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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

United States of America, ex rel. Robert Lalley, Courtney Davis and William Manos, individuals; State of California, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Illinois, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Florida, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Texas, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Georgia, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Tennessee, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Virginia, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Massachusetts, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Michigan, ex rel. Robert Lalley, Courtney Davis, and William Manos and State of New York, ex rel. Robert Lalley, Courtney Davis, and William Manos

Plaintiffs

vs.

Novartis Vaccines and Diagnostics, Inc.; and Express Scripts, Inc. (fdba Priority Healthcare Corporation),

Defendants.

Civil Action No: 06-06303 CRB

AMENDED COMPLAINT FOR DAMAGES (FALSE CLAIMS ACT, 31 U.S.C. § 3729 *et seq.*); RELATED STATE CAUSES OF ACTION AND DEMAND FOR JURY

DOCUMENT SUBMITTED

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~~FILED IN CAMERA AND UNDER SEAL~~

~~MAINTAINED UNDER SEAL AND NOT SERVED ON DEFENDANT~~

Plaintiff United States of America ex rel. Robert M. Lalley, Courtney Davis and William Manos (hereafter, "Qui Tam Plaintiffs/Relators"); State of California, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Illinois, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Florida, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Texas, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Georgia, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Tennessee, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Virginia, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Massachusetts, ex rel. Robert Lalley, Courtney Davis, and William Manos; State of Michigan, ex rel. Robert Lalley, Courtney Davis, and William Manos; and State of New York, ex rel. Robert Lalley, Courtney Davis, and William Manos (when referred to collectively, the "States") for their complaint against the defendants Novartis Vaccines and Diagnostics, Inc. and Express Scripts, Inc. (when referred to collectively, "Defendants") allege:

JURISDICTION AND THE PARTIES

1. Qui Tam Plaintiff/Relator Robert M. Lalley was Director of National Accounts for Chiron Corporation, and resides at 1052 Greymoor Road, Birmingham, AL 35242.

2. Qui Tam Plaintiff/Relator Courtney Davis was a National Account Manager for Chiron Corporation and resides at 248 Valley Street, Pembroke, MA 02359

3. Qui Tam Plaintiff/Relator William Manos was Chiron Corporation's Area Business Manager – Los Angeles North and resides at 24140 Mentry Drive, Santa Clarita, CA 91321-3947.

4. Plaintiffs State of California, State of Illinois, State of Florida, State of Texas, State of Georgia, State of Tennessee, State of Virginia, State of Massachusetts, State of Michigan, and State of New York (collectively, "the State Plaintiffs"), were, at all times herein mentioned, states within the United States which were harmed by the conduct of Defendant

Novartis Vaccines & Diagnostics, Inc. (Novartis) as herein alleged, in a like manner that harm was done, and continues to be done, to the United States as herein described. As alleged more specifically herein, the State Plaintiffs, Novartis wrongfully billed the State Plaintiffs in the same or substantially similar manner as it did the United States (as herein alleged) for pharmaceutical drugs provided by Novartis; and Novartis received reimbursement from the State Plaintiffs for those wrongfully billed drugs. The requests for reimbursement by Novartis were likewise improper and in violation of law, and harmed the State Plaintiffs and their citizens receiving services under Medicaid programs and other health benefit programs, funded in whole or in part by each of the State Plaintiffs.

5. Defendant Novartis Vaccines and Diagnostics, Inc. ("Novartis") is a Delaware corporation which has its principal place of business in New Jersey. Chiron Corporation ("Chiron"), which was acquired by Novartis, has its principal place of business in Emeryville, CA. Both are referred to collectively herein as "Chiron."

6. Defendant Express Scripts, Inc. ("Express Scripts") is a Delaware corporation which has its principal place of business in St. Louis, MO. Priority Healthcare Corporation ("Priority Healthcare"), the entity referred to herein, was acquired by Express Scripts, Inc. Both are referred to collectively herein as Priority Healthcare.

7. Defendant Novartis (and its predecessor, Chiron) is and was in the business, among other things, of manufacturing and promoting a pharmaceutical drug known as tobramycin under the trademark TOBI.

8. Defendant Express Scripts (and its predecessor Priority Healthcare) is and was in the business, among other things, of obtaining government reimbursement for Chiron's off-label prescriptions of TOBI, as herein described.

9. This Court has jurisdiction over this matter pursuant to the False Claims Act, particularly 31 U.S.C. § 3730(b), in that the claims for relief there under set forth in this action are brought by private persons in the name of the United States government; this Court further has federal question jurisdiction over this matter pursuant to 28 U.S.C.A. § 1331. There is pendent jurisdiction over the state law claims which are pleaded in this action because: (1) the

federal claim is sufficiently substantial to confer federal jurisdiction; and (2) there is common nucleus of operative fact between the state and federal claims, in that Novartis obtained, at the same times, wrongful reimbursement (as described herein) from both the United States and the plaintiff States.

10. Venue is proper pursuant to 28 U.S.C. § 1391(a), in that defendant Novartis conducts business in this judicial district, and the other defendants resided in this judicial district at the time of the activities pled in this Complaint.

11. As required under the False Claims Act, 31 U.S.C. § 3730(a)(2), the Relators have provided to the United States Attorney for the Northern District of California a statement of material evidence and information related to this Complaint. This is a case where Defendants improperly created a demand for a pharmaceutical product manufactured by Chiron under the trademark TOBI through violations of the Food, Drug, and Cosmetics Act ("FDCA"), then submitted to the government for reimbursement bills from the sale of the product, not otherwise payable, without disclosing to the government that the demand had been generated through violations of the FDCA.

12. Under the FDCA, pharmaceutical drug companies cannot distribute a drug in interstate commerce unless the Food and Drug Administration ("FDA") has approved its use. The FDA approves pharmaceutical drugs for marketing for one or more specific uses, and establishes recommended dosages for those uses. When the FDA approves a drug for marketing and sale, it also approves the labeling for the drug, which explains the manner in which the medication may be marketed as safe and effective. Use of an approved drug for any purpose other than those specifically contained in the label is referred to as an "off-label" use.

13. The FDCA does not prohibit physicians from prescribing an FDA approved drug for off-label uses. The FDCA does, however (except in certain situations not relevant here), prohibit drug manufacturers from marketing or promoting a drug for off-label uses, pursuant to statutory authority including 21 U.S.C. §§ 331 and 352.

14. While physicians may and do prescribe drugs for uses other than uses contained in the label, a pharmaceutical company, such as Chiron, may not promote a product as safe and

effective beyond its indicated use.

15. Pursuant to 42 U.S.C. § 1396r-8(k)(3), federal and state health care programs, such as Medicaid and Medicare, have strict limitations on the circumstances under which they will reimburse the cost of drugs prescribed for off-label uses.

BACKGROUND AS TO TOBI

16. This Complaint concerns the promotion and sale of a pharmaceutical known as TOBI, which is approved for the treatment of a particular type of lung infection in certain patients with cystic fibrosis.

17. Cystic fibrosis (hereafter "CF") is a genetic disease affecting approximately 30,000 children and adults in the United States. CF causes the body to produce abnormally thick, sticky mucus that clogs the lungs and obstructs the pancreas. According to the CF Foundation's National Patient Registry, the median age of survival for a person with CF is 33.4 years.

18. In the late 1990s, PathoGenesis Corporation of Seattle, Washington ("PathoGenesis") developed TOBI as tobramycin for inhalation. In particular, on December 22, 1997, the U.S. Food and Drug Administration approved TOBI for marketing and sale under new drug application NDA 50-753 as a drug device combination for the management of P. aeruginosa in certain CF patients.

19. The FDA-approved version of TOBI was a 300 mg solution of tobramycin as 60 mg/ml in 5 ml in 0.225 N saline for inhalation administered via a particular nebulizer (the Pari LC Plus jet nebulizer) using a particular power source to create the aerosol (the DeVillbus Pulmoaide compressor).

20. In particular, TOBI was approved for marketing and sale following clinical trials of patients chronically infected with the bacteria P. aeruginosa, who were otherwise stable upon admission into the trial, having lung functions between 25% and 75% predicted and who were 6 years of age and older.

21. TOBI immediately became the industry standard for the management of P. aeruginosa in CF patients when using a tobramycin solution for inhalation.

22. The FDA's approval prohibits, without deviation, the marketing of TOBI through

advertising or representations regarding any of the following:

a. The safety and efficacy of any dose other than 300 mg as 60 mg/ml in 5 ml,

b. The use of TOBI with any nebulizer delivery system other than the PARI LC Plus jet nebulizer and the DeVillbus Pulmoaide compressor,

c. The use of TOBI by children under the age of 6,

d. The use of TOBI in patients with lung function greater than 75%,

e. The use of TOBI in patients not chronically infected with P. aeruginosa, and

f. The use of TOBI for non-CF patients.

BACKGROUND AS TO THE QUI TAM PLAINTIFF/RELATORS

23. Chiron acquired PathoGenesis on or about August 14, 2000 and thereby acquired the rights to TOBI.

24. Thereafter, Chiron entered into employment agreements with each of the Relators whereby the Relators, as employees, were to render professional services, including the promotion and sale of TOBI, as well as obtaining payment by the U.S. Government through its federal assistance programs, primarily related to TOBI.

25. Reimbursement issues related to TOBI included fact that the price of TOBI is significantly higher than the price of generic tobramycin that might be prescribed and used for inhalation.

26. During their employment, the Relators attended sales meetings in which they and the Chiron sales force were instructed by Chiron to promote off-label uses of TOBI.

27. During their employment, the Relators learned of fraudulent activities by Defendants with respect to reimbursement for off-label uses of TOBI, as described below.

28. In particular, Chiron implemented a strategic marketing plan such that TOBI would be aggressively marketed to treat a wide array of ailments for which, and patients for whom, the FDA did not approve the drug as safe and effective. In particular, the company promoted TOBI for the treatment of lung diseases not associated with CF, including bronchiectasis ("BE") and ventilator assisted pneumonia ("VAP"), and promoted TOBI as a

first-line treatment for children not chronically infected with P. aeruginosa and/or with lung function greater than 75% ("Early Intervention"), and for those below the age of six ("Under Six"), as a means to increase its sales of TOBI.

29. In 2002, Chiron hired David Happel, who had a known history of involvement with alleged improper marketing and promotion for off-label use of pharmaceutical drugs. For example, Mr. Happel had managed a business, which the Department of Justice investigated, and later sued, for improper marketing and promotion of pharmaceuticals for off-label use.

30. Shortly after Mr. Happel joined Chiron, the company implemented new off-label promotion and marketing policies for TOBI. Mr. Happel also developed a team of managers to assist in the sales and promotion of off-label uses for TOBI.

31. Jennifer Stroman, a Chiron employee, was promoted to Product Manager in 2002. By organizational structure, Ms. Stroman reported directly to Brian Unger, Pulmonology Product Director, but in practice reported to Mr. Happel.

32. Ms. Stroman was in charge of development and implementation of TOBI speaker programs. She also provided direct instruction to the sales representatives through memoranda, training directives, and presentations as to how they were to promote the programs and services described herein.

33. Burt Kiethley, a Chiron employee, was in charge of the Pulmonology sales group in 2005. Under his direction, sales representatives were required to conduct the off-label sales campaign developed and directed by Mr. Happel and Ms. Stroman.

34. Joe Regan, a Chiron employee, was the acting Vice President of BioPharma Sales (Oncology & Pulmonology) from October 2004 to December 2005. Under his watch, sales representatives were directed to conduct the off-label sales campaign previously described. Mr. Regan authorized and directed the Chiron oncology sales representatives to be trained to sell TOBI, and had them make direct sales calls to non-CF physicians to sell TOBI.

35. Chiron's strategy was to enhance the demand for TOBI through violations of the FDCA. This demand, which was the result of illegal, fraudulent and improper activity by Chiron, in turn resulted in the false claims complained of herein. Chiron's tactics included the

following, among other things:

a. Chiron's business plans and incentive programs were to market and promote TOBI (and thereby increase it sales) for off-label applications.

b. Toward this end, Chiron promoted selling TOBI to Office Based Pulmonologists ("OBP"). OBP sales, by their very nature, are known to be heavily weighted toward off-label uses, since Office Based Pulmonologists generally do not treat CF patients. Most CF patients are treated at CF centers, not by Office Based Pulmonologists.

c. As part of, and to further, its illegal marketing and promotion scheme, Chiron provided to its sales representatives lists of potential doctors, typically pulmonologists, who did not have exclusively CF patients. Again, by targeting this doctor base, Chiron knew that most, if not all, of the prescription demand generated thereby would be off-label.

d. As part of, and to further, its illegal marketing and promotion scheme, Chiron provided training to its sales representatives in the off-label disease conditions to be targeted with TOBI. This training included, among other things, providing sales representatives with studies about off-label uses of TOBI (which the sales representatives were told to destroy or return to Chiron after review). The training also included scripted inquiries in which the sales representatives were coached to engage physicians in discussions regarding off-label applications. The training also included presentations to coach the sales representatives in how to guide the off-label discussions with physicians.

e. To facilitate these illicit sales, Chiron created a special database, called EDGE, for use by sales representatives. The database contained data on doctors so Chiron could track the success of its off-label sales and activities. The database was managed by Chiron's sales operations unit and marketing department.

f. As part of, and to further, its illegal marketing and promotion scheme, Chiron's sales representatives were taught to, and did, hide off-label promotions in the EDGE computer database by calling those activities "OBP."

g. Because Chiron knew that getting reimbursement from governmental agencies for off-label prescriptions was difficult (but necessary to monetize its scheme, since the cost of TOBI was too high – $3,000 to $4,000 ***per month*** – for most consumers to bear without reimbursement), to reap the benefits of its efforts to artificially and illegally enhance the demand for TOBI in off-label applications (and to snowball that demand even further), Chiron needed to take steps to assure that the largest volume possible of its burgeoning off-label demand was reimbursed by governmental agencies. For that reason, and as part of, and to further, its illegal marketing and promotion scheme, Chiron orchestrated a scheme whereby Defendant Express Scripts, dba Priority Healthcare, which specialized (among other things) in facilitating reimbursement requests to governmental agencies for off-label prescriptions, was retained to assist Chiron's sales representatives who were dealing with patients who had received prescriptions for predominately off-label uses. The sales representatives were urged by Chiron to tell these patients to process their prescriptions through Priority Healthcare.

h. As part of, and to further, its illegal marketing and promotion scheme, Chiron encouraged its sales representatives to provide one-on-one sales pitches to physicians about off-label uses of TOBI, in the absence of prior inquiry concerning such uses by doctors.

i. As part of, and to further, its illegal marketing and promotion scheme, Chiron provided its sales representatives with marketing materials (some of which were called, ironically – but accurately – "cheat sheets") about off-label promotion. Chiron also instructed its sales people to destroy and or to return certain of those documents to Chiron management.

j. As part of, and to further, its illegal marketing and promotion scheme, Chiron required as a condition of continued employment that its sales representatives make non-CF or OBP sales calls. Chiron required sales persons to spend 10% to 30% of their time calling on physicians in off-label areas, such as OBPs and non-CF center

physicians who were unlikely to have CF patients or to have CF patients for whom TOBI had been approved by the FDA.

k. As part of, and to further, its illegal marketing and promotion scheme, Chiron provided monetary incentives to sales representatives to participate in off-label promotion of TOBI through the use of reimbursement forms (known as "BIRFs"), which became a marketing program that paid incentives to sales persons for increased sales due to off-label promotion.

l. As a further part of its scheme to illegally enhance demand for TOBI by off-label marketing and promotion, when Chiron sales representatives approached the physician community to promote off-label uses (as the sales representatives were required to do), they were instructed by Chiron to "hook" the OBP by providing free samples of TOBI for patients to try for off-label uses. These free sample programs for off-label uses sometimes were referred to as Professional Courtesy Packages. The purpose was to induce physicians to develop a sufficient comfort level with TOBI for off-label indications that the doctors would prescribe it for such purposes.

m. As part of, and to further, its illegal marketing and promotion scheme, Chiron instructed its sales representatives to present physicians with papers (or information about such papers) on BE and VAP. TOBI is not approved for management of either of these diseases. Moreover, these diseases are not unique to CF victims. As part of its instructional program to illegally enhance the demand for TOBI through off-label marketing and promotion, Chiron conducted role-playing discussions with its sales people prior to sales calls for off-label indications.

n. As part of, and to further, its illegal marketing and promotion scheme, Chiron instructed its sales people to tell doctors that TOBI reduces hospital stays and reduces exacerbations in patients hospitalized for respiratory problems, but did not instruct its sales representatives to expressly qualify that as being in connection with the management of P. aeruginosa in CF patients within a specific age range and within a specific lung function range. Chiron also instructed its sales representatives to tell

doctors that TOBI has studies in CF and demonstrated a successful track record, but did not instruct its sales representatives to expressly qualify that as a being in connection with the management of P. aeruginosa in CF patients within a specific age range and within a specific lung function range. Chiron also instructed its sales representatives to explain to doctors – including those such as OBPs and non-CF center doctors who were known to be unlikely to be managing P. aeruginosa in CF patients of the approved age range and lung function range – that while TOBI was more expensive, it would save money based on the length of stay at hospitals and frequency of stays in hospitals.

o. As part of, and to further, its illegal marketing and promotion scheme, Chiron conducted sales meetings where off-label sales of TOBI were reported, discussed, and promoted.

p. As part of, and to further, its illegal marketing and promotion scheme, Chiron required its sales persons to profile physicians in off-label areas such as BE and newborns with pseudomonas lung infections.

q. As part of, and to further, its illegal marketing and promotion scheme, Chiron made false or misleading statements to health care professionals regarding TOBI's efficacy for off-label uses, by representing that TOBI's safety within its indication implied that it was safe for other indications. If a physician pressed with a question about whether TOBI had been approved by the FDA for such off-label uses, Chiron instructed its sales representatives to respond by providing a clinical trial that occurred with TOBI in BE and a clinical retrospective study in VAP, both of which were sponsored by Chiron, and neither of which had been vetted with the FDA or submitted to the FDA in connection with efforts to get TOBI approved for such off-label uses. For example, Chiron initiated a phase two safety study to determine if TOBI can improve the symptoms of extreme BE. The initial results showed that TOBI did not provide the same benefits in patients with BE as seen in patients as studied with CF. This distinction was not shared with physicians whom Chiron was encouraging to prescribe TOBI for off-label indications.

r. As part of, and to further, its illegal marketing and promotion scheme, Chiron sponsored purportedly "independent medical education" events facilitating and encouraging off-label TOBI uses with extensive input from Chiron regarding topics, speakers, content, and participants.

36. Chiron also assisted in obtaining federal reimbursement for these off-label indications, which it had actively promoted, in a false and misleading manner. These activities have included:

a. Institutionalizing sales of off-label uses of TOBI by maintaining and providing forecasts for both CF uses and non-CF uses of TOBI. To meet sales expectations it was necessary to promote and sell TOBI for off-label uses. In other words, sales representatives were expected to sell a certain number of cartons of TOBI for both CF and non-CF indications.

b. Contracting with Priority Healthcare to assist doctors in obtaining reimbursement, and, in particular, improperly to obtain federal reimbursement for the off-label uses of TOBI.

c. Working with Priority Healthcare to gain "adjudication" (reimbursement) for off-label prescriptions, including off-label prescriptions generated through the illegal and improper marketing and advertising of TOBI, which was not disclosed to the government.

37. These tactics were part of a widespread, coordinated, national effort to implement an off-label marketing plan and create a demand for TOBI which would not have existed had Chiron complied with the FDCA. Many of the TOBI sales thus generated were submitted to the government for reimbursement, without disclosing their false and fraudulent nature: that is, that the reimbursement submissions were for prohibited off-label uses, and that these uses had been knowingly, unlawfully and fraudulently promoted and marketed by Chiron. At the same time it was engaging in the aforementioned conduct, Chiron decided not to seek FDA approval for any of the off-label uses and, in fact, abandoned scientific research related to such uses.

38. While Chiron was engaging in the acts complained of herein resulting in false

claims being submitted for reimbursement, it also was drastically increasing the price of the product, which, of course, materially increased the amount of the false claims and damages flowing there from. Since it bought PathoGenesis, Chiron has doubled the wholesale price of TOBI through 5-6% average price increases every six months. Thus the wholesale price of TOBI for a month supply today is over $3,500.

39. In or about the Fall of 2005, Relator Robert Lalley had knowledge that Chiron's conduct, as set forth above, was a violation of Federal law, and that it was thereby falsely and fraudulently generating a demand for prescriptions which were then submitted to the government for reimbursement through federal assistance programs. At that time, Relator Robert Lalley verbally informed Chiron, and Mr. Happel, individually and in his sales capacity, that the conduct of Chiron, as described above, was illegal and improper.

40. In response, Relator Robert Lalley's employment reviews were retroactively changed, and he was fired, which were acts of retaliation.

41. Similarly, Relator William Manos' employment was terminated, as part of a redistricting, after he raised the issue of off-label sales. This was done as an act of retaliation.

42. At all times material to this Complaint, Defendants knew, or were grossly negligent or reckless in not knowing, that their conduct as described herein was illegal and improper.

43. On information and belief, Defendants knowingly, as that term is defined by 31 U.S.C. § 3729(b), filed or caused to be filed with the federal government applications for the payment of United States government funds, and, on information and belief, caused moneys of the United States government to be paid to themselves for reimbursement of TOBI for off-label uses which they illegally promoted, as described herein.

FIRST CLAIM FOR RELIEF AGAINST DEFENDANTS

(Violation of 31 U.S.C. § 3729(a)(1))

44. The Qui Tam Plaintiff/Relators repeat the allegations of Paragraphs 1 - 42 contained in this Complaint.

45. Defendants presented to, or caused to be filed with, the United States government

claims with knowledge of their falsity, or with grossly negligent or reckless disregard of facts and conditions that would indicate that the reimbursement claims were inaccurate or inappropriate and false, and caused payments for the reimbursement claims to be made by the United States government.

46. Defendants' illegal and improper conduct, as described herein, also deprived federal assistance programs across the country of the informed, impartial judgment of medical professionals – judgment on which the programs rely to allocate scarce financial resources to provide necessary and appropriate care.

47. In addition to the specifics set forth above, Defendants' conduct included recruiting doctors to influence other physicians and developing research solely to boost market share and the total value of the sales of TOBI, which was done without proper disclosure of the financial relationship between the doctor and Chiron. For example, Chiron's involvement with clinical trials, medical journal research and reviews, educational grants and continuing medical education was provided, in part, to obtain the assistance of doctors in the prescription of TOBI for off-label applications.

48. As a consequence of Defendants' unlawful scheme, patients who received the drug for unapproved and unproven uses (which uses were then submitted for reimbursement by government assistance programs such as Medicare) had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether the doctor was instead influenced by misleading statements made by, or inducements provided by, Defendants.

49. By reason of the violation of 31 U.S.C. § 3729(a)(1), Defendants have knowingly or recklessly damaged the United States government in an as yet undetermined amount in an amount in excess of $100,000,000.00.

SECOND CLAIM FOR RELIEF AGAINST DEFENDANTS

(Violation of 31 U.S.C. § 3729(a)(2))

50. The Qui Tam Plaintiff/Relators repeat the allegation of Paragraphs 1- 48 contained in this Complaint.

51. Defendants presented claims to, or caused claims to be filed with, the United States

government with knowledge of their falsity, or with grossly negligent or reckless disregard to facts and conditions that would indicate that the reimbursement claims were inaccurate or inappropriate and false, and caused payments for the reimbursement claims to be made by the United States government.

52. By its conduct as described herein, Chiron subjected the poor, the elderly, the very young and other persons insured by state and federal health care programs to experimental drug applications which have not been determined to be safe and effective by enlisting physicians to promote off-label uses of TOBI.

53. Chiron employed Priority Healthcare to assist in obtaining reimbursement for off-label use of TOBI. Priority Healthcare knowingly presented, or caused to be presented, to the United States Government false or fraudulent claims for payment or approval of TOBI for these off-label applications which had been generated through Chiron's improper and illegal marketing scheme.

54. Priority Healthcare 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 United States government for the off-label applications of TOBI, which had been generated through Chiron's improper and illegal marketing scheme.

55. By reason of the violation of 31 U.S.C. § 3729(a)(2), Defendants have knowingly or recklessly damaged the United States government in an as yet undetermined amount.

THIRD CLAIM FOR RELIEF AGAINST DEFENDANTS

(Violation of 31 U.S.C. § 3729(a)(3))

56. Qui Tam Plaintiff/Relators repeat the allegations of Paragraphs 1 - 54 contained in this Complaint.

57. The Defendants, in performing the acts set forth above, conspired to defraud the United States government in violation of 31 U.S.C. § 3729(a)(3) by getting false or fraudulent claims allowed or paid to the damage of the United States government.

FOURTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF CALIFORNIA]
(Violation of California Government Code Sections 12650-12656)

58. Plaintiff State of California, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

59. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of California Government Code Sections 12650-12656, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

FIFTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF ILLINOIS]
(Violation of IL ST CH 740 § 175/1-175/8)

60. Plaintiff State of Illinois, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

61. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of IL ST CH 740 § 175/1-175/8, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

SIXTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF FLORIDA]
(Violation of FL ST §§ 68.081-68.092)

62. Plaintiff State of Florida, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

63. The conduct of Defendant Novartis, as herein alleged, was at all times herein

mentioned in violation of FL ST §§ 68.081-68.092, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

SEVENTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF TEXAS]
(Violation of TX HUM RES §§ 32.039-36.110)

64. Plaintiff State of Texas, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

65. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of TX HUM RES §§ 32.039-36.110, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

EIGHTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF GEORGIA]
(Violation of GA ST §§ 49-4-168.1-168.6)

66. Plaintiff State of Georgia, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

67. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of GA ST §§ 49-4-168.1-168.6, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

NINTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF TENNESSEE]
(Violation of TN ST §§ 4-18-101-108)

68. Plaintiff State of Tennessee, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

69. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of TN ST §§ 4-18-101-108, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

TENTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF VIRGINIA]
(Violation of VA ST §§ 8.01-216.1 -216.190)

70. Plaintiff State of Virginia, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

71. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of VA ST §§ 8.01-216.1-216.19, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

ELEVENTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF MASSACHUSETTS]
(Violation of MA ST 12 §§ 5A-5O)

72. Plaintiff State of Massachusetts, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

73. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of MA ST 12 §§ 5A-5O, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

TWELFTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF NEW YORK]
(Violation of NY STATE FIN §§ 187-194)

74. Plaintiff State of New York, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by

reference thereto.

75. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of NY STATE FIN §§ 187-194, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

THIRTEENTH CLAIM FOR RELIEF AGAINST DEFENDANT NOVARTIS

[PLAINTIFF STATE OF MICHIGAN]
(Violation of MI ST 400.601-610a)

76. Plaintiff State of Michigan, by and through Qui Tam Plaintiffs/Relators, hereby incorporates each and every allegation of Paragraphs 1 through 57 of Plaintiff's Complaint by reference thereto.

77. The conduct of Defendant Novartis, as herein alleged, was at all times herein mentioned in violation of MI ST 400.601-610a, thereby entitling said Plaintiff to all damages, compensatory and otherwise, therein described.

PRAYER FOR RELIEF

78. WHEREFORE, Plaintiff, United States of America ex rel. Relators Robert M. Lalley, Courtney Davis and William Manos prays that judgment be entered against Defendants, and each of them jointly and severally, for damages and otherwise as follows:

a. In an amount, presently indeterminable, but in excess of $100,000,000.00, on the First, Second and Third Claims, for violation of 31 U.S.C. § 3729(a)(1), (2) and (3); and that such sum be duly trebled, in addition to a fine of not less than $5,000 per violation and not more than $10,000, together with attorneys' fees and costs;

b. In addition, Plaintiffs pray for such further and additional relief at law or in equity that this Court may deem appropriate or proper.

79. WHEREFORE, Plaintiff States ex rel. Relators Robert M. Lalley, Courtney Davis and William Manos pray that judgment be entered against Defendants, and each of them jointly and severally, for damages and otherwise as follows:

a. In an amount, presently indeterminable, but in excess of $100,000,000.00, on the Fourth through Thirteenth Claims, for violation of the state laws therein alleged; and for attorneys' fees and costs, where appropriate under each State's law;

b. In addition, Plaintiffs pray for such further and additional relief at law or in equity that this Court may deem appropriate or proper.

JURY DEMAND

Plaintiffs and Qui Tam Plaintiff/Relators demand a trial by jury on all issues so triable.

Dated: November 25, 2008

Respectfully submitted,

By: _____
Richard P. Doyle, Jr.
Attorneys for Plaintiff,
United States of America ex rel.
and
Plaintiffs/Relators
Robert M. Lalley,
Courtney Davis and
William Manos

By: _____
Rene Tatro
Attorneys for Plaintiff,
United States of America ex rel.
and
Plaintiffs/Relators
Robert M. Lalley,
Courtney Davis and
William Manos

JANSSEN DOYLE, LLP

PROOF OF SERVICE

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. I am employed in the office of a member of the bar of this court at whose direction the service was made. My business address is JANSSEN DOYLE LLP, 140 Brookwood Drive, Suite 102, Orinda, CA 94563. On **November 25, 2008,** I served the following document(s) by the method indicated below:

COMPLAINT FOR DAMAGES (FALSE CLAIMS ACT, 31 U.S.C. § 3729 *et seq.*); AND DEMAND FOR JURY

( ) by transmitting via facsimile on this date from fax number (925) 295-1801 the document(s) listed above to the fax number(s) set forth below. The transmission was completed before 5:00 p.m. and was reported complete and without error. The transmission report, which is attached to this proof of service, was properly issued by the transmitting fax machine. Service by fax was made by agreement of the parties, confirmed in writing.

( ) VIA HAND DELIVERY

(X) by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Walnut Creek, California addressed as set forth below. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.

JOSEPH P. RUSSONIELLO
United States Attorney
JOANN M. SWANSON
Chief, Civil Division
SARA WINSLOW
STEVEN J. SALTIEL
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JESSICA S. CHAMPA
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U.S. Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed at Walnut Creek, California on **November 25, 2008.**

Laura Morrison

Laura Morrison

JANSSEN DOYLE, LLP