.

49. See Sanford, Teplitzky, *HEALTH LAW HANDBOOK*, Part III, Chapt. 7, "Update on Fraud and Abuse" § 7.7, 2005 Edition and FALSE CLAIMS ACT & QUI TAM QUARTERLY REVIEW, Volume 35, October 2004 for general overviews of the decision.

50. United States ex rel. Quinn v. Omnicare, Inc., No. 98-2031 (DRD), slip op, 2003 WL 24296532 (D.N.J. filed March 28, 2003). The Third Circuit's complete procedural history of the litigation is contained in the BA, pp. 2–6.

51. The precedential decision in *Omnicare* was deemed controlling and compelled the Third Circuit to reject another litigant's FCA challenge to another long term care provider pharmacy's restocking practices. See *In re Genesis Health Ventures, Inc.*, 2004 WL 2296093 (3d Cir. 2004). In *Genesis*, identical crediting practices were engaged by the defendant. In an

In his appeal, Relator Quinn asserted four theories for the imposition of FCA liability against Omnicare. First, Omnicare, by failing to void the initial MC-6 claim form when unused pharmaceuticals were returned, violated the FCA by obtaining payment from Medicaid for goods that were never provided ("worthless services"). Second, Omnicare violated the FCA by accepting multiple Medicaid payments for the same goods ("successive claims for recycled products"). Third, Omnicare violated the FCA by submitting claims to Medicaid for pharmaceutical products which were not processed in compliance with New Jersey Board of Pharmacy regulations ("adulterated products claim"). Finally, Relator Quinn asserted that the FCA was violated when Omnicare failed to return one hundred percent of the amount initially billed for returned medications ("Reverse False Claim").⁵²

Regarding Quinn's assertion that Omnicare had violated the FCA when it failed to void its initial Medicaid claim forms when unused medications were returned for reuse, the Third Circuit held that the initial claim forms were accurate when they were originally submitted to Medicaid for reimbursement. Hence, since the forms could not be deemed false when they were originally submitted they were not actionable under the FCA.⁵³ Subsequent events, such as the return of medications, did not convert the initially accurate claim into a false one. Furthermore, the court held that New Jersey regulations did not specifically require that the forms be voided when medications were actually returned. The court noted that it would be "exceeding the intent of Congress in defining false claims if we were to permit the transforming of a valid claim into a false claim by the occurrence of a subsequent fortuitous event which is not itself the basis of any required adjustment."⁵⁴

Next, the court rejected Quinn's FCA claim based upon Omnicare's successive billing for recycled medications. The Court held that because New Jersey regulations permit the return and recycling of medications to long term care facilities, and there was no regulation specifically requiring the pharmacy to credit Medicaid for amounts it had already paid, no FCA liability could attach to this practice.⁵⁵ The court held that without the existence of a clear regulation prohibiting this practice, it could not properly impose FCA liability on Omnicare:

unreported decision issued a month and a half after *Omnicare*, the court held that "in the absence of any statute or regulation requiring health care providers in New Jersey to credit Medicaid for returned drugs, we conclude that neither West End's failure to do so, nor its alleged practice of successive billing based on a separate transaction theory, gives rise to a False Claims Act violation." *Id.*

52. The final theory of liability was asserted under "reverse false claims" provision of the FCA, 31 U.S.C. § 3729 (a)(7). *Omnicare*, 382 F.3d 432, 436.

Whereas the other sections of § 3729(a) create liability when individuals obtain excessive payments from the federal government due to their submission of a "false claim" for payment, § 3729(a)(7) creates liability when individuals fraudulently conceal or understate money owed back to the federal government. Liability attaches under the reverse false claims provision when a party knowingly decreases or conceals an obligation owed to the government. *United States v. Raymond & Whitcomb*, 53 Fed. Supp. 2d 436 (S.D.N.Y. 1999); *United States v. Pemco Aeroplex, Inc.*, 195 F.3d 1234 (11th Cir. 1999); *Pickens v. Kanawha River Towing*, 916 Fed. Supp. 702, 708 (S.D. Ohio WD 1996).

53. *Omnicare*, 382 F.3d 432, 436.

54. *Id.*

55. The court discussed applicable Medicaid regulations at length in the section of its decision which rejected Quinn's claim that Omnicare was legally obligated to credit Medicaid the full acquisition cost of returned medications. See *infra*, pp. 20-21.

In so concluding, we recognize that the second claim would be submitted to Medicaid for payment for the *same* medication. When Pompton submits the second claim, it knows that the medication, which is the subject of that claim, was already dispensed once and returned. Pompton also knows that Medicaid has already paid 50% of the cost of the medication. However, because New Jersey regulations allow Pompton to recycle returned medications and because no regulation requires Pompton and other Medicaid pharmacies to credit Medicaid for the returns, we conclude that we cannot impose FCA liability based on the submission of the second claim.⁵⁶

The court also rejected Quinn's successive claims theory of FCA liability on the ground that Quinn had failed to present clear evidence that any duplicate claims had actually been paid by Medicaid, even though it was clear that over 60% of Pompton's business was devoted to Medicaid participants and that some duplicate Medicaid claims had to have been submitted.⁵⁷ In support of this portion of its holding, the court cited two decisions that were decided outside the Third Circuit. Both decisions held that in order to defeat a motion to dismiss under Federal Rules of Civil Procedure, Rule 9 (b), an FCA plaintiff must allege in his or her complaint the existence of an actual false claim.⁵⁸ Omnicare's counsel, in fact, recently applauded this aspect of the ruling and proclaimed that it "should go a long way toward permitting healthcare providers, who have been sued by FCA relators, to challenge the legal underpinnings of the suit without risking a jury trial."⁵⁹

The court rejected Quinn's adulterated medications claim on grounds similar to its rejection of his successive billing claim. The court held that this portion of Quinn's suit must fail because he failed to produce any evidence that Medicaid had paid for improperly processed medications. The fact that over 60% percent of Omnicare's business was devoted to Medicaid was deemed legally insufficient for purposes of imposing FCA liability:

In the present case, however, Quinn cannot demonstrate either that an improperly recycled medication was paid for by Medicaid or that it was paid for by one of the other sources of payment for the medications that Pompton dispensed. Although we might hypothesize that 60% of the improperly recycled medications were paid by Medicaid, it is impossible to rule out the chance that they were paid by non-Medicaid sources. For this reason, we agree with the District Court that "even assuming that the MC-6 certified compliance with Board

56. *Quinn*, 382 F.3d 432, 441.

57. *Id.* at 439-40.

58. *United States ex rel. Alfarooni v. Kitsap Physicians Service*, 314 F.3d 995 (9th Cir. 2002); *United States ex rel. Clausen v. Lab. Corp. of America*, 290 F.3d 1301 (11th Cir. 2002).

59. See Harry R. Silver, *Third Circuit Rules That A Qui Tam Relator May Not Proceed To Trial Without First Establishing That False Claims Were, In Fact, Submitted*, November 2004 Patton Boggs News and Views, available at <http://www.patton-boggs.com/news/detail.aspx?news=128> (last visited November 1, 2007).

of Pharmacy regulations as a condition of payment, Plaintiff has not pointed to sales inconsistent with the certification [citations omitted].” As with our discussion on successive claims, Quinn did not provide the District Court with a single instance where Pompton submitted a claim for payment for medications recycled in violation of § 13:39-9.15. For that reason, Quinn’s false certification claim fails.⁶⁰

Nonetheless, though the court denied Quinn’s substantive claim for improperly recycled medications, it rejected the District Court’s holding that the “implied false certification” theory of FCA liability was inapplicable here.⁶¹ An implied false certification occurs when the government pays a claim based upon a claimant’s false assertion that they have complied with all regulatory or contractual preconditions to payment.⁶² In such a case, while the claim for payment is itself true, the certification of compliance is not.

The District Court held that since Medicaid’s payment obligation was not specifically conditioned on the provider’s compliance with the pharmacy regulation at issue here, § 13:39-9.15(a)(2), the false certification theory could not be asserted.⁶³ The Third Circuit disagreed. Since non-compliance with pharmacy regulations would disqualify a provider from continuing to participate in the Medicaid program,⁶⁴ compliance could not be deemed irrelevant to Medicaid’s decision to pay.⁶⁵ Hence, even though Medicaid’s payment obligation was not specifically conditioned on the provider’s compliance with applicable pharmacy regulations, the court found that an implied false certification claim could still exist. Unfortunately, since the pharmacy regulations were not actually proven to have been violated, the court held that Quinn’s implied false certification claim could not succeed.⁶⁶

Finally, the court, in the most troubling portion of its decision, dismissed Quinn’s reverse FCA claim⁶⁷ on the ground that in New Jersey, long term care provider pharmacies were under no clear obligation to credit Medicaid for the payments they received for returned medications which were resold back to Medicaid participants.⁶⁸

60. *Id.* at 443.

61. *Id.* at 442.

62. See *United States ex rel. Siewick v. Jamieson Sci & Eng’g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *United States ex rel. Mikes v. Strauss*, 274 F. Supp. 3d 687, 697, 702–703.

63. *Omnicare*, 382 F.3d at 442.

64. The MC-6 form specifically required providers to certify that the pharmaceutical services they provide comply with all Medicaid regulations; regulations which in this case specifically incorporate New Jersey pharmacy regulations.

65. *Omnicare*, 382 F.3d at 442.

66. *Omnicare* is significant in the respect that it is the first Third Circuit decision which has expressly adopted the “false certification” theory of FCA liability. *Id.* at 441. Furthermore, in it, the Third Circuit adopted the broader, less restrictive false certification approach adopted by several other circuit courts. *Id.* at 442, fn. 12. *Ab-Tech Construction v. U.S.*, 31 Fed. Cl. 429, 434 (Fed. Cl. 1994), *aff’d*, 57 F.3d 1084 (Fed. Cir. 1995); *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America*, 238 F. Supp. 2d 258, 263 (D.D.C. 2002) (“The theory of implied certification, as set out in *Ab-Tech*, is that where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent.”); *Lucky v. Baxter Healthcare Corporation*, 183 F.3d 730 (7th Cir. 1999); *U.S. ex rel. Kneepkins v. Ganbro Healthcare, Inc.*, 115 F. Supp. 2d 35, 42 (D. Mass. 2000).

67. 31 U.S.C. § 3729(a)(7).

68. *Omnicare*, 382 F.3d at 444.

The court held that the regulations cited by Quinn only require the long term care pharmacy provider to "monitor" the crediting mechanism which nursing homes have in place.⁶⁹ The pharmacy has no independent obligation to credit under New Jersey regulations as they currently exist. The fact that the legislative history of the regulations as well as the testimony of a New Jersey Medicaid representative tended to support Quinn's arguments was not deemed probative because of the clear lack of legal authority establishing that there was an obligation to credit.⁷⁰ The court also held that even if the regulations did establish a crediting obligation, they did not clearly require that any specific amount be paid for returned medications.⁷¹

V. ANALYSIS AND CRITIQUE

The *Omnicare* decision is an extremely troubling one. The Third Circuit has held that long term care provider pharmacies in New Jersey may legally bilk the United States by reselling it, multiple times, products it had already purchased—the very thing the FCA was intended to prevent! Certainly, this determination was not an easy one for the court, given its strong suggestion at the decision's conclusion that either the legislature or Medicaid close this loophole. However, the court's determination was not necessarily an inevitable one on the facts of this case.

First, it was contrary to the clear weight of the evidence presented to the court for it to have held that defendants were under no crediting obligation. While the regulations at issue in the suit were to some extent ambiguous,⁷² taking into account their legislative history, the defendants' actual crediting practices, the opinion of a key New Jersey Medicaid official and the 1985 audit report of the United States Department of Health and Human Services' Office of the Inspector General finding that there was a crediting obligation in New Jersey,⁷³ the court could have easily found that a legally binding obligation existed.

Further, there is ample case law suggesting that no clear regulation is needed to establish FCA liability where "worthless services" are provided to the government.⁷⁴ A valid FCA action may exist even in the absence of statutory or regulatory requirements

69. N.J.A.C. § 8:39-29.4(j).

70. *Omnicare*, 382 F.3d at 446.

71. *Omnicare*, 382 F.3d at 445.

72. N.J.A.C. § 8:39-29.4(j).

73. See OIG-RPT, Med Guide 1985 Med-Guide-TB ¶ 34.646, Credits to Medicaid Following the Return and Redispensing of Prescription Drugs (May 22, 1985), Office of Inspector General Audit Report, No. ACN 10-50201.

74. See, e.g., *United States v. Bornstein*, 423 U.S. 303 (1976) (subcontractor furnished obsolete surplus radio tubes rather than new ones); *U.S. ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1050-53 (9th Cir. 2001) (knowingly billing for worthless services is actionable under the FCA where an operator of a regional clinical laboratory falsified laboratory test data when test results fell outside the acceptable standard of error); *U.S. ex rel. Mikes v. Strauss*, 274 F.3d 687, 702-03 (2d Cir. 2001); *Shaw v. AAA Engineering & Drafting, Inc.*, 213 F.3d 519, 531-532 (10th Cir. 2000); *Daff v. U.S.*, 78 F.3d 1566, 1574 (Fed. Cir. 1996) (supplying the federal government with defective power conditioners for use in TOW missiles violated the FCA); *U.S. v. McLeod*, 721 F.2d 282, 284 (9th Cir. 1983) (cashing an erroneously issued government check constitutes a violation of the False Claims Act); *U.S. v. Areodex, Inc.*, 469 F.2d 1003, 1007-1008 (5th Cir. 1972) (FCA liability found where contractor furnished ostensibly new, but reworked renumbered aircraft engine bearings); *U.S. v. Hydroaire, Inc.*, 1995 WL 86733 (N.D. Ill. 1995) (submitting non-conforming goods pursuant to a government military contract violated the FCA).

prohibiting the fraudulent conduct, the exact situation encountered in *Omnicare*. This was made clear by the Ninth Circuit in *Lee v. SmithKline Beecham, Inc.* where it explained that, "in an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under §3729 [of the False Claims Act], regardless of any false certification conduct."⁷⁵ Even in *Mikes v. Strauss*, a decision in which the Second Circuit defined the parameters of false certification conduct, the Court recognized the viability of "worthless service" FCA claims which did not require certification conduct.⁷⁶

The court, unfortunately, was unwilling to find a viable worthless service claim in *Omnicare* since medications were actually delivered to Medicaid patients. The error in this line of reasoning, however, is that it fails to focus on whether Medicaid participants actually received the medical benefit which the medications were intended to provide to them. In reality, that is the service for which Medicaid is paying. It seems counterintuitive to believe that "services" are actually being provided to Medicaid participants where medications are not used by them and are simply returned to the pharmacy.⁷⁷ The court's approach was a mechanistic one which was based solely upon the delivery of the medications, not upon their actual utilization. Under this constricted analysis, it would have been impossible to assert a worthless service claim.⁷⁸

Next, Quinn's reverse FCA claim could have been sustained on the ground that *Omnicare* had acknowledged and represented to Medicaid that they were paying one hundred percent credit for returned medications when they submitted credit checks back. It was undisputed that *Omnicare* had regularly submitted reimbursement checks back to Medicaid.⁷⁹ Regardless of *Omnicare's* claimed motivation for making these payments, by virtue of the fact they were made, Medicaid expected and believed that they were for the full amount of the returned medications. The record was clear that through the defendants' conduct and representations to Medicaid, they had acknowledged an indebtedness to pay full credit.⁸⁰ *Omnicare's* own conduct created an enforceable legal obligation which in and of itself should have been sufficient to establish liability for a reverse false claim.⁸¹

Omnicare's conduct was rendered even more odious by the fact that for a substantial amount of time it was not even following its own internal policy of submitting to

75. U.S. ex rel *Lee v. SmithKline Beecham, Inc.*, 245 F. 3d 1048.

76. U.S. ex rel. *Mikes v. Strauss*, 274 F.3d. 607, 702 (2d Cir. 2001). (False certification conduct occurs when a claim for payment is submitted to the Government which certifies compliance, either expressly or implicitly, with a particular statute, regulation or contractual term.)

77. It should be emphasized as well that claims were required to be voided when services were not provided to the participant. The court failed to recognize that there is a distinction between failing to provide services and failing to provide medication.

78. While the court stated that it was not ruling on the "worthless service" claim because it had not been raised previously in the district court, it is clear that the court's rigid interpretation of the New Jersey regulation requiring the voiding of Medicaid claims when services are not provided to the Medicaid beneficiaries would have been fatal to such a claim. *Omnicare*, 382 F. 3d at 437 & 446 fn. 18.

79. See BA, p. 13, fn. 5.

80. *Omnicare*, 382 F. 3d at 446.

81. *Syle v. Freedley*, 99 A. 2d 541, (N.J. Super., App. Div. 1953) (checks may constitute an acknowledgment of an indebtedness actionable at law); *McPhilomy v. Lister*, 19 A. 2d 143, 153 (S. Ct. Pa. 1941) ("there can be no more unequivocal acknowledgment of a present existing debt than a payment on account of it").

Medicaid fifty percent credit.⁸² Omnicare's admission that it only credited Medicaid twenty-five percent between November 1996 and September 1997 could have been another basis for the court to find reverse FCA liability. Unfortunately, the decision did not even address the ramifications of this fact.

Finally, the court's denial of Quinn's duplicate payment and adulterated medications claims, based on his failure to produce evidence that improper Medicaid claims had actually been submitted, did not take into account the practical realities of the conduct engaged in by Omnicare. Omnicare failed to keep track of which returned medications were being resold to Medicaid.⁸³ Nor did Omnicare maintain any records which could have been used to demonstrate that improperly packaged medications were being sold to Medicaid. While it is true that submission of a false claim is the *sine qua non* of FCA liability, in this case, where even the court believed that duplicate claims were being submitted and compelling evidence existed that claims were being submitted in violation of pharmacy regulations, an exception to this requirement could have been made.⁸⁴ Certainly, the two Circuit Court decisions relied upon by the court did not mandate the dismissal of this claim under these particular circumstances.⁸⁵

The result in *Omnicare* actually rewards the defendants for irretrievably hiding their potentially fraudulent practices from discovery.⁸⁶ At the very least, the FCA should be amended to revise the burden of production in cases where proper record keeping was not employed by defendants.

VI. THE LEGISLATIVE RESPONSE

In 1985, United States Department of Health and Human Services' Office of the Inspector General conducted an audit of the medication returns programs of 32 States ("OIG Report").⁸⁷ With regard to federal regulations pertaining to returned reusable medications, the OIG Report noted that "[t]hose regulations, however, are silent re-

82. *Omnicare*, 382 F.3d at 435, fn. 6.

83. Obviously, *Omnicare* believed that a substantial amount of medications were being resold, or it never would have submitted any credit payments back to Medicaid.

84. *Omnicare*, 382 F.3d at 441 & 443, fn. 16.

85. See *United States ex rel. Alfatooni v. Kitsap Physicians Service*, 314 F.3d 995 (9th Cir. 2002); *United States ex rel. Clausen v. Lab. Corp. of America*, 290 F.3d 1301 (11th Cir. 2002). See also *U.S. ex rel. Crews v. NCS Healthcare of Illinois*, 2006 WL 2371457 (7th Cir. Ill., August 17, 2006) (dismissed a suit based on facts almost identical to *Quinn's* on the ground that no evidence of an actual false claim had been submitted by plaintiffs); *United States ex rel. Debra Hockett v. Columbia/HCA Healthcare Corp.*, ____ F.Supp.2d ____, 2007 WL 2039544 (D.D.C. 2007).

86. In fact, based upon the *Omnicare* decision, a major publication read by pharmacists throughout the country recently proclaimed that the practices engaged in by *Omnicare* are not fraudulent. With such public announcement, it is clear that other long term care provider pharmacies would soon mimic *Omnicare's* practices and take advantage of similarly ambiguous state regulations had the loophole not been closed. See *Medicaid Fraud or Not?*, Jesse C. Vivian, BS Pharm, JD, U.S. PHARMACIST, US Pharm. 2004; 12:55-58. South Dakota and Idaho have regulations almost identical to N.J.A.C. § 8:39-29.4(j). Title 20 of the Administrative Rules of South Dakota, § 20:51:13:02.1 states "unused drugs from patients in a nursing facility may be returned to the pharmacy that dispensed the drugs for credit and redispensing." Title 1, Agency 27 (Board of Pharmacy) of the Idaho Administrative Code, § 27.01.01.156.05 states: "unit dose packaged medications for in patients of licensed skilled nursing care facilities and hospitals may be returned to the dispensing pharmacy for credit."

87. See OIG-RPT, Med Guide 1985 Med-Guide-TB ¶ 34,646, Credits to Medicaid Following the Return and Redispensing of Prescription Drugs (May 22, 1985); Office of Inspector General Audit Report, No. ACN 10-50201.

garding recovery by pharmacies of reusable drugs. They do not require that reusable drugs be recovered by pharmacies nor appropriate credits be made to Medicaid if the drugs are recovered.”⁸⁸ As a result of the audit, the OIG Report recommended that “HCFA revise and strengthen the Medicaid regulations to require that, where State pharmacy policies and procedures allow for the return and redispensing of drugs provisions be made for appropriate credits to Medicaid.”⁸⁹ Even more recently, a congressional report released in 2004 indicated that the federal government was not doing enough to combat Medicaid fraud.⁹⁰ The *Omnicare* decision is a direct result of the government’s failure to heed the OIG Report’s recommendation to strengthen Medicaid regulations.

After the *Omnicare* decision was published, there was considerable public outcry for the closure of the regulatory loophole exposed by the court, which permitted pharmacies to bill the government multiple times for the same medication.⁹¹ In response to the decision, Taxpayers Against Fraud, a private watchdog group, advocated for the creation of a clear federal rule requiring pharmacies to reimburse Medicaid for drugs that were returned for resale.⁹²

As a result, former United States Senator Jon S. Corzine (D.NJ) proposed legislation in 2004 that would have amended Title XIX of the Social Security Act to require proper crediting for re-dispensed medications.⁹³ This legislation died in Committee. However, in 2005, the Senate Budget Committee submitted to Congress the Deficit Reconciliation Act of 2005 which contained a section specifically prohibiting the practice of charging Medicaid a second time for the sale of recycled medications, based upon Corzine’s 2004 proposal.⁹⁴ The Committee’s notes that accompanied the proposed legislation specifically referred to the *Omnicare* decision and remarked that Section 6033 (prohibition on restocking and double billing of prescription drugs) “prohibits federal matching payments for the cost of a covered outpatient drug claim if the claim has already been submitted and for which the pharmacy has already received payment.”⁹⁵ Section 6033 of the statute, as enacted, bars federal matching payment under the Social Security Act with respect to any amount expended for reimbursement to a pharmacy under that title for the ingredient cost of a drug for which the

88. *Id.*

89. *Id.*

90. See AP, Mark Sherman, *Study: U.S. Needs to Fight Medicare Fraud*, <http://www.cbhd.org/news/2004-08.htm> (last visited November 1, 2007).

91. See LIFE SCIENCE WEEKLY, *Loophole Lets Pharmacies Bill Government Twice*, 2004 WLNR 788097; ATLANTIC CITY PRESS, *Loophole Lets Druggist Double-Bill Government*, 2004 WLNR 17431438; THE STAR-LEDGER, *Medicaid Helpless To Fight Double Billing*, 2004 WLNR 18053017; CINCINNATI POST, *Loophole Lets Pharmacies Bill Government Twice*, 2004 WLNR 11505410; CINCINNATI POST, *Court: Suppliers Paid Twice For Drugs*, 2004 WLNR 11540764; HEALTH & MEDICINE WEEK, *Loophole Lets Pharmacies Bill Government Twice*, 2004 WLNR 762811; DRUG WEEK, *Loophole Lets Pharmacies Bill Government Twice*, 2004 WLNR 737170.

92. DRUG WEEK, *Loophole Lets Pharmacies Bill Government Twice*, 2004 WLNR 737170.

93. See S. 2950, 108th Cong.

94. See S. 1932 § 6025, 109th Cong.

95. See Chairman’s Mark of the Deficit Reduction Omnibus Reconciliation Act Of 2005, p. 24, available at <http://finance.senate.gov/sitepages/leg/10.250chmkmod.pdf> (last visited November 1, 2007).

pharmacy had already received payment under that title (other than a reasonable restocking fee).⁹⁶ This provision became effective in April 2006.

VI. CONCLUSION

The *Omnicare* decision was at the same time both a failure and a success for the plaintiff. While Quinn was unsuccessful in reviving his FCA claims and never received his "bounty," the court drew attention to the lack of regulation which led to Medicaid being billed multiple times for resold medications and its inability to redress this apparent abuse. Clearly, the decision resulted in federal legislation which will significantly reduce Medicaid expenditures. This is rarely, if ever, a result which litigation alone accomplishes.

In fact, the Medicaid reform which was accomplished because of this decision is just the type of advocacy envisioned by Third Circuit Senior Judge Max Rosenn in his 1983 address to the student body at the University of Iowa College of Law, which he entitled "The Social Conscience of a Lawyer."⁹⁷ In this address, Judge Rosenn remarked that it was "[m]y hope that these changes and demands upon the legal profession will not blot out your social conscience as lawyers. . . . I believe that that lawyers not only have an obligation to advance and support their profession, but also an obligation to society in general."⁹⁸ The decision to pursue *Omnicare* before the Third Circuit represented plaintiff and his counsel's recognition of their larger obligation to society to promote the closure of a widely abused loophole that is costing taxpayers millions of dollars.

Nonetheless, as demonstrated in Section VI, there was a legal basis for the court itself to close the loophole. The Third Circuit's failure to issue a ruling recognizing this was extremely disappointing and, unfortunately, until the loophole was corrected by the legislature, continued to allow opportunistic pharmacies to profit at the taxpayer's expense.

Enforcement of the new prohibition on restocking and double billing of prescription drugs will now rely upon the vigilance on the part of potential *qui tam* relators. Let's hope they keep a watchful eye.

96. A possible flaw in this legislation involves interpretation of what constitutes a "reasonable" restocking fee. *Omnicare*, during the litigation, contended that a 50% to 75% fee was appropriate, regardless of the cost of the medication. Clearly, a restocking fee of this magnitude does not appear reasonable.

97. See Senior Third Circuit Judge Max Rosenn, *The Social Conscience of a Lawyer*, 69 IOWA L. REV. 319 (1983-1984). Judge Rosenn was a member of the three-judge panel who decided *Omnicare*.

98. *Id.*