

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

THE UNITED STATES OF AMERICA
ex rel. DINESH S. THAKUR

and

STATE OF ARKANSAS
ex rel. DINESH S. THAKUR

and

STATE OF CALIFORNIA
ex rel. DINESH S. THAKUR

and

STATE OF DELAWARE
ex rel. DINESH S. THAKUR

and

DISTRICT OF COLUMBIA
ex rel. DINESH S. THAKUR

and

STATE OF FLORIDA
ex rel. DINESH S. THAKUR

and

STATE OF GEORGIA
ex rel. DINESH S. THAKUR

and

STATE OF HAWAII
ex rel. DINESH S. THAKUR

and

Civ. No. 1:07-cv-00962-JFM

**SECOND AMENDED
COMPLAINT UNDER
FEDERAL AND STATE
FALSE CLAIM ACTS**

**FILED *IN CAMERA* AND
UNDER SEAL PURSUANT
TO 31 U.S.C. § 3730(b)(2)**

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Defendants.

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SECOND AMENDED COMPLAINT

COMES NOW, Relator Dinesh S. Thakur, through the undersigned counsel, on behalf of himself and the United States of America (“United States”), the States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, and Utah, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (“States”), and brings this *qui tam* action under the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“Federal FCA”) and false claim statutes enacted by the States, to recover monetary damages, civil penalties, and all other remedies for violations of Federal and State health benefit programs and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), by Defendants Ranbaxy USA, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ranbaxy, Inc., Ohm Laboratories, Inc., and Ranbaxy Laboratories Ltd. (collectively “Ranbaxy”), and hereby alleges as follows.

1. This is a *qui tam* action to recover treble damages, civil penalties, and all other available remedies on behalf of the United States and the States under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (“FCA”), and analogous statutes enforced by the States, arising from Defendants’ scheme to knowingly cause false and fraudulent claims for payment or approval for adulterated and misbranded generic drugs to be presented to the United States and the States under the Medicare program, the Medicaid program, CHAMPUS/TRICARE, the Civilian Health and Medical Program of Veterans Affairs, the

Federal Employee Health Benefits Program, and other health benefit and relief programs, including, but not limited to, the President's Emergency Plan for AIDS Relief ("PEPFAR") program (collectively the "Benefit Programs").

2. Two categories of false claims and statements generally are challenged in the First Amended Complaint. First, Defendants falsified, and conspired to falsify, dossier and other data and documentation filed with the United States Food and Drug Administration ("FDA") in order to gain and retain approval, including First-to-File ("FTF") status, to market and sell their generic drugs in the United States in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Under the Benefit Programs, the United States and the States purchased Defendants' adulterated and misbranded generic drugs, which were not properly demonstrated to be, and in fact were not, bioequivalent to the branded drugs, stable, and/or efficacious to therapeutically treat the diseases for which the drugs were labeled, marketed, and sold. Second, Defendants submitted false data and statements to the United States to gain approval for adulterated generic antiretroviral ("ARV") drugs that were purchased for Federally appropriated relief programs, such as PEPFAR and other initiatives administered by the United States Agency for International Development ("USAID"), in order to provide ARV drug treatments to human immunodeficiency virus ("HIV") patients in developing countries. In each instance, Defendants' fraudulent scheme resulted in false claims and statements made to FDA, the Benefit Programs, health care providers, and private payor programs to induce payment or approval for their adulterated and misbranded drugs.

3. This First Amended Complaint has been filed *in camera* and under seal pursuant to 31 U.S.C. § 3730(b)(2). It will not be served on Defendants until the Court so orders. A copy of the original Complaint and initial written disclosure of substantially all material evidence and information Relator possesses previously were served on the Attorney General of the United States and the United States Attorney for the District of Maryland pursuant to 31 U.S.C. § 3730(b)(2) and Fed. R. Civ. P. 4.

JURISDICTION AND VENUE

4. This Court possesses subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732 because Relator seeks remedies on behalf of the United States and the States for Defendants' violations of 31 U.S.C. § 3729, some of which occurred in the District of Maryland. Defendants transact substantial business within the District of Maryland by marketing and selling generic drugs and regularly interacting with FDA, which is located within this District.

5. The Court may exercise personal jurisdiction over Defendants pursuant to MD. CODE ANN., CTS. & JUD. PROC. § 6-103.

6. This Court has pendant jurisdiction over the Government Entity claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367.

7. The Complaint has been filed timely within the period prescribed by 31 U.S.C. § 3731(b).

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c) because at least one of Defendants resides or transacts business in this

District. In addition, the acts proscribed by the Federal FCA, including the false statements and filings with FDA, were committed by Defendants in this judicial district.

PARTIES

A. Plaintiffs.

9. Plaintiff, the United States of America, by and through its administrative agencies including FDA and the Centers for Medicare & Medicaid Services (“CMS”), is responsible for the administration of all Federal health care programs. FDA, in particular, is responsible for protecting the public health by assuring the safety, efficacy, and security of generic drugs marketed and promoted in the United States.

10. The States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Indiana, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, and Utah, the Commonwealths of Massachusetts and Virginia, and the District of Columbia are named as Plaintiffs pursuant to the Court’s pendant jurisdiction under 31 U.S.C. § 3732 with respect to the related States’ false claims statutes.

B. Relator.

11. Relator is a citizen of the United States and a resident of the Commonwealth of Massachusetts. From June 2003 until April 2005, Relator was the Director of Project & Information Management with Defendant Ranbaxy Laboratories Limited in Gurgaon, Haryana, India. Pursuant to 31 U.S.C. § 3730(e)(4)(B), Relator is the “original source” of the information given to the United States regarding Defendants’

illegal conduct in violation of Federal and State laws. He has direct and independent knowledge of the allegations set forth herein. Relator states that the information concerning Defendants' misconduct was not disclosed publicly prior to his original disclosure to the United States in August 2005.

C. Defendants.

12. Defendant Ranbaxy Laboratories, Ltd. ("Defendant RLL") is a foreign pharmaceutical company organized and existing under the laws of India with its principal place of business located at Plot No. 90, Sector 32, Gurgaon 122001, Haryana, India. Directly and through the other Defendants, Defendant RLL manufactures, markets and sells finished generic drugs and active pharmaceutical ingredients in the United States and within this District. Service upon Defendant RLL is proper through the means authorized by The Hague Convention on the Service Abroad of Judicial and Extra-Judicial Documents in Civil or Commercial Matters ("The Hague Convention") as provided under Fed. R. Civ. P. 4(f). Under Articles Three and Five of The Hague Convention, a request, summons, and complaint may be forwarded to the Central Authority of India located at The Ministry of Law and Justice, Department of Legal Affairs, 4th Floor, A-Wing, Shastri Bhavan, 110 001 New Delhi, India.

13. In 2008, Daiichi Sankyo Company, Ltd. assumed the majority control of Defendant RLL by acquiring 63.92% of Ranbaxy shares in a transaction valued at \$4.6 billion. Daiichi Sankyo is a foreign pharmaceutical company organized under the laws of Japan with its principal place of business located at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan. It markets and sells finished pharmaceuticals throughout the

United States, including within this District. Pursuant to the acquisition, Defendant RLL is a subsidiary of Daiichi Sankyo. Daiichi Sankyo exercises control over Defendant RLL's operations, including those within the United States, and maintains majority control over Defendant RLL's board of directors.

14. As a generic pharmaceutical company doing business in the United States, Defendant RLL and its subsidiaries manufacture, market, and sell finished drugs purchased by the Benefit Programs for program beneficiaries. Defendant RLL claims to possess 241 approved or pending Abbreviated New Drug Applications ("ANDAs") filed with FDA, including 142 approved and 99 pending ANDAs. This includes 19 potential "Paragraph IV" First-to-File ("FTF") ANDAs with a value in excess of \$27 billion at innovator prices.¹ In addition to sales to the Medicare and Medicaid programs, Defendant RLL is a major producer of ARV drugs purchased directly or indirectly by the United States under Federal programs for humanitarian assistance such as PEPFAR.

15. Defendant Ranbaxy Pharmaceuticals, Inc. ("RPI") is a wholly owned subsidiary of Defendant RLL with a principal place of business located at 9431 Florida Mining Boulevard East, Jacksonville, Florida 32257. Its operations in the United States include locations in New Jersey (Princeton and New Brunswick), Jacksonville, Florida,

¹ A FTF ANDA filed with a Paragraph IV certification contains a written certification attesting to the generic manufacturer's belief that a patent for a new drug is "invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A generic company with a FTF ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity if the company prevails in litigation to invalidate the innovator patent. During this exclusivity period, the only competition for the generic manufacturer is the branded product.

and Gloversville, New York. Defendant RPI markets and sells finished generic drugs and active pharmaceutical ingredients manufactured by Ranbaxy. Upon information and belief, the profits from these sales and those of all subsidiaries of Defendant RLL were repatriated in whole or in part to Defendant RLL.

16. Defendant Ranbaxy Laboratories, Inc. (“RLI”) is a wholly-owned subsidiary of Defendant RLL located at 600 College Road East, Suite 2100, Princeton, New Jersey 08540. It is the branded prescription division of Defendant RLL in the United States.

17. Defendant Ranbaxy, Inc. (“RI”) is a Delaware corporation. It is the parent corporation of Defendant RPI in the United States.

18. Defendant Ranbaxy USA, Inc. is wholly-owned subsidiary of Defendant RLL located at 4801 Executive Park Court B-100, Jacksonville, Florida 32216.

19. Defendant Ohm Laboratories, Inc. (“Ohm”) is a subsidiary of RPI. It is located at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

20. At all times hereinafter mentioned, Defendants conspired to violate the FDCA, the Federal FCA, and the false claim statutes enacted by the States in connection with the approval, marketing, and sale of adulterated and misbranded generic drugs throughout the United States.

THE HEALTH CARE AND FEDERALLY-FUNDED RELIEF PROGRAMS

21. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Medicare is a health financing program for the elderly. Entitlement to Medicare is based on age, disability, or affliction with end-

stage renal disease. 42 U.S.C. §§ 426, 426A. Medicare is administered by the Center for Medicare and Medicaid Services (“CMS”).

22. Medicare pays for beneficiaries’ use of generic drugs under Parts A or D. Part A covers prescription drugs received by beneficiaries while inpatients at hospitals or skilled nursing facilities during covered stays. In most instances, payment for the drugs are bundled together with other Medicare Part A reimbursable items. Part D refers to the Federal program to subsidize the costs of prescription drugs for Medicare beneficiaries enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act effective January 2006. Under Part D, the United States pays for outpatient prescription drugs of eligible Medicare participants by joining a qualified prescription drug plan or participating in the Medicare Advantage plan.

23. The Medicaid program is a health insurance program for qualified beneficiaries funded by Federal and State monies and enacted pursuant to Title XIX of the Social Security Act. 42 U.S.C. §§ 1396-1396v. Each State is permitted to design its own medical assistance plan. 42 U.S.C. § 1396a. The plans permit medical assistance in the form of outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A) & 1396d(a)(12).

24. CHAMPUS/TRICARE is a health care program providing health benefits, including prescription generic drug coverage for active duty military personnel, retirees, and their dependents. The Civilian Health and Medical Program of Veterans Affairs (“CHAMPVA”) provides similar services and coverage for prescription generic drugs through the Veteran’s Administration health system. The Federal Employee Health Benefits Program provides health care benefits, including prescription drugs, to Federal

employees, former employees, and survivors. In addition to these health care programs, the United States directly purchased Defendants' adulterated and misbranded drugs pursuant to programs administered by the Department of Veteran Affairs, which maintains medical facilities for approximately four million veterans, and the Department of Defense, which provides medical benefits to approximately eight million active duty military personnel, retirees, and their families.

25. The PEPFAR program is a Federally-appropriated relief program designed to, among other aspects, provide generic ARV drugs to HIV-infected patients in 120 countries. By early 2006, FDA had approved only 15 ARV products for PEPFAR, three of which were ANDAs filed by Defendants. Congress authorized the creation of an HIV/AIDS Working Capital Fund for the purpose of purchasing ARV drugs. 22 U.S.C. §§ 7612a(1)-(2). Each year, the United States funds the HIV/AIDS Working Capital Fund "for HIV/AIDS pharmaceuticals and products provided from the HIV/AIDS Fund received from applicable appropriations and funds" of USAID, the Department of Health and Human Services, the Department of Defense, "or other Federal agencies and other sources at actual cost of the HIV/AIDS pharmaceuticals and other products, actual cost plus the additional costs of provide such HIV/AIDSS pharmaceuticals and other products, or at any other price agreed to by the" Coordinator of the United States Government Activities to Combat HIV/AIDS Globally. 22 U.S.C. § 7612a(3). In addition to PEPFAR, the United States has purchased the ARV drugs as a part of other Federally-funded programs such as The Global Fund.

FEDERAL AND STATE FALSE CLAIMS ACTS

26. The Federal FCA, 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim made, is liable to the United States for a civil money penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

27. The Federal FCA also provides that any person who conspires to violate any provision of the Federal FCA is liable to the United States for a civil money penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(C).

28. The terms “knowing” and “knowingly” are defined to mean “that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). These terms “require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1)(B).

29. The term “claim” is defined to mean “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such

contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded” 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

30. The States have enacted false claims statutes, the provisions of which mirror the Federal FCA provided in preceding paragraphs. Relator asserts claims under the statutes enacted by the States for the State portion of Medicaid false claims as stated herein. Relator’s disclosure of substantially all material evidence and information Relator possesses will be served upon State officials as required by State law, including any supplemental disclosure statements.

FEDERAL REQUIREMENTS FOR GENERIC DRUGS

31. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, amended the FDCA by, among other aspects, enacting an Abbreviated New Drug Application (“ANDA”) approval process allowing lower-priced generic drugs of previously approved innovator (listed) drugs to be approved and marketed in the United States. 21 U.S.C. § 355(j).

32. Among other requirements, ANDAs filed with FDA must include the following: (a) a statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug; (b) a statement that the active pharmaceutical ingredient in the drug is the same as the listed drug; (c) a statement that the route of administration, the dosage form, and the strength of the generic drug are the same as those of the listed drug; (d) a statement that the generic drug is bioequivalent to the listed drug; and (e) a statement that the labeling proposed for the new drug is the same as the labeling approved for the listed drug. 21

U.S.C. § 355(j)(2) and 21 C.F.R. § 314.94. An ANDA application must include a certification by the applicant that the underlying patent has not been filed (Paragraph I certification), the underlying patent has expired (Paragraph II certification), the date on which the patent will expire (Paragraph III certification), or a statement that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (Paragraph IV certification). In addition, a generic drug manufacturer is required by statute and regulation to timely file annual reports with FDA on Form FDA 2252 for each approved ANDA. The annual reports must identify chemistry, manufacturing, formulation, or control changes from those approved by FDA, along with batch-specific stability reports for the drug substance or product. 21 C.F.R. §§ 314.70 & 314.81. Mandatory annual reporting is designed to identify deviations that arise during commercialization of a drug, as compared to the protocols and specifications approved by FDA prior to commercial manufacturing, particularly as these deviations might affect the safety, effectiveness, or labeling of the product.

33. FDA has promulgated specific requirements for filing ANDAs and marketing generic drugs in the United States consistent with FDA's current good manufacturing practices ("cGMP"). The stated purpose of FDA's requirements is to ensure that drugs which are not safe and effective are not marketed and sold in the United States. 21 C.F.R. § 314.2.

34. Among other requirements, the generic drug subject to an ANDA must be demonstrated to be bioequivalent to the brand drug. Bioequivalence means "the absence of a significant difference in the rate and extent to which the active ingredient or active

moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 C.F.R. § 320.1.

35. The generic drug also must be stable. Stability refers to the capacity of a finished drug or drug product to remain with established specifications and maintain its identity, strength, quality and purity throughout its shelf life. FDA requires a written stability testing program to assess and monitor the stability characteristics of drug products in order to determine the appropriate storage conditions and expiration dates. 21 C.F.R. § 211.166. FDA’s stability regulations requires regular, reliable, and verifiable testing of the drug in the same container to be used in marketing the product.

36. The generic drug manufacturer, whether located in the United States or abroad, must comply with FDA’s current good manufacturing practices (“cGMP”) set forth at 21 C.F.R. § 211 *et seq.* in order to market and sell products in the United States. cGMP requirements regulate the control, management, and documentation of manufacturing and quality testing of generic drugs.

37. Deviation from cGMP regulations renders the generic drug adulterated or contaminated within the meaning of section 501(a)(2)(B) of the FDCA. 21 U.S.C. § 351(a)(1)(B). A generic drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with cGMPs to assure that the drug meets the requirements of the FDCA as to safety, identity, strength, quality, and purity characteristics it purports to possess. 21 U.S.C. § 351(a)(1)(B).

38. A generic drug is misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

39. FDA is authorized to reject an ANDA for any of the following reasons: (a) the application contains an untrue statement of material fact; (b) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity; (c) anomalies between the API in the innovator drug and the API in the ANDA, such as impurities or substandard API; (d) the information submitted in the ANDA is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug; or (e) the information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application. 21 U.S.C. § 355(j)(4).

40. The FDCA imposes civil and criminal penalties for violations of the FDCA or FDA's implementing regulations, including, for example, manufacturing, or shipping in interstate commerce an adulterated generic drug and the adulteration or misbranding of a generic drug. 21 U.S.C. § 331.

41. FDA is authorized to withdraw an ANDA if an approval was obtained through a material false statement or contains an untrue statement of material fact." 21 U.S.C. § 355(e).

DEFENDANTS' WRONGFUL ACTS

42. Relator is the former Director of Research Information & Project Management for Defendant RLL. He was hired on or about November 28, 2002. He

relocated from the United States to India and began working on-site at the company's Research and Development Center in Gurgaon, Haryana, India, at the end of June 2003. He resigned his position in or about April 2005.

43. Relator's job responsibilities gave him access to Defendants' portfolio of drugs sold in the United States and abroad. Relator had responsibility for portfolio and product management. He established a program management office which oversaw internal data created during the formulation and manufacturing of generic drugs. This complex process required Relator to compile information aggregating generic drug formulation, bioequivalence, and stability data, among other data. The purpose of the data management was to coordinate the filing and approval of ANDAs to coincide with two pivotal marketing opportunities: marketing exclusivity granted by FDA and patent invalidity. He prepared detailed status evaluations and revenue projections for each drug in Defendants' portfolio based on four global regions of business operations, including the United States market. Relator also was in charge of research and development informatics. This involved cutting-edge information technology initiatives designed and implemented by Relator to perform tasks, such as creating systems to file ANDAs electronically; collecting, managing, and reporting on Defendants' clinical data, including bioequivalence information; and creating an automated data archival system.

44. Relator's job responsibilities gave him comprehensive knowledge of, and access to, Defendant RLL's internal data pertaining to global operations, as well as specific data related to individual generic drugs under development, filed with regulatory

authorities, or approved by FDA in tentative or final form. Relator also had regular contact with Defendants' senior management.

45. In or about August 2004, Relator began a comprehensive, company-wide investigation and audit of Defendants' ARV drug and non-ARV drug portfolio. Relator undertook the investigation with the knowledge, authority, and support of Dr. Rajinder Kumar, then the Head of Research and Development for Defendant RLL. He reported to Dr. Kumar.

46. The purpose of the investigation was to assess whether Defendants and/or their authorized contract research organizations had falsified data for ARV and non-ARV drugs in order to gain approval for marketing the generic drugs in the United States and abroad.

47. Relator compiled a list of all Defendants' ARV drugs then in development or already approved for marketing. The list included, for example, (a) Lamivudine 150 mg plus Stavudine 30 mg; (b) Lamivudine 150 mg plus Stavudine 40 mg; (c) Lamivudine 150 mg plus Zidovudine 300 mg tablet; (d) Lamivudine 150 mg tablet; (e) Nevirapine 200 mg tablet; (f) Stavudine 30 mg capsule; (g) Zidovudine 300 mg tablet; and (h) Indinavir 400 mg capsule. The ARV drugs were sold in various combinations consistent with prescribed medical therapies to treat the HIV virus. Each of the products is a generic version of a patented (or then patented) listed drug.

48. After identifying the ARV drugs manufactured by Defendants, Relator contacted the functional groups responsible for the formulation, testing, and post-registration commercial manufacturing of the generic drugs. As part of his investigation,

Relator requested the underlying records and raw data (patient records, stability tests, chromatograms, etc.) allegedly substantiating the drugs' formulation, bioequivalence, and stability data filed with regulatory bodies.² He discovered that there was little or no underlying data or, to the extent the data existed at all, Defendants had fabricated it.

49. Relator interviewed management of Defendant RLL during the investigation to identify the extent and scope of the data fraud. Interviews were conducted with managers in charge of bioequivalence studies, stability studies, regulatory affairs, quality assurance, and scale-up operations, among other departments. During these meetings, Relator confirmed that Defendants had engaged in a pattern of conduct to knowingly fabricate data that was incorporated into filings with regulators in an effort to deceive regulators into approving Defendants' generic drugs. The falsified data affected the entire portfolio of generic ARV drugs manufactured by Defendants. The data was falsified with the knowledge, approval, and at the direction of senior management of Defendants located in India and the United States.

50. Defendants subsequently withdrew the generic ARV drugs from marketing globally. Upon information and belief, Defendants had substantial sales of the ARV drugs prior to withdrawing them from the market.

51. At or about the same time period of Relator's investigation, Defendants, including its subsidiaries based in the United States, filed applications with FDA to gain approval to sell numerous ARV drugs through the PEPFAR program. Ranbaxy filed these

² Defendants sell generic drugs in virtually every country in the world. They are required to satisfy country-specific regulatory requirements before marketing their drugs, as well as any multi-national regulations (e.g., European Union) concerning the approval and marketing of the products.

applications and certifications made thereto with the knowledge that the supporting data, in whole or in part, was fabricated. Ranbaxy concealed this from FDA.

52. Based on Defendants' false representations and certifications in the applications, FDA granted approval to three ARV drugs. On May 27, 2005, the Office of Generic Drugs granted tentative approval to ANDA 77-357 held by Defendant RLL for Lamivudine Tablets, 150 mg for sale into PEPFAR.³ In June 2005, Defendant RLL's application for Nevirapine 200 mg tablets was approved, which is a class of drugs called non-nucleoside reverse transcriptase inhibitors used in combination with other antiretroviral agents for the treatment of HIV-1 infection. On July 13, 2005, FDA tentatively approved Defendant's RLL's generic Zidovudine 300 mg tablets, and granted final approval of the drug on September 19, 2005, thereby clearing the way for full marketing authorization in the United States.

53. Relator broadened his investigation to include all generic products manufactured and sold by Defendants. During the next several months (August-November 2004), Relator compiled information about fraudulent practices and data in Defendants' entire generic portfolio. He regularly apprised Dr. Kumar of his investigation.

54. Relator identified specific drugs, their registration status in particular countries, and the missing or falsified data for each. The problems he identified implicated the quality of hundreds of generic drugs sold by Defendants, including the following fraudulent practices violating cGMP requirements and rendering the drugs adulterated:

³ Tentative approval means that existing patents or exclusivity prevent marketing of the product in the United States. However, the drug is eligible for purchase and use outside the United States under PEPFAR.

- A. Bioequivalence studies were filed with regulatory authorities based on formulations which were different from the formulation documented to the regulators;
- B. Bioequivalence data was falsified;
- C. Bioequivalence studies for some drugs were conducted on innovator drugs which were ground up, encapsulated, and misrepresented as a formulation developed by Defendants;
- D. Bioequivalence and stability studies were conducted on small research and development batches of product, as opposed to exhibit batches;
- E. Stability studies filed with regulatory authorities were fabricated;
- F. Stability studies filed with regulatory authorities were of a different formulation than proposed;
- G. Stability studies were performed in one manufacturing location but filed as at a different location;
- H. Individual dissolution values in the stability studies were fabricated;
- I. Batch sizes for stability and bioequivalence were intentionally misrepresented in the registration of the products;
- J. Stability shelf-life data was fabricated and submitted as part of the registration;
- K. Substandard API that failed testing and specifications was blended with good API in an effort to have the drug pass specifications;

- L. Research, development, and commercial manufacturing of the generic drugs were not in compliance with current good manufacturing practices as required by the FDCA.

Each of these fraudulent practices is a separate violation of the Federal FCA and States' false claims statutes, the FDCA, and Federal regulations.

55. The formulation problems, falsification of bioequivalence and/or stability data, and commercial manufacturing of drugs that failed to comply with cGMP requirements affected all ANDAs filed with FDA between 1998 and 2005 and continued thereafter. For example, the affected drugs include, but are not limited to, the following finished drugs, thereby rendering the drugs adulterated and misbranded:

- A. Cefuroxime Axetil 125 mg, 250 mg, 500 mg (generic of Ceftin®);
- B. Sotret (Isotretinoin) 10 mg, 20 mg, 40 mg (generic of Accutane®);
- C. Simvastatin 5 mg, 10 mg, 20 mg, 40 mg, 80 mg (generic of Zocor®);
- D. Quinapril Hydrochloride tablets 5 mg, 10 mg, 20 mg, and 40 mg (generic of Accupril®);
- E. Pravastatin Sodium tablets 10 mg, 20 mg, 40 mg, and 80 mg (generic of Pravachol®).

56. There were API, quality deficiencies, and data falsification with other generic products manufactured for sale in the United States rendering the products adulterated and misbranded including, but not limited to, the following drugs and drug products: Clarithromycin Gel, Esomeprazole, Cephalosporin antibiotics, Amoxicillin Chewable Tablets, Amoxicillin Oral Suspension 200 mg, Amoxicillin Oral Suspension 400

mg batch, Cefpodoxime Proxetil, Terbinafine, Sirolimus, Cefditoren, Pivoxil Tablets 200 mg, Calcitriol Softgels, Triviro LS 30/40 Tablets, Coviro LS 30/40 Tablets.

57. Relator notified Dr. Kumar of his findings, who reported them to senior management. On or about September 21-24, 2004, during a closed-door board of directors meeting in Thailand, Dr. Kumar addressed the board about the data falsification. In advance of the meeting, Relator prepared a spreadsheet and other documents illustrating the drugs impacted and the issue(s) with Defendants' false data. Upon information and belief, Dr. Kumar notified the board members of Relator's investigation and the systemic fraud in formulation, bioequivalence, and stability filings with regulators in the United States and other countries to obtain approval for the ARVs and non-ARV drugs in Defendants' portfolio.

58. In December 2004, Dr. Kumar addressed a subset of the board held out as a scientific committee. In advance of the meeting, Relator prepared documentation for use by Dr. Kumar to brief the meeting participants on Relator's findings. The documentation addressed the risk to Defendants ANDA portfolio, some of the affected drugs, the fraud discovered by Relator, and a patient-oriented mitigation plan.

59. Upon information and belief, Defendants knowingly concealed from authorities the FDCA and other law violations and requested that Dr. Kumar destroy the evidence of the fraud. Dr. Kumar responded by resigning, although his resignation was not formally announced until March 2005.

60. Defendants failed to disclose the violations of the FDCA and other laws as set forth herein to FDA or Federal or State authorities. As a result, false or fraudulent

claims for reimbursement related to the adulterated ARV drugs and non-ARV drugs manufactured by Defendants were paid or approved under the Government Benefit Programs, as well as other Federally-appropriated relief programs, such as PEPFAR.

61. At all times relevant to these false claims and certifications, Defendants knew that the generic drugs were not properly demonstrated to be, and in fact were not, bioequivalent to the branded drugs, stable, and/or efficacious to therapeutically treat the infectious diseases and other medical conditions claimed in labeling and marketing of the products and, thereby, directly endangered the health and welfare of patients.

62. As a result of the acts and practices described here, Defendants subjected patients to increased risks of morbidity and mortality.

DAMAGES

63. The United States and the States have been damaged by the acts and practices of Defendants, as described above, in presenting, causing to be presented, and conspiring to present false claims, statements and records to induce the payment for generic drugs which were adulterated and misbranded and not entitled to payment.

64. Defendants' false statements were material to the decision of the United States to approve the ANDAs and subsequently purchase the adulterated and misbranded generic drugs for use by beneficiaries of the Benefit Programs.

65. Defendants profited unlawfully from the payment of the false and fraudulent claims.

COUNT I

VIOLATIONS OF THE FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(A)

66. Relator restates and realleges the allegations contained in paragraphs 1-65 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

67. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), provides in relevant part that any person who:

knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . .

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of damages which the Government sustains because of the act of that person. . . .

68. By virtue of the acts described herein, Defendants knowingly presented, or caused to be presented, to officers, employees, or agents of the United States and the States under the Benefit Programs, false or fraudulent claims for payment or approval of adulterated and misbranded generic drugs. Defendants knew that these claims for payment or approval were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

69. Each claim presented or caused to be presented for reimbursement of one of Defendants' adulterated and misbranded generic drugs represents a false or fraudulent claim for payment under the Federal FCA and the States' false claim statutes.

70. Unaware that Defendants submitted fabricated data and other false statements to conceal their systemic violation of cGMPs, and unaware that Defendants routinely falsely certified compliance with cGMPs despite pervasive and substantial non-compliance with the regulations, the United States and the States paid and continue to pay the false claims submitted for Defendants' drugs. These claims would not have been paid but for Defendants' fraud and false statements.

71. In reliance on the accuracy of Defendants' data, representations, and certifications, the United States and the States have paid said claims and have suffered financial losses because of these acts by Defendants.

COUNT II

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(B)

72. Relator restates and realleges the allegations contained in paragraphs 1-71 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

73. The False Claims Act, 31 U.S.C. § 3729(a)(1)(B), provides in relevant part that any person who:

knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of damages which the Government sustains because of the act of that person. . . .

74. By virtue of the acts described herein, Defendants knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment or approval of adulterated and misbranded generic drugs. Defendants knew that the records or statements were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

75. Each claim presented or caused to be presented for reimbursement of one of Defendants' adulterated and misbranded generic represents a false or fraudulent record or statement under the Federal FCA and the States' false claim statutes.

76. Unaware that Defendants submitted fabricated data and other false statements to conceal their systemic violation of cGMPs, and unaware that Defendants routinely falsely certified compliance with cGMPs despite pervasive and substantial non-compliance with the regulations, the United States and the States paid and continue to pay the false claims submitted for Defendants' drugs. These claims would not have been paid but for Defendants' fraud and false statements.

77. In reliance on the accuracy of Defendants' data, representations, and certifications, the United States and the States have paid said claims and have suffered financial losses because of these acts by Defendants.

COUNT III

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(C)

78. Relator restates and realleges the allegations contained in paragraphs 1-77 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

79. The False Claims Act, 31 U.S.C. § 3729(a)(1)(C), provides in relevant part that any person who:

conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G) . . .

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of damages which the Government sustains because of the act of that person. . . .

80. By virtue of the acts described herein, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and (B) by knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval and by knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims. Defendants knew that these claims were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

81. Unaware of the conspiracy to submit fabricated data and other false statements to conceal their systemic violation of cGMPs, and unaware that Defendants routinely falsely certified compliance with cGMPs despite pervasive and substantial non-

compliance with the regulations, the United States and the States paid and continue to pay the false claims submitted for Defendants' drugs. These claims would not have been paid but for Defendants' fraud and false statements.

82. In reliance on the accuracy of Defendants' data, representations, and certifications, the United States and the States have paid said claims and have suffered financial losses because of these acts by Defendants.

PRAYER AS TO COUNTS I-III

WHEREFORE, Relator prays that this District Court enter judgment on behalf of Relator and against Defendants in Counts I-III, respectively, for the following:

- a. Damages in the amount of three (3) times the actual damages suffered by the United States Government as a result of each Defendants' conduct;
- b. Civil penalties against the Defendants, respectively, equal to not less than \$5,000 and not more than \$10,000, adjusted for inflation according to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, for each violation of 31 U.S.C. § 3729;
- c. The fair and reasonable sum to which Relator is entitled under 31 U.S.C. § 3730(b); additionally, Relator is entitled, in equity, to recover attorneys' fees from the fund created for non-participating beneficiaries (those not contributing material time and expense to generating any settlement or recovery from any Defendant) under the Common Fund doctrine to be paid from the recovery fund generated for such non-participatory beneficiaries from the defendants;

- d. All costs and expenses of this litigation, including statutory attorneys' fees and costs of court;
- e. Pre-judgment and post-judgment, as appropriate, interest at the highest rate allowed by law;
- f. Relator's individual damages, if any, which may be alleged; and
- g. All other relief on behalf of Relator or the United States Government to which they may be justly entitled, under law or in equity, and the District Court deems just and proper.

COUNT IV

VIOLATIONS OF THE ARKANSAS MEDICAID FCA

ARK. CODE ANN. § 20-77-902(1)-(3)

83. Relator restates and realleges the allegations contained in paragraphs 1-82 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

84. This action is brought by Dinesh S. Thakur and the State of Arkansas to recover treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, ARK. CODE ANN. § 20-77-902(1)-(3) *et seq.*

85. Arkansas Code Ann. § 20-77-902 provides liability for any person who-

- (1) Knowingly makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program;
- (2) At any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment; or

- (3) Having knowledge of the occurrence of any event affecting his or her initial or continued right to any benefit or payment or the initial or continued right to any benefit or payment of any other individual in whose behalf he or she has applied for or is receiving a benefit or payment knowingly conceals or fails to disclose that event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized.

86. Any person violating § 20-77-902(1)-(3) is subject to liability in the amount of full restitution and for a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation, plus three (3) times the amount of all payments judicially found to have been fraudulently received from the Arkansas Medicaid program or its fiscal agents because of the act of that person.

87. Defendants knowingly made or caused to be made false statements and representations of material facts and concealed or failed to disclose the information alleged herein with respect to payments under the Arkansas Medicaid Program for Defendants' adulterated and misbranded generic drugs in violation of § 20-77-902(1)-(3).

88. The State of Arkansas, by and through the Medicaid program and other State health care programs, was unaware of Defendants' fraudulent and illegal practices and paid the claims submitted by health care providers and third party payers for Defendants' adulterated and misbranded generic drugs.

89. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Arkansas. Had the State of Arkansas known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

90. The State of Arkansas has sustained damages relating to its portion of Medicaid losses from Medicaid claims filed in Arkansas because of these acts by Defendants.

91. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to ARK. CODE ANN. § 20-77-902 on behalf of himself and the State of Arkansas.

92. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Arkansas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF ARKANSAS:

- (1) Three times the amount of actual damages which the State of Arkansas has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Arkansas;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to Arkansas Code Ann. § 20-77-902 *et seq.* and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;

- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT V

VIOLATIONS OF THE CALIFORNIA FCA

CAL. GOV'T CODE § 12651(a)

93. Relator restates and realleges the allegations contained in paragraphs 1-92 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

94. This is a *qui tam* action brought by Dinesh S. Thakur and the State of California to recover treble damages and civil penalties under the California False Claims Act, CAL. GOV'T CODE § 12650 *et seq.*

95. CAL. GOV'T CODE § 12651(a) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
- (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.

96. Defendants violated CAL. GOV'T CODE § 12651(a)(1)-(3) and knowingly caused false claims to be made, used and presented to the State of California by their violations of Federal and State laws, including, CAL. BUS. & PROF. CODE § 650 and 650.1

To the STATE OF CALIFORNIA:

- (1) Three times the amount of actual damages which the State of California has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of California;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to CAL. GOV'T CODE § 12652 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VI

VIOLATIONS OF THE DELAWARE FCA

DEL. CODE ANN. tit. 6, § 1201

102. Relator restates and realleges the allegations contained in paragraphs 1-101 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

103. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, DEL. CODE ANN. tit. 6, ch. 12.

104. DEL. CODE ANN tit. 6, § 1201(a) provides liability for any person who, inter alia:

- (1) Knowingly presents, or causes to be presented to an officer or employee of the Government a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government;
- (3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

105. Defendants violated DEL. CODE ANN tit. 6, § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by their violations of Federal and State laws, for Defendants' adulterated and misbranded generic drugs.

106. The State of Delaware, by and through the Delaware Medicaid program and other State health care programs, was unaware of Defendants' fraudulent and illegal practices and paid the claims submitted by health care providers and third party payers in connection therewith.

107. Compliance with applicable Medicare, Delaware Medicaid, and various other Federal and State laws was a condition of payment of claims submitted to the State of Delaware. Had the State of Delaware known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

108. As a result of Defendants' violations of DEL. CODE ANN tit. 6, § 1201(a), the State of Delaware has been damaged.

109. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to DEL. CODE ANN tit. 6, § 1201(b) on behalf of himself and the State of Delaware.

110. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF DELAWARE:

- (1) Three times the amount of actual damages which the State of Delaware has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which each Defendant presented or caused to be presented to the State of Delaware;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to DEL. CODE ANN tit. 6, § 1205 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VII

**VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT
REFORM AMENDMENT ACT**

D.C. CODE ANN. § 2-308.13 *et seq.*

111. Relator restates and realleges the allegations contained in paragraphs 1-110 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

112. This is a *qui tam* action brought by Dinesh S. Thakur and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. CODE ANN. § 2-308-13 *et seq.*

113. D.C. CODE ANN § 2-308-14(a) provides liability for any person who:

- (a) Knowingly presents, or causes to be presented, to an officer of employee of the District a false claim for payment or approval;
- (b) Knowing makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
- (c) Conspires to defraud the District by getting a false claim allowed or paid by the District

114. Defendants violated these Code provision and knowingly caused false claims to be made, used and presented to the District of Columbia by their violations of Federal and State laws for Defendants' adulterated and misbranded generic drugs as alleged herein.

115. The District, by and through the District's Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

116. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the District.

117. Had the District known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

118. As a result of Defendants' violations, the District has been damaged.

119. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to the Code provisions on behalf of himself and the District.

120. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the DISTRICT OF COLUMBIA:

- (1) Three times the amount of actual damages which the District of Columbia has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which each Defendant presented or caused to be presented to the District of Columbia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to D.C. CODE ANN. § 2-308-13 *et seq.* and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VIII

VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. ANN. § 68.081 *et seq.*

121. Relator restates and realleges the allegations contained in paragraphs 1-120 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

122. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, FLA. STAT. ANN. § 68.081 *et seq.*

123. FLA. STAT. ANN. § 68.082(2) provides liability for any person who-

- (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
- (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;
- (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

124. Defendants violated FLA. STAT. ANN. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by their violations of Federal and State laws for Defendants' adulterated and misbranded generic drugs as alleged herein.

125. The State of Florida, by and through the Florida Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

126. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Florida.

127. Had the State of Florida known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

128. As a result of Defendants' violations of FLA. STAT. ANN. § 68.082(2), the State of Florida has been damaged.

129. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to FLA. STAT. ANN. § 68.083(2) on behalf of himself and the State of Florida.

130. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

To the STATE OF FLORIDA:

- (1) Three times the amount of actual damages which the State of Florida has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Florida;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to FLA. STAT. ANN. § 68.085 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT IX

VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. § 49-4-168.1

131. Relator restates and realleges the allegations contained in paragraphs 1-130 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

132. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Georgia to recover treble damages and civil penalties under the Georgia State False Medicaid Claims Act, GA. CODE ANN. §§ 49-4-168 to 168.6.

133. GA. CODE ANN. § 49-4-168.1 provides liability for any person who:

- (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
- (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

134. Defendants violated GA. CODE ANN. § 49-4-168.1 and knowingly caused false claims to be made, used and presented to the State of Georgia by their violations of Federal and State laws for Defendants' adulterated and misbranded generic drugs as alleged herein.

135. The State of Georgia, by and through the Georgia Medicaid program, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

136. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Georgia. As a result of Defendants' violations of GA. CODE ANN. § 49-4-168.1, the State of Georgia has been damaged.

137. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint who has brought this action pursuant to GA. CODE ANN. § 49-4-168.2 on behalf of himself and the State of Georgia.

138. This Court is requested to accept pendant jurisdiction of this related State claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF GEORGIA:

- (1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Georgia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to GA. CODE ANN. § 49-4-168.2(i) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT X

VIOLATIONS OF THE HAWAII FALSE CLAIMS ACT

HAW. REV. STAT. § 661-21

139. Relator restates and realleges the allegations contained in paragraphs 1-138 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

140. This is a *qui tam* action brought by Dinesh. S. Thakur and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, HAW. REV. STAT. § 661-21 *et seq.*

141. HAW. REV. STAT. § 661-21 provides liability for any person who:

- (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
- (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

142. Defendants violated HAW. REV. STAT. § 661-21 and knowingly caused false claims to be made, used and presented to the State of Hawaii by their violations of Federal and State laws for Defendants' adulterated and misbranded generic drugs as described herein.

143. The State of Hawaii, by and through the Hawaii Medicaid program, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

144. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Hawaii. As a result of Defendants' violations of HAW. REV. STAT. § 661-21, the State of Hawaii has been damaged.

145. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint who has brought this action pursuant to HAW. REV. STAT. § 661-25 on behalf of himself and the State of Hawaii.

146. This Court is requested to accept pendant jurisdiction of this related State claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF HAWAII:

- (1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to HAW. REV. STAT. § 661-27 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XI

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. 175/1 *et seq.*

147. Relator restates and realleges the allegations contained in paragraphs 1-146 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

148. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. 175/1 *et seq.* 740 ILL. COMP. STAT. 175/3(a) provides liability for any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
- (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

149. Defendants violated 740 ILL. COMP. STAT. 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by their violations of Federal and State laws, including 305 ILL. COMP. STAT. 5/8A-3(b), for Defendants' adulterated and misbranded generic drugs as described herein.

150. The State of Illinois, by and through the Illinois Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

151. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Illinois. As a result of Defendants' violations of 740 ILL. COMP. STAT. 175/3(a), the State of Illinois has been damaged.

152. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint who has brought this action pursuant to 740 ILL. COMP. STAT. 175/3(b) on behalf of himself and the State of Illinois.

153. This Court is requested to accept pendant jurisdiction of this related State claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

- (1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' fraudulent and illegal

practices;

- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Illinois;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to 740 ILL. COMP. STAT. 175/4(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XII

VIOLATIONS OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE ANN. § 5-11-5.5-1 *et seq.*

154. Relator restates and realleges the allegations contained in paragraphs 1-153 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

155. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-1 *et seq.* IND. CODE ANN. § 5-11-5.5-2(b) provides liability for any person who knowingly or intentionally:

- (1) presents a false claim to the state for payment or approval;

- (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the State;

* * *

- (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
- (8) causes or induces another person to perform an act described in subdivisions (1) through (6);

156. Defendants violated IND. CODE ANN. § 5-11-5.5-2(b) and knowingly or intentionally caused false claims to be made, used and presented to the State of Indiana by their violations of Federal and State laws, for Defendants' adulterated and misbranded generic drugs as described herein.

157. The State of Indiana, by and through the Indiana Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

158. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Indiana. As a result of Defendants' violations of IND. CODE ANN. § 5-11-5.5-2(b), the State of Indiana has been damaged.

159. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint who has brought this action pursuant to IND. CODE ANN. § 5-11-5.5-4 on behalf of himself and the State of Indiana.

160. This Court is requested to accept pendant jurisdiction of this related State claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF INDIANA:

- (1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of at least \$5,000 for each false claim which Defendants caused to be presented to the State of Indiana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XIII

**VIOLATIONS OF THE LOUISIANA MEDICAL ASSISTANCE
PROGRAMS INTEGRITY LAW**

LA. REV. STAT. ANN. § 46:437.1 *et seq.*

161. Relator restates and realleges the allegations contained in paragraphs 1-160 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

162. This is a *qui tam* action brought by Dinesh S. Thakur and the State Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. ANN. § 46:437.1 *et seq.*

163. LA. REV. STAT. ANN. § 46:438.3 provides:

- A. No person shall knowingly present or cause to be presented a false or fraudulent claim.
- B. No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.
- C. No person shall knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.
- D. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

164. Defendants violated the Louisiana Medical Assistance Programs Integrity Law and knowingly caused false claims to be made, used and presented to the State of Louisiana by their violations of Federal and State laws for Defendants' adulterated and misbranded generic drugs as described herein.

165. The State of Louisiana, by and through the Louisiana Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

166. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Louisiana. Had the State of Louisiana known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

167. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to LA. REV. STAT. ANN. §439.1(A) on behalf of himself and the State of Louisiana.

168. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

- (1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to LA. REV. STAT. ANN. § 439.4(A) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XIV

VIOLATIONS OF THE MASSACHUSETTS FCA

MASS. GEN. LAWS Ann. ch. 12, § 5(A) *et seq.*

169. Relator restates and realleges the allegations contained in paragraphs 1-168 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference

170. This is a *qui tam* action, brought by Dinesh S. Thakur and the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, MASS. GEN. LAWS ANN. ch. 12, § 5A *et seq.*

171. MASS. GEN. LAWS ANN. ch. 12, § 5B provides liability for any person who:

- (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;
- (3) conspires to defraud the commonwealth or any political subdivision

thereof through the allowance or payment of a fraudulent claim;

- (4) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

172. Defendants violated MASS. GEN. LAWS ANN. ch. 12, § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts for Defendants' adulterated and misbranded generic drugs as described herein.

173. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

174. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the Commonwealth of Massachusetts. Had the Commonwealth of Massachusetts known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

175. As a result of Defendants' violations of MASS. GEN. LAWS ANN. ch. 12, § 5B, the Commonwealth of Massachusetts has been damaged.

176. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to

MASS. GEN. LAWS ANN. ch. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

177. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF MASSACHUSETTS:

- (1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to MASS. GEN. LAWS ANN. ch. 12, §5F and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XV

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS § 400.601 *et seq.*

178. Relator restates and realleges the allegations contained in paragraphs 1-177 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

179. This is a *qui tam* action brought Dinesh S. Thakur and the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act, MICH. COMP. LAWS § 400.601 *et seq.* Section 400.603 states:

- (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.
- (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit.
- (3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf he has applied for or is receiving a benefit, shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.

180. MICH. COMP. LAWS § 400.606 states:

- (1) A person shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false 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.

181. MICH. COMP. LAWS § 400.607 states:

- (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false.

182. Defendants violated MICH. COMP. LAWS §§ 400.603, 400.606, & 400.607 and knowingly caused false claims to be made, used and presented to the State of Michigan for Defendants' adulterated and misbranded generic drugs as described herein.

183. Defendants' violations of MICH. COMP. LAWS §§ 400.603, 400.606, & 400.607 and various other Federal and State laws caused false claims to be submitted for payment to the State of Michigan.

184. The State of Michigan, by and through the Michigan Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

185. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Michigan.

186. Had the State of Michigan known that Defendants violated the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

187. As a result of Defendants' violations of MICH. COMP. LAWS §§ 400.603, 400.606, & 400.607, the State of Michigan has been damaged.

188. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to MICH. COMP. LAWS § 400.610a on behalf of himself and the State of Michigan.

189. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MICHIGAN:

- (1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Michigan;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to MICH. COMP. LAWS § 400.610a and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XVI

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT

Mont. Code Ann. § 17-8-401 *et seq.*

190. Relator restates and realleges the allegations contained in paragraphs 1-189 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference

191. This is a *qui tam* action brought by Dinesh S. Thakur for treble damages and penalties under the Montana False Claims Act, MONT. CODE ANN. § 17-8-401 *et seq.*

192. MONT. CODE ANN. § 17-8-403 provides liability for any person who:

- (a) knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
- (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
- (c) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity;

193. In addition, MONT. CODE ANN. § 45-6-313 prohibits “purposely or knowingly making, submitting, or authorizing the making or submitting of a false or misleading Medicaid claim, statement, representation, application, or document to a Medicaid agency for a service or item that the person is not entitled to” as well as the solicitation, offer, or receipt of bribes or kickbacks regarding medical services provided under Medicaid.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MONTANA:

- (1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Montana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XVII

VIOLATIONS OF THE NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. ANN. §§ 357.010 *et seq.*

201. Relator restates and realleges the allegations contained in paragraphs 1-200 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

202. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Nevada for treble damages and penalties under the Nevada False Claims Act, NEV. REV. STAT. ANN. §§ 357.010 *et seq.*

203. NEV. REV. STAT. ANN. § 357.040 provides liability for any person who:

- (a) Knowingly presents or causes to be presented a false claim for payment or approval.
- (b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.
- (c) Conspires to defraud by obtaining allowance or payment of a false claim.

* * *

- (h) Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

204. Defendants violated NEV. REV. STAT. ANN. § 357.040 and knowingly caused false claims to be made, used and presented to the State of Nevada for Defendants' adulterated and misbranded generic drugs as described herein.

205. The State of Nevada, by and through the Nevada Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

206. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Nevada.

207. Had the State of Nevada known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

208. As a result of Defendants' violations of NEV. REV. STAT. ANN. § 357.040, the State of Nevada has been damaged.

209. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to NEV. REV. STAT. ANN. § 357.080 on behalf of himself and the State of Nevada.

210. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEVADA:

- (1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to NEV. REV. STAT. ANN. § 357.210 and/or any other applicable provision of law;

- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XVIII

VIOLATIONS OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. REV. STAT. ANN. §§ 167:61 *et seq.*

211. Relator restates and realleges the allegations contained in paragraphs 1-210 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference

212. This is a *qui tam* action brought by Dinesh S. Thakur and the State of New Hampshire for treble damages and penalties under the New Hampshire False Claims Act, N.H. REV. STAT. ANN. §§ 167:61 *et seq.*

213. N.H. REV. STAT. ANN. § 167:61-a(I) states that no person shall:

(a) Knowingly make, present or cause to be made or presented, with intent to defraud, any false or fraudulent claim for payment for any good, service, or accommodation for which payment may be made in whole or in part under RSA 161 or RSA 167;

(b) Knowingly make, present, or cause to be made or presented, with intent to defraud, any false or fraudulent statement or representation for use in determining rights to benefits or payments which may be made in whole or in part under RSA 161 or RSA 167;

(c) Knowingly make, present, or cause to be made or presented, with intent to defraud, any false or fraudulent report or filing which is or may be used in computing or determining a rate of payment for goods, services, or accommodations for which payment may be made in whole or in part under RSA 161 or RSA 167; or make, present, or cause to be made or presented any false or fraudulent statement or representation in connection with any

such report or filing;

(d) Knowingly make, present, or cause to be made or presented, with intent to defraud, any claim for payment, for any good, service, or accommodation for which payment may be made in whole or in part under RSA 161 or RSA 167, which is not medically necessary in accordance with professionally recognized standards.

214. Defendants violated N.H. REV. STAT. ANN. § 167:61-a(I) and knowingly caused false claims to be made, used and presented to the State of New Hampshire for Defendants' adulterated and misbranded generic drugs as described herein.

215. The State of New Hampshire, by and through the New Hampshire Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

216. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of New Hampshire.

217. Had the State of New Hampshire known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

218. As a result of Defendants' violations of N.H. REV. STAT. ANN. § 167:61-a(I), the State of New Hampshire has been damaged.

219. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to N.H. REV. STAT. ANN. § 167:61-c on behalf of himself and the State of New Hampshire.

220. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW HAMPSHIRE:

- (1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to N.H. REV. STAT. ANN. § 167:61-e and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XIX

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §§ 2A:32C-1 *et seq.*

221. Relator restates and realleges the allegations contained in paragraphs 1-220 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

222. This is a *qui tam* action brought by Dinesh S. Thakur and the State of New Jersey for treble damages and penalties under the New Jersey False Claims Act, N.J. STAT. ANN. §§ 2A:32C-1 *et seq.*

223. N.J. STAT. ANN. §§ 2A:32C-3 provides liability for any person who:

- (a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
- (c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

224. Defendants violated N.J. STAT. ANN. §§ 2A:32C-3 and knowingly caused false claims to be made, used and presented to the State of New Jersey for Defendants' adulterated and misbranded generic drugs as described herein.

225. The State of New Jersey, by and through the New Jersey Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal

practices, paid the claims submitted by health care providers and third party payers in connection therewith.

226. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of New Jersey.

227. Had the State of New Jersey known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

228. As a result of Defendants' violations of N.J. STAT. ANN. §§ 2A:32C-3, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

229. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to N.J. STAT. ANN. §§ 2A:32C-5 on behalf of himself and the State of New Jersey.

230. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW JERSEY:

- (1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' fraudulent and illegal practices;

- (2) A civil penalty of not less than \$5,000 and not more than \$10,000, adjusted for inflation according to N.J. STAT. ANN. § 2A:32C-3, for each false claim which Defendants caused to be presented to the State of New Jersey;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to N.J. STAT. ANN. §§ 2A:32C-7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XX

VIOLATIONS OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. § 27-14-1 *et seq.*

231. Relator restates and realleges the allegations contained in paragraphs 1-230 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

232. This is a *qui tam* action brought by Dinesh S. Thakur and the State of New Mexico for treble damages and penalties under the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. §§ 27-14-1 *et seq.* and the New Mexico Fraud Against Taxpayers Act, N.M. STAT. ANN. §§ 44-9-1 *et seq.*

233. N.M. STAT. ANN. § 27-14-4 provides liability for any person who:

- A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;

* * *

- C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
- D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent.

234. N.M. STAT. ANN. §§ 44-9-3 makes it illegal to:

- (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
- (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
- (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim;
- (4) conspire to make, use or cause to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state;

* * *

- (9) as a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the state within a reasonable time after discovery.

235. Defendants violated N.M. STAT. ANN. §§ 27-14-4 and 44-9-3 and knowingly caused false claims to be made, used and presented to the State of New Mexico for Defendants' adulterated and misbranded generic drugs as described herein.

236. The State of New Mexico, by and through the New Mexico Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

237. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of New Mexico.

238. Had the State of New Mexico known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

239. As a result of Defendants' violations of N.M. STAT. ANN. §§ 27-14-4 and 44-9-3, the State of New Mexico has been damaged.

240. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to N.M. STAT. ANN. §§ 27-14-7 and 44-9-5 on behalf of himself and the State of New Mexico.

241. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW MEXICO:

- (1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to N.M. STAT. ANN. §§ 27-14-9, 44-9-7, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXI

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT

N.Y. CLS ST. FIN. §§ 187-194

242. Relator restates and realleges the allegations contained in paragraphs 1-241 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

243. This is a *qui tam* action brought by Dinesh S. Thakur and the State of New York for treble damages and penalties under the New York False Claims Act, N.Y. CLS ST. FIN. §§ 187-194.

244. N.Y. CLS ST. FIN. § 189 provides liability for any person who:

- (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

* * *

- (c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

245. Defendants violated N.Y. CLS ST. FIN. § 189 and knowingly caused false claims to be made, used and presented to the State of New York for Defendants' adulterated and misbranded generic drugs as described herein.

246. The State of New York, by and through the New York Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

247. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of New York.

248. Had the State of New York known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

249. As a result of Defendants' violations of N.Y. CLS ST. FIN. § 189, the State of New York has been damaged.

250. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to N.Y. CLS ST. FIN. § 190 on behalf of himself and the State of New York.

251. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW YORK:

- (1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$6,000 and not more than \$12,000 for each false claim which Defendants caused to be presented to the State of New York;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to N.Y. CLS ST. FIN. § 190 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXII

VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

OKLA. STAT. tit. 63, § 5305 *et seq.*

252. Relator restates and realleges the allegations contained in paragraphs 1-251 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference

253. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Oklahoma for treble damages and penalties under the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5305 *et seq.*

254. OKLA. STAT. tit. 63, § 5053.1(B) provides liability for any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

* * *

3. Conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

255. In addition, OKLA. STAT. tit. 56, § 1005 makes it illegal to:

1. Make or cause to be made a claim, knowing the claim to be false, in whole or in part, by commission or omission;

2. Make or cause to be made a statement or representation for use in obtaining or seeking to obtain authorization to provide a good or a service knowing the statement or representation to be false, in whole or in part, by commission or omission;

3. Make or cause to be made a statement or representation for use by another in obtaining a good or a service under the Oklahoma Medicaid Program, knowing the statement or representation to be false, in whole or in part, by commission or omission;

* * *

6. Solicit or accept a benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

256. Defendants violated OKLA. STAT. tit. 63, § 5053.1(B) and OKLA. STAT. tit. 56, § 1005 and knowingly caused false claims to be made, used and presented to the State of Oklahoma for Defendants' adulterated and misbranded generic drugs as described herein.

257. The State of Oklahoma, by and through the Oklahoma Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

258. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Oklahoma.

259. Had the State of Oklahoma known that Defendants' were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

260. As a result of Defendants' violations of OKLA. STAT. tit. 63, § 5053.1(B) and OKLA. STAT. tit. 56, § 1005, the State of Oklahoma has been damaged.

261. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to OKLA. STAT. tit. 63, § 5053.2 on behalf of himself and the State of Oklahoma.

262. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF OKLAHOMA:

- (1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to OKLA. STAT. tit. 63, § 5053.4 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXIII

VIOLATIONS OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

TENN. CODE ANN. § 71-181 *et seq.*

263. Relator restates and realleges the allegations contained in paragraphs 1-262 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

264. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. §§ 71-5-181 *et seq.* Section 71-5-182(a)(1) provides liability for any person who:

- (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
- (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
- (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

265. Defendants violated TENN. CODE ANN. § 71-5-182(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee for Defendants' adulterated and misbranded generic drugs as described herein.

266. The State of Tennessee, by and through the Tennessee Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal

practices, paid the claims submitted by health care providers and third party payers in connection therewith.

267. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Tennessee.

268. Had the State of Tennessee known that Defendants violated the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

269. As a result of Defendants' violations of TENN. CODE ANN. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

270. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to TENN. CODE ANN. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

271. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

- (1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' fraudulent and illegal practices;

- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to TENN. CODE ANN. § 71-5-183(c) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXIV

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE ANN. § 36.001 *et seq.*

272. Relator restates and realleges the allegations contained in paragraphs 1-271 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

273. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Texas to recover damages and civil penalties under TEX. HUM. RES. CODE ANN. § 36.001 *et seq.*

274. TEX. HUM. RES. CODE ANN. § 36.002 provides liability for any person who:
- (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
 - (a) on an application for a contract, benefit, or payment under the Medicaid program; or

- (b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.
- (2) knowingly or intentionally concealing or failing to disclose an event:
 - (a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:
 - (i) the person; or
 - (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
 - (b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
- (3) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
 - (a) information required to be provided by a Federal or State law, rule, regulation, or provider agreement pertaining to the Medicaid program;
 - (b) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

275. Defendants violated TEX. HUM. RES. CODE ANN. § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas for Defendants' adulterated and misbranded generic drugs as described herein.

276. The State of Texas, by and through the Texas Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices,

paid the claims submitted by health care providers and third party payers in connection therewith.

277. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Texas.

278. Had the State of Texas known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

279. As a result of Defendants' violations of TEX. HUM. RES. CODE ANN. § 36.002, the State of Texas has been damaged.

280. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to TEX. HUM. RES. CODE ANN. § 36.101 on behalf of himself and the State of Texas.

281. his Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TEXAS:

- (1) Two times the amount of actual damages which the State of Texas has sustained as a result of each Defendant's fraudulent and illegal practices;

- (2) A civil penalty as described in TEX. HUM. RES. CODE ANN. § 36.025(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to TEX. HUM. RES. CODE ANN. § 36.110, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXV

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. CODE ANN. § 8.01-216.01 *et seq.*

282. Relator restates and realleges the allegations contained in paragraphs 1-281 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

283. This is a *qui tam* action brought by Dinesh S. Thakur and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayer Act, VA. CODE ANN. § 8.01-216.01 *et seq.*

284. VA. CODE ANN § 8.01-216.01 *et seq.* provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;

- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
- (3) conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;
- (4) has possession, custody, or control of property or money used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth or willfully to conceal the property, delivers or causes to be delivered, less property than the amount for which the person receives a certificate of receipt;
- (5) authorizes to make or deliver a document certifying receipt of property used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (6) knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the Commonwealth who lawfully may not sell or pledge the property; or
- (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

285. Defendants violated VA. CODE ANN § 8.01-216.03 and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia for Defendants' adulterated and misbranded generic drugs as described herein.

286. The Commonwealth of Virginia, by and through the Commonwealth of Virginia Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

287. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the Commonwealth of Virginia.

288. Had the Commonwealth of Virginia known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

289. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to VA. CODE ANN § 8.01-216.5 on behalf of himself and the Commonwealth of Virginia.

290. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF VIRGINIA:

- (1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to VA. CODE ANN § 8.01-216.7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXVI

VIOLATIONS OF THE UTAH FALSE CLAIMS ACT

UTAH CODE ANN. § 26-20-1 *et seq.*

291. Relator restates and realleges the allegations contained in paragraphs 1-290 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

292. The Utah False Claims Act, UTAH CODE ANN. §§ 26-20-1 *et seq.* provides that a person may not present or cause to be made or presented to an employee or officer of the State a claim for a medical benefit which is wholly or partially false, fictitious, or fraudulent.

293. Defendants violated UTAH CODE ANN. §§ 26-20-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Utah for Defendants' adulterated and misbranded generic drugs as described herein.

294. The State of Utah, by and through the Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

295. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Utah.

296. Had the State of Utah known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

297. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to UTAH CODE ANN. §§ 26-20-1 *et seq.* on behalf of himself and the State of Utah.

298. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Utah in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF UTAH:

- (1) Three times the amount of actual damages which the State of Utah has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Utah;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to UTAH CODE ANN. §§ 26-20-1 *et seq.* and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXVII

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

WISC. CODE ANN. § 20.931 *et seq.*

299. Relator restates and realleges the allegations contained in paragraphs 1-298 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

300. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, WISC. CODE ANN. § 20.931 *et seq.*

301. WISC. CODE ANN. § 20.931(2) provides liability for any person who-

- (a) knowingly presents, or causes to be presented, to an officer or employee, or agent of Wisconsin a false claim for medical assistance;
- (b) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance;
- (c) conspires to defraud Wisconsin by obtaining allowance or payment of a false claim for medical assistance.

302. Defendants violated WISC. CODE ANN. § 20.931(2) and knowingly caused false claims to be made, used and presented to the State of Wisconsin for Defendants' adulterated and misbranded generic drugs as described herein.

303. The State of Wisconsin, by and through the Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

304. Compliance with applicable Medicare, Medicaid and the various other Federal and State laws cited herein was a condition of payment of claims submitted to the State of Wisconsin.

305. Had the State of Wisconsin known that Defendants were violating the Federal and State laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

306. Mr. Thakur is a private person with direct and independent knowledge of the allegations of this First Amended Complaint, who has brought this action pursuant to WISC. CODE ANN. § 20.931(2) on behalf of himself and the State of Wisconsin.

307. This Court is requested to accept pendant jurisdiction of this related State claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF WISCONSIN:

- (1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to WISC. CODE ANN. § 20.931(2) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXVIII

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT

COLO. REV. STAT. ANN. § 25.5-4-303.5 *et seq.*

308. Relator restates and realleges the allegations contained in paragraphs 1-307 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

309. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, COLO. REV. STAT. ANN. § 25.5-4-303.5 *et seq.*

310. COLO. REV. STAT. ANN. § 25.5-4-305(1) provides liability for any person who:

- (a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
- (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the “Colorado Medical Assistance Act” and knowingly delivers, or causes to be delivered, less than all of the money or property;
- (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the “Colorado Medical Assistance Act” and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the “Colorado Medical Assistance Act” who lawfully may not sell or pledge the property;
- (f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the “Colorado Medical Assistance Act”, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the “Colorado Medical Assistance Act”;
- (g) Conspires to commit a violation of paragraphs (a) to (f).

311. Defendants violated COLO. REV. STAT. ANN. § 25.5-4-305(1) and knowingly caused false claims to be made, used and presented to the State of Colorado for Defendants’ adulterated and misbranded generic drugs as described herein.

312. The State of Colorado, by and through the Colorado Medicaid program and other State health care programs, was unaware of Defendants’ fraudulent and illegal

practices and paid the claims submitted by health care providers and third party payers in connection therewith.

313. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Colorado. Had the State of Colorado known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

314. As a result of Defendants' violations of COLO. REV. STAT. ANN. § 25.5-4-305(1), the State of Colorado has been damaged.

315. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to COLO. REV. STAT. ANN. § 25.5-4-306(2) on behalf of himself and the State of Colorado.

316. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Colorado in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF COLORADO:

- (1) Three times the amount of actual damages which the State of Colorado has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Colorado;
- (3) Prejudgment interest; and

- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to COLO. REV. STAT. ANN. § 25.5-4-306(3) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXIX

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT

CONN. GEN. STAT. ANN. § 17b-301a *et seq.*

317. Relator restates and realleges the allegations contained in paragraphs 1-316 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

318. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Connecticut for treble damages and penalties under Connecticut False Claims Act, CONN. GEN. STAT. ANN. § 17b-301a *et seq.*

319. CONN. GEN. STAT. ANN. § 17b-301b(a) provides liability for any person who:

- (1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;
- (2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;

(3) Conspire to commit a violation of this section

320. Defendants violated CONN. GEN. STAT. ANN. § 17b-301b(a) and knowingly caused false claims to be made, used and presented to the State of Connecticut for Defendants' adulterated and misbranded generic drugs as described herein.

321. The State of Connecticut, by and through the Connecticut Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

322. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Connecticut. Had the State of Connecticut known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

323. As a result of Defendants' violations of CONN. GEN. STAT. ANN. § 17b-301b(a), the State of Connecticut has been damaged.

324. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to CONN. GEN. STAT. ANN. § 17b-301d on behalf of himself and the State of Connecticut.

325. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Connecticut in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF CONNECTICUT:

- (1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Connecticut;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to CONN. GEN. STAT. ANN. § 17b-301e and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXX

VIOLATIONS OF THE IOWA FALSE CLAIMS ACT

IOWA CODE ANN. § 685.1 *et seq.*

326. Relator restates and realleges the allegations contained in paragraphs 1-325 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

327. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Iowa for treble damages and penalties under Iowa False Claims Act, IOWA CODE ANN. § 685.1 *et seq.*

328. IOWA CODE ANN. § 685.2 provides liability for any person who:

- a. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.
- b. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
- c. Conspires to commit a violation of this section.

329. Defendants violated IOWA CODE ANN. § 685.2 and knowingly caused false claims to be made, used and presented to the State of Iowa for Defendants' adulterated and misbranded generic drugs as described herein.

330. The State of Iowa, by and through the Iowa Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

331. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Iowa. Had the State of Iowa known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

332. As a result of Defendants' violations of IOWA CODE ANN. § 685.2, the State of Iowa has been damaged.

333. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to IOWA CODE ANN. § 685.3 on behalf of himself and the State of Iowa.

334. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Iowa in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF IOWA:

- (1) Three times the amount of actual damages which the State of Iowa has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Iowa;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to IOWA CODE ANN. § 685.3 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXXI

VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT

MD. CODE, HEALTH - GEN., § 2-601 *et seq.*

335. Relator restates and realleges the allegations contained in paragraphs 1-334 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

336. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Maryland for treble damages and penalties under Maryland False Health Claims Act, MD. CODE, HEALTH – GEN., § 2-601 *et seq.*

337. MD. CODE, HEALTH – GEN., § 2-602(a) provides liability for any person who:

- (1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;
- (2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim;
- (3) Conspire to commit a violation under this subtitle

338. Defendants violated MD. CODE, HEALTH – GEN., § 2-602(a) and knowingly caused false claims to be made, used and presented to the State of Maryland for Defendants' adulterated and misbranded generic drugs as described herein.

339. The State of Maryland, by and through the Maryland Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

340. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Maryland. Had the State of Maryland known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

341. As a result of Defendants' violations of MD. CODE, HEALTH – GEN., § 2-602(a), the State of Maryland has been damaged.

342. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to MD. CODE, HEALTH – GEN., § 2-604 on behalf of himself and the State of Maryland.

343. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Maryland in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF MARYLAND:

- (1) Three times the amount of actual damages which the State of Maryland has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Maryland;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to MD. CODE, HEALTH – GEN., § 2-605 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXXII

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT

MINN. STAT. ANN. § 15C.01 *et seq.*

344. Relator restates and realleges the allegations contained in paragraphs 1-343 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

345. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Minnesota for treble damages and penalties under Minnesota False Health Claims Act, MINN. STAT. ANN. § 15C.01 *et seq.*

346. MINN. STAT. ANN. § 15C.02(a) provides liability for any person who:

- (1) Knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;
- (2) Knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision;
- (3) Knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses,

or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim

347. Defendants violated MINN. STAT. ANN. § 15C.02(a) and knowingly caused false claims to be made, used and presented to the State of Minnesota for Defendants' adulterated and misbranded generic drugs as described herein.

348. The State of Minnesota, by and through the Minnesota Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

349. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Minnesota. Had the State of Minnesota known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

350. As a result of Defendants' violations of MINN. STAT. ANN. § 15C.02(a), the State of Minnesota has been damaged.

351. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to MINN. STAT. ANN. § 15C.05 on behalf of himself and the State of Minnesota.

352. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF MINNESOTA:

- (1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which each Defendant presented or caused to be presented to the State of Minnesota;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to MINN. STAT. ANN. § 15C.13 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXXIII

**VIOLATIONS OF THE MISSOURI HEALTH CARE PAYMENT
FRAUD AND ABUSE ACT**

MO. ANN. STAT. § 191.900 *et seq.*

353. Relator restates and realleges the allegations contained in paragraphs 1-352 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

354. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Missouri for treble damages and penalties under Missouri Health Care Payment Fraud and Abuse Act., MO. ANN. STAT. § 191.900 *et seq.*

355. MO. ANN. STAT. § 191.905 provides liability for any health care provider who knowingly makes or causes to be made a false statement or false representation of a material fact in order to receive a health care payment, including but not limited to:

- (1) Knowingly presenting to a health care payer a claim for a health care payment that falsely represents that the health care for which the health care payment is claimed was medically necessary, if in fact it was not;
- (2) Knowingly concealing the occurrence of any event affecting an initial or continued right under a medical assistance program to have a health care payment made by a health care payer for providing health care;
- (3) Knowingly concealing or failing to disclose any information with the intent to obtain a health care payment to which the health care provider or any other health care provider is not entitled, or to obtain a health care payment in an amount greater than that which the health care provider or any other health care provider is entitled;
- (4) Knowingly presenting a claim to a health care payer that falsely indicates that any particular health care was provided to a person or persons, if in fact health care of lesser value than that described in the claim was provided.

356. Defendants violated MO. ANN. STAT. § 191.905 and knowingly caused false claims to be made, used and presented to the State of Missouri for Defendants' adulterated and misbranded generic drugs as described herein.

357. The State of Missouri, by and through the Missouri Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

358. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Missouri.

Had the State of Missouri known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

359. As a result of Defendants' violations of MO. ANN. STAT. § 191.905, the State of Missouri has been damaged.

360. Mr. Thakur is a private person and the original source of the allegations of the Second Amended Complaint, who has brought this action pursuant to MO. ANN. STAT. § 191.907 on behalf of himself and the State of Missouri.

361. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Missouri in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF MISSOURI:

- (1) Three times the amount of actual damages which the State of Missouri has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Missouri;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to MO. ANN. STAT. § 191.907 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred

in connection with this action;

- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXXIV

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. GEN. STAT. ANN. § 1-607 *et seq.*

362. Relator restates and realleges the allegations contained in paragraphs 1-361 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

363. This is a *qui tam* action brought by Dinesh S. Thakur and the State of North Carolina for treble damages and penalties under North Carolina False Claims Act, N.C. GEN. STAT. ANN. § 1-607 *et seq.*

364. N.C. GEN. STAT. ANN. § 1-607(a) provides liability for any person who:

- (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
- (3) Conspires to commit a violation of this section.

365. Defendants violated N.C. GEN. STAT. ANN. § 1-607(a) and knowingly caused false claims to be made, used and presented to the State of North Carolina for Defendants' adulterated and misbranded generic drugs as described herein.

366. The State of North Carolina, by and through the North Carolina Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and

illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

367. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of North Carolina. Had the State of North Carolina known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

368. As a result of Defendants' violations of N.C. GEN. STAT. ANN. § 1-607(a), the State of North Carolina has been damaged.

369. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to N.C. GEN. STAT. ANN. § 1-608 on behalf of himself and the State of North Carolina.

370. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF NORTH CAROLINA:

- (1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which each Defendant presented or caused to be presented to the State of North Carolina;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to N.C. GEN. STAT. ANN. § 1-610 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XXXV

VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT

R.I. GEN. LAWS § 9-1.1-1 *et seq.*

371. Relator restates and realleges the allegations contained in paragraphs 1-370 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

372. This is a *qui tam* action brought by Dinesh S. Thakur and the State of Rhode Island for treble damages and penalties under Rhode Island State False Claims Act, R.I. GEN. LAWS § 9-1.1-1 *et seq.*

373. R.I. GEN. LAWS § 9-1.1-3(a) provides liability for any person who:

- (1) Knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid

374. Defendants violated R.I. GEN. LAWS § 9-1.1-3(a) and knowingly caused false claims to be made, used and presented to the State of Rhode Island for Defendants' adulterated and misbranded generic drugs as described herein.

375. The State of Rhode Island, by and through the Rhode Island Medicaid program and other State health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

376. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the State of Rhode Island. Had the State of Rhode Island known that Defendants violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

377. As a result of Defendants' violations of R.I. GEN. LAWS § 9-1.1-3(a), the State of Rhode Island has been damaged.

378. Mr. Thakur is a private person with direct and independent knowledge of the allegations of the Second Amended Complaint, who has brought this action pursuant to R.I. GEN. LAWS § 9-1.1-4(b) on behalf of himself and the State of Rhode Island.

379. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the Federal claim, and merely asserts separate damages to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants, respectively:

To the STATE OF RHODE ISLAND:

- (1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of each Defendant's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which each Defendant presented or caused to be presented to the State of Rhode Island;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR:

- (1) A fair and reasonable amount allowed pursuant to R.I. GEN. LAWS § 9-1.1-3(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Mr. Thakur incurred in connection with this action;
- (3) An award of statutory attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury.

Respectfully submitted,



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June 12, 2012

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 12th day of June, 2012, a copy of the foregoing

Second Amended Complaint was sent via certified mail to the following:

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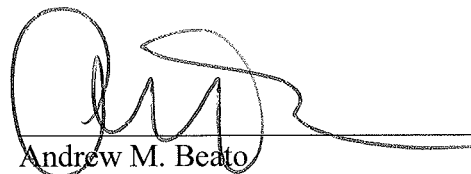
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