UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA, STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, TEXAS, and VIRGINIA, THE DISTRICT OF COLUMBIA and THE CITIES OF CHICAGO AND NEW YORK, *ex rel.* CHERYL D. ECKARD,

Plaintiffs,

v.

SMITHKLINEBEECHAM CORPORATION D/B/A/ GLAXOSMITHKLINE, SB PHARMCO PUERTO RICO, INC., and GLAXOSMITHKLINE PUERTO RICO, INC.

Defendants.

CASE NO.:

C.A. No: 04 CV10375 (JLT)

THIRD AMENDED COMPLAINT AND JURY DEMAND

FILED PURSUANT TO 9/8/08 ORDER

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GLOSSARY OF TERMS

CFRs	Code of Federal Regulations
cGMPs	current Good Manufacturing Practices
DQRS	The FDA's Drug Quality Reporting System
FCA	False Claims Act, 31 U.S.C. § 3729, *et. seq.*
FDA	Food and Drug Administration
FDA-483	FDA Form FD483, a list of "observations" representing violations the FDA believes a manufacturer has committed
FDC Act	Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*
GQA	Global Quality Assurance, a division of GSK
NDA	New Drug Application
OOS	Out-of-specification
QA	Quality Assurance
R&D	Research & Development
RTP	GSK headquarters in Research Triangle Park, North Carolina
SMIRT	Senior Management Incident Reporting Team, a senior management team established at Cidra in 2002
SOPs	Standard Operating Procedures

Plaintiff/relator, Cheryl D. Eckard, in the name of and on behalf of the United States of America, the State of California, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, 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 Nevada, the State of New Hampshire, the State of New Mexico, the State of New York, the State of Tennessee, the State of Texas, the State of Virginia, the City of Chicago and the City of New York, by her attorneys, Getnick & Getnick, as and for her complaint, alleges as follows:

INTRODUCTION

1. As more fully alleged herein, this action arises out of a scheme or schemes to defraud the United States of America, the fifty states, and the District of Columbia perpetrated by the defendants, commencing in or before 2000 and continuing to the date hereof. The Defendants made and/or caused to be made to the United States, the fifty state governments and the District of Columbia false claims for payment for prescription drugs covered by Medicare, State Medicaid programs, the Department of Veterans Affairs, the Public Health Service and other federal, state and city purchasers of prescription drugs. The claims were false and

fraudulent because the drugs, which were manufactured at Defendants' plant in Cidra, Puerto Rico, were defective, misidentified as a result of product mix-ups, not manufactured in accordance with FDA approved processes, and/or did not come with the assurance of identity, strength, quality and purity required for distribution to patients; and/or approvals for the drugs were obtained through false representations to the FDA. The false claims arose out of chronic, serious deficiencies in the quality assurance function at the Cidra plant and the defendants' ongoing serious violations of the laws and regulations designed to ensure the fitness of drug products for use, including the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*., and the Code of Federal Regulations, Title 21.

2. The drugs affected by the defendants' conduct include Paxil, Paxil CR, Avandia, Avandamet, Coreg, Bactroban, Abreva, Cimetidine, Compazine, Denavir, Dyazide, Thorazine, Stelazine, Ecotrin, Tagamet, Relafen, Kytril, Factive, Dyrenium and Albenza.

3. Examples of defective and/or misidentified products that the defendants released to the United States market from the Cidra plant are:

a. Drug product that was mixed up with drug product of a different type or strength, e.g., 30mg and 10 mg tablets of an

anti-depressant mixed in the same bottle, and 12.5 and 6.25 mg tablets of a heart medication mixed in the same bottle (see paragraphs 87-92 below);

b. A diabetes medication that was sub-potent and/or super-potent (see paragraph 106 below);

c. An antibiotic ointment used to treat a skin infection common in small children that was contaminated with a micro-organism associated with bacteranemia, urinary tract infections, meningitis, wound infection, and peritonitis (see paragraph 113 below);

d. An injectable drug used to treat nausea and vomiting in patients undergoing chemotherapy that was contaminated with micro-organisms (see paragraph 112 below).

4. Further, on information and belief, during the times relevant to this complaint employees of the defendants diverted reject drug product from the Cidra plant to black markets in Latin America. The defendants' management failed adequately to investigate these allegations. On information and belief, this resulted in the distribution of reject drug product to the United States market and the submission of false claims for drug product that was defective.

5. These acts constitute violations of the federal False Claims

Act, 31 U.S.C. § 3729, *et. seq.* ("FCA"), and numerous equivalent state and city statutes.[1] The FCA provides, *inter alia*, that any person who knowingly presents and/or causes to be presented to the United States a false or fraudulent claim for payment is liable for a civil penalty of up to $11,000 for each claim, plus three times the amount of the damages sustained by the Government. The FCA allows any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. The complaint in an FCA action is filed under seal for 60 days (without service on the Defendant within such 60-day period) to enable the Government (1) to conduct its own investigation

[1] As set forth below, the defendants' acts constitute violations of the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201 et seq.; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 2-308.13-21; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081-092; the Georgia State False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21-29; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-115.5 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46:437.1-14; the Massachusetts False Claims Act, Mass. Gen. L. Ch. 12, §§ 5B et seq.; the Michigan Medicaid False Claims Act, MCL §§ 400.601 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 et seq.; the New Hampshire Medicaid Fraud and False Claims Act, RSA §§ 167.58 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-12-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law §§ 187-194; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-182 et seq.; the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 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. §§ 8.01-216.3 et seq.; the Chicago False Claims Act, Chicago Municipal Code Ch. 1-21 et seq.; and the New York City False Claims Act, Local Law 53 of 2005, Title 7, New York City Admin. Code §§ 7-801 et seq.

without the defendant's knowledge and (2) to determine whether to join in the action.

6. Plaintiff/relator Cheryl D. Eckard (“Eckard”)is a former Manager of Global Quality Assurance for defendant SmithKlineBeecham Corporation d/b/a/ GlaxoSmithKline (“GSK”). Eckard is an expert in Code of Federal Regulations, Title 21, compliance and an experienced pharmaceutical professional. She has a B.A. in Chemistry. She worked for GSK from 1992 through 2003. She is an expert on the technical, legal, regulatory and compliance aspects of the pharmaceutical Good Manufacturing Practices and quality systems regulations relating to the development, manufacture, packaging, testing, holding and distribution of drug products. She has performed compliance functions including quality management of multiple manufacturing sites and preparing manufacturing sites for FDA pre-approval and current Good Manufacturing Process profile inspections. She has managed international commercial investigation teams, technical working parties and Warning Letter Recovery teams, and worked closely with the FDA and other regulatory bodies in developing implementation plans to respond to regulatory sanctions.

7. Eckard seeks to recover damages and civil penalties in the name of the United States and the states for the violations

alleged herein. On information and belief, as set forth in paragraph 41 below, the damages and civil penalties that may be assessed against the defendants under the facts alleged in this Complaint amount to at least hundreds of millions of dollars.

JURISDICTION AND VENUE

8. This court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367 and 31 U.S.C. § 3732.

9. Personal jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), as at least one of the defendants is found, has or had an agent or agents, has or had contacts, and transacts or transacted business and their affairs in this judicial district.

PARTIES

10. Plaintiff/relator Eckard is a citizen of the United States and a resident of North Carolina. Eckard is a self-employed consultant. Prior to June 2003, Eckard was a Manager of Global Quality Assurance for GSK, located in Research Triangle Park, North Carolina.

11. Defendant GSK is headquartered at 5 Moore Drive, Research

Triangle Park, North Carolina 27709, and at One Franklin Plaza, Philadelphia, Pennsylvania 19102. GSK's parent company, GlaxoSmithKline PLC, is located at Charges House, 6-12 Charges Street, London, England WIY8DH. GSK is engaged in the development, manufacture, promotion, sale, interstate and international distribution of, *inter alia*, prescription drugs. GSK holds the second highest market share in the world pharmaceutical market. GSK has 100,000 employees in 100 countries, with 50% of its sales of prescription drugs in the United States.

12. Defendants SB Pharmco Puerto Rico, Inc. and GlaxoSmithKline Puerto Rico, Inc. are wholly-owned subsidiaries of GSK. Together with GSK, they operate and manage a manufacturing plant located at Rd. 172, Km 9.2, Bo. Certenejas, Cidra, PR 00739 ("Cidra"). Unless otherwise indicated, references herein to GSK include SB Pharmco Puerto Rico, Inc. and GlaxoSmithKline Puerto Rico, Inc.

INDIVIDUAL PARTICIPANTS

13. David Pulman was GSK's Vice President of Manufacturing and Supply for North America until December 2002, when he became President, Global Manufacturing and Supply.

14. Janice Whitaker is GSK's Senior Vice President for Global

Quality.

15. Steve Plating was GSK's Vice President for Quality, North America. He left GSK in early 2005.

16. Peter Savin is GSK's Vice President of Global Quality Assurance.

17. Diane Sevigny was Director of Global Quality Assurance for North America Pharma until July 2003 when she was promoted to Director, Global Quality Assurance, Risk Management and Compliance.

18. Jonathon Box is the Vice President of Manufacturing and Supply for North America.

19. Jose Luis Rosado was the President of SB Pharmco Puerto Rico, Inc. and General Manager of the Cidra plant until April 2003, when he left the company.

20. Edwin Lopez was the Director of Quality at Cidra until the first quarter of 2003 when he was replaced in that role by Adalberto Ramirez and became Director of Laboratories at Cidra. He is no longer employed by GSK.

21. Adalberto Ramirez was the Director of Solid Manufacturing and Packaging at Cidra until the first quarter of 2003 when he was promoted to Director of Quality at Cidra. He left GSK in July 2003.

22. Gloria Martinez was the Quality Assurance and Regulatory Manager at Cidra until 2003 when she replaced Adalberto Ramirez as Director of Quality. She left GSK in December 2004.

23. Marion Lon was the site director of Cidra who took over from Rosado in or about April 2003. She left GSK in October 2004.

GOVERNMENT PROGRAMS

24. Medicaid is the nation's medical assistance program for the needy, the medically-needy aged, blind, and disabled and families with dependent children. 42 U.S.C. §§ 1396-1396v. Medicaid is largely administered by the states and funded by a combination of Federal and State funds. Approximately 57% of Medicaid funding is provided by the Federal Government. Among other forms of medical assistance, the Medicaid programs cover outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A) and 1396d(a)(12).

25. Medicare is the nation's health program for persons over 65 and the disabled. Medicare is funded by the federal government.

Medicare Part B has long covered outpatient prescription drugs that are provided to a patient "incident to" a physicians' services, including injectable medications, and drugs that are required for the effective use of durable medical equipment. 42 U.S.C. § 1395x(s)(2)(A). Commencing on January 1, 2006, Medicare Part D provides comprehensive outpatient prescription drug coverage for brand name and generic drugs according to National and Local Coverage Determinations. Medicare Prescription Drug Improvement and Modernization Act 2003, Pub. L. 108-173.

26. The Department of Veterans Affairs ("VA") provides medical assistance, including prescription drug coverage, for persons who have been discharged from active duty service in the military, naval, or air service.

27. The Public Health Service ("PHS") provides funding, including outpatient drug coverage, for entities such as black lung clinics, AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, disproportionate share hospitals, and other entities listed in § 340B(a)(4) of the Public Health Service Act.

28. The Department of Defense ("DOD") administers the TRICARE health care program for active duty and retired members of the

uniformed services, their families, and survivors. TRICARE benefits include comprehensive prescription drug coverage.

29. The Food and Drug Administration ("FDA") is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA administers, *inter alia*, the Federal Food, Drug and Cosmetics Act, ("FDC Act"), 21 U.S.C. §§ 301 *et seq*.

ASPECTS OF THE FDA REGULATORY SCHEME

30. The federal government endeavors to ensure the safety and efficacy of drug products consumed daily by millions of Americans through a combination of approvals, inspections, enforcement, and self-regulation by drug manufacturers. As the FDA's Deputy Associate General Counsel, Eric M. Blumberg, Esq., wrote, drug manufacturers "occupy a virtual fiduciary relationship to the public ... FDA shares this trustee relationship to the consumer with industry leaders, but the initial and ultimate responsibility remains with those leaders. This is true not only because the law makes it so, but also for the practical reason that the FDA cannot be in every factory, much less monitor every decision that is made every day that affects the quality of our

food and drugs." Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug and Cosmetic Act, 55 Food and Drug L.J., 145, 147.

The current Good Manufacturing Practices

31. The current Good Manufacturing Practices ("cGMPs") contain the minimum requirements that pharmaceutical companies must meet in manufacturing, processing, packing, and holding drugs to assure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess. The cGMPS are codified in 21 C.F.R. Parts 210 and 211. Manufacturers demonstrate compliance with cGMPs through written documentation of procedures and practices. The cGMPs dictate, *inter alia*, standards for: personnel engaged in quality control; the design, construction and maintenance of buildings and facilities; the construction, cleaning and maintenance of equipment; the storage, inspection and testing of drug components and containers; the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage and distribution; laboratory controls including testing of drug product batches for conformity with final specifications; the

maintenance of records and reports and conduct of investigations; and procedures for handling of returned and salvaged product.

32. Drugs are deemed to be adulterated if they are not manufactured in compliance with the cGMPs or if they are contaminated. See 21 U.S.C. §§ 351(a)(2)(A) and(B). It is a violation of the FDC Act, 21 U.S.C. §§ 331(a) to directly or indirectly cause adulterated drugs to be introduced or delivered for introduction into interstate commerce.

Establishment Inspections, 483s and Warning Letters

33. Under the FDC Act § 704, 21 U.S.C. § 374, the FDA is authorized to conduct inspections of drug manufacturing facilities, including inspections of records, files, papers, processes, controls, and facilities. At the conclusion of the inspection, the FDA provides the manufacturer with a Form FD483 (“FDA-483"), or a list of “observations” representing violations the FDA believes the manufacturer has committed. The manufacturer is expected to respond in writing to each observation stating its position and any corrective action it proposes to take. The FDA takes this response into account in deciding whether further enforcement action is warranted.

34. Following an inspection or discovery of a violation, the FDA may issue a Warning Letter to the manufacturer representing its official findings of violations. FDC Act § 309, 21 U.S.C. § 336. The Warning Letter is the FDA's primary means of notifying manufacturers of serious violations and of achieving prompt corrective action. The manufacturer must respond in writing to the Warning Letter within 15 days stating what action is being taken to correct the violations, what action will be taken to prevent similar violations, and the time frame for such action.

Post-marketing surveillance

35. The FDA operates a Drug Quality Reporting System, which includes the MedWatch reporting program. This is designed to rapidly identify significant health hazards associated with the manufacturing and packaging of drugs, and to establish a central reporting system for detecting problem areas or trends requiring regulatory action. Doctors and pharmacists can report drug quality problems, such as defective components, poor packaging or labeling, suspected contamination or questionable stability to the FDA, the manufacturer, or both, using a standard form.

36. Pursuant to 21 C.F.R. § 314.81 (b)(1)(i) and (ii), manufacturers are required to notify the FDA by filing a "Field

Alert" within 3 working days of the receipt, via the Medwatch system or otherwise, of: (i) information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; (ii) information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the new drug application.

Product Recalls

37. The FDA expects manufacturers to take full responsibility for recall of defective products, including follow-up checks to assure that recalls are successful. The FDA does not have authority to order the recall of drug products. Under 21 C.F.R. § 7.40, "[r]ecall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." The FDA's guidelines "categorize all recalls into one of three classes according to the level of hazard involved: Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death.

Examples of products that could fall into this category [include] ... a label mix-up on a life saving drug ... Class II recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations. Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations." FDA Recall Policies, FDA Center for Food Safety and Applied Nutrition, Industry Affairs Staff Brochure, June 2002. *See also* FDA Investigations Operations Manual, Chapter 800 (801.1).

Consent Decrees

38. The FDA, acting through the Department of Justice, is authorized to seek injunctions. FDC Act § 302; 21 U.S.C. § 332. Injunctions are sought when there is a likelihood that violative acts will continue or recur. A consent decree of permanent injunction may be obtained, *inter alia*, where there have been multiple and continuing cGMP violations that have not been voluntarily corrected by the manufacturer. In such cases, the facility will typically be placed under the monitorship of an independent expert or shut down until the manufacturer has brought itself into compliance, for example, by destroying

adulterated product and revising Standard Operating Procedures ("SOPs"). Certification of compliance by an independent expert is often required before the FDA will permit normal operations to resume.

OVERVIEW OF FACTUAL BASIS FOR FALSE CLAIMS

39. GSK's chronic quality assurance problems and ongoing, serious cGMP violations went to the heart of Cidra's manufacturing, processing and packaging systems. As further detailed in paragraphs 86 through 123 below, they included and/or resulted in:

a. Product mix-ups, i.e., a drug of a different type or strength found in the same bottle (see paragraphs 87 through 92 below);

b. Inadequate investigation of out-of-specification ("OOS") results detected during laboratory testing (see paragraphs 93 through 97 below);

c. Inadequate process validation and non-existent validation review processes for some products (see paragraphs 98 through 99 below);

d. Inadequate or non-existent calibration of equipment and instruments and incomplete investigations relating to equipment found to be out-of-calibration (see paragraphs 100 through 103 below);

e. Overdue process investigations, at times numbering in the hundreds (see paragraphs 104 through 107 below);

f. Understaffing in the Quality Assurance Unit (see paragraphs 108 through 109 below);

g. Poor documentation quality, including unsigned, undated and/or lost or missing validation, investigation and change control documents, and hundreds of SOPs overdue for revision (see paragraphs 110 through 111 below);

h. Contamination in products manufactured in the sterile facility, including Kytril injection and Bactroban ointment (see paragraphs 112 through 113 below);

i. Substandard quality and control of the plant’s water systems, resulting in build up of stagnant water and microbial contamination (see paragraph 114 below);

j. Manufacturing areas and purportedly clean equipment that repeatedly failed routine environmental testing and exhibited microbial contamination (see paragraphs 115 through 116 below);

k. Destruction of internal audit reports immediately after discussion with the responsible personnel, contrary to GSK policy and industry practice requiring 3 year retention (see paragraphs 117 through 118 below);

l. Serious deficiencies in the functioning of the Microbiology Laboratory, where testing of products and equipment for contamination by objectionable organisms is conducted (see

paragraphs 119 through 120 below);

m. Substandard air handling systems not meeting cGMP standards and creating the potential for cross contamination (see paragraph 121 below);

n. Inadequate monitoring to ensure containment of a cytotoxic product (Topotecan, a chemotherapy drug) manufactured in the facility (see paragraph 122 below);

o. Various other cGMP violations and quality assurance failures, including inadequate identification, control and storage of drug materials, waste and cleaning agents, poor disinfection procedures, leaking equipment, and inadequate verification of product labels (see paragraph 123 below).

SUMMARY OF FALSE CLAIMS ACT LIABILITY

40. Defendants violated the False Claims Act as follows:

a. Defective products

Defendants submitted and/or caused to be submitted false claims to the federal, state and city governments for drug products manufactured at the Cidra plant that were defective. The defective products and false claims arose out of chronic, serious deficiencies in the quality assurance function at the Cidra plant and the defendants' ongoing serious violations of the

laws and regulations designed to ensure the fitness of drug products for use. As a result, the government paid for an assurance of quality and fitness for use that it did not receive, and all claims to the government for products manufactured at Cidra during the times relevant to this complaint were false. Examples of the chronic quality assurance problems and ongoing, serious cGMP violations that went to the heart of Cidra's manufacturing, processing and packaging systems and resulted in the submission of false claims are detailed in paragraphs 86 through 123 below. Examples of the resulting false claims submitted and/or caused to be submitted by GSK to the government for products manufactured at Cidra during the times relevant to this complaint, stating the dates of the claims per quarter year, the identification numbers of the claims, the amounts paid by the government, the particular drugs for which the government was billed, and the individuals involved in the billing, are attached at Appendix A.[2]

b. Drug approvals obtained through false statements to the FDA

GSK obtained FDA approval for drug products by making false and fraudulent statements to the FDA. In particular,

[2] The names of individual prescribing physicians in Appendix A have been redacted. The defendants and the government have been provided with an unredacted copy of Appendix A.

defendants obtained approval for Avandamet and Factive[3] in October 2002 and April 2003 respectively by:

(1) falsely representing to the FDA, in or about October 2002, that commitments to correct violations identified by the FDA in and prior to a Warning Letter issued to GSK and Cidra on or about July 1, 2002, would be and/or had been fulfilled;

(2) stating in Field Alert reports to the FDA that product mix-ups reported by consumers could not have occurred on premises, when similar mix-ups had been identified on premises at the same time.

(3) concealing from the FDA systemic quality assurance failures and significant violations of the cGMPs, including violations that defendants were required by law to report to the FDA.

As a result, all claims submitted to the government for Avandamet and Factive during the times relevant to this complaint were false. Examples of the resulting false claims submitted and/or caused to be submitted by GSK to the government for Avandamet are included in Appendix A.

[3] Factive, an antibiotic for treatment of chronic bronchitis, was developed by GSK. The marketing and regulatory rights are now owned by Oscient Pharmaceuticals, formerly Genesoft, Inc.

c. Drug product not "covered" under laws governing government health plans

i. For purposes of Medicare, Medicaid and other government programs, a "covered outpatient drug" is defined, *inter alia*, as one that "is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act." See 42 U.S.C. 1396r-8(k).

ii. The intent and purpose of the FDC Act and the regulatory schemes administered by the FDA are to ensure that drugs are both approved for safety and effectiveness and reach the market in a condition that renders them fit for their intended use. Under 21 U.S.C. § 355(e)(5), approval of any drug may be suspended if "there is an imminent hazard to the public health," and approval may be withdrawn following notice to the drug maker and an opportunity to be heard if "the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity ..."

iii. GSK manufactured, processed, packed and/or held, and GSK held and distributed, drug product that did not come with the assurance of identity, strength, quality and purity required for approval and distribution under the FDC Act, and GSK lied to the FDA in order to conceal its inability and/or unwillingness to

correct these failures. Therefore, drugs manufactured at Cidra were not "covered" by Medicare, Medicaid and other government health programs under the Social Security Act and all claims for those drugs during the times relevant to this complaint were false. Examples of the methods, facilities and controls used in the manufacture, processing and packing of drugs at Cidra that were inadequate to assure and preserve their identity, strength, quality, and purity are set forth in paragraphs 86 through 123 below. Examples of GSK's lies to the FDA in order to conceal these inadequacies are set forth in paragraphs 63, 88-92, 95-96, 99, 102-103, 106, 109, and 113. Examples of the resulting false claims submitted and/or caused to be submitted by GSK to the government for products manufactured at Cidra during the times relevant to this complaint are attached at Appendix A.

d. Drug product not manufactured in accordance with NDAs

i. 21 U.S.C. §§ 355(b)(1)(B)-(D) provides that applications to the FDA for approval of new drugs ("NDAs") must include: "(B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug[.]" Approval by the FDA of this drug formula and method of manufacture is required for introduction of the drug in

interstate commerce and distribution for human use. 21 C.F.R. §§ 314.70 and 314.81 respectively require manufacturers to obtain FDA approval for, or make the FDA aware of, changes in the conditions established in an approved application.

ii. As a result of the chronic, serious deficiencies in the quality assurance function at the Cidra plant and the defendants' ongoing serious violations of the laws and regulations designed to ensure the fitness of drug products for use, the defendants released to the market drugs from the Cidra plant that were not manufactured in accordance with the NDAs filed with the FDA in that, to defendants' knowledge within 31 U.S.C. Sec. 3729(b), the components, composition and/or methods and controls used in manufacturing, processing and/or packing had been changed without FDA approval and/or knowledge. At a minimum, as a result of GSK's inability to control critical factors that cause variability in the manufacturing process, GSK was recklessly indifferent to whether, and could provide no assurance that, Cidra's manufacturing processes were capable of consistently producing products that met approved specifications. Therefore, drugs manufactured at Cidra were of unknown safety and effectiveness and were not "covered" drugs for the purpose of Medicaid and other government health plans under 42 U.S.C. 1396r-8(k), and all claims for those drugs during the times relevant to this complaint were false. Examples of the chronic, serious

deficiencies in the quality assurance function at the Cidra plant and the defendants' ongoing serious violations of the laws and regulations designed to ensure the fitness of drug products for use are set forth in paragraphs 86 through 123 below. Examples of the resulting false claims submitted and/or caused to be submitted by GSK to the government for products manufactured at Cidra during the times relevant to this complaint are attached at Appendix A.

DAMAGE TO THE GOVERNMENT

41. Eckard does not know the precise extent of the financial damage suffered by Medicaid, Medicare, the VA, and other government health programs arising from the knowing submission of false claims by the defendants in this action. However, Eckard believes that the damages amount to at least hundreds of millions of dollars, based on the following: (a) the violations were significant and systemic, affecting key aspects of the Cidra plant's operations including the quality assurance unit, and defective products were released to the market and paid for by the government as a result; (b) the Cidra plant was the most important of all GSK's plants worldwide and provided $5.5 billion of GSK's product; (c) almost 100% of Cidra's product was sold in the United States; and (d) amongst the drugs manufactured at the Cidra plant were Paxil and Paxil CR(top selling antidepressants),

Coreg (a widely-prescribed heart medication), and Avandia and Avandamet (popular diabetes medications). During the times relevant to this complaint, Paxil and Avandia were in the 50 top selling drug products in the world.

PARTICULARS OF FALSE CLAIMS ACT VIOLATIONS

Background

42. Cidra has a history of significant cGMP violations. A report prepared by Eckard for GSK senior executives in April 2003 (referred to herein as "the April 2, 2003, report") listed six areas in which Cidra had been repeatedly cited by the FDA for cGMP violations since 1991, namely documentation, process validation, laboratory investigations, other investigations, sterile facility and computer validation.

43. An FDA inspection conducted at Cidra from March 29, 2001, to July 6, 2001, found significant cGMP deficiencies such as process validation deficiencies in Paxil OS (Oral Suspension) batches, inadequate OOS and complaint investigations, inadequate laboratory controls, inadequate media fills, non-stability indicating analytical methods (i.e., inadequate testing to ensure that drug products could meet their purported shelf life) and deficiencies related to the aseptic (i.e. sterile) filling

operation (relating to the production of injectable drugs). The FDA investigator who conducted this inspection initially recommended issue of a Warning Letter; however, following a meeting with GSK the FDA judged GSK's response adequate and the inspection was classified VAI (Voluntary Action Indicated). An FDA-483 was issued to GSK on or about July 6, 2001.

44. Another FDA inspection was conducted from February 7, 2002 to April 10, 2002 and again the FDA found significant cGMP violations such as the release to market of Bactroban ointment not meeting specifications, inadequate process validation of Paxil OS and Thorazine tablets, inadequate microbiological controls in Bactroban ointment production areas, inadequate laboratory investigations, inadequate instrument calibrations, and inadequate water sampling techniques. On April 10, 2002, another FDA-483 was issued to GSK. GSK submitted a written response to the FDA stating its position on each observation and describing corrective and preventive steps it proposed to take. The FDA was not satisfied with this response, and issued a Warning Letter to Cidra on or about July 1, 2002 ("Warning Letter").

45. The Warning Letter detailed a number of significant cGMP violations at Cidra, including:

a. Release to the market of Bactroban Ointment that was contaminated with microorganisms;

b. Failure to manufacture Paxil OS in accordance with established specifications and to demonstrate a reproducible and reliable manufacturing process;

c. Failure to adequately validate the manufacturing process for Thorazine tablets, including failure to test Thorazine tablets for friability and content uniformity;

d. Failure to conduct statutorily-mandated investigations in a timely manner and to take corrective actions to prevent recurrence, including investigations of High Total Plate Count results in water samples that took more than five months to complete or that were not completed at all.

e. Media fill vials (used to test for sterility of injectable drug product) were not incubated for the required time to assure bacterial growth for both slow and fast microorganisms.

GSK's Response to the FDA: Warning Letter "Recovery"

46. On or about July 2, 2002, GSK met with the FDA to discuss issues arising from the FDA-483 and the Warning Letter. GSK's representatives at that meeting included Janice Whitaker ("Whitaker"), Senior Vice President for Global Quality, Steve Plating ("Plating"), Vice President for Quality North America, Jose Luis Rosado ("Rosado"), the President and General Manager of

Cidra, and Adalberto Ramirez ("Ramirez"), Director of Solid Manufacturing and Packaging at Cidra. At that meeting, the FDA informed GSK that pending approvals for GSK's new diabetes drug, Avandamet, and a new antibiotic, Factive, would not proceed until GSK's response to the Warning Letter was deemed adequate by the FDA and the FDA had reinspected the Cidra plant. Avandamet and Factive are manufactured at the Cidra plant.

47. In early July 2002, Eckard traveled to Cidra in order to assist in the preparation of Cidra's preliminary response to the Warning Letter, which was delivered to the FDA on or about July 17, 2002. At approximately that time, GSK undertook to immediately notify the FDA if any problems were found that could present a public health risk.

48. On or about July 17, 2002, GSK made the following specific commitments to the FDA in response to the Warning Letter received on July 1, 2002, and the FDA-483 received on April 10, 2002:

a. Provide a progress report to the FDA on or before August 15, 2002;

b. Review laboratory investigations:

i. Review all investigation reports from 2000 to date and prepare a summary of findings, this review to be conducted by consultants;

ii. Define an action plan for corrective actions;

iii. Evaluate the adequacy of current SOPs for handling OOS investigation results;

iv. Determine the adequacy of corrective actions taken.

c. Activate functions of the Senior Management Incident Reporting Team ("SMIRT") (Quality Council), a team established in 2002 after the FDA observed that Cidra senior managers were insufficiently involved in quality control;

d. Prepare a Site Validation Master Plan;

e. Review all process validation reports to assure compliance with current guidelines;

f. Conduct training on handling of laboratory investigations;

g. Activate the Lab Calibration/Metrology Unit;

h. Discuss with the FDA's Compliance Division and Division of Anti-Infectives the microbial specification requirements for Bactroban;

i. Define the sampling and testing for Paxil OS batches;

j. Establish a plan to assure that all investigations are completed within 30 days;

k. Review adequacy of media fills documentation from 2001 to July 2002;

l. Assessment of all systems;

m. Hire additional Quality Assurance ("QA") Staff;

n. Ensure adequate validation of Thorazine tablets;

o. Perform additional validation of the tablet process rejection system for Factive;

p. Ensure adequate validation of Paxil OS.

49. On or about August 7, 2002, Eckard was assigned by GSK headquarters in Research Triangle Park, NC, ("RTP") to lead the Warning Letter Recovery Team in Cidra.

50. Eckard's role was to coordinate and oversee the work of Compliance Action Plan Team Leaders who were assigned to each functional area, including Materials, Equipment, Facilities/Utilities, Validation, Laboratory, Computer Validation, Quality Assurance, Production, and Calibration. The Team Leaders were to work on their action plans on a fully dedicated basis for the seven weeks following August 7, 2002, and to communicate serious incidents to top management with the objective of resolving the Warning Letter issues and making the site ready for FDA reinspection, which was a precondition to obtaining FDA approval for Avandamet and Factive. The reinspection was scheduled to commence on or about October 9, 2002. There were over 100 people on the Warning Letter Recovery Team, approximately 75 of them from the Cidra Plant and 25 from GSK headquarters.

51. Shortly after her arrival at Cidra, Eckard asked Cidra's Quality Assurance and Regulatory Manager, Gloria Martinez ("Martinez") to report on any compliance issues that the FDA had not identified in its recent inspections.

52. Martinez presented an internal report during a SMIRT meeting on or about August 14, 2002, which was attended by Cidra senior managers including Rosado. Martinez outlined the following compliance issues:

a. Product mix-ups: Cidra had filed at least 7 Field Alert reports with the FDA during 2002 due to complaints of product comingling from patients, pharmacies or physicians, i.e., tablets of a different type or strength were found in the same bottle. Martinez also stated that Cidra had internally identified nine similar (though distinct) product mix-ups at the plant. Eckard also learned that in the Field Alerts filed with the FDA arising from consumer complaints, Cidra had assured the FDA that, for a variety of reasons, the mix-ups could not have happened at the plant, despite the fact that nine separate and contemporaneous similar incidents had been identified inside the plant. Product mix-ups typically are treated in the industry as Class I or Class II recall events, and yet no recalls had been initiated. Cidra had made no attempt to correct the cause of the mix-ups and had

lied to the FDA in its Field Alert filings by stating that the mix-ups must have occurred outside of Cidra's control. The product mix-ups are discussed in detail in paragraphs 87 through 92 below.

b. Overdue process investigations: As further described in paragraph 104 below, process investigations must be completed within 30 days. Process investigations are conducted when deviations in the manufacturing process give rise to concerns that product quality may be compromised. In August 2002, there were 283 overdue process investigations. As further described in paragraph 105 below, Cidra continued to manufacture and release product notwithstanding the potential impact on the quality of released batches.

c. Equipment not calibrated: As further described in paragraphs 100 through 103 below, equipment calibration is a requirement of the cGMPs. Cidra did not have a calibration program for the laboratory, and over 20,000 pieces of equipment were in urgent need of calibration in the manufacturing areas. As a result, the validity of data gathered during manufacture and testing to assure product quality could not be relied upon as accurate.

d. Standard Operating Procedures overdue: As further described in paragraph 111 below, written procedures, commonly referred to as SOPs, are the foundation of the manufacturing plant's documentation system. These SOPs must be routinely reviewed and revised to take account of changing conditions and circumstances. In August 2002, 366 SOPs were overdue for review and revision at Cidra.

e. Annual product reviews overdue: 21 C.F.R. § 211.180 requires that manufacturers conduct reviews of data, at least annually, for the purpose of evaluating the quality standards of each product. Martinez described numerous product reviews that were more than a year out of date.

53. Immediately after the SMIRT meeting on or about August 14, 2002, Eckard phoned Plating at GSK's headquarters in RTP. She gave him the information that she had received at the meeting. She recommended that GSK stop shipping all product from the Cidra plant, stop manufacturing product for two weeks in order to investigate and resolve the issues raised and the impact on released batches, and notify the FDA about the product mix-ups. Eckard faxed to Plating the overheads that Martinez had used in her presentation, consisting of approximately 13 pages ("the Martinez presentation").

54. On or about August 15, 2002, Eckard returned to GSK headquarters in Research Triangle Park, NC, where she immediately reported her concerns to Whitaker. Eckard reached Whitaker, who was out of the country, by phone. Eckard gave Whitaker the information that she had received at Cidra, including that Cidra had lied to the FDA. She recommended that GSK stop shipping all product from the Cidra plant, stop manufacturing product for two weeks in order to investigate and resolve the issues raised and the impact on released batches and notify the FDA about the product mix-ups. Eckard reminded Whitaker of GSK's promise to the FDA at the meeting on July 17, 2002, that GSK would immediately notify the FDA if any problems were found that could present a public health risk. Eckard told Whitaker that she believed the Cidra plant was headed for a Consent Decree if the problems were not handled with speed and integrity. Eckard left a copy of the Martinez presentation on Whitaker's desk.

55. On or about August 18, 2002, Eckard met with Plating to reiterate the concerns she had communicated to him by phone on August 14, 2002.

56. In September 2002, Eckard spoke by phone with David Pulman ("Pulman"), who was then Vice President of Manufacturing and Supply for North America. Pulman was promoted to President,

Global Manufacturing and Supply in December 2002. Plating had provided Pulman with a copy of the Martinez presentation on or about August 15, 2002. Pulman's overriding concern was to make the Cidra plant ready for the FDA reinspection to commence on or about October 9, 2002. As stated above, passing this inspection was a precondition to obtaining FDA approval for Avandamet and Factive. Pulman asked Eckard for specific examples of the quality problems at the plant. She gave him a few examples and later sent him, via email, a report prepared by the Director of Validation for the sterile facility at GSK's Barnard Castle plant in the United Kingdom, who had been brought in to review validation in the sterile suite in Cidra. His report was scathing. Eckard told Pulman that nothing had improved at the Cidra plant since her report to Plating on or about August 24, 2002.

57. Eckard did not have the authority to order recalls or suspension of manufacturing or shipment of product, or to report regulatory concerns to the FDA. Pulman and Whitaker had ultimate authority to order action of this kind. Throughout 2002 and into April 2003, Eckard continued to urge GSK managers to take the action that she had recommended and to correct the quality and compliance problems at the Cidra plant. They failed to do so.

58. Eckard now believes that Whitaker, Pulman and other GSK executives were unwilling to acknowledge the gravity of the cGMP violations at the Cidra plant and to take the action that Eckard had recommended in part because the FDA had indicated that it would not consider approvals for Avandamet and Factive until the Warning Letter issues were resolved. Such approvals were unlikely to be obtained if the FDA were aware of the gravity of the quality assurance deficiencies at the Cidra plant. Once the objective of approval for Avandamet was achieved, GSK and Cidra management alike lost interest in correcting the deficiencies at the Cidra site and resumed their focus on maximizing productivity at the plant. As stated above, the Cidra plant manufactured $5.5 billion of GSK's product and was the most important of all GSK's plants worldwide.

59. On or about August 20, 2002, Eckard returned to Cidra. The Compliance Action Teams continued to prepare for the Avandamet reinspection, which was held in October. The focus of the inspection was on the progress of the recovery effort. During the inspection, Cidra informed the FDA that it had begun to put together Corrective and Preventive Action Plans but had not yet fully implemented them. Avandamet was approved by the FDA on October 8, 2002. Factive was approved on April 4, 2003.

60. Eckard left Cidra and returned to North Carolina immediately after the inspection, having been at the plant for a period of ten weeks. After three weeks, she returned to Cidra to resume work on Warning Letter recovery and the longer-term correction of Cidra's systemic quality assurance and compliance problems. However, Rosado and Ramirez stated that they wanted to take over the leadership of that effort, including leadership of the Compliance Action Teams. Following a meeting with Plating, it was agreed that Ramirez would lead the effort and Eckard would play an "oversight" role and report to Plating.

61. Thereafter, Eckard visited Cidra periodically for 1-3 days at a time, on each occasion receiving a progress report from Ramirez and reporting to Plating almost on a daily basis.

62. On or about January 24, 2003, Rosado, Plating, Ramirez and Edwin Lopez, Cidra's Director of Quality ("Lopez") met with the FDA to discuss the FDA-483 and Warning Letter Commitments set forth above, paragraph 48. Eckard attended that meeting, but was not on the agenda and did not present any items.

63. In or about February 2003, Eckard learned that Ramirez had repeatedly lied to her about the status of work in the written and verbal progress reports he had provided to her since assuming

control of Warning Letter recovery. She also learned that the Compliance Action Teams had been disbanded immediately after the FDA's October reinspection and the approval of Avandamet, and that Rosado, Ramirez and Lopez had misrepresented the true status of Warning Letter recovery to the FDA at the January 24, 2003 meeting (as further set forth in paragraphs 95, 96, 99, 102, 109 and 113 below). Eckard reported these concerns to Plating and to her immediate boss, Diane Sevigny ("Sevigny"), Director of Global Quality Assurance for North America Pharma.

64. From February 4 through 8, 2003, Eckard and two other RTP personnel, representing the Global Quality Assurance team, conducted an internal audit at Cidra ("the February 2003 RTP audit"). That audit found continuing serious quality control problems and cGMP violations. The findings were communicated to Rosado, Ramirez, Lopez, and senior GSK managers Sevigny, Plating and Jonathon Box ("Box"), the Vice President of Manufacturing and Supply for North America who took Pulman's job when Pulman was promoted in December 2002. Aspects of the February 2003 RTP audit are discussed further below, paragraphs 99.b., 102 and 107.

65. Following her findings in the February 2003 RTP audit and her discovery that Ramirez had lied to her about the status of progress by the Compliance Action Teams, Eckard told Sevigny in

substance that she would not participate in a cover-up of the quality assurance and compliance problems at Cidra and would not take part in any further meetings with the FDA about the Cidra plant. During this period and thereafter, Eckard and Sevigny were in frequent and increasing conflict about GSK's management of the quality and compliance problems at Cidra.

66. In or about March 2003, GSK made a general call to employees for volunteers to accept a redundancy package arising from the merger of Glaxo Welcome and SmithKlineBeecham, which took place in December 2000. Eckard was so demoralized that she initially expressed interest in this package. However, upon reflection and discussion with colleagues, she soon withdrew her expression of interest, believing that she should continue to seek to make things right from within GSK rather than simply resign.

67. Eckard continued to press GSK senior management for action. In or about March 2003 Eckard put together a binder of materials detailing the quality assurance and compliance problems at Cidra and presented it to Plating and Marion Lon ("Lon"), who was to become and became the site director of Cidra when Rosado retired on or about April 1, 2003. Eckard also asked to meet with Plating and Lon.

68. On or about April 2, 2003, Eckard delivered to GSK senior managers Box, Peter Savin (Vice President of Global Quality Assurance), Whitaker, Plating and Sevigny, and Cidra managers Lon and Ramirez, a non-routine detailed memorandum on Current Compliance Risks for Manufacturing and Supply of Drug Products at Cidra ("the April 2, 2003, report"). Eckard provided Ramirez with a copy. She detailed the following high risk compliance problems:

a. Product mix-ups: see further, paragraphs 87 through 92 below;

b. Documentation quality: see further, paragraphs 110 through 111 below;

c. Computer validation;

d. Sterile manufacturing facility activities and documentation, including Kytril injection: see further, paragraphs 112 through 113 below;

e. Quality and control of water systems: see further, paragraph 114 below; and

f. OOS events for environmental monitoring of manufacturing areas and clean equipment: see further, paragraph 115 through 116 below.

69. Eckard called for increased monitoring by GSK management of compliance improvement initiatives at Cidra. However, she did

not receive any response to her memorandum from any of the seven managers to whom she sent the report.

Alleged Product Diversion

70. In or about early April 2003 Eckard learned of internal allegations that persons at the Cidra plant were skimming product during manufacture, including reject product, and diverting the product to Latin America.

71. Corporate Security and GSK senior manager Box were notified of these allegations in February 2003. The allegations were made by a current and a former Cidra employee, both unidentified. Background checks conducted by an outside private investigation company identified connections between a senior manager at Cidra, and companies alleged to distribute the “black market” product. One of these companies was identified as MOVA Pharmaceuticals, Inc., (“MOVA”) a contract manufacturer located in Caguas, Puerto Rico.

72. In or about the week beginning April 7, 2003, Sevigny took a team to Cidra to investigate these allegations, bypassing Eckard who would normally have been assigned leadership of the investigation. Sevigny took Eckard’s employee, Kristal Adams, as part of the team. Although she had been told by Sevigny, in

substance, to “stay out of it,” Eckard nonetheless provided informal advice to Kristal Adams and received information from her about the investigation.

73. On or about April 27, 2003, following a consumer complaint, Cidra filed a Field Alert reporting that Avandamet 40 mg tablets had been found in the United States mixed up with unidentified tablets stamped “MOVA” or “MBO.”

74. GSK had no legitimate business with MOVA, so there was no legitimate reason for Avandamet tablets and MOVA products to be at the same site.

75. Further, a considerable quantity of Avandamet batches had been rejected because of manufacturing problems in late 2002 because of lack of content uniformity, so that some tablets were sub-potent and others were super-potent.

76. On information and belief, based on paragraphs 70, 71, and 73 through 75, rejected batches of drug product, including Avandamet, were sent from Cidra to MOVA, (which is located near Cidra) for “black market” packaging and distribution, resulting in the mix-up.

77. On information and belief, based on paragraphs 70, 71, and 73 through 76, rejected batches of drug product, including Avandamet, were distributed to the United States market.

78. Additionally, the FDA and other experts have identified the cross-border sale to the United States of drugs, some of which are diverted, counterfeit, stolen or fraudulent, as a growing threat to patient safety. There is growing evidence of efforts by increasingly well-organized groups in other countries, backed by increasingly sophisticated technologies and criminal operations, to profit from such drugs at the expense of American patients, who increasingly are purchasing drugs at lower prices over the Internet and via other means from foreign sources. Drugs from countries along the United States border have been identified as a particular threat.

79. On information and belief, based on paragraphs 70, 71, and 78, product diverted from the Cidra plant to the “black market” in Latin America was sold to such groups and channeled back into the United States as legitimate product.

80. In or about April or May of 2003, GSK closed its internal investigation for lack of sufficient evidence. On information and belief, based on paragraphs 70 through 75 and paragraph 78

above, GSK's investigation was inadequate.

Eckard's Termination, Report to GSK's Compliance Department and Report to the FDA

81. In early May 2003 Eckard received a phone call from the GSK Human Resources Department advising her that she was being offered a redundancy package. Eckard stated that she was not interested in a package and was told that she had no choice. She was advised to take a couple of weeks off with pay. In late May the Human Resources Department asked her to attend a meeting at RTP, at which the Vice President of Human Resources for Global Operations formally presented the redundancy package to her, took her security badge, and escorted her from the premises.

82. Even after her termination, Eckard continued her efforts to have GSK address Cidra's quality and compliance problems. In or about July 2003, she called GSK's general counsel and Chief Executive Officer in the United Kingdom, who declined to speak with her. She then called GSK's general counsel in the United States and explained the general nature of her concerns to his secretary. She referred Eckard to the Vice President for Compliance, whom Eckard phoned on or about July 14, 2003. She detailed the serious quality assurance and compliance problems at Cidra, including the product diversion allegations.

83. On or about August 27, 2003, she participated in a teleconference with other GSK compliance personnel, in which she again detailed her concerns. As a result of this call, she formed the view that the Compliance Department lacked authority internally and that regardless of the outcome of their investigation, if any, GSK was unlikely to take any corrective action. On the same day, she called the FDA's San Juan District Office, where she spoke with Compliance Officer Carmelo Rosa ("Rosa"). For two to three hours, she detailed all of the serious quality assurance and compliance problems at Cidra, including the alleged product diversion.

84. On or about October 3, 2003, following a phone conversation with the Compliance Department, Eckard called Rosa at the San Juan District Office of the FDA and informed him that GSK did not intend to take any corrective actions as a result of her report.

85. On or about October 22, 2003, GSK announced in an SEC filing that in October 2003 the FDA had begun an investigation of its manufacturing facility in Cidra, Puerto Rico.

DETAILS OF QUALITY ASSURANCE FAILURES AND VIOLATIONS OF THE FDC ACT AND CFRs

86. The defendants' failure to assure quality of drug products

manufactured at Cidra and violations of the FDC Act and the Code of Federal Regulations, Title 21, include those set forth below.

Product Comingling

87. As set forth in paragraph 52 above, Eckard learned on or about August 14, 2002, that Cidra had received a number of complaints of product comingling from patients, pharmacies and hospitals in 2002. In other words, consumers found tablets of a different drug type or different strength in the same bottle. Additional complaints were received during 2003. To June 2003, these complaints reported the following:

a. Avandia 8 mg mixed with Avandia 4 mg;

b. Paxil 30 mg mixed with Paxil 10 mg;

c. Coreg 12.5 mg mixed with Coreg 6.25 mg;

d. Coreg 6.25 mg mixed with Coreg 3.125 mg;

e. Paxil 40 mg mixed with Paxil 20 mg;

f. Avandia 4 mg mixed with Avandia 8 mg; and

g. Paxil 20 mg mixed with Benadryl 25 mg;

h. Paxil 10 mg bottle contained unidentified pink tablets (Paxil 10 mg is yellow);

i. Paxil 40 mg mixed with Paxil 30 mg;

j. Paxil 10 mg bottle contained unidentified peach/brownish tablets;

k. Avandamet 40 mg mixed with unidentified tablets stamped

“MOVA” or “MBO” (As to MOVA, see paragraphs 71, 73, 74 and 76 above);

l. Three Paxil CR 12.5 mg bottles contained unidentified pink tablets (Paxil CR 12.5 is yellow);

m. Avandia 2 mg mixed with Avandia 4 mg;

n. Paxil CR 25 mg pink mixed with Paxil CR 12.5 mg; and

o. Paxil CR 37.5 mg mixed with Paxil CR 25 mg.

88. Cidra filed Field Alert reports with the FDA with respect to these consumer complaints. Cidra told the FDA in each case that, following an investigation, it had determined that the product mix-ups were very unlikely to have occurred at the Cidra plant, for example, because of “the extensive controls in our packaging areas.”

89. Between approximately January 2002 and June 2003 Cidra generated the following internal investigation reports describing product comingling that it had identified at the plant:

a. Avandia 4 mg mixed with Tagamet OTC 200 mg;

b. Avandia 8 mg mixed with Avandia 4 mg;

c. Coreg 25 mg mixed with Coreg 6.25 mg;

d. Ecotrin 81 mg mixed with Stelazine 2 mg;

e. Paxil 30 mg mixed with Avandia 4 mg;

f. Paxil 30 mg mixed with Paxil CR 12.5 mg;

g. Paxil 20 mg mixed with Paxil 25 mg;

h. Tagamet HB mixed with Avandia 4 mg;

i. Tagamet OTC mixed with Avandia 8 mg;

j. Avandia 8 mg mixed with Paxil 10 mg;

k. Coreg 6.25 mg mixed with Paxil 20 mg;

l. Coreg 25mg mixed with overweight tablets found during packaging;

m. Paxil DC 10mg mixed with two defective tablets found during packaging;

n. Tagamet OTC mixed with Coreg 6.25; and

o. Paxil DC 10mg mixed with Coreg 3.125mg.

90. Despite these contemporaneous mix-ups discovered at the site, Cidra repeatedly represented to the FDA in Field Alert reports responding to consumer complaints referred to in paragraphs 87 and 88 above that its manufacturing and packaging processes were beyond reproach, that it was extremely unlikely that the mix-ups occurred on site and that they must have occurred outside GSK's control. For example, in January 2003 Cidra filed a Field Alert report with the FDA following a pharmacist's complaint of finding Paxil 30 mg tablets in a Paxil 40 mg bottle. Cidra told the FDA that "given the current process controls in place, it was highly unlikely that this situation occurred on our premises." The above-listed mix-ups identified

at the site, however, show that the similar incidents reported by consumers were, in fact, highly likely to have occurred on Cidra's premises.

91. When Eckard learned of the mix-ups in or about August 2002, she pressed Cidra managers for additional information about the cause. She was told that they likely arose from the re-use of undedicated bulk fiber board drums in tablet suites. In other words, drums used in the processing of one type or strength of tablet had been re-used for a different type or strength of tablet. Eckard was also told that uncoated tablets of one type were being mixed with uncoated tablets of another type, so that a tablet of a different type in a final batch would only be recognizable by its size or shape, and not by its color.

92. In or about August 2002, Eckard asked Cidra management to conduct a full analysis of the problem as a matter of priority. A report was not issued until May 2003. This report concluded that "most mix-ups occurred in the compression area in Cidra II Building and were found to be related to drum cleaning and preparation." In other words, Cidra's internal investigation confirmed that the consumer-reported mix-ups likely did not occur outside the plant (as it had earlier informed the FDA) but were a result of failure to properly clean out drums that were used to

prepare one type or strength of drug before the drum was reused for another type or strength of drug. Still, Cidra did not inform the FDA of these findings or initiate any product recalls.

Laboratory Investigations

93. Manufacturers are required to conduct laboratory testing of each drug lot prior to release to determine conformance to the final specifications of the drug product, including the identity and strength of each active ingredient. 21 C.F.R. § 211.165(a). When OOS results are found, i.e., products fail to meet specifications or other quality control criteria, the batch must be rejected. 21 C.F.R. § 211.165(f).

94. OOS results may be due to either error made in the laboratory during testing or to a drug sample that indeed does not conform to the specifications. When the initial assessment cannot document laboratory error, a full-scale failure investigation must be conducted. 21 C.F.R. § 211.192. This is a crucial step in the quality assurance process: root cause must be identified so that appropriate preventive action can be taken. Examples of potential causes of OOS results not attributable to laboratory error are: an improperly validated process (see paragraph 98 below), production operator error, improperly functioning production equipment, use of OOS components, and improper

environmental conditions.

95. As stated above, on or about January 24, 2003, Rosado, Plating, Ramirez and senior Cidra staff members met with the FDA to discuss Warning Letter Commitments ("the January 24, 2003 meeting"). One of the Corrective and Preventive Action items that GSK represented to be complete was its Review of Laboratory Investigations. GSK represented that a review of all investigation reports from 2000 to date had been conducted by consultants and a summary of findings prepared; that an action plan had been defined for corrective actions; that an evaluation of the adequacy of current SOPs for handling OOS investigations had been conducted; and that the adequacy of corrective actions taken had been determined.

96. In fact, Cidra's laboratory investigation review was not complete. In or about August 2002, GSK had hired a consulting firm, The Weinberg Group, Inc. ("Weinberg") to conduct a retrospective OOS laboratory investigations audit for the period from 2000 to August 2002, i.e., to review Cidra's findings arising from investigations of OOS results for products that had been released to the market still containing shelf life (i.e., unexpired batches) and to state whether they concurred or did not concur with those findings and with Cidra's decision to release

the product. This encompassed some 500 investigations. At that time, GSK told the FDA that in the event of any "do not concur" findings by the consultants that could present a public health risk, it would immediately advise the FDA. At the time of the January 24, 2003, meeting, Weinberg had conducted its review and prepared a summary of findings, including that it did not concur with at least 30 of Cidra's findings. Unbeknownst to the FDA, Cidra had agreed with Weinberg that any investigations resulting in a "do not concur" finding would be reinvestigated by Cidra and re-evaluated by Weinberg. Further, a March 2003 internal report prepared by Cidra personnel ("the March 2003 Cidra report") listed some four additional laboratory investigations during the 2000-2002 period that the relator believes had not been reviewed by Weinberg at all at the time of the January 24, 2003, meeting. Therefore, GSK's representation to the FDA that the laboratory investigations review was complete was not accurate, since more than 30 investigations were still outstanding.

97. In addition, in many cases Cidra did not conduct laboratory investigations with adequate skill and diligence and failed to conduct follow-up investigations required by the cGMPS. For example:

a. A great many of Cidra's investigations, both those that

were covered by the Weinberg review, and those that post-dated the period of that review (August 2002), incorrectly assigned a root cause of “determinate” laboratory error, when in fact the root cause was “indeterminate laboratory error.” In other words, the investigation purported to find the cause of the OOS result as an identified laboratory error, when such cause had not been proved but was merely theoretical. As stated above, 21 C.F.R. § 211.192 requires that a full-scale failure investigation be conducted when the initial assessment cannot document laboratory error. As a result of Cidra’s incorrect assignment of cause, the required follow-up investigations were never conducted and thus product released to the market was potentially suspect.

b. An unusually and unacceptably high number of laboratory investigations conducted by Cidra arose as a result of “unknown peaks” detected during routine laboratory testing. “Unknown peaks” appearing on a chromatograph during routine laboratory testing of drug samples indicate that the drug lots may be contaminated. These investigations frequently assigned the root cause of the “unknown peak” as contamination from glassware or other equipment used in the analytical process without adequate proof. As a result, Cidra limited the root cause to laboratory error and did not conduct any additional investigation. The number of reported cases of contamination from glassware was so

high that any objective investigator would have considered and investigated cross-contamination in the production facility, including contamination arising from environmental conditions, manufacturing equipment, air handling systems, and water systems. All of these areas of the production facility were classified in a June 2003 audit of the Cidra facility conducted by Global Quality Assurance ("GQA") personnel ("the June 2003 GQA audit") as areas in which there were serious deficiencies that could significantly impact product quality and required immediate corrective action, and yet Cidra ignored cross-contamination and corrective action arising from "unknown peaks" was focused on re-evaluation of its procedures for laboratory glassware washing.

Process Validation

98. Process validation is a quality control measure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. Manufacturers are required to establish written procedures for production and process control designed to assure that drug products have the identity, strength, quality, and purity they are represented to possess. 21 C.F.R. § 211.100. The execution of the validation protocol, the test results and approvals are documented in a validation report. Changes in process may render the process no

longer valid, and manufacturers are expected to establish a system that monitors processes, equipment and personnel so that unintended changes are identified, as well as conducting periodic process reviews. Process validation is key to assuring that quality, safety and effectiveness are designed and built into the product rather than relying on quality inspection of the finished product, and that each step in the manufacturing process is controlled to maximize the probability that the finished product meets all quality and design specifications.

99. Inadequate validation of Paxil OS and Thorazine were cited by the FDA in the April 2002 FDA-483 and Warning Letter to Cidra. In addition to correcting these specific problems, GSK promised the FDA in or about August 2002 that it would review process validation for all products, many of which had not been reviewed for periods of up to ten or more years. GSK told the FDA on January 24, 2003, that it had reviewed all process validation reports to assure compliance with current guidelines. In fact, many elements of this review were incomplete. For example:

a. In the March 2003 Cidra report, Cidra documented 29 laboratory investigations, dating from 1995 through 2002, that required review in order to determine the impact on validation certification for the drugs in question. Those drugs included

Avandia, Paxil, Relafen, Ecotrin, Tagamet, Albenza, Compazine, Factive, Dyrenium, Batroban and Kytril injection. While the report marked this review as being complete on 12/30/02, the relator believes that the review was in fact still outstanding.

b. The February 2003 RTP audit identified the need for specific compliance questions concerning the validation of Kytril injection to be rectified before additional batches of the drug could be manufactured. Cidra nonetheless proceeded with the manufacture of Kytril injection. The March 2003 Cidra report identified an action item described as: "Issue a document addressing the concerns raised by Richard Kettlewell [the Director of Validation for the sterile facility at GSK's Barnard Castle plant in the United Kingdom] in the process validation assessment of Kytril." See paragraph 56 above. While this item is marked as complete at 12/30/02, it was not, in fact, complete, as evidenced by the findings of the February 2003 RTP audit.

c. Further, the June 2003 GQA Audit noted that Cidra did not have any validation review processes in place for non-sterile products and that reviews must be conducted at no less than three-yearly intervals. (Non-sterile refers to all drug products other than injectable drugs.) The auditors classified this deficiency as one that could significantly impact product quality

and required immediate corrective action.

Equipment Calibration

100. 21 C.F.R. § 211.68(a)requires that automatic, mechanical and electronic equipment be inspected or checked according to a written program to ensure proper performance, and that written records of calibration and inspection be maintained according to a written program. The FDA expects that calibration will be performed both before and after validation studies to ensure the validity of the data gathered. If equipment is found to be out of calibration, investigations should be conducted to determine whether there was any impact of product quality.

101. Inadequate instrument calibration was one of the areas of non-compliance cited by the FDA in the FDA-483 issued to Cidra in April 2002. When the Warning Letter was issued in August 2002, Cidra still had no calibration program at all for the laboratory. As part of the Warning Letter recovery process, Cidra established a calibration program for the laboratory and calibrated some 20,000 pieces of equipment in the manufacturing facility. However, Cidra did not coordinate this process with validation studies as required by the FDA, and thus the validity of data gathered could not be relied upon as accurate.

102. At the January 24, 2003, meeting, Cidra told the FDA that it had completed the task of activating the Laboratory Calibration/ Metrology Unit. However, at the time of the February 2003 RTP audit, the timeline for the calibration corrective action plan was not on target. For example, the auditors cited one item for which the completion date was unknown, and one item that had not even been started by the stated completion date.

103. Further, the June 2003 GQA Audit found that investigations of equipment found to be out of calibration were not being conducted in a timely manner. The auditors noted that due to the high number of incomplete investigations it was difficult to assess the impact of out-of-calibration conditions on product quality. The auditors classified this deficiency as one that could significantly impact product quality and required immediate corrective action.

Overdue Process Investigations

104. Process investigations are conducted whenever a mistake or irregularity is detected during the manufacturing process. These may arise, for example, from an OOS result that is not proven to be caused by laboratory error (see paragraph 94 above), from the discovery of mixed up product, or from a finding that purportedly cleaned equipment is dirty. Process investigations must be

completed within 30 days. See U.S. v. Barr Laboratories, Inc., et al., 812 F. Supp. 458, 468 (D.N.J. 1993)

105. As stated in paragraphs 53, 54 and 55, when Eckard learned, in August 2002, that hundreds of process investigations were overdue, she urged GSK management to shut the plant down immediately while the matters identified therein were resolved. The March 2003 Cidra report confirmed that in August 2002, there were 283 overdue process investigations. Cidra continued to manufacture and release product notwithstanding the potential impact on the quality of released batches.

106. An example of Cidra's inability to complete investigations within 30 days is its process investigation relating to Avandamet commenced in or about April 2003.

a. As stated in paragraph 59 above, Avandamet was approved by the FDA in October 2002. The process investigation should have been initiated in or about December 2002 when a number of failures and problems were observed during manufacture. These failures resulted in the rejection of several batches of the product for lack of content uniformity, assays (tests for purity) that failed to meet specification, and granulation that did not flow appropriately, so that some tablets were sub-potent and others were super-potent.

b. Finally, a process investigation was undertaken in or about April 2003 to determine root cause and any impact on batches that had been released to the market. To Eckard's knowledge, the investigation was still outstanding in May 2003, when she was terminated. No Field Alert was filed with the FDA as required when the quality of batches or product released to the market are suspect. 21 C.F.R. § 314.81 (b)(1)(ii).

107. Further, in the February 2003 RTP audit, Eckard and the other auditors noted that while Cidra had provided computer printouts for process investigations conducted during 2002 and 2003, no clear data for process investigations conducted during 2000 and 2001 had been made available. The auditors noted that they had been provided with log books for the period 2000-2001, which appeared to show that numerous (perhaps several hundred) process investigations were still outstanding. Cidra denied that any investigations were overdue from that time period, but never provided the auditors with any definitive data.

Understaffing in the Quality Assurance Unit

108. The cGMPs require drug manufacturers to have a distinct QA unit that is responsible for ensuring that drug products produced and released to the market meet all applicable standards. Personnel employed in the unit must be appropriately trained and

must be of adequate numbers. 21 C.F.R. 211.25(c). The QA unit is responsible for ensuring that procedures are implemented during the manufacturing process to ensure drug product quality and for conducting investigations of apparent errors, including ensuring that investigations of laboratory testing results that may impact the identity, strength, purity and/or safety of drug products are completed in a timely manner and that corrective actions are taken when necessary. 21 C.F.R. 211.22.

109. Cidra's QA unit was chronically understaffed. In or about August 2002, Cidra told the FDA that it would increase the QA Staff by 17 additional resources. At the January 24, 2003, meeting, Cidra told the FDA that it had hired 23 people. However, it did not tell the FDA that many experienced staff had resigned from the QA unit. Therefore, the actual increase in staff fell short of the promised number. This attrition rate continued in 2003.

Poor Documentation Quality

110. Documentation is crucial to the maintenance of drug quality. Drug manufacturing operations and related quality control and quality assurance systems are required by the cGMPs to be managed and documented according to detailed written procedures covering manufacturing, testing, packaging and storing. See, e.g., 21

C.F.R. § 211.100(a); 21. C.F.R. § 211.180-198. In the April 2, 2003, report, Eckard noted that Cidra had been cited for regulatory violations related to poor documentation quality during FDA inspections in 1991, 1992, 1993, 1994, 2001 and 2002. In that report, Eckard noted that critical documents, including validation, investigation and change control documents, were often not signed and/or dated, or were lost or missing. She noted that Cidra had not responded to regulatory scrutiny by establishing systems to correct the problems.

111. Written procedures, commonly referred to as SOPs, are the foundation of the manufacturing plant's documentation system. The cGMPs require that there be written procedures for the preparation of master records (21 C.F.R. § 211.186(a)), and the "current good" aspect of the cGMPs requires that procedures be reviewed and updating considered on a regular basis. Most responsible manufacturers review procedures on a one or two year cycle. In August 2002, 366 SOPs were overdue for review and revision at Cidra.

Contamination in Products Manufactured in the Sterile Facility

112. Injectable medications are manufactured in the sterile facility. In the April 2, 2003, report, Eckard cited the sterile facility and Kytril injection as a high risk compliance area.

Further, the June 2003 GQA Audit called for the manufacture of Kytril injection to be immediately suspended due to high levels of contamination. The report called for capital expenditure to improve conditions of sterile operations or else close the sterile facility with a sense of urgency.

113. Bactroban ointment, while not a sterile product, is also manufactured in the sterile facility at Cidra. Bactroban is an antibiotic ointment that is used, amongst other things, to treat impetigo, a contagious skin infection that is common in small children. Release to the market of Bactroban ointment that was contaminated with microorganisms was cited by the FDA in both the April 2002 FDA-483 and the July 2002 Warning Letter. At the January 24, 2003 meeting, GSK told the FDA that it had completed a line item entitled: "Discuss with FDA (Compliance and Division of Anti-Infective) the microbial specification requirements for Bactroban." Cidra, however, failed to correct the problem. The June 2003 GQA Audit documented the release to the market on March 4, 2003, of a further lot of Bactroban contaminated with the same microorganism as the one that resulted in an FDA-mandated recall of Bactroban in February/May 2002. This microorganism, ***Ralstonia paucula***, is associated with human infection such as bacteranemia, urinary tract infections, meningitis, wound infection, and peritonitis. The June 2003 GQA Audit also found that there was

no formal validation to support the microbial cleaning of the holding tank for Bactroban ointment. They classified Bactroban production as a major problem area that could significantly impact product quality requiring immediate corrective action.

Substandard Quality and Control of Water Systems

114. In the April 2, 2003 report, Eckard cited quality and control of water systems as a high risk compliance area at Cidra due to an increase in the number of investigations related to the isolation of objectionable organisms in the water system. Eckard noted that there was a project underway to upgrade the water system. However, this project was not progressing. The June 2003 GQA Audit identified water systems as a major problem that could significantly impact product quality requiring immediate corrective action. The auditors noted that the system design allowed for build up of stagnant water exhibiting microbial contamination. They called for the critical assessment and redesign of the water systems with swift implementation.

OOS Events for Environmental Monitoring of Manufacturing Areas and Clean Equipment

115. In the April 2, 2003 report to GSK management, Eckard noted that manufacturing areas and equipment that had purportedly been cleaned to eliminate chemical and microbial contamination failed

routine environmental testing on more than a dozen occasions during 2002. She also noted that the microbiology laboratory investigated 8 events of contamination in negative controls (i.e., control swabs used in testing for microbial contamination of equipment and manufacturing areas) in 2002, as well as inadequate investigation of root cause.

116. The June 2003 GQA Audit cited continuing contamination of negative controls in 2003, and the recovery of objectionable organisms from sampling plates collected during manufacture. The auditors noted that production continued even though two separate investigations failed to determine root cause. The auditors classified this as a major problem that could significantly impact product quality requiring immediate corrective action.

Destruction of Audit Reports

117. It is current good practice in the pharmacuetical industry to routinely conduct internal audits. Further, the cGMPs require that the quality assurance unit review all production records to ensure errors are fully investigated (21 C.F.R. § 211.22(a)) and that written production and process control procedures be reviewed (21 C.F.R. § 211.100(a)). In order to promote self-auditing, it is FDA policy to obtain copies of internal audit reports only when investigating a serious health problem or upon

order of the court.

118. GSK policy requires that internal audit reports be retained for 3 years after all actions have been completed to facilitate tracking for future observations and that a 7 year log/record be maintained including the date, scope, auditor and completion of identified actions. This is consistent with industry practice. The June 2003 GQA Audit found that Cidra's standard procedure was to destroy audit reports once the problems had been discussed with the responsible personnel and to keep no evidence of same. The auditors found that action plans were not documented. They also found that the audit program did not include the aseptic area or the air handling system. They classified auditing as a major problem that could significantly impact product quality requiring immediate corrective action.

Microbiology Laboratory ("Micro Lab")

119. Testing of products and equipment for contamination by objectionable organisms is conducted in the Micro Lab. The June 2003 RTP found a number of serious deficiencies in the functioning of the Micro Lab, including:

a. Poor controls of materials used in testing functions, including lack of assurance that media (used to test for growth of microorganisms) meets quality standards;

b. Poor document control and lack of data integrity;

c. Poor controls of water samples prior to testing for presence of microorganisms;

d. Lack of assurance that test samples and materials are maintained at the required temperatures for the duration of incubation and storage periods and no alarms on equipment for notification of out-of-range conditions;

e. No procedures for identification of trends in water and environmental monitoring; and

f. Lack of timeliness in the review and approval of test results.

120. Deficiencies in environmental monitoring (discussed in paragraphs 115 through 116 above) are further evidence of problems impacting the effective functioning of the Micro Lab. The auditors classified the Micro Lab as a major problem area that could significantly impact product quality requiring immediate corrective action.

Substandard Air Quality

121. The cGMPS provide that air handling systems must be balanced to ensure that they are functioning correctly. Equipment for controlling air pressure, microorganisms, dust, humidity and temperature must be provided. 21 C.F.R. § 211.46. The June 2003

GQA Audit found that the design of Cidra's air handling did not meet cGMP standards and created the potential for cross contamination. The auditors found that pressure differentials were misdirected allowing improper airflow in certain areas. They classified this as a major problem that could significantly impact product quality requiring immediate corrective action. As stated above, poor air quality likely contributed to the high incidence of "unknown peaks" observed during routine laboratory testing.

Cytotoxic Research & Development ("R&D") Manufacturing

122. Cytotoxic substances cause the destruction or inhibit the function of cells. Manufacture of cytotoxic substances must, for obvious reasons, be strictly quarantined from manufacture of other products. The June 2003 GQA Audit found that Cidra was engaged in the R&D manufacture of Topotecan, a chemotherapy drug that is associated with serious side-effects, in a contained area in the midst of commercial manufacturing. The auditors found that air pressure differentials that are crucial to containment of the cytotoxic substance were not properly monitored and documented: the most recent data was dated April 2002. Further, they found that there was no baseline monitoring in surrounding areas to ensure that toxic substances were contained to the R&D area and had not been tracked into other areas where prescription

and over-the-counter drugs were made. The auditors also found that an area formerly used for Topotecan trials had not been properly decontaminated and decommissioned. They classified this as a major problem that could significantly impact product quality requiring immediate corrective action.

Other cGMP Issues

123. The June 2003 GQA Audit identified the following miscellaneous cGMP issues, and collectively classified this as a major problem that could significantly impact product quality requiring immediate corrective action:

a. Raw materials with no identification or status control;

b. Product waste inappropriately stored;

c. Equipment allowing product leakage creating the potential for cross-contamination;

d. Containers of drug product open in unprotected areas;

e. Poor controls of lubricants and cleaning agents creating the potential for misuse leading to product contamination;

f. H&K encapsulator for Dyazide (a machine that fills and seals capsules) was not cleaned after use;

g. Poor controls of disinfectants to ensure that they are free of contamination and within expiry date;

h. No studies to demonstrate effectiveness of disinfection procedures on surfaces in controlled areas;

i. Improper storage and inventory tracking of materials used in process validation; and

j. 9 of 28 packaging lines not equipped to carry out the required 100% electronic verification of printed materials.

CONCLUSION

124. During the times relevant to this Complaint, the defendants released to the market and made and/or caused to be made claims to government health programs for drugs manufactured at Cidra that were defective, misidentified as a result of product mix-ups, not manufactured in accordance with FDA approved processes, and/or did not come with the assurance of identity, strength, quality and purity required for distribution to patients; and/or the approvals for which were obtained through false representations to the FDA.

125. These false claims arose out of chronic, serious deficiencies in the quality assurance function at the Cidra plant and the defendants' ongoing serious violations of the laws and regulations designed to ensure the fitness of drug products for use, including the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*., and the Code of Federal Regulations, Title 21. GSK lied to the FDA in the process of Warning Letter recovery and beyond in order to conceal its inability and/or

unwillingness to correct these quality failures and legal and regulatory violations.

126. Further, on information and belief, GSK employees diverted reject drug product from the Cidra plant to black markets in Latin America. On information and belief, this resulted in the distribution of reject drug product to the United States market and the submission of false claims for drug product that was defective.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Federal False Claims Act
31 U.S.C. § 3729(a)(1))

127. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein again at length.

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

129. By virtue of the acts described above, Defendants, for the purpose of defrauding the Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or

approval under the Medicare, Medicaid and other Government health programs to officers, employees or agents of the United States Government, within the meaning of 31 U.S.C. § 3729(a)(1).

130. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

131. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

132. Additionally, the Federal Government 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 and arising from their fraudulent conduct as described herein.

SECOND CAUSE OF ACTION
(Federal False Claims Act
31 U.S.C. § 3729(a)(2))

133. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein again at length.

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

135. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicare, Medicaid and other Government health programs, within the meaning of 31 U.S.C. § 3729(a)(2).

136. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

137. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

138. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRD CAUSE OF ACTION
(California False Claims Act
Cal. Gov't Code § 12651(a)(1))

139. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

141. By virtue of the acts described above, Defendants, for the purpose of defrauding the California State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other California State funded programs to officers or employees of the state within the meaning of Cal. Gov't Code § 12651(a)(1).

142. As a result, California State monies were lost through payments made in respect of the claims and other costs were sustained by the California State Government.

143. Therefore, the California State Government has been damaged in an amount to be proven at trial.

144. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FOURTH CAUSE OF ACTION
(California False Claims Act
Cal. Gov't Code § 12651(a)(2))

145. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

147. By virtue of the acts described above, Defendants, for the purpose of defrauding the California State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other California State funded programs within the meaning of Cal. Gov't Code § 12651(a)(2).

148. As a result, California State monies were lost through payments made in respect of the claims and other costs were sustained by the California State Government.

149. Therefore, the California State Government has been damaged in an amount to be proven at trial.

150. Additionally, the California State Government is entitled to

the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

FIFTH CAUSE OF ACTION
(Delaware False Claims and Reporting Act
6 Del. C. § 1201(a)(1))

151. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

153. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly presented and/or caused to be presented, directly or indirectly, false or fraudulent claims for payment or approval under Medicaid and other Delaware State funded programs to officers or employees of the state within the meaning of 6 Del. C. § 1201(a)(1).

154. As a result, Delaware State monies were lost through payments made in respect of the claims and other costs were sustained by the Delaware State Government.

155. Therefore, the Delaware State Government has been damaged in an amount to be proven at trial.

156. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

SIXTH CAUSE OF ACTION
(Delaware False Claims and Reporting Act
6 Del. C. § 1201(a)(2))

157. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

159. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly made, used, and/or caused to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Delaware State funded programs within the meaning of 6 Del. C. § 1201(a)(2).

160. As a result, Delaware State monies were lost through payments made in respect of the claims and other costs were sustained by the Delaware State Government.

161. Therefore, the Delaware State Government has been damaged in an amount to be proven at trial.

162. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

SEVENTH CAUSE OF ACTION
(District of Columbia Procurement Reform Amendment Act
D.C. Code § 2-308.14(a)(1))

163. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

165. By virtue of the acts described above, Defendants, for the purpose of defrauding the District of Columbia Government, knowingly presented and/or caused to be presented, false claims for

payment or approval under Medicaid and other District of Columbia funded programs to officers or employees of the District within the meaning of D.C. Code § 2-308.14(a)(1).

166. As a result, District of Columbia monies were lost through payments made in respect of the claims and other costs were sustained by the District of Columbia Government.

167. Therefore, the District of Columbia Government has been damaged in an amount to be proven at trial.

168. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

EIGHTH CAUSE OF ACTION
(District of Columbia Procurement Reform Amendment Act
D.C. Code § 2-308.14(a)(2))

169. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

171. By virtue of the acts described above, Defendants, for the purpose of defrauding the District of Columbia Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other District of Columbia funded programs within the meaning of D.C. Code § 2-308.14(a)(2).

172. As a result, District of Columbia monies were lost through payments made in respect of the claims and other costs were sustained by the District of Columbia Government.

173. Therefore, the District of Columbia Government has been damaged in an amount to be proven at trial.

174. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

NINTH CAUSE OF ACTION
(Florida False Claims Act
Fla. Stat. § 68.082(2)(a))

175. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

177. By virtue of the acts described above, Defendants, for the purpose of defrauding the Florida State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Florida State funded programs to officers or employees of the state within the meaning of Fla. Stat. § 68.082(2)(a).

178. As a result, Florida State monies were lost through payments made in respect of the claims and other costs were sustained by the Florida State Government.

179. Therefore, the Florida State Government has been damaged in an amount to be proven at trial.

180. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TENTH CAUSE OF ACTION
(Florida False Claims Act
Fla. Stat. § 68.082(2)(b))

181. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

183. By virtue of the acts described above, Defendants, for the purpose of defrauding the Florida State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Florida State funded programs within the meaning of Fla. Stat. § 68.082(2)(b).

184. As a result, Florida State monies were lost through payments made in respect of the claims and other costs were sustained by the Florida State Government.

185. Therefore, the Florida State Government has been damaged in an amount to be proven at trial.

186. Additionally, the Florida State Government is entitled to the

maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

ELEVENTH CAUSE OF ACTION
(Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1(a)(1))

187. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

188. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

189. By virtue of the acts described above, Defendants, for the purpose of defrauding the Georgia State Government, knowingly presented and/or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval within the meaning of Ga. Code Ann. § 49-4-168.1(a)(1).

190. As a result, Georgia State monies were lost through payments made in respect of the claims and other costs were sustained by the Georgia State Government.

191. Therefore, the Georgia State Government has been damaged in an

amount to be proven at trial.

192. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented or caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWELFTH CAUSE OF ACTION
(Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1(a)(2))

193. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

194. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

195. By virtue of the acts described above, Defendants, for the purpose of defrauding the Georgia State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program within the meaning of Ga. Code Ann. § 49-4-168.1(a)(2).

196. As a result, Georgia State monies were lost through payments

made in respect of the claims and other costs were sustained by the Georgia State Government.

197. Therefore, the Georgian State Government has been damaged in an amount to be proven at trial.

198. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTEENTH CAUSE OF ACTION
(Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(1))

199. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

201. By virtue of the acts described above, Defendants, for the purpose of defrauding the Hawaii State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Hawaii State

funded programs to officers or employees of the state within the meaning of Haw. Rev. Stat. § 661-21)(a)(1).

202. As a result, Hawaii State monies were lost through payments made in respect of the claims and other costs were sustained by the Hawaii State Government.

203. Therefore, the Hawaii State Government has been damaged in an amount to be proven at trial.

204. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FOURTEENTH CAUSE OF ACTION
(Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(2))

205. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

207. By virtue of the acts described above, Defendants, for the purpose of defrauding the Hawaii State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Hawaii State funded programs within the meaning of Haw. Rev. Stat. § 661-21)(a)(2).

208. As a result, Hawaii State monies were lost through payments made in respect of the claims and other costs were sustained by the Hawaii State Government.

209. Therefore, the Hawaii State Government has been damaged in an amount to be proven at trial.

210. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

FIFTEENTH CAUSE OF ACTION
(Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/3(a)(1))

211. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

213. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Illinois State funded programs to officers or employees of the state within the meaning of 740 Ill. Comp. Stat. 175/3(a)(1).

214. As a result, Illinois State monies were lost through payments made in respect of the claims and other costs were sustained by the Illinois State Government.

215. Therefore, the Illinois State Government has been damaged in an amount to be proven at trial.

216. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

SIXTEENTH CAUSE OF ACTION
(Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/3(a)(2))

217. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

219. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Illinois State funded programs within the meaning of 740 Ill. Comp. Stat. 175/3(a)(2).

220. As a result, Illinois State monies were lost through payments made in respect of the claims and other costs were sustained by the Illinois State Government.

221. Therefore, the Illinois State Government has been damaged in an amount to be proven at trial.

222. Additionally, the Illinois State Government is entitled to the

maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

SEVENTEENTH CAUSE OF ACTION
(Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(1) and (8))

223. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

225. By virtue of the acts described above, Defendants, for the purpose of defrauding the Indiana State Government, knowingly or intentionally presented and/or caused or induced another to present false claims under Medicaid and other Indiana State funded programs to the state for payment or approval within the meaning of Ind. Code § 5-11-5.5-2(b)(1) and (8).

226. As a result, Indiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Indiana State Government.

227. Therefore, the Indiana State Government has been damaged in an amount to be proven at trial.

228. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as describe herein.

EIGHTEENTH CAUSE OF ACTION
(Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(2) and (8))

229. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

231. By virtue of the acts described above, Defendants, for the purpose of defrauding the Indiana State Government, knowingly or intentionally made, used, and/or caused or induced another to make or use, false records or statements to obtain payment or approval of a false claim under Medicaid and other Indiana State funded programs within the meaning of Ind. Code § 5-11-5.5-2(b)(2) and (8).

232. As a result, Indiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Indiana State Government.

233. Therefore, the Indiana State Government has been damaged in an amount to be proven at trial.

234. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as describe herein.

NINETEENTH CAUSE OF ACTION
(Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. 46:438.3(A))

235. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

236. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

237. By virtue of the acts described above, Defendants, for the purpose of defrauding the Louisiana State Government,

knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Louisiana State funded programs within the meaning of La. Rev. Stat. 46:438.3(A).

238. As a result, Louisiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Louisiana State Government.

239. Therefore, the Louisiana State Government has been damaged in an amount to be proven at trial.

240. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. 46:438.6(B)(2).

TWENTIETH CAUSE OF ACTION
(Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. 46:438.3(B))

241. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

242. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

243. By virtue of the acts described above, Defendants, for the purpose of defrauding the Louisiana State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of La. Rev. Stat. 46:483.3(B).

244. As a result, Louisiana State monies were lost through payments made in respect of the defendants' conduct and other costs were sustained by the Louisiana State Government.

245. Therefore, the Louisiana State Government has been damaged in an amount to be proven at trial.

246. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. 46:438.6(B)(2).

TWENTY-FIRST CAUSE OF ACTION
(Massachusetts False Claims Act
Mass. Gen. L. Ch. 12, §§ 5B(1))

247. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

248. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

249. By virtue of the acts described above, Defendants, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Massachusetts Commonwealth funded programs within the meaning of Mass. Gen. L. Ch. 12, §§ 5B(1).

250. As a result, Massachusetts Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Massachusetts Commonwealth Government.

251. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proven at trial.

252. Additionally, the Massachusetts Commonwealth Government is

entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-SECOND CAUSE OF ACTION
(Massachusetts False Claims Act
Mass. Gen. L. Ch. 12, §§ 5B(2))

253. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

254. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

255. By virtue of the acts described above, Defendants, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth within the meaning of Mass. Gen. L. Ch. 12, §§ 5B(2).

256. As a result, Massachusetts Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Massachusetts Commonwealth Government.

257. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proven at trial.

258. Additionally, the Massachusetts Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

TWENTY-THIRD CAUSE OF ACTION
(Michigan Medicaid False Claims Act
Mich. Comp. Laws § 400.610a)

259. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

260. This is a claim for damages and a civil penalty under the Michigan Medicaid False Claims Act.

261. By virtue of the acts described above, Defendants, for the purpose of defrauding the Michigan State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Michigan a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan

Compiled Laws, upon or against the State, knowing the claim to be false within the meaning of Mich. Comp. Law §§ 400.601 et seq.

262. As a result, Michigan State monies were lost through payments made in respect of the claims and other costs were sustained by the Michigan State Government.

263. Therefore, the Michigan State Government has been damaged in an amount to be proven at trial.

264. Additionally, the Michigan State Government is entitled to a civil penalty equal to the full amount of the benefit received by the Defendants plus triple the amount of damages suffered by the state as a result of the conduct by Defendants as described herein.

TWENTY-FOURTH CAUSE OF ACTION
(Nevada False Claims Act
Nev. Rev. Stat. § 357.040(1)(a))

265. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

266. This is a claim for penalties and treble damages under the

Nevada False Claims Act, entitled “Submission of False Claims to State or Local Government”.

267. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Nevada State funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(a).

268. As a result, Nevada State monies were lost through payments made in respect of the claims and other costs were sustained by the Nevada State Government.

269. Therefore, the Nevada State Government has been damaged in an amount to be proven at trial.

270. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-FIFTH CAUSE OF ACTION
(Nevada False Claims Act
Nev. Rev. Stat. § 357.040(1)(b))

271. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

272. This is a claim for penalties and treble damages under the Nevada False Claims Act, entitled “Submission of False Claims to State or Local Government”.

273. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Nevada State funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(b).

274. As a result, Nevada State monies were lost through payments made in respect of the claims and other costs were sustained by the Nevada State Government.

275. Therefore, the Nevada State Government has been damaged in an amount to be proven at trial.

276. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

TWENTY-SIXTH CAUSE OF ACTION
(New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b(I)(a))

277. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

279. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Hampshire State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New Hampshire State funded programs to officers or employees of the state within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(a).

280. As a result, New Hampshire state monies were lost through payments made in respect of the claims and other costs were sustained by the New Hampshire State Government.

281. Therefore, the New Hampshire State Government has been damaged in an amount to be proven at trial.

282. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-SEVENTH CAUSE OF ACTION
(New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b(I)(b))

283. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

285. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Hampshire State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Hampshire State funded programs within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(b).

286. As a result, New Hampshire State monies were lost through payments made in respect of the claims and other costs were sustained by the New Hampshire State Government.

287. Therefore, the New Hampshire State Government has been damaged in an amount to be proven at trial.

288. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

TWENTY-EIGHTH CAUSE OF ACTION
(New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-4(A))

289. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

291. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government,

knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State funded programs to the State within the meaning of N.M. Stat. Ann. § 27-14-4(A).

292. As a result, New Mexico State monies were lost through payments made in respect of the claims and other costs were sustained by the New Mexico State Government.

293. Therefore, the New Mexico State Government has been damaged in an amount to be proven at trial.

294. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-NINTH CAUSE OF ACTION
(New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-4(C))

295. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

296. This is a claim for penalties and treble damages under the

New Mexico Medicaid False Claims Act.

297. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Mexico State funded programs within the meaning of N.M. Stat. Ann. § 27-14-4(C).

298. As a result, New Mexico State monies were lost through payments made in respect of the claims and other costs were sustained by the New Mexico State Government.

299. Therefore, the New Mexico State Government has been damaged in an amount to be proven at trial.

300. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTIETH CAUSE OF ACTION
(New York False Claims Act
N.Y. State Fin. Law § 189(1)(a))

301. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

303. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York State funded programs to officers or employees or agents of the state within the meaning of N.Y. State Fin. Law § 189(1)(a).

304. As a result, New York State monies were lost through payments made in respect of the claims and other costs were sustained by the New York State Government.

305. Therefore, the New York State Government has been damaged in an amount to be proven at trial.

306. Additionally, the New York State Government is entitled to

the maximum penalty of $12,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-FIRST CAUSE OF ACTION
(New York False Claims Act
N.Y. State Fin. Law § 189(1)(b))

307. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

309. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York State funded programs within the meaning of N.Y. State Fin. Law § 189(1)(b).

310. As a result, New York State monies were lost through payments made in respect of the claims and other costs were sustained by the New York State Government.

311. Therefore, the New York State Government has been damaged in an amount to be proven at trial.

312. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTY-SECOND CAUSE OF ACTION
(Tennessee False Claims Act
Tenn. Code Ann. § 4-18-103(a)(1))

313. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

314. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

315. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Tennessee State funded programs to officers or employees of the state within the meaning of Tenn. Code Ann. § 4-18-103(a)(1).

316. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

317. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

318. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-THIRD CAUSE OF ACTION
(Tennessee False Claims Act
Tenn. Code Ann. § 4-18-103(a)(2))

319. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

320. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

321. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, false

records or statements to get false claims paid or approved under Medicaid and other Tennessee State funded programs within the meaning of Tenn. Code Ann. § 4-18-103(a)(2).

322. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

323. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

324. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTY-FOURTH CAUSE OF ACTION
(Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(A))

325. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

327. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented to the state claims for payment under the Medicaid program knowing such claims were false or fraudulent within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(A).

328. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

329. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

330. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-FIFTH CAUSE OF ACTION
(Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(B))

331. Plaintiff/relator repeats and realleges each and every

allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

333. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the state knowing such record or statement were false within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(B).

334. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

335. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

336. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants'

fraudulent conduct as described herein.

THIRTY-SIXTH CAUSE OF ACTION
(Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code § 36.002(1)(A))

337. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

338. This is a claim for restitution, interest, penalties and double damages under the Medicaid Fraud Prevention Law.

339. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, and/or caused to be made, false statements or representations of material facts on applications for contracts, benefits, or payments under the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(1)(A).

340. As a result, Texas State monies were lost through payments made in respect of the false statements or representations and other costs were sustained by the Texas State Government.

341. Therefore, the Texas State Government has been damaged in an

amount to be proven at trial.

342. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by the Defendants under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

THIRTY-SEVENTH CAUSE OF ACTION
(Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code § 36.002(4)(B))

343. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

344. This is a claim for restitution, interest, penalties and double damages under the Medicaid Fraud Prevention Law.

345. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, caused to be made, induced, and/or sought to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, within the meaning of Tex. Hum. Res. Code §

36.002(4)(B).

346. As a result, Texas State monies were lost through payments made in respect of the false statements or representations and other costs were sustained by the Texas State Government.

347. Therefore, the Texas State Government has been damaged in an amount to be proven at trial.

348. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by the Defendants under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

THIRTY-EIGHTH CAUSE OF ACTION
(Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(1))

349. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

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

351. By virtue of the acts described above, Defendants, for the

purpose of defrauding the Virginia Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Virginia Commonwealth funded programs to officers or employees of the Commonwealth within the meaning of Va. Code Ann. § 8.01-216.3(A)(1).

352. As a result, Virginia Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Virginia Commonwealth Government.

353. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proven at trial.

354. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-NINTH CAUSE OF ACTION
(Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(2))

355. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as

though fully set forth herein.

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

357. By virtue of the acts described above, Defendants, for the purpose of defrauding the Virginia Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth under Medicaid and other Virginia Commonwealth funded programs within the meaning of Va. Code Ann. § 8.01-216.3(A)(2).

358. As a result, Virginia Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Virginia Commonwealth Government.

359. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proven at trial.

360. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

FORTIETH CAUSE OF ACTION
(Chicago False Claims Act
Chicago Mun. Code ch. 1-22-020(1))

361. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

362. This is a claim for penalties and treble damages under the Chicago False Claims Act.

363. By virtue of the acts described above, Defendants, for the purpose of defrauding the Chicago City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Chicago City funded programs to officers or employees of the City within the meaning of Chicago Mun. Code ch. 1-22-020(1).

364. As a result, Chicago City monies were lost through payments made in respect of the claims and other costs were sustained by the Chicago City Government.

365. Therefore, the Chicago City Government has been damaged in an amount to be proven at trial.

366. Additionally, the Chicago City Government is entitled to the

maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FORTY-FIRST CAUSE OF ACTION
(Chicago False Claims Act
Chicago Mun. Code ch. 1-22-020(2))

367. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

368. This is a claim for penalties and treble damages under the Chicago False Claims Act.

369. By virtue of the acts described above, Defendants, for the purpose of defrauding the Chicago City Government, knowingly made, used, and/or caused to be made or used, false records or statement to get false claims paid or approved under Medicaid and other Chicago City funded programs within the meaning of Chicago Mun. Code ch. 1-22-020(2).

370. As a result, Chicago City monies were lost through payments made in respect of the claims and other costs were sustained by the Chicago City Government.

371. Therefore, the Chicago City Government has been damaged in an amount to be proven at trial.

372. Additionally, the Chicago City Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FORTY-SECOND CAUSE OF ACTION - [PROPOSED]
(New York City False Claims Act
NYC Admin. Code § 7-803(a)(1))

373. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

374. This is a claim for penalties and treble damages under the New York City False Claims Act.

375. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York City funded programs to officers or employees of the City within the meaning of NYC Admin. Code § 7-803(a)(1).

376. As a result, New York City monies were lost through payments made in respect of the claims and other costs were sustained by the New York City Government.

377. Therefore, the New York City Government has been damaged in an amount to be proven at trial.

378. Additionally, the New York City Government is entitled to the maximum penalty of $15,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FORTY-THIRD CAUSE OF ACTION - [PROPOSED]
(New York City False Claims Act
NYC Admin. Code § 7-803(a)(2))

379. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 126 above as though fully set forth herein.

380. This is a claim for penalties and treble damages under the New York City False Claims Act.

381. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York City Government, knowingly made, used, and/or caused to be made or used, false records or

statements to get false claims paid or approved under Medicaid and other New York City funded programs within the meaning of NYC Admin. Code § 7-803(a)(2).

382. As a result, New York City monies were lost through payments made in respect of the claims and other costs were sustained by the New York City Government.

383. Therefore, the New York City Government has been damaged in an amount to be proven at trial.

384. Additionally, the New York City Government is entitled to the maximum penalty of $15,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

1. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the United States, plus a civil penalty of up to $11,000 for each violation of 31 U.S.C. § 3729 proven at trial;

2. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of California, plus a civil penalty of $10,000 for each violation of Cal. Gov't Code § 12651 proven at trial;

3. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Delaware, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201 proven at trial;

4. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the District of Columbia, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14 proven at trial;

5. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Florida, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082 proven at trial;

6. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Georgia, plus a civil penalty of $11,000 for each violation

of Ga. Code Ann. § 49-4-168.1 proven at trial;

7. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Hawaii, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21 proven at trial;

8. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Illinois, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3 proven at trial;

9. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Indiana, plus a civil penalty of at least $5,000 for each violation of Ind. Code § 5-11-5.5-2(b) proven at trial;

10. Judgment in an amount equal to the damages to be proven at trial against Defendants and in favor of the State of Louisiana, plus a civil fine in the amount of three times the amount of actual damages sustained for each violation of La. Rev. Stat. 46:438.3 proven at trial;

11. Judgment in an amount equal to threefold the damages to be

proven at trial against Defendants and in favor of the Commonwealth of Massachusetts, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12, § 5B proven at trial;

12. Judgment in an amount equal to the damages to be proven at trial against Defendants and in favor of the State of Michigan, plus a civil penalty equal to the full amount of the benefit received by the Defendants plus triple the amount of damages suffered by the state for each violation of Mich. Comp. Laws § 400.610a proven at trial;

13. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Nevada, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §§ 357.040 proven at trial;

14. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of New Hampshire, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I) proven at trial;

15. Judgment in an amount equal to threefold the damages to be

proven at trial against Defendants and in favor of the State of New Mexico, plus a civil penalty for each violation of N.M. Stat. Ann. § 27-14-4 proven at trial;

16. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of New York, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. Law § 189 proven at trial;

17. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § Tenn. Code Ann. § 4-18-103 proven at trial;

18. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182 proven at trial;

19. Judgment in an amount equal to restitution, interest, and twofold the damages to be proven at trial against Defendants and in favor of the State of Texas, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §§

36.002 proven at trial;

20. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the Commonwealth of Virginia, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3 proven at trial;

21. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the City of Chicago, plus a civil penalty of $10,000 for each violation of Chicago Mun. Code ch. 1-22-020 proven at trial;

22. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the City of New York, plus a civil penalty of $15,000 for each violation of NYC Admin. Code § 7-803 proven at trial;

23. An award to Cheryl Eckard of the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and equivalent provisions in the state statutes set forth above, including the costs and expenses of this action and reasonable attorneys' fees;

24. Such other, further and different relief, whether preliminary or permanent, legal or equitable, as the Court deems just and

proper.

[CONTINUED ON NEXT PAGE]

DEMAND FOR JURY TRIAL

Plaintiff demands that her claims for relief against the Defendant be tried by a jury to the full extent permitted by law.

GETNICK & GETNICK

Dated: October 17, 2008 By: /s/ Lesley Ann Skillen
Neil V. Getnick (9864)
Lesley Ann Skillen (5156)
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LOCAL COUNSEL

Dated: October 17, 2008 By: /s/ Scott Tucker
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Telephone: (617) 557-9696

Attorneys for Qui Tam
Plaintiff, Cheryl D. Eckard

Appendix A

Drug Name	Amount Paid ($)	Quantity	Transaction Control Number (TCN)	Date	Pharmacy Name and Address	Prescriber Name and Address
AVANDAMET 1MG/500MG TABLET	$59.53	60	20405400006027861	2004 Q1	OLDEN'S PHARMACY INC, SO Weymouth, MA 02190	[REDACTED] MD, North Quincy, MA 02171
AVANDAMET 1MG/500MG TABLET	$61.00	60	20502100002013961	2005 Q1	WAL-MART PHARMACY 10-2157, NO Dartmouth, MA 02747	[REDACTED] MD, Fall River, MA 02721
AVANDAMET 2MG/500MG TABLET	$173.22	120	20306200008011870	2003 Q1	STOP & SHOP PHARMACY #014, Pembroke, MA 02359	[REDACTED] MD, Scituate, MA 02066
AVANDAMET 2MG/500MG TABLET	$2.00	60	20627600004098561	2006 Q4	NASSIFS PROF PHARMACY, North Adams, MA 01247	[REDACTED] MD, Pittsfield, MA 01201
AVANDAMET 4MG/500MG TABLET	$141.42	60	20321900002092531	2003 Q3	CVS PHARMACY #73, Amesbury, MA 01913	[REDACTED] MD, Salisbury, MA 01952
AVANDAMET 4MG/500MG TABLET	$93.72	30	20631800003070501	2006 Q4	STOP & SHOP PHARMACY #404, Springfield, MA 01129	[REDACTED] NP, Wilbraham, MA 01095
AVANDIA 2MG TABLET	$102.53	60	20214200004093551	2001 Q2	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Quincy, MA 02169
AVANDIA 2MG TABLET	$61.29	30	20627400001015621	2006 Q4	CVS PHARMACY #1212, Brookline, MA 02146	[REDACTED] MD, Norwood, MA 02062
AVANDIA 4MG TABLET	$71.64	30	20205900006015521	2001 Q1	NORTH SHORE PHARM SERVICES, Peabody, MA 01960	[REDACTED] MD, Reading, MA 01867
AVANDIA 4MG TABLET	$93.97	30	20627400001004311	2006 Q4	CVS PHARMACY #0938, N Attleboro, MA 02760	[REDACTED] MD, NO Attleboro, MA 02760
AVANDIA 8MG TABLET	$128.29	30	20214300002056911	2001 Q3	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Springfield, MA 01107
AVANDIA 8MG TABLET	$165.28	30	20627400001039211	2006 Q4	CVS PHARMACY #1021, South Dennis, MA 02638	[REDACTED] MD, Orleans, MA 02653
BACTROBAN 2% CREAM	$45.93	30	20210800006064451	2001 Q1	WESTGATE PHCY OF HYANNIS, Hyannis, MA 02601	[REDACTED] MD, Orleans, MA 02653
BACTROBAN 2% CREAM	$16.28	30	20627600001051571	2006 Q4	RITE AID PHARMACY#0210, Fairhaven, MA 02719	[REDACTED] DO, N Dartmouth, MA 02747

Appendix A

Drug Name	Amount Paid ($)	Quantity	Transaction Control Number (TCN)	Date	Pharmacy Name and Address	Prescriber Name and Address
BACTROBAN 2% OINTMENT	$37.47	22	20203100000050821	2001 Q2	NORTH SHORE PHARM SERVICES, Peabody, MA 01960	[REDACTED] MD, Lowell, MA 01852
BACTROBAN 2% OINTMENT	$35.91	22	20628900004005561	2006 Q4	PERROTTA SUPER DRUG, Lawrence, MA 01841	[REDACTED] MD, Lawrence, MA 01842
BACTROBAN NASAL 2% OINTMENT	$48.21	10	20210000001054131	2001 Q3	STAT-CARE PHARMACY LLC, N. Grafton, MA 01536	[REDACTED] MD, Amherst, MA 01002
BACTROBAN NASAL 2% OINTMENT	$63.01	10	20627600001046211	2006 Q4	MAIN STREET ATHOL CVS INC, Athol, MA 01331	[REDACTED] MD, Holden, MA 01520
CIMETIDINE 150MG/ML VIAL	$2.62	1	20202200002091201	2002 Q1	PHARMCA CR SPEC PHARM#2516, Boston, MA 02111	[REDACTED] MD, Boston, MA 02111
CIMETIDINE 150MG/ML VIAL	$1.63	2	20627500001076171	2006 Q4	SPECIALTY SCRIPT PHARMACY, Fall River, MA 02721	[REDACTED] MD, Boston, MA 02115
COMPAZINE 2.5MG SUPPOSITORY	$10.44	4	20201600003094001	2002 Q1	CVS PHARMACY #1068, Athol, MA 01331	[REDACTED], Athol, MA 01331
COMPAZINE 2.5MG SUPPOSITORY	$23.56	10	20411800006058811	2004 Q2	RITE AID PHARMACY #0581, Westford, MA 01886	[REDACTED] MD, Ayer, MA 01432
COMPAZINE SPANSULE 15MG	$38.29	20	20205000005043661	2001 Q4	PHARMERICA, Brockton, MA 02301	[REDACTED] MD, Newton, MA 02462
COMPAZINE SPANSULE 15MG	$65.77	36	20318500001012600	2003 Q3	ELMWOOD PHARMACY, Malden, MA 02148	[REDACTED] MD, Melrose, MA 02176
COREG 3.125MG TABLET	$47.15	30	20201500006063251	2001 Q2	NORTH SHORE PHARM SERVICES, Peabody, MA 01960	[REDACTED] MD, Fall River, MA 02721
COREG 3.125MG TABLET	$21.00	60	20627400001001941	2006 Q4	NORTH SHORE PHARM SERVICES, Peabody, MA 01960	[REDACTED] MD, Billerica, MA 01862

Appendix A

Drug Name	Amount Paid ($)	Quantity	Transaction Control Number (TCN)	Date	Pharmacy Name and Address	Prescriber Name and Address
COREG 6.25MG TABLET	$91.29	60	20221400004003761	2001 Q2	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Newton Centre, MA 02159
COREG 6.25MG TABLET	$4.02	60	20627400001075631	2006 Q4	CVS PHARMACY #2282, Dorchester, MA 02122	Unknown
DENAVIR 1% CREAM	$18.92	2	20207900004055971	2001 Q4	BAYSTATE PHARMACY, Springfield, MA 01107	[REDACTED] MD, Springfield, MA 01199
DENAVIR 1% CREAM	$29.57	1.5	20627700005068081	2006 Q4	SAIGON PHARMACY, Dorchester, MA 02125	[REDACTED] MD, Dorchester, MA 02124
DYAZIDE 37.5/25 CAPSULE	$12.04	30	20200300006054401	2001 Q4	WALGREENS MEDI MART 01867, Revere, MA 02151	[REDACTED] MD, Boston, MA 02108
DYAZIDE 37.5/25 CAPSULE	$102.73	180	20527800002081551	2005 Q4	CVS PHARMACY #55, Brighton, MA 02135	[REDACTED] MD, Wellesley, MA 02481
ECOTRIN 325MG TABLET EC		3	20629900001044931	2006 Q4	GEORGETOWN PHARMACY, Georgetown, MA 01833	[REDACTED] MD, W Springfield, MA 01089
KYTRIL 1MG/ML VIAL	$1,032.16	6	20200400003023101	2002 Q1	PHARMCA CR SPEC PHARM #2516, Boston, MA 02111	[REDACTED] MD, Stoughton, MA 02072
KYTRIL 1MG/ML VIAL	$166.53	1	20402300005059591	2004 Q1	PHARMCA CR SPEC PHARM #2516, Boston, MA 02111	[REDACTED] MD, Brockton, MA 02402
KYTRIL 2MG/10ML SOLUTION	$202.49	25	20416000005054521	2004 Q2	CVS PHARMACY #1130, Springfield, MA 01108	[REDACTED] MD, Springfield, MA 01199
KYTRIL 2MG/10ML SOLUTION	$250.42	30	20610200005052431	2006 Q2	CVS PHARMACY #1056, Lowell, MA 01851	[REDACTED] MD, Boston, MA 02211
PAXIL 10MG TABLET	$68.48	30	20202300005080941	2001 Q1	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Cumberland, RI 01568
PAXIL 10MG TABLET	$2.35	30	20734700003095851	2007 Q4	WALGREENS #06349, Dorchester, MA 02124	[REDACTED] MD, Boston, MA 02446
PAXIL 20MG TABLET	$37.17	15	20205700005043771	2001 Q1	NORTH SHORE PHARM SERVICES, Peabody, MA 01960	[REDACTED] MD, Boston, MA 02375

Appendix A

Drug Name	Amount Paid ($)	Quantity	Transaction Control Number (TCN)	Date	Pharmacy Name and Address	Prescriber Name and Address
PAXIL 20MG TABLET	$97.04	30	20812400003058201	2008 Q2	CVS PHARMACY #01249, Hanson, MA 02341	[REDACTED] MD Address Unknown
PAXIL 30MG TABLET	$73.38	30	20209400002061251	2001 Q2	SUNSCRIPT PHARMACY CORP, Marlborough, MA 01752	[REDACTED] MD, Salem, MA 01970
PAXIL 30MG TABLET	$99.97	30	20809300005093401	2008 Q2	WALSH PHARMACY, Fall River, MA 02720	[REDACTED] MD, Brookline, MA 02143
PAXIL 40MG TABLET	$77.34	30	20203100001001801	2001 Q1	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Holden, MA 01520
PAXIL 40MG TABLET	$105.61	30	20810700005036281	2008 Q2	CVS PHARMACY #01000, Lowell, MA 01852	[REDACTED] CS Address Unkown
PAXIL 10MG/5ML SUSPENSION	$28.00	60	20200100000032181	2001 Q4	CVS PHARMACY #2878, Fall River, MA 02721	[REDACTED] MD, Fall River, MA 02724
PAXIL 10MG/5ML SUSPENSION	$22.38	30	20809700001074981	2008 Q2	MASS GENERAL HOSPITAL, Boston, MA 02114	[REDACTED], Charlestown, MA 02114
PAXIL CR 12.5MG TABLET	$72.89	30	20211300007072021	2002 Q2	RITE AID PHARMACY #0527, Amesbury, MA 01913	[REDACTED] MD, Boston, MA 02130
PAXIL CR 12.5MG TABLET	$83.35	30	20627600001055701	2006 Q4	RITE AID PHARMACY #0569, Somerville, MA 02143	[REDACTED] MD, Medford, MA 02155
PAXIL CR 25MG TABLET	$77.05	30	20211400001023031	2002 Q2	SPRING ST DRUG INC, Springfield, MA 01105	[REDACTED] PC, Springfield, MA 01105
PAXIL CR 25MG TABLET	$86.99	30	20627400001069441	2006 Q4	CVS PHARMACY #0765, Southbridge, MA 01550	[REDACTED] MD, Charlton, MA 01507
PAXIL CR 37.5MG TABLET	$78.30	30	20211300001059271	2002 Q2	CVS PHARMACY #1217, Boston, MA 02116	[REDACTED] NP, Boston, MA 02111
PAXIL CR 37.5MG TABLET	$41.14	30	20627900003022341	2006 Q4	THE MEDICINE SHOPPE, Adams, MA 01220	[REDACTED] MD, Williamstown, MA 01267
RELAFEN 500MG TABLET	$35.50	45	20200500002012681	2001 Q4	SUNSCRIPT PHARMACY CORP, Marlborough, MA 01752	[REDACTED] MD, Salem, MA 01970

Appendix A

Drug Name	Amount Paid ($)	Quantity	Transaction Control Number (TCN)	Date	Pharmacy Name and Address	Prescriber Name and Address
RELAFEN 500MG TABLET	$119.67	90	20311400003087290	2003 Q2	GT BROOK VLLY HLTH CTR INC, Worcester, MA 01605	[REDACTED] MD, Southboro, MA 01772
RELAFEN 750MG TABLET	$93.86	60	20205000006048351	2001 Q4	PHARMERICA, Brockton, MA 02301	[REDACTED] MD, Brighton, MA 02135
RELAFEN 750MG TABLET	$156.10	100	20312700005024350	2003 Q2	WINTHROP APOTHECARY INC, Worcester, MA 01604	[REDACTED] MD, Worcester, MA 01604
STELAZINE 5MG TABLET	$11.47	21	20202400003021531	2001 Q4	SHOPPERS DRUG STORE, Springfield, MA 01108	[REDACTED] MD, Springfield, MA 01104
STELAZINE 5MG TABLET	$111.70	84	20328000004014151	2003 Q4	CVS PHARMACY #1265, East Boston, MA 02128	[REDACTED] MD, Newton, MA 02158
TAGAMET 300MG TABLET	$189.42	180	20421700008083251	2004 Q3	CVS PHARMACY #1071, Brookline, MA 02146	[REDACTED] MD, Brookline, MA 02446
TAGAMET 400MG TABLET	$3.32	7	20201800004049351	2001 Q4	SHOPPERS DRUG STORE, Springfield, MA 01108	[REDACTED] MD, Springfield, MA 01107
TAGAMET 400MG TABLET	96.79	60	20231000004062931	2002 Q4	FALLON CLINIC, Leominster, MA 01453	[REDACTED] MD, Leominster, MA 01453
THORAZINE 25MG/ML AMPUL	$32.53	4	20202400006044791	2001 Q4	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Worcester, MA 01608
THORAZINE 25MG/ML AMPUL	$36.92	4	20214300007096431	2002 Q2	OMNICARE OF MASSACHUSETTS, West Boylston, MA 01583	[REDACTED] MD, Westboro, MA 01581
THORAZINE 25MG/ML VIAL	$8.52	1	20209400004094821	2002 Q1	PHARMERICA, Brockton, MA 02301	[REDACTED] MD, Waltham, MA 02154
THORAZINE 25MG/ML VIAL	$55.74	10	20400300001008741	2004 Q1	PHARMERICA, Brockton, MA 02301	[REDACTED] MD, Worcester, MA 01605

Certificate of Service

I, Scott Tucker, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: October 17, 2008

/s/Scott Tucker