FOR IMMEDIATE RELEASE: **Contact:** James Hallinan

September 15, 2016 (505) 660-2216

Attorney General Balderas Sues Bristol-Myers Squibb for False & Deceptive Marketing

Drug Company failed to disclose Plavix may have increased patients' risk of internal bleeding

Albuquerque NM - Today, New Mexico Attorney General Hector Balderas announced that he filed a lawsuit against the pharmaceutical manufacturer Bristol-Meyers Squibb for false and deceptive marketing of the prescription drug Plavix. The complaint alleges that the drug company knew that its drug was ineffective in a percentage of the population and may have increased a patient's risk of internal bleeding, but the company failed to disclose that to prescribing doctors and the public.

"My office will continue to protect vulnerable New Mexican families and consumers through targeted, impact consumer litigation that will secure economic justice and recover pilfered taxpayer funds," said Attorney General Balderas. "Companies like this must be held accountable for deceiving the public and profiteering off of taxpayer monies and vulnerable New Mexicans who badly need safe, effective medical treatment."

Besides alleging deceptive and unfair trade practices, the suit alleges violations of New Mexico's Medicaid Fraud statutes and the Fraud Against Taxpayers Act. This lawsuit comes out of Attorney General Balderas' Fraud Against Taxpayers Strike Force. The Strike Force is focused on holding companies accountable for putting profits above New Mexicans and ensuring that New Mexico tax dollars are spent with transparency and accountability.

See attached for a copy of the complaint that was filed yesterday afternoon.

# # #

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

STATE OF NEW MEXICO, *ex rel.* HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff,

vs.

NO. D-101-CV-2016-02176

Case assigned to Singleton, Sarah

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC SANOFI US SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1 to 100

Defendants.

PLAINTIFF'S COMPLAINT FOR DECLARATORY RELIEF, DAMAGES, RESTITUTION AND CIVIL PENALTIES

1. Plaintiff, the State of New Mexico (hereinafter "the State"), by and through its Attorney General, Hector Balderas, hereby brings this action against Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo Inc. (collectively, "Defendants") and alleges, upon information and belief, as follows:

2. This action arises from Defendants' false, deceptive, and unfair labeling and promotion of their prescription antiplatelet drug Plavix (clopidogrel bisulfate), which are actionable under the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 *et seq.*, the New Mexico Medicaid Fraud Act, NMSA 1978, Sections 30-44-1, *et seq*., and the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 *et seq*., and for other common law and equitable causes of action stated herein by the New Mexico Attorney General in the exercise of his statutory powers.

3. Beginning in March 1998, until the present, Defendants have engaged in a false, deceptive, and unfair marketing strategy designed to increase revenues from Plavix. Since at least March 1998, Defendants knew or should have known that Plavix has diminished or no effect on a substantial and significant percentage of the patient population and that those patients for whom Plavix would not work could be identified through a simple genetic test. Yet, Defendants failed to disclose that negative efficacy information because it would adversely affect the number of Plavix prescriptions written and, thus, sales and revenues. For such patients, Plavix does not prevent heart attacks, strokes, or vascular death, and it presents a considerable risk of gastrointestinal bleeding and other complications. After scientists began to learn that Plavix has diminished or no effect on a significant percentage of the patient population, Defendants sought to protect Plavix's sales and increase revenues by marketing higher (and more expensive) doses of Plavix for such patients, placing them at even greater risk, while triggering substantially higher pharmacy costs incurred by government payors.

4. Since March 1998, Defendants have also falsely and misleadingly sought to replace aspirin with Plavix, which costs one hundred times more than aspirin, for treatment of patients at risk for ischemic events. Defendants ignored, concealed, and minimized clinical trial data and other information showing that Plavix is only as effective as – or in some cases even less effective than – aspirin in treating such patients, and that Plavix has a higher chance of causing gastrointestinal bleeding and other complications. Despite that information, Defendants falsely and misleadingly marketed Plavix as being more effective and safer than aspirin. Defendants also falsely and misleadingly marketed Plavix as being more effective and safer than other competitor drugs. In 2010, the American Stroke Association ("ASA") confirmed what Defendants knew or by the exercise of reasonable care should have known at all relevant times: "No studies have

compared clopidogrel [Plavix] with placebo, and studies comparing it with other antiplatelet agents [including aspirin] have not clearly established that it is superior or even equivalent to any one of them."

5. In addition, Defendants falsely, deceptively, and unfairly marketed Plavix as effective and safe for uses for which the drug had not been shown to be effective or safe. Defendants also, through deliberate deception or otherwise, knowingly caused false claims to be submitted to the State for reimbursement in connection with prescriptions for a drug that was not medically necessary and was not cost-effective.

6. Defendants' aggressive marketing strategy, combined with Defendants' successful cover-up of mounting adverse efficacy and safety evidence, produced billions of dollars in profits for Defendants. Plavix's sales in the United States peaked at $6.62 billion in 2011.

7. Plaintiff seeks to recover the costs of Plavix and the costs of Plavix-related illnesses, including, but not limited to, expenditures for:

a. Medical assistance provided under New Mexico's Medicaid Program pursuant to the Public Assistance Act, N.M. STAT. ANN. § 27-2-1 *et seq.*;

b. Public employees' health insurance coverage costs pursuant to the Group Benefits Act, N.M. STAT. ANN. § 10-7B-6;

c. Retired public employees' group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, N.M. STAT. ANN. § 10-7C-8;

d. Public employees and school board retirees' group health insurance costs from the Public School Insurance Fund, pursuant to the Public School Insurance Authority Act, N.M. STAT. ANN. § 22-2-6.6 and/or N.M. STAT. ANN. § 22-29-1; and

e. Any other expenditures by the New Mexico Human Services Department, the New Mexico Department of Health, the New Mexico Department of Corrections, the Risk Management Division of the General Services Department, the Retiree Health Care Authority and/or the Public Schools Insurance Authority.

f. Patients who have received Plavix prescriptions and/or treatment for Plavix-related illnesses in connection with expenditures made by the above-described State programs, agencies and/or departments are hereinafter collectively referred to as "State of New Mexico participants".

8. The State brings this action exclusively under the law of the State of New Mexico. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

9. Nor does the State bring this action on behalf of a class or any group of persons that can be construed as a class. Nor does the State bring this as a mass action or state its claims and causes of action in any way that can be construed as a mass action. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual users of Plavix may have against Defendants.

THE PARTIES

10. Plaintiff, the State of New Mexico, is a body politic created by the Constitution and laws of the State of New Mexico, and as such is not a citizen of any State.

11. Attorney General Hector Balderas is the present Attorney General of the State of New Mexico. Attorney General Hector Balderas is acting pursuant to his authority under, *inter alia*, NMSA 1978, Sections 8-5-1 *et seq*., the New Mexico Unfair Practices Act, NMSA 1978,

Sections 57-12-1 *et seq.*, the New Mexico Medicaid Fraud Act, NMSA 1978, Sections 30-44-1, *et seq*., and the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 *et seq*.

12. Upon information and belief, Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation with its principal corporate offices at 345 Park Avenue, New York, New York 10154 and facilities throughout the State of New Jersey. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times BMS has manufactured, advertised, labeled, marketed, promoted, sold, and distributed Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico. BMS is registered to do business in New Mexico.

13. Upon information and belief, Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with headquarters and research facilities located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times Sanofi-Aventis U.S. LLC has engaged in the business of manufacturing, developing, advertising, labeling, marketing, promoting, selling, and/or distributing Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico.

14. Upon information and belief, Defendant Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S. Inc., is a Delaware corporation with offices located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times Defendant Sanofi US Services Inc. fka Sanofi-Aventis U.S., Inc. has engaged in the business of manufacturing, developing, advertising, labeling, marketing,

promoting, selling, and/or distributing Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico.

15. Upon information and belief, Defendant Sanofi-Synthelabo Inc. is a Delaware corporation. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times Sanofi-Synthelabo Inc. has engaged in the business of manufacturing, developing, advertising, labeling, marketing, promoting, selling, and/or distributing Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico.

16. Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo Inc. are collectively referred to as "Sanofi" in this Complaint.

17. At all relevant times, Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform users regarding the benefits and risks associated with the use of the prescription drug Plavix.

18. DOE DEFENDANTS 1 to 100 are sued herein under fictitious names for the reason that after diligent and good faith efforts their names, identities, and capacities, whether individual, corporate, associate, or otherwise, are presently unknown to Plaintiff. Plaintiff will make the names or identities of said Defendants known to the Court after the same have been ascertained. Plaintiff is informed and believes, and based thereupon alleges, that each of the Defendants designated herein as a DOE DEFENDANT has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein and

has been in some manner responsible for some or all of the deceptive and unfair practices and violations of New Mexico's Medicaid Fraud Act and Fraud Against Taxpayers Act, and all common law violations alleged herein.

19. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times, each Defendant has occupied agency, employment, joint venture, or other relationships with each of the other named and DOE DEFENDANTS; that at all times herein mentioned each Defendant has acted within the course and scope of said agency, employment, joint venture, and/or other relationship; that each other Defendant has ratified, consented to, and approved the acts of its agents, employees, joint venturers, and representatives; and that each has actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

20. At all relevant times, Defendants, and each of them, have engaged in the business of, or were successors in interest to, entities engaged in the business of researching, licensing, designing, formulating, developing, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing, and/or selling the prescription drug Plavix as an antiplatelet medication to individuals and entities in the State of New Mexico, including the City and County of Santa Fe, New Mexico.

21. At all relevant times, Defendants have been authorized to do business within the State of New Mexico and have in fact sold and supplied Plavix to individuals and entities located within every county of the State of New Mexico.

JURISDICTION AND VENUE

22. The courts of New Mexico have jurisdiction over the subject matter of this action pursuant to, *inter alia*, Article VI, Section 13 of the New Mexico Constitution.

23. This Court has personal jurisdiction over Defendants because Defendants do business in New Mexico and/or have the requisite minimum contacts with New Mexico necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also being within the contemplation of the New Mexico "long arm" statute, NMSA 1978, Section 38-1-16.

24. Defendants did distribute, supply, market, sell, promote, advertise, warn and otherwise distribute Plavix and otherwise commit the wrongful acts and omissions described herein in New Mexico and specifically in Santa Fe County.

25. Venue is proper in Santa Fe County pursuant to NMSA 1978, Section 38-3-1 because: (1) the Attorney General resides in Santa Fe County, New Mexico; and (2) the causes of action alleged herein originated in part in Santa Fe County. Venue is also proper in Santa Fe County pursuant to NMSA 1978, Section 57-12-8 because Defendants have used methods, acts or practices in Santa Fe County which are unlawful under the Unfair Practices Act.

26. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against Defendants. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant Complaint do not implicate significant federal issues; do not turn on the substantial federal interpretation of federal law; nor do they raise a substantial federal question. Indeed, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common, and decisional laws of the State of New Mexico. Further, assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

Neither this case, nor any issue in this case has any effect on the federal system as a whole. Accordingly, any improvident and dilatory attempt by Defendant to remove this case to federal court would be without a reasonable legal basis in fact or law.

FACTUAL BACKGROUND

I. DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF PLAVIX

27. Plavix is an oral tablet formulation of clopidogrel bisulfate manufactured by BMS and jointly marketed in the United States by Defendants. All marketing and pricing decisions for Plavix have been made and implemented jointly by Defendants. Since March 17, 1998, Plavix has been exclusively marketed in the United States by Defendants under the registered trademark "Plavix®."

28. Plavix was first approved by the FDA on November 17, 1997 for the reduction of atherosclerotic events, *i.e.*, myocardial infarction (also known as a heart attack), stroke, and vascular death, in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease ("PAD"). On February 27, 2002, the FDA approved Plavix for the treatment of patients with a certain type of Acute Coronary Syndrome (unstable angina/non-ST-elevation myocardial infarction), also known as "NSTEMI." On August 17, 2006, the FDA approved Plavix for the treatment of patients with another type of Acute Coronary Syndrome (ST-elevation myocardial infarction), also known as "STEMI."

A. Failure to Disclose Plavix's Diminished Effectiveness in a Significant Percentage of the Patient Population

29. On March 25, 2010, Defendants added a black box warning to Plavix's label that states that Plavix does not become effective until it is metabolized into its active form by the CYP2C19 liver enzyme. Individuals with particular CYP2C19 genotypes are CYP2C19 poor

metabolizers. The black box warning added in March 2010 cautions that Plavix has diminished effectiveness in patients who are CYP2C19 poor metabolizers, and recommends alternative therapies in such patients.

30. It is believed that a significant percentage of the patient population in New Mexico consists of CYP2C19 poor metabolizers.

31. The black box warning added in March 2010 also states that patients who are CYP2C19 poor metabolizers treated with Plavix have higher cardiovascular event rates than patients with normal CYP2C19 function. The black box warning further states that tests are available to identify a patient's CYP2C19 genotype and aid in determining prescribing decisions, and to consider alternative treatment in patients identified as CYP2C19 poor metabolizers.

32. Plaintiff is informed and believes, and based thereupon alleges, that since at least March 1998, 12 years before the black box warning was added, Defendants knew or by the exercise of reasonable care should have known that Plavix has diminished or no effect on patients who are CYP2C19 poor metabolizers. Upon information and belief, Defendants, however, failed to disclose that information in order to protect Plavix's sales and revenues.

33. Plaintiff is also informed and believes, and based thereupon alleges, that since at least 2003, Defendants knew or by the exercise of reasonable care should have known that Plavix has diminished or no effect on patients who are also taking drugs that are CYP2C19 inhibitors. Upon information and belief, Defendants, however, failed to disclose that information in order to protect Plavix's sales and revenues.

34. Plaintiff is further informed and believes, and based thereupon alleges, that when information about Plavix's lack or utter absence of efficacy in patients who are poor CYP2C19 metabolizers became known in the scientific community through other channels, Defendants

attempted to undermine that information and protect Plavix's sales and increase its revenues by urging physicians to prescribe higher (and more expensive) doses of Plavix to such patients, putting them at a higher risk of gastrointestinal bleeding and other complications associated with Plavix.

35. Scientific literature available years before Defendants submitted Plavix's new drug application ("NDA") in 1997 described the genetic variations of the CYP2C19 enzyme that cause it to metabolize poorly in a significant percentage of the patient population, and the prevalence of those genetic variations in certain populations (e.g., Caucasian, African, and Asian). Such literature also described the effect of those genetic variations on drugs dependent on the CYP2C19 enzyme. An article in the Journal of Biological Chemistry concluded in 1994 that a defect in the CYP2C19 enzyme interfered with metabolization of numerous drugs. However, and importantly, the article's authors stated that they were able to test for the defect through a simple genetic test.

36. When Defendants submitted their NDA for Plavix in 1997, they relied on a very small data set and claimed not to understand exactly how the drug was metabolized. However, Defendants indicated that they knew that Plavix was metabolized in the liver, and that the CYP2C19, CYP2B6, and CYP3A4 enzymes of the cytochrome P450 system were principally involved.

37. In 2002 and 2003, published studies distinguished between responders and non-responders to Plavix. In 2002, individual variations in responsiveness to Plavix were reported.

38. Several articles published in 2004 and 2005 confirmed that Plavix has diminished or no effect on a significant portion of Plavix patients because they metabolize the drug poorly.

39. In 2005, the Journal of the American College of Cardiology published the results of a study, which Defendants sponsored, examining the effectiveness of 544 individuals to Plavix, concluding that "there is a very large range of responsiveness to ex vivo testing" in patients using

Plavix, and that "it is likely that a small but significant portion of patients are receiving inadequate protection from thrombotic events despite currently standard antiplatelet therapy, whereas a similar proportion may be at higher risk for bleeding complications."

40. In February 2006, the Journal of the American College of Cardiology published an abstract concluding that patients with a CYP2C19*2 allele are associated with a diminished response to Plavix, which may also explain why patients had previously reported variability in response to the drug.

41. In June 2006, the American Society of Hematology published the results of a study in an article stating that "pharmacodynamic response to [Plavix] varies widely from subject to subject, and about 25% of patients treated with standard [Plavix] doses display low ex vivo inhibition of ADP-induced platelet aggregation." The authors concluded that "response to [Plavix] was strongly influenced by the CYP2C19 genotypic status."

42. In January 2009, a study in the New England Journal of Medicine concluded that among persons treated with Plavix, "carriers of a reduced-function CYP2C19 allele had significantly lower levels of the active metabolite of [Plavix], diminished platelet inhibition, and a higher rate of major adverse cardiovascular events, including stent thrombosis, than did noncarriers." That study found that approximately 30% of the study participants had at least one reduced-function CYP2C19 allele. A different study published in 2009 estimated that the presence of such an allele is even more prevalent in African-American and Asian populations.

43. Plaintiff is informed and believes, and based thereupon alleges, that Defendants have known or should have known of additional information regarding Plavix's diminished or complete lack of effectiveness in many patients since at least March 1998.

44. There is no indication that Defendants brought any of the foregoing information about Plavix's lack of effectiveness to the public's attention until after the FDA notified Defendants in March 2009 of "new safety information" that should be included in Plavix's labeling; Defendants knew or should have known of information regarding Plavix's diminished or complete lack of effectiveness in many patients for over a decade.

45. Plaintiff is further informed and believes, and based thereupon alleges, that Defendants have misrepresented and failed to adequately disclose that Plavix is less effective in elderly patients than in younger patients, which Defendants knew or in the exercise of reasonable care should have known since at least August 2001.

46. By making statements about Plavix's efficacy and/or safety without disclosing information regarding Plavix's diminished or complete lack of effectiveness in many patients, Defendants made false and misleading statements and representations when marketing the drug, including in its labeling, sales materials, and other promotional materials and efforts.

47. Upon information and belief, at all relevant times, Defendants made the foregoing statements and omissions concerning Plavix's efficacy and safety to healthcare providers and the general public throughout the nation, including New Mexico.

B. False, Deceptive, and Unfair Superiority Claims

48. Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have sought to increase Plavix sales and market share by making false and misleading superiority claims about Plavix relative to aspirin, the traditional treatment for patients with or at risk for atherosclerosis. Aspirin costs approximately $.04 per pill, while Plavix costs approximately $4.00 per pill.

49. The efficacy and safety of Plavix and aspirin for treatment of patients at risk for ischemic events were studied in the *Clopidogrel vs. Aspirin in Patients at Risk for Ischemic Events* ("CAPRIE") clinical trial, the results of which were published in 1996. The CAPRIE trial studied 19,185 patients who were divided into three subgroups of approximately 6,300 patients. The three subgroups were respectively comprised of: (1) patients who experienced a recent stroke; (2) patients who experienced recent myocardial infarction; and (3) patients who experienced symptomatic PAD. Half of the patients in each subgroup were given 325 mg of aspirin once daily and the other half were given 75 mg of Plavix once daily. The primary objective of the study was to compare the rates of ischemic stroke, myocardial infarction, and vascular death between patients taking Plavix and patients taking aspirin.

50. The CAPRIE trial results showed an absolute risk reduction of only 0.5%. In other words, out of every 1,000 patients, a mere 5 patients experienced a benefit from treatment with Plavix in comparison to treatment with aspirin. While Plavix showed a slightly significant relative risk reduction of 8.7%, that figure was based in large part on the results in the PAD subgroup, which demonstrated a relative risk reduction of 23.8%. In the subgroups comprised of patients who had a recent stroke or myocardial infarction, the trial results did not show that Plavix had a statistically significant risk reduction; in fact, aspirin had a greater relative risk reduction than Plavix in patients who had a recent myocardial infarction. Plaintiff is informed and believes, and based thereupon alleges, that notwithstanding those results, since Plavix's product launch in March 1998, Defendants have falsely and misleadingly marketed Plavix as being superior to aspirin in treating stroke and heart attack patients in order to take market share away from aspirin medications.

51. Plaintiff is also informed and believes, and based thereupon alleges, that since March 1998, Defendants have falsely and misleadingly promoted Plavix and the CAPRIE trial results by not fully disclosing the results of the trial's subgroups, and by minimizing and failing to provide all of the data concerning adverse events occurring in the CAPRIE trial and other clinical trials involving Plavix.

52. Relatedly, Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have falsely and misleadingly promoted Plavix for primary prevention of disease, including primary prevention of strokes and myocardial infarctions, in all patients at risk for atherosclerosis. Plavix has not been approved for primary prevention, and it is not the standard of care. Generic aspirin remains the standard of care for patients with or at risk for atherosclerosis.

53. Similarly, Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have also falsely and misleadingly promoted Plavix as being more effective and safer than other competitors, such as Aggrenox, in order to increase Plavix's sales and market share. On information and belief, Defendants' strategy with respect to such competitors was similar to its strategy regarding aspirin in that Defendants made false and misleading statements about clinical trials involving those competitors when the trial results did not support Defendants' marketing messages.

54. Plaintiff is also informed and believes, and based thereupon alleges, that Defendants falsely and misleadingly promoted Plavix at much higher dosages than those approved by the FDA in order to compensate for the drug's low efficacy, while failing to disclose that Plavix is associated with hemorrhagic adverse events at its recommended dosage and that higher dosages of Plavix increase the risk of those and other adverse events associated with Plavix.

55. Further, Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have also increased Plavix's sales and market share by falsely and misleadingly promoting the drug as being effective and safe for uses for which it had not been demonstrated to be effective or safe.

56. In 2010, the ASA confirmed what Defendants knew or should have known all along when the ASA amended its *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack* (the "2010 ASA *Guidelines*") and stated that "[n]o studies have compared clopidogrel with placebo, and studies comparing it with antiplatelet agents have not clearly established that it is superior or equivalent to any one of them."

57. The 2010 ASA *Guidelines* also stated that "there have been no clinical trials to indicate that switching antiplatelet agents reduces the risk for subsequent events." Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew or should have known that switching patients from another antiplatelet medication to Plavix had not been shown to reduce the risk for subsequent events, yet Defendants have falsely, deceptively, and unfairly misrepresented and promoted such medication changes at all relevant times in order to increase Plavix's sales and market share.

58. In addition, Plaintiff is informed and believes, and based thereupon alleges, that Defendants have falsely, deceptively, and unfairly marketed Plavix by failing to timely disclose the results of the *Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance* ("CHARISMA") trial that showed no benefit of combination therapy in patients taking Plavix and aspirin versus patients taking aspirin alone. The CHARISMA trial also showed a significant increase in bleeding symptoms in patients taking Plavix and aspirin versus patients taking aspirin alone.

59. Defendants' marketing efforts also encompassed their labeling of Plavix, as indicated above. At all relevant times, Defendants made false or misleading statements and representations about Plavix's efficacy in the drug's labeling, including its package insert or label, as well as in sales materials, and other promotional materials and efforts.

60. Upon information and belief, at all relevant times, Defendants made the foregoing statements and omissions about Plavix's purported efficacy and superiority to healthcare providers and the general public throughout the nation, including New Mexico.

C. Additional False, Deceptive, and Unfair Conduct Concerning Important Safety Information

61. With respect to safety, the CAPRIE trial results showed less gastrointestinal bleeding in patients taking Plavix than in patients taking aspirin. But, the dosage of aspirin used in the trial—325 mg daily—is more than four times higher than the average dosage physicians advise for their patients. Physicians' average recommended dosage of 81 mg daily is just as effective as the 325 mg daily dosage, but much less likely to lead to gastrointestinal bleeding. Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew or should have known of the misleading nature of the CAPRIE trial results since at least March 1998, yet Defendants falsely and misleadingly marketed Plavix as being as safe or safer than aspirin based on the CAPRIE trial results. Plaintiff is also informed and believes, and based thereupon alleges, that since March 1998, Defendants have misrepresented and failed to adequately disclose important safety information about Plavix revealed in the CAPRIE trial, other clinical trials, and other sources of adverse event information, including information showing that Plavix is less safe than aspirin.

62. Although Defendants have never compared Plavix to a lower dosage of aspirin in a clinical trial, in *Clopidogrel versus Aspirin and Esomepraxole to Prevent Recurrent Ulcer*

Bleeding, a study published in the New England Journal of Medicine in January 2005, Plavix was demonstrated to cause appreciably more gastrointestinal bleeding than aspirin taken in conjunction with Prilosec, an inexpensive over-the-counter drug, in patients with a history of aspirin-induced ulcers. The study demonstrated that switching patients who had aspirin-induced ulcers from aspirin to Plavix is neither safe nor anywhere near as cost-effective as adding Prilosec to aspirin therapy. Plaintiff is informed and believes, and based thereupon alleges, that Defendants were aware of that circumstance many years before that study was published, and did not disclose the results of that study to healthcare professionals or the general public after the study was published, but rather continued to falsely and misleadingly market Plavix as being as safe or safer than aspirin.

63. Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have falsely and misleadingly marketed Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding.

64. Plaintiff is informed and believes, and based thereupon alleges, that since at least March 1998, Defendants knew or should have known that Plavix causes more gastrointestinal bleeding and other complications than other antiplatelet medications, yet Defendants misrepresented and failed to adequately disclose that information to healthcare providers and the general public.

65. Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have misrepresented and failed to adequately disclose that patients are at a higher risk of gastrointestinal bleeding and other complications when taking aspirin in conjunction with Plavix than when taking aspirin alone.

66. Plaintiff is informed and believes, and based thereupon alleges, that since at least August 2001, Defendants have misrepresented and failed to adequately disclose that elderly

patients taking Plavix have an increased risk of gastrointestinal bleeding as compared to younger patients taking Plavix.

67. As noted above, Defendants' marketing efforts also encompassed their labeling of Plavix. At all relevant times, Defendants made false or misleading statements and representations about Plavix's safety in the drug's labeling, including its package insert or label, sales materials, and other promotional materials and efforts.

68. Upon information and belief, at all relevant times, Defendants made the foregoing statements and omissions about Plavix's safety to healthcare providers and the general public throughout the nation, including New Mexico.

D. Defendants' False and Misleading Representations and Omissions Regarding the Alleged Effectiveness, Safety and Superiority of Plavix Caused Third Parties to Submit Claims for Reimbursement to the State of New Mexico That Were False Within the Meaning of New Mexico Law

69. Defendants, in marketing Plavix, knew that pharmacies and other facilities supplying Plavix to patients throughout New Mexico would routinely be seeking reimbursement from the State of New Mexico under its Medicaid (and related) programs. As a result, Defendants, by promoting Plavix as safer and more effective than other medications when it was not, at 100 times the cost of available alternatives, knowingly caused innocent third parties to submit claims for reimbursement to the State of New Mexico that Defendants knew or should have known did not qualify for payment.

70. By doing so, Defendants obtained, by means of false or fraudulent representation or promise, large sums of money from the State of New Mexico in connection with delivery of or payment for health care benefits that are in whole or in part paid for or reimbursed or subsidized by the state.

71. Defendants benefited from this deception by increased prescriptions of Plavix, resulting in increased profits for Defendants.

72. In addition, Defendants' misleading conduct, statements and omissions regarding the alleged effectiveness, superiority, and safety of Plavix deprived physicians and the State of New Mexico of the ability to accurately determine whether the drug was in fact "medically necessary" in any given situation.

73. By writing prescriptions for Plavix for which reimbursement would be sought through public assistance programs, physicians were certifying by implication that the treatment was safe, medically necessary and cost-effective, when in fact it was not, because Plavix was ineffective or unsafe or both.

74. Therefore, by causing physicians to unwittingly certify that Plavix was medically necessary and cost-effective when it was not, Defendants knowingly caused the submission of a false claims to the State of New Mexico in violation of New Mexico law.

E. The FDA's Repeated Objections to Defendants' False, Deceptive, and Unfair Marketing

75. As discussed more fully above, Defendants have systematically and deliberately promoted Plavix through false and misleading marketing that overstates the drug's efficacy, advances unsubstantiated superiority claims, and minimizes critical adverse event and risk information. As a result, the FDA has repeatedly admonished Defendants' promotion of Plavix.

76. For example, on November 23, 1998, the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") reprimanded Sanofi, stating that Defendants' dissemination of a letter, purportedly authored by a physician, violated the Federal Food, Drug, and Cosmetic Act ("FDCA") because it promoted Plavix for an unapproved use (immediately prior to coronary artery stent placement) and an unapproved dose (300 mg loading dose), as well as

because it lacked fair balance in failing to disclose safety risks associated with the use of Plavix. In particular, the letter explained as follows: "Because Plavix is associated with hemorrhagic adverse events at recommended 75 mg/day dose, promotion of Plavix in patients receiving coronary artery intervention, at four times the recommended dose, in combination with other agents known to increase the risk of bleeding, raises significant patient safety concerns."

77. On December 18, 1998, DDMAC again admonished Sanofi, stating that multiple promotion materials it disseminated—a brochure, a journal advertisement, and a video—contained promotional claims that were false or misleading and lacking in fair balance because they made unsubstantiated superiority claims about Plavix relative to aspirin, overstated Plavix's efficacy, and minimized or failed to adequately present adverse event and risk information.

78. On May 9, 2001, DDMAC alerted Sanofi that its dissemination of a particular visual aid for Plavix contained false or misleading promotional claims because it overstated the drug's efficacy, included an unsubstantiated superiority claim about Plavix relative to aspirin, and included a misleading efficacy presentation. In particular, the Warning Letter stated:

> On page 4 of the visual aid you present the claim, "Significant overall risk reduction vs. aspirin 325 mg in CAPRIE, a 3 year study of 19,185 patients." This claim is misleading because it suggests that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence. ***As previously stated in our December 18, 1998, untitled letter, the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin. Therefore, claims suggesting that Plavix is significantly better than aspirin are misleading*** because they are not based on substantial evidence.

79. On June 9, 2001, DDMAC again reprimanded Sanofi, stating that the dissemination of a direct-to-consumer television advertisement for Plavix was misleading and violated regulatory requirements because it minimized the role of physicians in determining whether Plavix is the appropriate therapy for a patient's condition, and because it did not ensure adequate provision for disseminating Plavix's approved product labeling.

80. On March 26, 2009, DDMAC again reprimanded Sanofi, stating that three of its internet advertisements were misleading because they made representations or suggestions about the efficacy of Plavix but failed to communicate any risk information associated with the use of the drug, thereby indicating that Plavix is safer than has been demonstrated.

F. The Impact of Defendants' False, Deceptive, and Unfair Marketing of Plavix

81. As discussed above, Defendants launched and maintained a massive promotional campaign to increase Plavix's sales and market share. Plavix's blockbuster sales were driven by Defendants' decision to put marketing, sales, and corporate profits ahead of science and patient safety. Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew that the dissemination of information about Plavix's true efficacy and safety profile would devastate Plavix's sales and make Plavix unable to compete with other established, cheaper, and safer atherosclerosis therapies. Thus, Defendants chose, and continue to choose, to put their corporate profits ahead of patients' safety and repeatedly failed, and continued to fail, to disclose critical efficacy and safety information about Plavix, including information about diminished or no responsiveness to Plavix that has led to the need for a black box warning on Plavix's label.

82. As shown above, Defendants' corporate strategy and business model is dictated not by science, but by sales and marketing. Plaintiff is informed and believes, and based thereupon alleges, that Defendants' marketing and commercial personnel exert extensive control over scientific and medical decisions, such as the initiation of clinical trials, the types of trials done, the design of those trials, and the reporting and publication of trial data, all with the ultimate goal of producing further support for Defendants' marketing messages and bolstering sales of Plavix.

83. On information and belief, Defendants also obscured or failed to report important safety information, including information relating to Plavix's risk of gastrointestinal bleeding,

because doing so would jeopardize Plavix's sales and would be inconsistent with Defendants' key marketing and sales messages, as discussed above. Defendants' top priority is neither science nor safety, but rather marketing. Marketing concerns infected and distorted Defendants' entire Plavix scientific program and continue to do so to this today.

84. Further, Plaintiff is informed and believes, and based thereupon alleges, that Defendants maintained a marketing-based publication strategy designed to misleadingly influence medical and scientific literature by promoting the publication of medical and scientific articles that would support their marketing messages about Plavix's efficacy and safety and/or suggest dissatisfaction with competing therapies. On information and belief, that strategy included practices such as ghostwriting articles and hiring outside ghostwriting companies, giving Defendants' marketing personnel editorial and substantive input into decisions about what scientific studies to publish and the actual content of such publications, and forming misleading financial and promotional relationships with authors, "opinion leaders," and other physicians. On information and belief, Defendants gave their marketing departments' extensive control over Defendants' research and publication decisions so that medical and scientific publications could be used as tools to promote Defendants' Plavix marketing messages.

85. In short, Defendants have profited tremendously by making false and misleading statements and representations regarding Plavix's efficacy and safety, as detailed above.

86. Plaintiff is informed and believes, and based thereupon alleges, that Defendants' conduct described herein is only a fraction of their false and misleading Plavix marketing.

87. Defendants failed to adequately disclose facts sufficient to arouse suspicion of the existence of the claims that Plaintiff now asserts. Plaintiff was not alerted to the existence and scope of Defendants' wrongful conduct and the claims arising from such conduct, and could not

have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' self-concealing scheme and affirmative conduct to perpetuate that scheme deprived New Mexico patients, their insurers, public healthcare providers, public entities, and government payors of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

88. Defendants' far-reaching, massive, and widespread promotional campaign to drive Plavix's sales was specifically directed at and did influence the State of New Mexico. Defendants' sales representatives, lobbyists, Defendants' "opinion leaders", and company "scientists" presented false and misleading information regarding the safety and efficacy of Plavix which was reasonably relied upon by the State of New Mexico.

89. In addition, Defendants, through their control and manipulation of studies and research publications, their sponsorship of medical education programs, their submission of false and misleading information to the FDA, their use of "opinion leaders", their failure to adequately warn of Plavix's true risks in their labeling and other marketing materials, and their false and deceptive marketing conducted by Defendants' sales representatives, lobbyists, "opinion leaders", and company "scientists", caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

90. Defendants engaged in a premeditated program to influence consumers, prescribers, and the State of New Mexico to believe that Plavix was a superior drug when it was not.

91. The financial toll that Defendants' false and deceptive marketing of Plavix has had on the State of New Mexico has been dramatic. Relying upon Defendants; promises of superior treatment and better outcomes compared with aspirin and other competitor drugs, the State of New

Mexico paid a hefty premium for a drug that in truth was no more efficacious than far cheaper drugs, but was far more dangerous.

92. The State of New Mexico seeks the most effective and safest treatment for its residents and relies on pharmaceutical companies to fairly and accurately represent the safety and efficacy of their products. Defendants have wholly violated that trust, and instead have perpetrated their fraudulent scheme to defraud the State of New Mexico, and have bilked the State of New Mexico out of millions of dollars from various sources by making false representations that Plavix was better than existing medications, and could decrease ischemic risks.

93. Defendants' false, misleading, and deceptive marketing of Plavix resulted in millions of dollars of Plavix sales to the State of New Mexico, sales that otherwise would not have been made. Defendants were unjustly enriched and profited from the suppression of the truth and misleading promotion of Plavix.

94. Defendants' false, misleading and deceptive marketing of Plavix also resulted in State of New Mexico participants who took Plavix experiencing gastrointestinal bleeding. As a result, the State of New Mexico has borne and will bear additional costs for the care and treatment of these undisclosed increased incidents of bleeding.

95. This Complaint is based solely upon the laws of the State of New Mexico, and contains causes of action found within those laws. To the extent that the Defendant asserts that any claim contained herein raises a substantial question of federal law or a federal cause of action, Plaintiff hereby disavows any such claim.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

96. The running of any statute of limitations has been tolled by reason of Defendants'

fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff the true risks associated with taking Plavix.

97. As a result of Defendants' actions, Plaintiff and, upon information and belief, State of New Mexico participants, and prescribers within the State of New Mexico, were unaware, and could not reasonably have known, have ascertained, or have learned through reasonable diligence, the true risks associated with taking Plavix and/or the damages resulting from the Defendants' wrongful acts, and/or that the concealment of those risks were the direct and proximate result of Defendants' acts and omissions.

98. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Plavix. Defendants were under a duty to disclose the true character, quality and nature of Plavix because this was non-public information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, State of New Mexico participants, and prescribers within the State of New Mexico. In addition, the Defendants are estopped from relying on any statute of limitations because of their intentional concealment of their wrongful and fraudulent conduct.

99. Plaintiff had no knowledge that the Defendants were engaged in the wrongdoing and unlawful conduct alleged herein. Because of the fraudulent acts of concealment of wrongdoing and unlawful conduct by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing and unlawful conduct, nor was the damage resulting from the Defendants' wrongful acts capable of ascertainment by the Plaintiff, nor, upon information and belief, State of New Mexico participants, and/or prescribers within the State of New Mexico. Also, the economics of this fraud should be considered. The Defendants had the ability to and did spend

enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff, State of New Mexico participants, and prescribers within the State of New Mexico could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on the Defendants' representations.

COUNT I

VIOLATIONS OF THE NEW MEXICO UNFAIR PRACTICES ACT [NMSA 1978, Section 57-12-3]

100. The State repeats and reiterates the allegations previously set forth herein.

101. Defendants' acts and omissions complained of in paragraphs 27-99, constitute false or misleading oral or written statements or other representations and omissions that Defendants knowingly made in the regular course of their trade and in connection with the sale of their goods, which may have, tended to, or did deceive or mislead consumers and medical professionals. These acts and omissions constitute unfair and deceptive trade practices as defined under Section 57-12-2(D) and in violation of Section 57-12-3.

102. Defendants engaged in the above-described acts and omissions intentionally and with knowledge that harm might result, and thus willfully as defined under Section 57-12-11.

103. Defendants engaged in unfair or deceptive acts or practices by failing to disclose, in Plavix's labeling and otherwise, that Plavix has diminished or no effect on a significant percentage of the patient population.

104. Defendants also engaged in unfair or deceptive acts or practices by making statements about Plavix's efficacy and/or safety, in Plavix's labeling and otherwise, without

disclosing that Plavix has diminished or no effect on a significant percentage of the patient population.

105. Defendants also engaged in unfair or deceptive acts or practices by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin in Plavix's labeling and otherwise.

106. Defendants also engaged in unfair or deceptive acts or practices by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin.

107. Defendants' willful and repeated acts and omissions relating to Plavix, as described above constitute unfair or deceptive acts or practices in the conduct of commerce, both of which violate the New Mexico Unfair Practices Act, NMSA 1978, Section 57-12-3, including:

a. Defendants represented that Plavix has characteristics, uses and benefits that it does not have, in violation of NMSA 1978, Section 57-12-2 (D)(5).

b. Defendants represented that Plavix has superior benefits as compared to other competitor medications that it does not have, in violation of NMSA 1978, Section 57-12-2 (D)(7).

c. Defendants represented that Plavix was a safe and effective drug when such representations were untrue, false and misleading, in violation of NMSA 1978, Section 57-12-2 (D)(7).

d. Defendants engaged in conduct using exaggeration, innuendo or ambiguity as to material facts regarding the risk-benefit profile of Plavix which created a likelihood of confusion and misunderstanding, in violation of NMSA 1978, Section 57-12-2 (D)(14).

e. Defendants made deceptive representations of material facts regarding Plavix, in violation of NMSA 1978, Section 57-12-2 (D)(14).

f. Defendants' promotional activities regarding Plavix, including publishing and distributing statements which were misleading and deceptive, and which omitted material information necessary to make the statements not be misleading and deceptive, or tending to deceive, were in violation of NMSA 1978, Section 57-12-2 (D)(14).

g. Defendants' conduct constitutes an unconscionable trade practice in that it took advantage of the lack of knowledge of the State, New Mexico health care professionals and State of New Mexico participants regarding Plavix's risk-benefit profile, in violation of NMSA 1978, Section 57-12-2 (E)(1).

h. Defendants' conduct constitutes an unconscionable trade practice in that it resulted in a gross disparity between the value received and the price paid, in violation of NMSA 1978, Section 57-12-2 (E)(2).

108. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to misleading and deceptive information regarding Plavix communicated in any manner by a sales representative constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

109. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to a misleading and/or deceptive print advertisement regarding Plavix constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

110. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to a misleading and/or deceptive brochure regarding Plavix constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

111. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to other misleading and/or deceptive information regarding Plavix, provided directly or indirectly by Defendants, e.g., by means of package labeling, warning, Dear Healthcare Provider letters, CD-ROMs, DVDs, dinners sponsored by Defendants, PowerPoint presentations, promotional items, continuing medical education materials and events sponsored by Defendants and meetings sponsored by Defendants, constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

112. Each piece of marketing material used or disseminated in New Mexico which contained false or deceptive representations constitutes a separate, distinct, knowing and willful violation of the Unfair Practices Act.

113. Each Plavix prescription written in New Mexico without an adequate warning constitutes a separate and distinct violation of the Unfair Practices Act.

114. Each exposure of a New Mexico resident to Plavix resulting from the aforementioned conduct of Defendants constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

115. Defendants' violations of the Unfair Practices Act were and continue to be willful.

116. Unless enjoined from doing so, Defendants will continue to violate the New Mexico Unfair Practices Act.

117. The State seeks reimbursement of all monies paid for Plavix by the State of New Mexico.

118. The State of New Mexico also seeks restitution for all monies paid for Plavix in connection with State of New Mexico programs and/or by state agencies and/or departments.

119. The State of New Mexico also seeks disgorgement of profits from Defendants for all sales of Plavix in connection with State of New Mexico programs and/or by state agencies and/or departments.

120. The State of New Mexico also seeks all recoverable penalties under Section 57-12-11 for violations of the New Mexico Unfair Practices Act.

COUNT II

VIOLATION OF THE NEW MEXICO MEDICAID FRAUD ACT [NMSA 1978, Section 30-44-7]

121. The State repeats and reiterates the allegations previously set forth herein.

122. Pursuant to NMSA 1978, Section 30-44-7(A), Medicaid fraud consists of, *inter alia,*:

> (3) presenting or causing to be presented for allowance or payment with intent that a claim be relied upon for the expenditure of public money any false, fraudulent, excessive, multiple or incomplete claim for furnishing treatment, services or goods; or
>
> (4) executing or conspiring to execute a plan or action to:
>
> > (a) defraud a state … funded or mandated managed health care plan in connection with the delivery of or payment for health care benefits, including engaging in any intentionally deceptive marketing practice in connection with proposing, offering, selling, soliciting or providing any health care service in a state …funded or mandated managed health care plan; or
> >
> > (b) obtain by means of false or fraudulent representation or promise anything of value in connection with delivery of or payment for health care benefits that are in whole or in part paid for or reimbursed or subsidized by a state …funded or mandated managed health care plan.

123. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance

of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants committed violations of subsections (3) and (4) of NMSA 1978, Section 30-44-7(A) in connection with the State's Medicaid program.

124. On information and belief, Defendants' clinical research and publication strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns. Defendants repeatedly failed to disclose important safety information; it improperly and deceptively influenced the medical and scientific literature and the perception of Plavix within the medical community; it consistently downplayed Plavix's risks; it formed deceptive and misleading financial and promotional relationships with "opinion leaders," speakers and other physicians for the purpose of promoting the product; it engaged in misleading sales training, sales tactics, and marketing to prescribers, Medicaid participants, and/or the State of New Mexico that misrepresented the safety and efficacy of Plavix; it engaged in the ghostwriting of medical and scientific articles; and it engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein. Defendants marketed Plavix as safe and effective with the intent that the State rely on its representations so that the medical providers would not prescribe, and the State pay for, other effective, safe prescription competitor drugs.

125. In addition, through the actions described above, Defendants caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

126. Defendants' aggressive, illegal promotions have induced a misallocation of State Medicaid funds through a pattern of fraudulent conduct. Defendants made or caused false claims, statements and representations of material fact to be made in connection with the New Mexico Medicaid program. In addition, Defendant knowingly and willfully concealed or failed to disclose material facts, events and/or transactions which affected Defendants' entitlement to payment, reimbursement, or benefits under the State's Medicaid plan and/or the amount of payment, reimbursement, or benefit to which the Defendants were entitled for services, goods or assistance rendered in connection with the New Mexico Medicaid program. Defendants' scheme included the implementation of intentionally deceptive marketing practices. Defendants intended that their fraudulent promotions be relied upon for the expenditure of public money, and result in the reimbursement of prescriptions by the New Mexico Medicaid program.

127. As a result of Defendants' fraudulent marketing of Plavix, the New Mexico Medicaid program has paid millions of dollars for Plavix and has paid excessive prices for Plavix. As a result, Defendants have been illegally enriched at the expense of the New Mexico Medicaid program. Further, the New Mexico Medicaid program has been required and will be required to pay the costs of treatment for Medicaid recipients actively harmed by Defendants' actions.

128. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance

of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information. Defendants' wrongful conduct resulted in charges to the New Mexico Medicaid program for goods or services that were so deficient as to be worthless.

129. Each claim submitted for Plavix for payment by the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

130. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to misleading and deceptive information regarding Plavix in connection with the New Mexico Medicaid program communicated in any manner by a sales representative constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

131. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to a misleading and/or deceptive print advertisement regarding Plavix in connection with the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

132. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to a misleading and/or deceptive brochure regarding Plavix in

connection with the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

133. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to other misleading and/or deceptive information regarding Plavix in connection with the New Mexico Medicaid program, provided directly or indirectly by Defendants, e.g., by means of package labeling, Dear Healthcare Provider letters, CD-ROMs, DVDs, dinners sponsored by Defendants, PowerPoint presentations, promotional items, continuing medical education materials and events sponsored by Defendants and meetings sponsored by Defendants, constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

134. Each piece of marketing material used or disseminated in New Mexico in connection with the New Mexico Medicaid program which contained false or deceptive representations constitutes a separate, distinct, knowing and willful violation of the Medicaid Fraud Act.

135. Each Plavix prescription written in New Mexico without an adequate warning constitutes a separate and distinct violation of the New Mexico Medicaid Fraud Act.

136. As a direct and proximate result of Defendants' wrongful conduct, the State of New Mexico and it citizens have suffered and will continue to suffer substantial damage and injury as a result of Defendants' violations of the New Mexico Medicaid Fraud Act.

137. Pursuant to the New Mexico Medicaid Fraud Act, the State is entitled to reimbursement for all monies paid for Plavix in connection with the New Mexico Medicaid Program, a civil penalty of three times the amount of excess payments, a civil penalty of ten thousand dollars ($10,000) for each false or fraudulent claim submitted or representation made,

reasonable attorneys' fees, interest, and all other fees and costs of investigation and enforcement of civil remedies.

COUNT III

VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT [NMSA 1978, Section 44-9-3]

138. The State repeats and reiterates the allegations previously set forth herein.

139. Defendants' willful and repeated acts and omissions relating to Plavix, as described above, violate the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Section 44-9-3.

140. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants knowingly presented, or caused to be presented, false claims for payment or approval, in violation of NMSA 1978, Section 44-9-3A(1).

141. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient

population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants knowingly made, used, or caused to be made or used, false, misleading or fraudulent statements to obtain or support the approval of, or the payment on, false or fraudulent claims, in violation of NMSA 1978, Section 44-9-3A(2).

142. By engaging in the wrongful conduct described herein, Defendants conspired to defraud the State by obtaining approval or payment on false or fraudulent claims.

143. On information and belief, Defendants' clinical research and publication strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns, and Defendants' management allowed marketing personnel to direct the company's so-called scientific research rather than enabling independent analysis. Defendants repeatedly failed to disclose important safety information; they improperly and deceptively influenced the medical and scientific literature and the perception of Plavix within the medical community; they consistently downplayed Plavix's risks; they formed deceptive and misleading financial and promotional relationships with "opinion leaders," speakers and other physicians for the purpose of promoting the product; they engaged in misleading sales training, sales tactics, and marketing to

prescribers, participants in State programs, and/or the State of New Mexico that misrepresented the safety and efficacy of Plavix; they engaged in the ghostwriting of medical and scientific articles; and they engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein. Defendants marketed Plavix as safe and effective with the intent that the State rely on their representations so that the medical providers would not prescribe, and the State pay for, other effective, safe competitor drugs.

144. In addition, Defendants, through their control and manipulation of studies and research publications, their sponsorship of medical education programs, their submission of false and misleading information to the FDA, their use of "opinion leaders", their failure to adequately warn of Plavix's true risks in their labeling and other marketing materials, and their false and deceptive marketing conducted by their sales representatives, lobbyists, and "opinion leaders," caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

145. Defendants' aggressive, illegal promotions have induced a misallocation of State funds through a pattern of fraudulent conduct. Defendants made or caused false claims, statements and representations of material fact to be made in connection with the State of New Mexico programs and/or in connection with expenditures made by State agencies and/or departments. In addition, Defendants knowingly and willfully concealed or failed to disclose material facts, events and/or transactions which affected Defendants' entitlement to payment, reimbursement, or benefits under the State's programs or by State agencies and/or departments, and/or the amount of payment, reimbursement, or benefit to which the Defendants were entitled for services, goods or assistance rendered in connection with the State's programs and/or to State agencies and/or departments. Defendants' scheme included the implementation of intentionally deceptive marketing practices.

Defendants intended that their fraudulent promotions be relied upon for the expenditure of public money, and result in the reimbursement of prescriptions by the State of New Mexico.

146. As a result of Defendants' fraudulent marketing of Plavix, the State of New Mexico has paid millions of dollars for Plavix and has paid excessive prices for Plavix. As a result, Defendant has been illegally enriched at the expense of the State of New Mexico. Further, the State of New Mexico has been required and will be required to pay the costs of treatment of State of New Mexico participants actively harmed by Defendants' actions.

147. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information. Defendants' wrongful conduct resulted in charges to the State of New Mexico for goods or services that were so deficient as to be worthless.

148. Each claim for Plavix presented to the State of New Mexico or to a contractor, grantee or other recipient of state funds constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

149. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to misleading and deceptive information regarding Plavix communicated in any manner by a sales representative made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

150. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to a misleading and/or deceptive print advertisement regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

151. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to a misleading and/or deceptive brochure regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

152. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to other misleading and/or deceptive information regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

153. In addition to, or in the alternative, each piece of marketing material used or disseminated in New Mexico which contained false or deceptive representations regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

154. In addition to, or in the alternative, each Plavix prescription written in New Mexico in connection with State of New Mexico programs without an adequate warning constitutes a separate and distinct violation of the New Mexico Fraud Against Taxpayer's Act.

155. As a direct and proximate result of Defendants' wrongful conduct, the State of New Mexico and it citizens have suffered and will continue to suffer substantial damage and injury as a result of Defendants' violations of the New Mexico Fraud Against Taxpayer's Act.

156. Pursuant to the New Mexico Fraud Against Taxpayer's Act, the State is entitled to three times the amount of damages sustained by the State because of Defendants' violations of the New Mexico Fraud Against Taxpayer's Act, a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation, reasonable attorneys' fees, and costs.

COUNT IV

FRAUD

157. Plaintiff repeats and reiterates the allegations previously set forth herein.

158. Defendants' warnings of Plavix contained false representations and/or failed to accurately represent the material facts of the full range and severity of risks and adverse reactions associated with the product.

159. Defendants' Plavix-related representations and assertions to the State of New Mexico, prescribers, and State of New Mexico participants contained intentional misrepresentations and material omissions as to the safety of Plavix and its defective design.

160. Defendants were negligent in not making accurate representations regarding the side effects and adverse medical conditions associated with the use of Plavix.

161. Defendants knew or reasonably should have known through adequate testing that the representations made to the State with regard to the safety and efficacy of Plavix were false or incomplete, and misrepresented the material facts of Plavix's unsafe and defective condition.

162. The State, through its programs, departments and agencies, expended millions of dollars for Plavix prescriptions which were directly caused by the fraudulent and misleading statements of the Defendants.

163. Defendants willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Plavix from the State of New Mexico, prescribers, and State of New Mexico participants.

164. Defendants intentionally withheld information regarding the safety risks and side effects associated with Plavix with the intent to induce the State of New Mexico, prescribers and State of New Mexico participants.

165. The State of New Mexico, prescribers and State of New Mexico participants were justified in their reliance on Defendants to educate them as to the risks and dangerous and potentially life-threatening side effects associated with Plavix use.

166. Defendants' far-reaching, massive, and widespread promotional campaign to drive Plavix's sales was specifically directed at and did influence the State of New Mexico. Defendants' sales representatives, lobbyists, "opinion leaders", and company "scientists" directly

communicated with the State of New Mexico, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Plavix which was reasonably relied upon by the State of New Mexico.

167. In addition, Defendants, through their control and manipulation of studies and research publications, their submission of false and misleading information to the FDA, their use of "opinion leaders", their failure to adequately warn of Plavix's true risks in their labeling and other marketing materials, and their false and deceptive marketing conducted by Defendant sales representatives, lobbyists and "opinion leaders," caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

168. Defendants' aggressive, illegal promotions have induced a misallocation of State funds through a pattern of fraudulent conduct which caused false claims to be submitted to the State of New Mexico's programs, agencies and departments. Defendants executed and conspired to execute a plan to defraud the State of New Mexico in connection with the delivery of or payment for Plavix. Defendants' plan included the implementation of intentionally deceptive marketing schemes. Defendants intended that their fraudulent promotions would result in the reimbursement of prescriptions by the State of New Mexico's programs, agencies and departments.

169. Each of the Defendants' misleading and deceptive statements, representations and advertisements related to Plavix were material to the State's reimbursement of Plavix.

170. As a proximate and legal result of Defendants' fraudulent misrepresentations, the State of State of New Mexico has suffered and will continue to suffer damages, and is therefore entitled to recover for those damages.

171. The reprehensible nature of the Defendants' conduct further entitles the State to an award of punitive damages.

COUNT V

NEGLIGENCE

172. Plaintiff repeats and reiterates the allegations previously set forth herein.

173. Defendants owed a duty to exercise reasonable care in the testing, marketing, manufacture, sales, labeling, and/or distribution of Plavix, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed, or misrepresented side effects or risks. Defendants owed this duty to the State of New Mexico, as the State funded the distribution of Plavix in the State of New Mexico.

174. Defendants breached this duty, as they were negligent in the testing, marketing, manufacture, sale, advertising, labeling and distribution of Plavix.

175. Defendants further negligently, carelessly, recklessly, willfully and/or intentionally engaged in the following conduct:

(a) Supplying a product that it knew, or should have known, contained inadequate warnings of side effects and risks that were known to, or based on facts available to the Defendants;

(b) Supplying a product lacking sufficient warnings and/or instructions when it knew, or should have known, the side effects and risks associated with Plavix were not generally known by the State of New Mexico, prescribers, and patients;

(c) Misrepresenting the safety and efficacy of Plavix;

(d) Representing that Plavix was safer and more effective than cheaper, safer and equally (or more) effective medications;

(e) Failing to disclose the true facts regarding the safety and efficacy of Plavix;

(f) Bringing Plavix to market when it knew or should have known of the dangerous and defective condition of Plavix;

(g) Bringing Plavix to market when it knew or should have known of the Plavix's diminished effectiveness on a significant percentage of the patient population;

(h) Failing to remove Plavix from the market when it knew or should have known of the dangerous and defective condition of Plavix; and

(i) Continuing to promote, market and sell Plavix after it knew, or should have known, of the serious side effects and risks associated with Plavix use.

176. Defendants breached this duty, as they were negligent in the testing, marketing, manufacture, sale, advertising, labeling and distribution of Plavix.

177. Defendants' negligent, careless, reckless, willful and/or intentional conduct was the proximate cause of the injuries and damages sustained by the State.

178. At all relevant times, Defendants knew, or should have known, that Plavix may be hazardous to human health.

179. Plavix is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Plavix greatly outweigh any claimed utility of Plavix to patients.

180. As a direct result of the unreasonable marketing and promotional practices of Defendants, Plavix could be defective and unreasonably dangerous.

181. Plavix reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendants. At the time Plavix was sold or placed on the market, it was in a defective condition and unreasonably dangerous to New Mexico patients.

182. The State participants used Plavix in the manner in which it was intended to be used, without any substantive alteration or change in the product.

183. Due to the negligent, careless, reckless, willful and/or intentional conduct of the Defendants, as set forth above, the State dispensed millions of dollars of State funds in purchasing Plavix prescriptions and was also forced and will be forced to expend significant sums of money for the care and treatment of State of New Mexico participants injured by Plavix, all of which was foreseeable to Defendants.

184. As a direct and proximate result of Defendants' negligence, the State of New Mexico has suffered and will suffer damages and is therefore entitled to recover those damages.

COUNT VI

UNJUST ENRICHMENT

185. Defendants knowingly, willfully and intentionally marketed and promoted Plavix in a false and deceptive manner.

186. Defendants knowingly, willfully and intentionally withheld information from the State, prescribers and State of New Mexico participants regarding the risks associated with Plavix use.

187. The State paid, reimbursed or otherwise conferred a benefit upon Defendants that directly resulted from the Defendants' fraudulent marketing practices.

188. Further, Defendants have been unjustly enriched in the form of profits as a result of their fraudulent marketing practices.

189. As a matter of equity, Defendants should be required to disgorge their unjustly obtained profits from purchases of Plavix.

RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of New Mexico, respectfully requests that the Court enter judgment in its favor and against Defendants, as follows:

A. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Unfair Practices Act, §57-12-1, *et seq*.,

B. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Medicaid Fraud Act, §30-44-2, *et seq*.;

C. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Fraud Against Taxpayers Act, §44-9-1, *et seq.;*

D. Grant permanent injunctive relief and award restitution against Defendants pursuant to §57-12-8(B) NMSA 1978;

E. Award the State its damages as set forth herein;

F. Award the state restitution as set forth herein;

G. Award the State disgorgement of all Defendant's profits obtained as a result of Plavix sales in New Mexico;

H. Award maximum civil penalties as provided by law;

I. Award the State punitive damages;

J. Award the State the costs of prosecuting this action, together with interest, including prejudgment interest, and reasonable attorneys' fees in connection with the prosecution of this case; and

K. Grant further relief as this Court may deem just and proper under the circumstances.

Respectfully Submitted,

HECTOR H. BALDERAS
NEW MEXICO ATTORNEY GENERAL

By: /s/ P.Cholla Khoury
P. Cholla Khoury
Consumer & Environmental Protection
Division Director
Assistant Attorney General

Office of the New Mexico Attorney General
408 Galisteo Street
Santa Fe, NM 87501
Telephone: (505) 827-600
Facsimile: (505) 827-5826
ckhoury@nmag.gov

/s/ Marcus J. Rael, Jr.
Marcus J. Rael, Jr.
Robles, Rael and Anaya, P.C.
500 Marquette Ave NW Suite 700
Albuquerque, NM 87102
Telephone: (505) 242-2228
Facsimile: (505) 242-1106
marcus@roblesrael.com

/s/ Russell Budd
Russell Budd
Baron & Budd, P.C.
The Centrum
3102 Oak Lawn Ave #1100
Dallas, Texas 75219
Telephone: (214) 521-3605
Facsimile: (214) 520-1181
rbudd@baronbudd.com

/s/ Daniel Alberstone
Daniel Alberstone
Peter Klausner
Baron & Budd, P.C.
15910 Ventura Blvd., Suite 1600
Encino, CA 91436
Tel: (818) 839-2333
Fax: (818) 986-9698
dalberstone@baronbudd.com
pklausner@baronbudd.com

/s/Burton LeBlanc
Burton LeBlanc
Baron & Budd, P.C.
2600 CitiPlace Dr.
Baton Rouge, LA 70808
Tel: (225) 927-5441
Fax: (225) 927-5449
bleblanc@baronbudd.com
Attorneys for Plaintiff