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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel.
[UNDER SEAL],

Plaintiffs,

vs.

[UNDER SEAL],

Defendants.

) Case No. 06 CV 1189 (JG) (KAM)
)
) FIRST AMENDED COMPLAINT
)
)
)
) **(FILED IN CAMERA AND UNDER SEAL**
) **PURSUANT TO 31 U.S.C. §§3729 et seq.)**
)
)
)

TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §§4-18-101 et seq. and 71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §2-308.14 et seq.]

JURY TRIAL DEMANDED

(FILED IN CAMERA AND UNDER SEAL)

Plaintiff-Relator Melanie Hagan (“Relator”), through her attorneys Phillips & Cohen LLP and Jonathan A. Willens LLC, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of Tennessee, the State of Texas, the State of Virginia, and the District of Columbia (collectively “the States”), for her Complaint against defendants McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation (collectively the “Big Three Wholesalers”), Henry Schein, Inc. (“Henry Schein”), and Does 1-1000, alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent statements, records, and claims made and caused to be made by defendants and/or their agents, employees and co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq., and the false claims acts of the States set forth below.

2. This action alleges that the Big Three Wholesalers, Henry Schein, and Does 1-1000 (collectively “defendants”) knowingly diverted or caused the diversion of pharmaceuticals and vaccines into the uncontrollable gray market, rendering such drugs unsafe, adulterated, and non-reimbursable by government health care programs.

3. Drug diversion occurs when pharmaceutical drugs flow through improper and unauthorized distribution channels from manufacturer to consumer. Among the sources of diverted drugs are institutional purchasers that are eligible to purchase deeply discounted drugs, buy more than they need, and clandestinely sell the remainder to wholesalers at a profit. Such transactions typically flow through “secondary wholesalers” that buy the diverted drugs and resell them to other wholesalers who, in turn, resell them further into the distribution chain.¹ These drugs might follow a complicated and lengthy series of transactions before finally being dispensed to the patient.

4. Meaningful and effective oversight of diverted drugs is extremely difficult, if not impossible. Drug diversion (also referred to as selling drugs in the “gray market”) poses a serious threat to the public health. As Congress has recognized, the gray market “prevents effective control or even routine knowledge of the true sources of prescription drugs in a significant number of cases.” P.L. 100-293, Section 2(2) (1987). A task force on drug diversion for the National Association of Boards of Pharmacies has declared that “diversion of prescription pharmaceuticals has been found to be an extensive enterprise affecting the safety, quality, cost, and availability of those products to consumers, thereby endangering the public health and welfare.” NABP, Resolution 96-5-2000.

¹ The term “secondary wholesalers” refers to wholesalers that purchase drugs from sources other than the drug manufacturers. The term “primary wholesalers” refers to wholesalers that purchase drugs directly from the drug manufacturers.

5. The threat to public health occurs because of the risk of improper storage and shipment (especially for products requiring specialized environments for storage), sale of expired drugs, dilution, adulteration, counterfeiting, forged labeling, and drug abuse. See “Dirty Deals: The Drug Diversion Trade, How it Victimizes the Vulnerable and How to Stop It,” The Center for Regulatory Effectiveness (Working Draft, July 2003); see also U.S. Department of Justice, “United States Attorneys’ Manual,” Title 4, 113 Prescription Drug Marketing Act (stating that the drug diversion market “provides a portal through which mislabeled, subpotent, adulterated, expired, and counterfeit drugs are able to enter the nation’s drug distribution system”).

6. Diverted drugs violate federal and state laws requiring compliance with current good manufacturing practices, laws prohibiting the adulteration of drugs, and laws establishing minimum requirements for safety, storage and handling of these drugs. Regulatory concerns are heightened with respect to certain fragile and unstable drugs, such as vaccines and other biologics, that require special handling. Drugs that are diverted pose unreasonable safety risks to the public and are deemed “adulterated” under the law. As such, these drugs are not eligible for reimbursement under federal and state health care programs. Moreover, the serious doubt cast on the safety and efficacy of these diverted drugs renders them subject to withdrawal of the FDA-approval, seizure, and/or recall.

7. This Complaint alleges that the Big Three Wholesalers, Schein, and others disregarded these prohibitions and knowingly caused, encouraged, and engaged in the diversion into the gray market of drugs manufactured by Merck & Co., Inc. (“Merck”). Schein was one of the companies that diverted Merck’s drugs and sold them to wholesalers. The Big Three Wholesalers purchased diverted Merck drugs and traded them in the gray market. Merck facilitated the extensive trading of its diverted products. Merck also directly participated in transactions with product diverters. The defendants engaged in these practices knowing that

claims for reimbursement for these diverted drugs would be submitted to federal and state health care programs. These claims for reimbursement constitute “false and fraudulent” claims under the Federal Civil False Claims Act (“FCA”), 31 U.S.C. §3729 et seq., and under the FCA’s state-law counterparts. Such claims cheated the federal and state governments out of funds that should not have been paid, unlawfully enriched defendants, and exposed patients to potentially serious health risks.

8. The FCA was originally enacted during the Civil War and was substantially amended in 1986. Congress enacted the 1986 amendments to enhance and modernize the government’s tools for recovering losses sustained by frauds against it. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government’s behalf.

9. The FCA prohibits knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval. 31 U.S.C. §3729(a)(1). Additionally, it prohibits knowingly making or using a false or fraudulent record or statement (a) to get a false or fraudulent claim paid or approved by the federal government or (b) to conceal, avoid, or decrease an obligation to pay or transmit money or property to the federal government. 31 U.S.C. §§3729(a)(2), (a)(7). The FCA also prohibits two or more parties from conspiring to defraud the government by getting a false or fraudulent claim allowed or paid. 31 U.S.C. §3729(a)(3). Any person who violates the FCA is liable for a civil penalty of up to \$11,000 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. §3729(a)(7).

10. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the

Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

11. As set forth below, defendants' actions alleged in this Complaint also violate the California False Claims Act, Cal. Govt Code §12650 et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Indiana False Claims And Whistleblower Protection Act, Ind. Code 5-11-55 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437 et. seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Michigan Medicaid False Claims Act. Mich. Public Act 337 et seq.; the Montana False Claims Act, Mont. Stat. Ann. 17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-1 et seq.; the Tennessee False Claims Act and Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§4-18-101 et seq. and 71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§2-308.14 et seq.

12. Based on these provisions, qui tam Plaintiff and Relator Melanie Hagan seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which defendants' misconduct has extended.

II. PARTIES

13. Plaintiff/Relator Melanie Hagan (“Relator”) is a resident of Newtown, Pennsylvania. From October 1998 to July 2004, Merck employed Ms. Hagan in its Vaccine Division in West Point, Pennsylvania. At Merck, Ms. Hagan was an International Pricing Analyst, then a Senior Analyst in Pricing and Economic Analysis. She has extensive knowledge of drug sales, pricing, customer, and distribution practices both at Merck and in the pharmaceutical industry generally. She has worked for years in the pharmaceutical industry in marketing, business analysis, and sales forecasting. Before Merck, she worked for Wyeth-Ayerst Laboratories as a Forecasting Business Analyst and as a Marketing Administrator.

14. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation, with its principal office at One Post Street, San Francisco, California. Among its many business activities, McKesson is a wholesale distributor of pharmaceutical products, including Merck’s pharmaceutical drugs.

15. Defendant Cardinal Health, Inc. (“Cardinal”) is an Ohio corporation with its principal office at 7000 Cardinal Place, Dublin Ohio. Among its many business activities, Cardinal is a wholesale distributor of pharmaceutical products, including Merck’s pharmaceutical drugs. Until recently, Cardinal’s direct secondary wholesale operations were headquartered in Groveport, Ohio.

16. Defendant AmerisourceBergen Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal office at 1300 Morris Drive, Chesterbrook, Pennsylvania. AmerisourceBergen was created in August 2001 following the merger of Amerisource Healthcare Corporation and the Bergen Brunswig Corporation (“Bergen”). Among its many business activities, AmerisourceBergen is a wholesale distributor of pharmaceutical products, including Merck’s pharmaceutical drugs.

17. Defendant Henry Schein, Inc. (“Henry Schein”) is a Delaware corporation with its principal office in Melville, New York. Henry Schein, Inc. is one of the largest distributors of healthcare products to office-based physicians in the United States. It is a major supplier to organizations that bundle physician members’ purchasing power.

18. Defendants Does 1-1000 are individuals and entities that participated in the fraudulent course of conduct that is the subject matter of this Complaint. Relator has not, as yet, ascertained the names and/or specific conduct of the entities sued as Does 1-1000, and therefore sues these defendants by fictitious names. The Doe defendants encompass the following two categories of defendants:

a. Secondary Wholesalers. At present, the only wholesalers named as defendants in this Complaint are the Big Three Wholesalers. However, several other wholesalers, commonly referred to as “secondary wholesalers” (see fn. 1 above), are also integrally involved in the events on which this lawsuit is based. These secondary wholesalers include but are not limited to P.D.I. Enterprise, Quality King Distributors, Inc., Supreme Distributors Company, and Victory Wholesale Grocers Company. These and numerous other secondary wholesalers trade aggressively in discounted drugs. As further information is developed concerning the specific role of particular secondary wholesalers in the unlawful conduct alleged in this Complaint, Relator will seek leave to amend this Complaint to name those companies as defendants.

b. Other Product Diverters. At present, this Complaint names only one physician supply house, Henry Schein, as a defendant. However, several other physician supply houses and institutional purchasers are also integrally involved in the events on which this lawsuit is based. These entities include but are not limited to H.D. Smith, Besse Medical Supply, and Metro Medical Supply, Inc. As further information is developed concerning the specific role of

these or other entities in the unlawful conduct alleged in this Complaint, Relator will seek leave to amend this Complaint to name those entities as defendants.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. In addition, 31 U.S.C. §3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in Counts 4-20 of this Complaint. Under 31 U.S.C. §3730(e), and under the comparable provisions of the state statutes listed in ¶11 above, there has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint. Relator is the original source of the facts and information alleged in this Complaint.

20. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendants can be found in this District and transact business in this District.

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the defendants can be found in and transact business in this District. At all times relevant to this Complaint, defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

IV. APPLICABLE LAW

A. Drug Reimbursement Under Government Health Care Programs

22. Pharmaceutical drugs are reimbursed by the federal and state governments under a variety of publicly-funded health care programs. During most of the period covered by this

Complaint, the Medicaid program subsidized the purchase of more prescription drugs than any other program. Starting in January 2006, Part D of the Medicare Program became the largest prescription drug subsidy program, providing prescription drug coverage for Medicare beneficiaries.

23. Medicaid is a public assistance program providing for payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the federal government and state governments. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

24. The diversion of Merck pharmaceutical drugs alleged in this Complaint violated numerous federal and state laws, including but not limited to laws requiring compliance with “current good manufacturing practices,” (see 21 U.S.C. § 351(a)(2)(B) & regulations promulgated thereunder); laws prohibiting the adulteration and misbranding of drugs (see 21 U.S.C. §§ 331, 334, 351 & regulations promulgated thereunder); and laws establishing minimum requirements for safety, storage and handling of these drugs (see id.). These and other violations rendered the affected drugs “adulterated” under the law and non-reimbursable under the reimbursement standards of the federal and state health care programs.

25. In addition to Medicaid, the federal and state governments reimburse a portion of the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Champus/Tricare, ChampVA, the Federal Employees Health Benefit Program, federal workers’ compensation programs, and comparable state programs. For purposes relevant to this Complaint, the drug reimbursement requirements of these programs are substantially similar manner to Medicaid requirements.

B. Causation Under The FCA

26. The FCA does not require direct contact between a defendant and the Government. By its terms, the FCA imposes liability on any person who presents or *causes* to be presented a false or fraudulent claim to the Government (or false statement in support of a false or fraudulent claim). See 31 U.S.C. § 3729(a)(1), (2), (7). The States' false claims acts contain similar provisions.

27. To "cause" an FCA violation, it is not necessary that the defendant's fraudulent conduct be the last in the series of events that results in financial loss to the Government. As applied by the courts, the standard for "causation" under the FCA is whether the submission of a false or fraudulent claim was "reasonably foreseeable" from a defendant's actions. Under this standard, a defendant's fraudulent conduct can occur anywhere in the chain of events leading to financial loss by the Government, and can be an indirect, as well as direct, cause of the loss. Moreover, the defendant need not be the recipient or beneficiary of the false claim. All that is required is that the defendant by its fraudulent conduct set in motion a series of events which results in reasonably foreseeable loss to the Government.

V. BACKGROUND

A. Pharmaceutical Drug Distribution

28. Wholesalers play a unique and central role in the drug industry. The most straightforward pattern of distribution occurs when a "primary" wholesaler purchases drugs directly from the manufacturers, stocks them, and resells them directly to the manufacturers' customers, usually "dispensing" organizations (those that dispense directly to a patient). These customers prefer to deal with a wholesaler rather than each manufacturer separately because of the relative simplicity in working with a single supplier who stocks the different manufacturers'

drugs. This uncomplicated pattern of distribution allows for minimal handling of a drug before it is consumed by the patient.

29. Price negotiations between drug manufacturers and their customers (usually dispensing organizations) take into account the wholesalers' role. Wholesalers buy manufacturers' products at an undiscounted, or "catalog," price. Some end-user dispensing organizations and other customers, however, receive steep discounts on drugs based on various factors. Such most-favored customers include physician supply houses, group purchasing organizations, health maintenance organizations, pharmacy benefit managers, and other institutional customers. The price these customers negotiate is referred to as the "contract price."

30. If a manufacturer sells product directly to these favored customers, it does so at the negotiated contract price. If a manufacturer sells product to these favored customers through a wholesaler, however, the pricing arrangement with the wholesaler must take into account the fact that the wholesaler purchased the product from the manufacturer at an undiscounted, catalog price. When a wholesaler that has purchased full-priced product sells that product to favored customers, it must do so at the customers' negotiated contract price. The wholesaler is then made whole by submitting a "chargeback" to the manufacturer. The chargeback is the difference between the catalog price and the discounted contract price. This chargeback arrangement between wholesalers and manufacturers figures prominently in Relator's discovery of the illegal activity alleged in this Complaint, discussed further below.

31. "Drug diversion" or "gray marketing" is an abuse of the drug distribution system. Diversion occurs when certain wholesalers, typically "secondary" wholesalers, purchase discounted products outside of the sanctioned channels of distribution and resell them for profit throughout the chain of drug distribution. The unauthorized secondary wholesale market is also known as the "gray market" or "diversion market." Secondary wholesalers that deal in diverted

drugs will risk large capital investments to purchase substantial volumes of discounted products. These drug diverters must resell the discounted drugs as quickly as possible to maximize profits, much like discounting practices in other industries. See “Wholesaling Profile” at §1.3.4.

32. To move the discounted products quickly, diverters must widely disperse the drugs among a vast network of customers, including other wholesalers and diverters. These other wholesalers and diverters, in turn, must re-disperse the discounted product. Often there are a large number of transactions before the drugs finally reach a dispenser and ultimately a consumer. While these drugs move from one location to another, they are held and maintained in unknowable conditions and environments that may not satisfy the drugs’ handling requirements.

33. The more reliable and transparent the route from manufacturer to ultimate consumer, the more likely the drug will be safe, effective, and potent. This provides less opportunity for the drugs to be mishandled, mislabeled, subjected to extremes in temperature or humidity, tainted, counterfeited, or otherwise treated improperly. In the gray market, because diverted articles often change hands many times (and between parties unknown) before reaching the ultimate consumer, the lack of control and oversight of the methods of storage and handling, and consequent risk to health and safety, is manifest.

34. There are many potential sources of diverted product. Among the sources that figure prominently in this Complaint are the drug manufacturers “favored” customers (typically institutional customers), who receive products at significant discounts. Diversion occurs when a favored customer, such as a physician supply house, buys more drugs than it needs, and then resells the surplus discounted articles in unauthorized, clandestine transactions for a profit. Because the diverter’s resale price is still lower than the manufacturer’s regular catalog price (which is the price normally charged to wholesalers), wholesalers, including the defendants in this case, have an incentive to buy the diverted drugs, and in turn resell them for profit.

35. The drug wholesaling industry is comprised of the “Big Three” primary wholesalers, regional wholesalers, and “secondary” wholesalers. Defendants McKesson, Cardinal and AmerisourceBergen are the “Big Three” that distribute the vast majority of pharmaceuticals. The Big Three Wholesalers buy product both directly from drug manufacturers and from other distributors who offer lower prices. The Big Three Wholesalers sell products to a number of types of entities: (1) “dispensing organizations,” such as retail pharmacies and health care facilities, (2) regional and smaller wholesalers, and (3) secondary wholesalers.

36. Some secondary wholesalers are more prominent than others. P.D.I. Enterprise and Quality King Distributors, Inc. are among the more well-known secondary wholesalers. These and numerous other secondary wholesalers trade aggressively in discounted gray market drugs. The number of secondary wholesalers is impossible to completely quantify based on available data; given this, government agencies cannot effectively regulate, monitor, and inspect this submarket of pharmaceutical wholesaling. Id.

B. Merck’s Structure and Role Pertinent to This Complaint

37. Merck & Co., Inc. is a worldwide pharmaceutical company that develops, manufactures, and markets a broad range of human health products. Merck is the third-largest manufacturer of pharmaceutical drugs in the world. Merck distributes its products primarily through wholesalers and retailers, hospitals, clinics, government agencies, and managed health care providers. Merck sells its pharmaceutical products to the Big Three Primary Wholesalers as well as directly to other wholesalers, including smaller, regional wholesalers, and secondary wholesalers. Merck also ships product directly to retailers, hospitals, clinics, government agencies, and managed health care providers such as health maintenance organizations and other institutions.

38. Merck's drug business is organized into two divisions, the Vaccines Division and United States Human Health Division.

a. Merck's Vaccines Division ("Vaccines Division") markets and sells its vaccine products, many of which require special storage and handling. These vaccines include but are not limited to the following branded drugs: *Varivax*, a vaccine for chickenpox; *M-M-R II*, a vaccine for measles, mumps and rubella; *PedvaxHIB*, a vaccine for influenza type b; *Comvax*, a vaccine for influenza type b and hepatitis B; *Vaqta (Adult and Pediatric)*, a vaccine for hepatitis A; *Recombivax HB (Adult and Pediatric)*, a vaccine for hepatitis B; and *Pneumovax 23*, a vaccine for pneumococcal disease. The Vaccines Division's main offices are located in West Point, Pennsylvania; Atlanta, Georgia; and Scottsdale, AZ.

b. Merck's United States Human Health Division ("USHH") markets and sells Merck's non-vaccine branded pharmaceuticals, including but not limited to: *Cancidas*, for candida infections; *Cosopt*, an eye medicine; *Cozaar*, for treatment of hypertension; *Crixivan*, an HIV treatment; *Emend*, a medicine to prevent and control nausea and vomiting; *Fosamax*, for treatment of osteoporosis; *Hyzaar*, for treatment of hypertension; *Invanz*, for treatment of infections; *Maxalt*, for treatment of migraines; *Propecia*, for treatment of hair loss; *Proscar*, for treatment of enlargement of the prostate gland; *Singulair*, for treatment of allergies; *Vioxx*, an arthritis pain medication (now withdrawn from the market); and *Zocor*, for treatment of high cholesterol. USHH's main offices currently are located in Upper Gwynedd Township, Pennsylvania.

39. Some Merck products, especially vaccines and other biologics, require special handling. The federal government licenses Merck to sell such products only under the condition that Merck specify these special handling requirements on its products. For example, the

government requires Merck to distribute with its vaccines packaging, labeling, or inserts directing specific storage temperatures and warning about loss of potency due to freezing. See American Home Assurance Co. v. Merck & Co., 386 F. Supp. 2d 501, 507 (S.D.N.Y. 2005); see also 21 C.F.R. section 610.61(h) (requiring biological package labels to contain recommended storage temperatures).

40. Moreover federal regulations provide specific temperature requirements that must be maintained for certain biologics during shipment. See 21 C.F.R. § 600.15. For example, Merck's measles, mumps and rubella vaccine live (*M-M-R II*) must be kept at 10 degrees Celsius or colder. Id. In addition to the product labeling requirements tied to biological licenses, the federal government's Centers For Disease Control and Prevention ("CDC") has recommended specific storage and handling temperatures for other Merck vaccines, such as Haemophilus influenza type b (Merck's Comvax and Pedvax), Hepatitis A and B (Merck's Vaqta and Recombivax) and pneumococcal polysaccharide (Merck's Pneumovax 23) at 2 to 8 degrees Celsius. See Vaccine Management: Recommendations for Storage and Handling of Selected Biologicals (CDC publication, June 2005). The Chicken Pox (varicella) vaccine (Merck's Varivax) should be shipped at -20 Celsius or colder. Id.

C. The Big Three Wholesalers

41. The Big Three Wholesalers buy Merck products at full catalog prices. When these wholesalers resell the product to Merck-contracted customers that have negotiated discounted prices, the wholesalers submit "chargebacks" to Merck to be made whole for the price difference. The shipping terms and conditions on Merck's shipping labels contain the requirement that the Big Three Wholesalers submit chargebacks only for product purchased directly from Merck (at full price).

D. Physician Supply Houses

42. The term “physician supply houses” (“PSHs”) refers to companies that conduct group purchasing activities on behalf of physicians who join together to increase their purchasing power. By bundling their members’ purchasing power, PSHs can negotiate significant discounts with medical suppliers and drug manufacturers. Defendant Henry Schein is one of the nation’s largest PSHs. Schein and other PSHs negotiate special contracts with Merck that provide them with deeply discounted pricing. On information and belief, Merck’s contracts with these PSHs contain significant restrictions as to whom the PSH may sell the discounted product (such as, permitting the sale only to physician members), and under what circumstances.

VI. DEFENDANTS’ ILLEGAL AND FRAUDULENT PRACTICES

A. Relator’s Discovery of Defendants’ Gray Market Activities

43. In her positions as International Pricing Analyst and Senior Pricing and Economic Analyst in Merck’s Vaccines Division, Relator became thoroughly familiar with Merck’s product price and sales data, including all of the Merck computer systems that capture, identify and report customers, wholesalers, classes of trade, contracts, terms of sale, shipping, and billing information.

44. Merck’s pharmaceutical orders are processed through the Order Management Center, located in West Point, Pennsylvania. Records of all sales are maintained in a “STARS” database. Information about contracted (or “favored”) customers, including customer name and shipping location, channel of distribution, and eligibility for discounts or other price concessions, is maintained in a database referred as CCAS (“Customer Communication and Support”). STARS and CCAS provide transactional records to Consolidated Sales (“CONSALES”) for the Vaccines Division.

45. Through her work and special assignments at Merck, Relator examined the information in these computer systems in great detail and discovered that defendants engaged in substantial drug diversion activity. Relator's discovery of the diversion activity occurred as follows.

46. In 2002, Merck asked Relator to conduct an investigation into large "negative" revenue figures for sales to wholesalers for the vaccine Vaqta Adult. The revenue data surprisingly had shown that Merck in fact was paying out more money in Vaqta Adult chargebacks to wholesalers than it was receiving from them for direct Vaqta Adult sales. Over a period of approximately eight months, Relator conducted research to determine why the Vaqta Adult sales did not reconcile with chargebacks over time. Her investigation culminated in a presentation entitled "Vaccine Distribution Risk Analysis" ("Risk Analysis").

47. Relator's Risk Analysis focused on sales to the Big Three Wholesalers over the 1996 to 2002 period. She examined direct sales in doses and dollars to Bergen (predecessor to defendant AmerisourceBergen), Cardinal, and McKesson, and chargebacks paid in both doses and dollars to those wholesalers. She found a significant disparity between doses sold and doses charged back. For example, from 1997 to 2002, Merck paid excess chargebacks in the amounts of:

- a. \$5 million to McKesson on Recombivax Pediatric
- b. \$10.6 million to McKesson on Recombivax Adult
- c. \$2 million to Bergen on Vaqta Adult
- d. \$8.5 million to Bergen on Recombivax Pediatric

48. Relator also reviewed information indicating that for USHH sales (for non-vaccine pharmaceutical products), Bergen received approximately \$18 million in excess chargeback

payments in 2000, and McKesson received approximately \$3.5 million in excess payments in 2001.

49. Relator's analysis found that the reason for these significant excess chargebacks and the disparity in doses sold and "charged back" was the result of product diversion on a large scale. This occurred when Merck contract customers (such as some physician supply houses) purchased drugs from Merck at discounted below-catalog prices and diverted excess product into the gray market. Relator discovered that the Big Three Wholesalers subsequently bought product diverted by contract customers, such as PSH Henry Schein, at below-catalog prices and resold it to other Merck contract customers. Upon selling the diverted discounted goods to such customers, the Big Three Wholesalers then submitted chargebacks to Merck for these re-sales, even though they did not originally purchase the product from Merck at full catalog price and therefore were not entitled to a chargeback on these sales. Merck nonetheless regularly paid these unwarranted chargeback requests and continued to do so even after Relator made it aware of the practice.

50. A manufacturer such as Merck will engage in the expensive practice of paying excess chargebacks to the Big Three Wholesalers for a variety of reasons. For one, the practice buys favor with the Big Three Wholesalers, whose decisions can affect a manufacturer's market share. In addition, the practice of paying excess chargebacks also enhances the manufacturer-wholesaler relationship and promotes wholesaler loyalty. Wholesalers, especially the Big Three Wholesalers, control much of the drug distribution market and are deeply involved in other aspects of prescription drug marketing and sales, and thus have the ability significantly to help or hinder Merck product sales.

51. Relator's internal findings were confirmed by an external data source, *i.e.*, the outside consulting firm of IMS Health ("IMS"). IMS is a leading provider of business

intelligence and strategic consulting services for the pharmaceutical and healthcare industries. On information and belief, wholesalers, including the Big Three Wholesalers and secondary wholesalers, report detailed purchase and sales data on various manufacturers' products to IMS. This data is sold by IMS to those in the industry in formats intended to preserve confidentiality.

52. In the fourth quarter of 2002, IMS confirmed to Relator that product diversion was the underpinning of the excess chargebacks that Relator had discovered. An IMS representative provided Relator with information showing both directly and circumstantially drug diversion activity involving Merck drugs. For example, IMS provided Relator with information for two vaccines, Vaqta Adult and Recombivax Adult and Pediatric, for a two-year period (2000 and 2001). This data revealed that contracted Merck customers (such as PSHs Henry Schein, H.D. Smith, Besse Medical Supply, and many others that received these vaccines at discount) re-sold \$27 million in product to the following six secondary wholesalers: Quality King Distributor (Ronkonkomo, New York), P.D.I. Enterprise (California), National Specialty Service (a public sector entity), RNS Sales, Anda Generics (a generic manufacturer in Fort Lauderdale, Florida), and Medpath. As alleged below, Relator was informed by Merck that Quality King and P.D.I. are known as suspected drug diverters. According to IMS, the data further revealed that these six wholesalers re-sold \$4 million of Vaqta and Recombivax (during the two-year period) to the Big Three Wholesalers. While Relator was not made privy to the whereabouts of the remaining \$23 million in secondary sales of this product, this data clearly showed that the Big Three purchased diverted Merck vaccines. IMS further informed Relator that the data showed that other contracted customers (such as the PSH Metro Medical Supply) were diverting discounted product to secondary wholesalers. In order to keep the analysis manageable, Relator only asked for data from IMS concerning the above two products in a two-year time period; however, this sampling

indicated a trend toward much larger diversion activity with respect to Merck vaccines and pharmaceuticals.

53. Relator presented this data to Merck management. In November 2002, Relator discussed the diversion issues particularly with Merck's "product diversion specialist" (who also was the head of Merck Global Security and Crisis Management). This diversion specialist confirmed that Relator's Risk Analysis had identified at least two large pharmaceutical diverters, Quality King and PDI, and advised that Merck legal counsel get involved.

54. IMS also told Relator that at least two of the Big Three Wholesalers had "secretive" operations that received diverted Merck product from the secondary market and sold it out of special locations. Specifically, the data showed that a "Bergen Trading Company" in Louisville, Kentucky did not purchase Merck product directly, yet reported significant Merck vaccine and USHH sales out of that location. IMS referred to this as a "secret sell out" location. In fact, IMS specifically told Relator that Merck-contracted PSH Henry Schein had purchased large quantities of Vaqta Adult and Recombivax Adult and Pediatric at discount and then transferred the product to Bergen's secret sell-out location in Louisville. IMS further told Relator that in the same two-year time period, the data revealed that a McKesson warehouse in Santa Fe Springs, California had only "sell out" activity for the vaccine Vaqta Adult (1,268 records), with no corresponding Merck "sell in" of the product. This information further constituted evidence of these parties' participation in the diversion market. Relator conveyed this information to Merck management as well.

55. Relator's analysis of the data for the Risk Analysis uncovered further abuse of Merck systems intended to restrict and control to whom Merck "shipped" and "billed" products, and at what price. Relator learned that Merck focused only on "Bill To" locations, and turned a blind eye to suspicious "Ship To" locations. Relator found that Merck frequently utilized a

“temporary drop ship” indicator to override controls and allow shipments of drugs to locations not listed as valid “Ship To” locations and otherwise not validated as locations registered with the Drug Enforcement Administration. Relator also found data showing that Merck sold discounted product to contracted-PSH Henry Schein as the “Bill To” entity, but delivered the ordered product to suspected diverter Quality King Healthcare as the “Ship To” entity. Relator further discovered that often one of the Big Three Wholesalers (e.g., McKesson or Cardinal) would be the “Bill To” customer on a transaction where the “Ship To” was another Big Three Wholesaler (e.g., Bergen). IMS verified that there existed a substantial amount of improper “warehouse to warehouse” transactions such as these. This uncontrolled manipulation of delivery sites for drugs further facilitated the diversion activity.

56. Relator also uncovered various evidence of Merck directly facilitating discounted product sales to suspected product diverters. Relator found data showing that Merck sold drugs at contracted discount prices to secondary wholesalers that did not have contracts with Merck and that did not qualify for discounted products. These secondary wholesalers included Quality King Healthcare and P.D.I. Enterprises, Inc. For example, Relator found data showing that Merck sold vaccines (specifically Recombivax Adult) at a discount directly to Quality King Healthcare for a number of years. Relator also researched all shipments to addresses for P.D.I. Enterprises, Inc., and found that multiple entities (not apparently related to P.D.I.) shared the exact address; that the contract “title” (or entities) for these P.D.I. locations varied from “Dialysis Purchasing Alliance, Inc.” to “Centers For Disease Control” to “Recombivax Retention Four” to “Government Optional Use”; and that the classification for these entities varied from “clinic” to “public-non-hospital” to “hospital,” etc. Similarly, shipments to Quality King in Ronkonkoma, New York, were classified variously as “wholesaler,” “PSH,” and “clinic.” This variability in classification permits the secondary wholesaler to purchase the same drug both at full catalog price (as a

wholesaler) and at discount (as a PSH). This is wholly improper since these wholesalers are not authorized to buy drugs at the PSH contract price. Such variability in classification indicates a lack of control and oversight by Merck over these transactions, which facilitates the diversion of drugs into the gray market. Relator obtained similar evidence with respect to other secondary wholesalers.

57. Relator presented her analyses and resulting concerns to numerous Merck personnel, including high-level management, in meetings, documents, and other communications. It became clear from these internal discussions that Merck was not willing to “cut off a customer” in order to fix the abuses. Merck continued to pay the excess chargebacks to the Big Three Wholesalers, ignoring whether they had purchased the drugs legitimately from Merck, or whether the drugs were diverted products. Merck did not attempt to link the chargeback request to an original transaction with Merck. Merck thus failed to verify whether the product for which the chargeback was submitted was acquired properly by the primary wholesaler at catalog price directly from Merck, or if it was acquired at discount from the gray market. Merck continued this practice, even after presented with evidence of the impropriety.

58. Defendants’ conduct alleged above corrupted the integrity of the pharmaceutical distribution system. This conduct significantly undermined the assurance of safety, efficacy, purity, and potency of the affected drugs, thereby placing the public health in jeopardy. Defendants specifically violated federal and state laws requiring conformance with current good manufacturing practices, laws prohibiting the adulteration of drugs, and laws establishing minimum requirements for safety, storage and handling of these drugs.

59. Drugs sold in violation of these laws are deemed adulterated and non-reimbursable by government health programs. Defendants defrauded the federal and state governments health by causing reimbursement claims for these drugs to be submitted to federal

and state health programs. These claims were false and fraudulent in that the drugs were not what they were represented to be — *i.e.*, drugs properly distributed under federal and state law. As a foreseeable consequence of defendants' conduct alleged herein, the federal and state governments paid these false and fraudulent claims and were thereby damaged in a substantial amount.

B. Other Unlawful Practices

60. In addition, on information and belief, Merck did not include its excess chargeback payments to the Big Three Wholesalers in Merck's "Best Price" calculations for purposes of the Medicaid Rebate program. The basis for this belief is Relator's discovery, while working for Merck, that Merck's record-keeping system fails to capture these payments, even though Merck officials are aware that substantial sums are paid in excess chargebacks. Merck makes no attempt to link chargebacks resulting from gray market sales back to the original sale of the product. As a result, these chargebacks are not reported as a price reduction on the original sale.

61. By virtue of this systematic underreporting of chargebacks, Relator is informed and believes that Merck does not report its true "Best Price" to the Medicaid program. This causes federal and state governments to be underpaid Medicaid rebate monies owed by Merck. Defendants aided and abetted this conduct.

Count I
False Claims Act
31 U.S.C. §§3729(a)(1) and (a)(2)

62. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

63. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, *et seq.*, as amended.

64. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval, within the meaning of 31 U.S.C. §3729(a)(1).

65. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2).

66. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

67. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

68. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by defendants arising from their unlawful conduct as described herein.

Count II
False Claims Act
31 U.S.C. §§3729(a)(3)

69. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

70. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

71. By virtue of the acts described above, defendants conspired with each other and with others unknown to defraud the United States by inducing the United States to pay or approve false and fraudulent claims, within the meaning of 31 U.S.C. §3729(a)(3). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

72. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

73. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every violation of 31 U.S.C. §3729(a)(3) as described herein.

COUNT III

False Claims Act
31 U.S.C. §3729(a)(7)

74. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

75. This is a claim for penalties and treble damages under the Federal False Claims Act.

76. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

77. As a result, monies were lost to the United States through the non-payment or non-transmittal of money or property owed to the United States by the defendants, and other costs were sustained by the United States.

78. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

79. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

Count IV
California False Claims Act
Cal Govt Code §12651(a)(1)-(3)

80. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

81. This is a claim for treble damages and penalties under the California False Claims Act.

82. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

83. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

84. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the California State Government.

85. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

86. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

87. Additionally, the California State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count V
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1)-(3)

88. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

89. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

90. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

91. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

92. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Delaware State Government.

93. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

94. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

95. Additionally, the Delaware State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count VI
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

96. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

97. This is a claim for treble damages and penalties under the Florida False Claims Act.

98. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

99. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

100. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Florida State Government.

101. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

102. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

103. Additionally, the Florida State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count VII
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

104. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

105. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

106. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

107. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

108. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Hawaii State Government.

109. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

110. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

111. Additionally, the Hawaii State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count VIII
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1)-(3)

112. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

113. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

114. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

115. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

116. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Illinois State Government.

117. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

118. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

119. Additionally, the Illinois State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count IX
Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5-2(b)(1) and (2)

120. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

121. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

122. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

123. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

124. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Indiana State Government.

125. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

126. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

127. Additionally, the Indiana State Government is entitled to a penalty of at least \$5,000 for each and every violation alleged herein.

Count X
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 437 et seq.

128. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

129. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

130. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

131. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

132. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Louisiana State Government.

133. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

134. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

135. Additionally, the Louisiana State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XI
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1)-(3)

136. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

137. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

138. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

139. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

140. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Massachusetts State Government.

141. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

142. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

143. Additionally, the Massachusetts State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XII
Michigan Medicaid False Claims Act
Mich. Public Act 337

144. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

145. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

146. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

147. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

148. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Michigan State Government.

149. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

150. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

151. Additionally, the Michigan State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XIII
Montana False Claims Act
Mont. Gen. Laws 17-8-403 (1)(a) and (b)

152. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

153. This is a claim for treble damages and penalties under the Montana False Claims Act.

154. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

155. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

156. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Montana State Government.

157. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

158. By reason of the defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

159. Additionally, the Montana State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XIV
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a)-(c)

160. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

161. This is a claim for treble damages and penalties under the Nevada False Claims Act.

162. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

163. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

164. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Nevada State Government.

165. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

166. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

167. Additionally, the Nevada State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XV
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(a)-(c)

168. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

169. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

170. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

171. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

172. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Hampshire State Government.

173. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

174. By reason of the defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

175. Additionally, the New Hampshire State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XVI
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-2F-4

176. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

177. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

178. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

179. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

180. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Mexico State Government.

181. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

182. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

183. Additionally, the New Mexico State Government is entitled to civil penalties for each and every violation alleged herein.

Count XVII
Tennessee False Claims Act and Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a) and 71-5-182(a)(1)

184. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

185. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

186. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

187. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

188. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Tennessee State Government.

189. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

190. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

191. Additionally, the Tennessee State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XVIII
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

192. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

193. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

194. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

195. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

196. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Texas State Government.

197. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

198. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

199. Additionally, the Texas State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XIX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1)-(3)

200. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

201. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

202. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

203. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

204. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Virginia State Government.

205. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

206. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

207. Additionally, the Virginia State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XX
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §2-308.14(a)(1)-(3)

208. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 61 above as though fully set forth herein.

209. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

210. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

211. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

212. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia Government.

213. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

214. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

215. Additionally, the District of Columbia Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Prayer

WHEREFORE, Relator prays for judgment against the defendants as follows:

1. that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the counterpart provisions of the state statutes set forth above;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of \$11,000 for each violation of 6 Del. C. §1201(a);

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Fla. Stat. Ann. §68.082(2);

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Haw. Rev. Stat. §661-21(a);

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

9. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus a civil penalty of at least \$5,000 for each violation of IC 5-11-55;

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of La. Rev. Stat. §437 et. seq;

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of MI Public Act 337;

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Mont. Stat. Ann. 17-8-401;

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-2F-4;

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(1);

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of \$10,000 for each violation of D.C. Code Ann. §2-308.14(a);

21. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

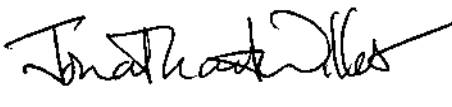
22. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

23. that Relator recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: May 22, 2007

By: 

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