UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| THE UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, and WISCONSIN; THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA,<br><br>*ex rel.* MICHELE CLARKE, TRICIA MULLINS, and KRISTI WINGER SZUDLO,<br><br>Plaintiffs,<br><br>v.<br><br>AEGERION PHARMACEUTICALS, INC.; MARC BEER; GREG FENNER; and CRAIG FRASER,<br><br>Defendants. | CIVIL ACTION NO.: 13-cv-11785-RWZ<br><br>***FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)***<br><br>**JURY TRIAL DEMANDED** |

**FIRST AMENDED COMPLAINT**

**PLAINTIFFS/RELATORS DEMAND A TRIAL BY JURY ON ALL COUNTS**

Pursuant to the Federal False Claims Act, as well as various state analogs, Plaintiffs/Relators Michele Clarke, Tricia Mullins, and Kristi Winger Szudlo (collectively, "Relators"), hereby bring the within action against Defendants Aegerion

Pharmaceuticals, Inc. ("Aegerion"), Marc Beer ("Beer"), Greg Fenner ("Fenner"), and Craig Fraser ("Fraser") (collectively, "Defendants") and state as follows:

## INTRODUCTION

1. Relators Michele Clarke, Tricia Mullins, and Kristi Winger Szudlo hereby bring this action on behalf of the United States of America, the District of Columbia ("the District"), and 28 States[1] to recover monies wrongfully paid by those entities as a result of false claims caused by Defendants.

2. Aegerion is a pharmaceutical company that currently manufactures and distributes a single drug product: Juxtapid (lomitapide). Juxtapid is approved by the FDA to treat homozygous familial hypercholesterolemia ("HoFH"), a rare genetic lipid disorder inherited from both parents that results in a limited or complete inability to remove low-density lipoprotein ("LDL cholesterol, or LDL-C") from the blood. Patients with HoFH develop atherosclerosis, or narrowing and blockage of the arteries, as early as their first decade of life. HoFH patients are at extremely high risk of cardiovascular problems and many are at risk for a serious cardiac event starting in their 20s. Untreated, many die by the time they reach their 30s.

3. The FDA estimates that there are only 300 people in the United States with HoFH. This is based on the estimate that the odds of having the disease are 1 in

[1] The States on whose behalf the Relators bring this action are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin. These States collectively will be referred to as "the Plaintiff States."

1 million. Due to its rarity, HoFH qualifies as an orphan disease under FDA regulations. On October 23, 2007, the FDA designated Juxtapid as an "orphan drug." This determination was critical, as it allowed Aegerion, among other things, to bypass the usual clinical trial testing requirements. The rarity and severity of HoFH also has allowed Aegerion to set its own price for the drug: a year's worth of therapy currently costs $311,000.

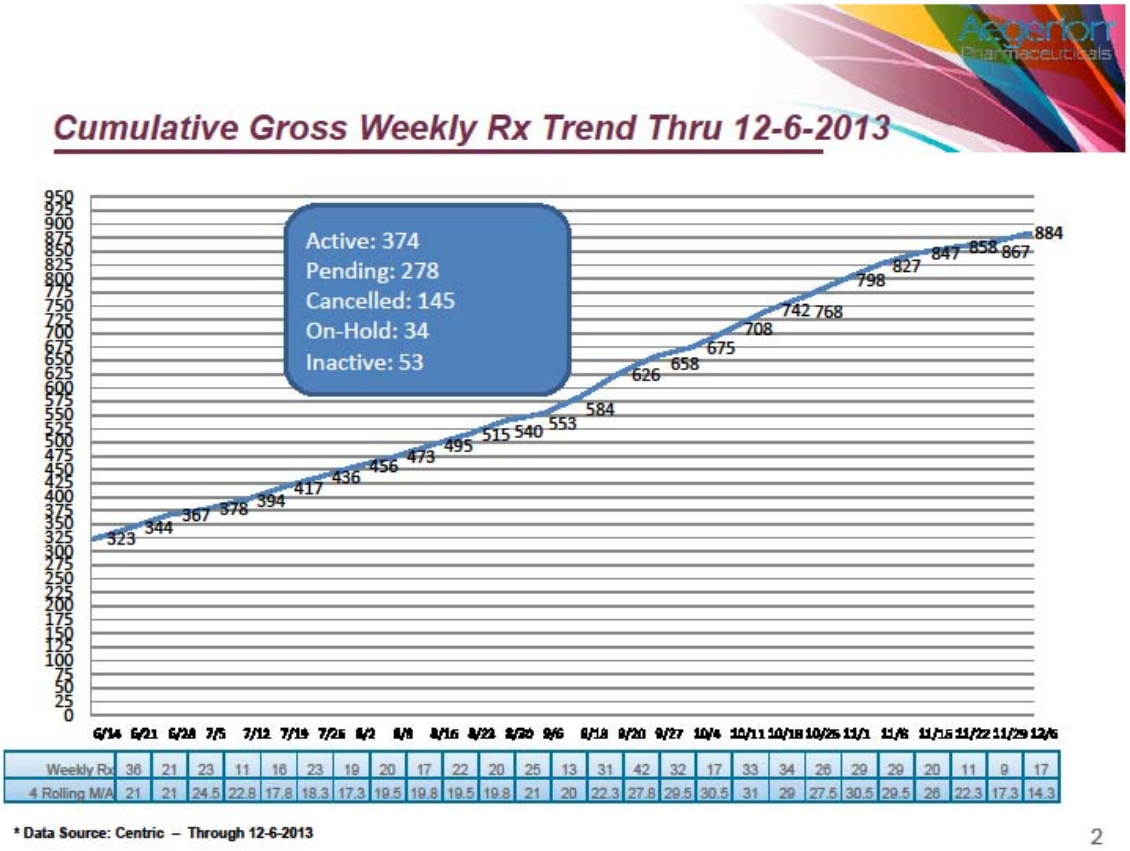
4. Because there are only 300 people in the United States that have HoFH, Aegerion made repeated efforts during the regulatory approval process to broaden the FDA-approved indication beyond HoFH. For example, Aegerion tried to argue that HoFH should be defined not by the underlying genetic diagnosis (*i.e.* the genotype), but rather by a patient's observable signs and symptoms that merely resembled HoFH (*i.e.* the phenotype), in the absence of a genuine diagnosis.

5. The problem is that there are many thousands and perhaps hundreds of thousands of patients in the United States that may have symptoms that are consistent with HoFH, but who do not have the genetic disorder. Because Juxtapid has not been proven safe and effective in the broader population, the FDA has consistently rejected efforts to employ a "functional definition" of HoFH.

6. Once it obtained FDA-approval for Juxtapid, Aegerion intentionally ignored the FDA's mandate and employed the very same functional definition in its sales and marketing expressly prohibited by the FDA. Specifically, Aegerion's marketing now targets the following: (a) people with signs and symptoms consistent with HoFH, but who do not have HoFH; (b) people with heterozygous familial

hypercholesterolemia ("HeFH") (only one parent with the genetic disorder), but who do not have HoFH; (c) people with a family history of high cholesterol, but who do not have HoFH; (d) people with moderately high LDL-C (greater than 200 mg/dL), but who do not have HoFH; (e) people with elevated LDL-C (greater than 150 mg/dL), but who do not have HoFH; and (f) people who are statin-intolerant, but who do not have HoFH.

7. This off-label marketing has caused a tremendous growth in Juxtapid prescriptions, many of which are paid for by government programs. Since its approval, 374 patients already have been placed on Juxtapid, and another 278 are waiting for their prescriptions to be processed. This means that Aegerion has already surpassed the entire U.S. HoFH market:




8. The reaction from investors to Aegerion's forecasts has been no less dramatic. The price of Aegerion's stock appreciated tenfold since its public debut to a peak of $101 per share. And, despite a recent decline in the company's stock price, Aegerion's market capitalization still exceeds $1.5 billion.


9. Defendants have been and continue to knowingly and deliberately engage in conduct they know will lead to violations of federal Medicare and Medicaid statutes and regulations designed to restrict government reimbursement for Juxtapid. This conduct began even before FDA approval in December 2012. Specifically, Defendants intentionally have embarked on a course of unlawful conduct that they know will lead to the submission by physicians and pharmacists of hundreds and perhaps ultimately thousands of Medicare and Medicaid claims for Juxtapid for patients that do not have HoFH. Accordingly, Defendants are liable for knowingly causing these false claims to

be presented to the United States for payment in violation of 31 U.S.C. § 3729. Defendants are similarly liable for causing false claims to be presented to the Plaintiff States under their respective false claims acts.

**PARTIES**

10. Relator Michele Clarke ("Relator Clarke") is an individual who resides in Lexington, Massachusetts. She was employed by Defendant Aegerion as a Lipid Specialty Manager ("LSM") for the Boston area, which includes all of Eastern New England. Relator Clarke has worked in medical device and biotechnology sales for more than twenty-five years and she has been involved in four company "start-ups" within the industry. Relator Clarke has held both regional and national sales leadership/marketing roles and has sold two orphan drugs.

11. Relator Tricia Mullins ("Relator Mullins") is an individual who resides in New York, New York. She is currently employed by Defendant Aegerion as an LSM for the New York metropolitan area (Manhattan, Brooklyn, Queens, Part of Westchester and Long Island). Relator Mullins has worked in pharmaceutical/biotech sales and patient advocacy for nineteen years. She has worked on three different orphan drugs for three startup companies, and she has been involved in eight new product launches and was an Advocacy Director in rare diseases.

12. Relator Kristi Winger Szudlo ("Relator Szudlo") is an individual who resides in Powell, Ohio. She was employed by Defendant Aegerion as an LSM for the Ohio Valley area, which includes much of Ohio, Indiana, West Virginia, and Kentucky. Relator Szudlo has been in pharmaceutical and healthcare sales for eighteen years.

During that time, she has been involved in two startup companies and seven drug launches – two were complex biologics, two required REMS certification, and three were orphan drugs.

13. Defendant Aegerion Pharmaceuticals, Inc. ("Aegerion") is a Delaware corporation with a principal place of business in Cambridge, Massachusetts. Aegerion conducts business in each and every state in the United States.

14. Defendant Marc Beer is Aegerion's Chief Executive Officer.

15. Defendant Greg Fenner is Aegerion's Sales Director for the Eastern United States.

16. Defendant Craig Fraser is Aegerion's President in charge of U.S. Commercial and Global Manufacturing and Supply Chain.

## JURISDICTION AND VENUE

17. Pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"). In addition, the FCA specifically confers jurisdiction upon this Court pursuant to 31 U.S.C. § 3732(b).

18. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the Plaintiff States on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

19. This Court has personal jurisdiction over Aegerion pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and Aegerion has sufficient minimum contacts with the United States of America.

20. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because Aegerion is based in and transacts business in this judicial district.

21. The Relators are unaware of any public disclosure of the information or allegations that are the basis of the original Complaint or this First Amended Complaint. In the event that there has been a public disclosure, the Relators are the original source of the information and allegations contained in the original Complaint and the First Amended Complaint. Prior to the filing of this action, Relators voluntarily provided information to the United States Government and the Plaintiff States regarding the false claims that are the subject of this Complaint. The Relators sent notice to the United States Government and Plaintiff States of the false claims alleged in this Complaint on or about July 23, 2013. The Relators sent further notice to the United States Government and Plaintiff States of additional false claims alleged in this First Amended Complaint on or about March 13, 2013.

## FACTUAL ALLEGATIONS

### I. CHOLESTEROL GENERALLY

22. Lipids are a variety of naturally occurring fats, waxes, sterols (steroid alcohol), fat-soluble vitamins, tri-, di-, monoglycerides, and phospholipids. Lipids serve important biological functions, including energy storage, signaling, and acting as structural components of cell membranes. Within the class of lipids is cholesterol, a

sterol considered to be an essential structural component of animal cell membranes and it is required to establish proper membrane permeability and fluidity.

23. More than 50% of American adults—more than 100 million people—have some form of lipid imperfection. More than 50 million of these people, or 27% of all adults, have elevated low-density lipoprotein ("LDL" cholesterol, or "LDL-C"), otherwise known as "bad cholesterol." Almost 23% of adults, or nearly 50 million people, have insufficient high-density lipoprotein ("HDL" cholesterol, or "HDL-C"), also known as "good cholesterol." More than 40 million American adults suffer from mixed dyslipidemia, which involves the combination of high LDL-C and low HDL-C.

24. In 2010 alone, Americans spent $19 billion on drugs to treat cholesterol problems. This included $7.2 billion spent on Lipitor alone, as well another $3.8 billion spent on Crestor.

## II. HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

25. Homozygous familial hypercholesterolemia (HoFH) is a rare genetic lipid disorder inherited from both parents that results in a limited or complete inability to remove LDL-C from the blood. As a result of this condition, LDL-C accumulates in the blood. Untreated HoFH patients have extremely high LDL-C levels, typically between 400 mg/dL and 1,000 mg/dL. Patients with HoFH develop atherosclerosis, or narrowing and blockage of the arteries, as early as their first decade of life. HoFH patients are at extremely high risk of cardiovascular problems and many are at risk for a serious cardiac event starting in their 20s. Many may never live beyond their 30s.

26. HoFH is so rare that the FDA estimates that only 1 in 1 million people in the United States have the disorder. As the U.S. population is just over 300 million, it is estimated that there are only 300 people in the country with HoFH.

27. There is no cure for HoFH other than liver transplantation. This provides a liver with normally functional LDL receptors, but at the risk of complications associated with solid organ transplantation. Thus, HoFH patients who are medically managed need to remain on treatment for life.

28. Statins are the pharmacological agents of choice for HoFH, but unfortunately, this class of drugs is not particularly effective in reducing LDL-C in this population because they act primarily by up-regulating LDL-R, which is defective or absent in these individuals. Other non-statin lipid-lowering drugs, such as ezetimibe, produce reductions in LDL-C that are usually insufficient to reach LDL-C goals. LDL apheresis is an extracorporeal therapy that selectively removes LDL particles from plasma and achieves significant reductions of LDL-C through repeated sessions, typically weekly or biweekly. Although time-averaged LDL-C reductions of approximately 50% can result, the procedure is accompanied by its own set of challenges and complications, and LDL-C typically remains far above the LDL-C goal for high-risk individuals in the general population.

29. Thus, there is certainly an unmet medical need for this life-threatening, rare disease, and this requires a net risk/benefit assessment that is distinct from the general population with hypercholesterolemia.

## III. JUXTAPID

30. Juxtapid is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

31. The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH. The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.

32. Juxtapid is an oral pill taken once a day.

33. Aegerion has set the price of Juxtapid at $311,000 per year of therapy.

34. As it is a treatment rather than a cure, patients with HoFH can expect to be on Juxtapid for life.

## IV. FEDERAL REIMBURSEMENT FOR JUXTAPID

35. The United States Government, through Medicare and Medicaid, and the Plaintiff States, through Medicaid, reimburse a large percentage of all drug prescriptions.

36. Since 2006, the Medicare program has purchased prescription drugs for those persons eligible for Medicare Part D coverage. Medicare not only covers individuals over age 65, but it also provides medical coverage for many individuals who are permanently disabled under the Social Security Act.

37. Medicaid is a joint program of the United States Government and state governments to provide medical services, including prescription drugs, to persons who could not otherwise afford them. More prescription drugs are purchased through the Medicaid program than through any other insurance program in the United States. All of the States and the District of Columbia participate in Medicaid and use State or District funds blended with federal funds for the purchase of pharmaceuticals.

38. The United States also purchases prescription drugs through a number of other programs, including the Department of Veterans Affairs, the Department of Defense's TRICARE program, and the Federal Employees Health Benefit Plan (these governmental health care insurance programs will collectively be referred to as "Government Healthcare Programs"). Government Healthcare Programs reimburse at least 33% of the prescriptions for Juxtapid and likely much more. Relator Clarke is aware of several Medicare patients in California who are actively taking Juxtapid even though they do not have HoFH.

39. The programs identified above spend billions of dollars each year on prescription drugs. Not surprisingly, in order to prevent waste, fraud, and abuse, and to protect the health of patients, the federal and state programs restrict the types and uses of drugs which may be paid for with government funds. These regulatory schemes are designed to ensure that the federal and state programs only pay for drugs which are found to be safe and effective for their prescribed uses.

40. The Medicare and Medicaid programs are only authorized to purchase prescription drugs that are "covered outpatient drugs," as defined by 42 U.S.C. § 1396r-

8(k)(2), and that are used for "medically accepted indications," as defined by 42 U.S.C. § 1395w-102(e)(4) (for Medicare) or 42 U.S.C. § 1396r-8(k)(6) (for Medicaid). In order to meet the definition of a "covered outpatient drug," either a New Drug Application (NDA) or an Abbreviated New Drug Application ("ANDA") must be approved by the Federal Food and Drug Administration ("FDA"). In order to be used for a "medically accepted indication" under either program, the drug must be used as approved by the FDA or its use must be supported by a citation in the medical compendia. Conversely, if a drug's usage is not in compliance with its FDA-approved labeling, and such usage is not favorably cited in one of the specified compendia, it is not eligible for reimbursement under Medicare or Medicaid.

41. Of all of the recognized compendia, Drugdex is the most expansive and thus is the most common source for information on "medically accepted indications." Drugdex is an online data service provided by Thomson Reuters. It has admitted that it relies on drug companies to provide it with abstracts of studies and that it generally lists those abstracts as studies without scrutinizing them or making any editorial determinations of appropriateness or accuracy.

## V. JUXTAPID IS A FAILED DRUG GRANTED A SECOND CHANCE

42. In 1996, Bristol-Myers Squibb ("BMS") submitted an Investigational New Drug Application ("IND") to the FDA with an aim to develop the lomitapide for mixed dyslipidemia. At the time, the drug, which was known as BMS-201038, was thought to be potentially valuable, as an estimated 40 million people in the U.S. have mixed dyslipidemia.

43. BMS abandoned development of lomitapide in 2000 as a result of concerns regarding liver damage and gastrointestinal tolerability. The chief safety concerns were hepatic steatosis, the accumulation of fat in the liver, which may be a risk factor for progressive liver disease, including steatohepatitis and cirrhosis and diarrhea/vomiting.

44. In August 2002, BMS transferred the lomitapide IND to the University of Pennsylvania's Daniel Rader, MD. Dr. Rader licensed the rights to lomitapide from BMS in part because he felt that for patients with HoFH who could be facing an early death, lomitapide's benefits could outweigh its risks. But Dr. Rader admitted that he also thought the drug could be used for patients who did not have HoFH. Indeed, Dr. Rader stated: "I'm pretty confident that this drug does have a niche, but that niche could be as small as homozygous familial hypercholesterolemia—basically 300 patients in the US—or it could be as large as the several million patients who are statin-intolerant or who don't achieve LDL goals on statins plus [ezetimibe] therapy…It's probably going to be somewhere in between."

45. Because HoFH qualified as an "orphan disease," Dr. Rader pursued "orphan drug" status for lomitapide. To be an orphan drug, the FDA requires that the prevalence of the disease to be treated be fewer than 200,000 people in the United States. Orphan drugs receive a variety of benefits not available for other drugs. First and foremost, orphan drugs can more easily and cheaply gain FDA approval, avoiding the need to obtain as rigorous evidence of safety and efficacy as non-orphan drugs.

Second, there are various financial incentives, including federal research grants, tax credits, extended marketing exclusivity, and waiver of the FDA's user fees.

46. Dr. Rader conducted a six-subject pilot study in the HoFH population from June 2003 to February 2004. In a teleconference between Dr. Rader and the FDA on July 20, 2004, the FDA informed Dr. Rader that "any expanded use of lomitapide beyond the HoFH population would shift the risk/benefit profile of the development program" in an adverse direction.

47. In early 2006, Dr. Rader's colleague Marina Cuchel, MD received a significant grant (Grant 1R01 FD003098-01) from the FDA's Office of Orphan Products Development ("OOPD") for a Phase III trial of lomitapide in the HoFH population. Subsequently, Drs. Rader and Cuchel proposed to expand the patient population to "severe refractory hypercholesterolemia" (patients with high cholesterol who did not respond to other treatments) but the FDA insisted that this change would require a trial of more than the 36 subjects being proposed. Drs. Rader and Cuchel chose to remain with the HoFH population they had proposed.

48. In a face-to-face meeting on February 7, 2007, Dr. Rader and the FDA discussed lomitapide's Phase III pivotal trial for its orphan indication (HoFH). Because Dr. Rader had decided against pursuing an adequately-sized Phase III trial for a broader population, the FDA suggested a single-arm trial design to increase the safety database in the orphan population. Dr. Rader accepted this proposal, but he reduced the number of patients due to problems with patient recruitment. This is perhaps not surprising as patients with HoFH are literally one in a million.

49. One month later, Dr. Rader transferred to Aegerion the license to develop lomitapide in patients with moderate hypercholesterolemia and severe refractory hypercholesterolemia. Dr. Rader owns stock in Aegerion. Aegerion referred to the product as AEGR-733, before finally giving it the trade name Juxtapid.

50. In October 2007, the FDA formally granted Juxtapid an orphan drug designation for the treatment of HoFH.

51. The HoFH Phase III pivotal trial was initiated on December 18, 2007, and Dr. Rader transferred the IND for Juxtapid to Aegerion in February 2008 to facilitate the conduct of multi-site trials.

52. On November 9, 2009, the FDA had another face-to-face "End of Phase II" meeting with Aegerion to discuss Aegerion's interest in the refractory heterozygous familial hypercholesterolemia ("HeFH") population. Topics of discussion included: "uncertainty regarding the long-term consequences of lomitapide-associated hepatic steatosis." At this meeting, the FDA told Aegerion that a trial could be initiated in the refractory HeFH population, but this would need to be accompanied by a second trial in high-risk HeFH patients as well, and possibly an additional outcomes trial. Aegerion has not pursued such trials, despite being given the option.

53. On May 17, 2010, Aegerion held an "End of Phase II" meeting with FDA, where the FDA expressed concern about potential "off-label use" of Juxtapid. Aegerion agreed to the need for implementation of post-approval supply constraints. Aegerion informed the FDA that it would only be pursuing the HoFH indication due to "financial constraints." Aegerion also stated that it was amenable to "whatever post-approval

supply constraints were necessary to ensure that the drug was available only to the HoFH population."

54. On June 15, 2011, the FDA informed Aegerion that exposure data from the single pivotal Phase III study was sufficient to support a New Drug Application ("NDA") for HoFH based on the orphan designation. This news was delivered at a "pre-NDA meeting" held on that date. However, the FDA was critical of Aegerion's attempt to use a "functional HoFH" definition, where patients had an average fasting LDL greater than 300 mg/dL on maximally tolerated lipid-lowering therapy, because the "functional" definition "closely resembles" the severe refractory HeFH population that the FDA previously had warned would change the risk-benefit ratio. Accordingly, the FDA encouraged Aegerion to provide detailed plans of how distribution would be restricted to the HoFH population studied in the Phase III trial, including how documentation of HoFH status would be collected and confirmed, how distribution would be accomplished, and how the system would be monitored for compliance. These concerns eventually resulted in the requirement that Juxtapid have a Risk Evaluation and Mitigation Strategy ("REMS"). Additionally, Dr. Rader "recognized that the treatment indication for lomitapide will need to align with the inclusion criteria of the Phase III trial," *i.e.* patients with a diagnosis of HoFH.

55. In a follow-up teleconference on July 28, 2010, the FDA and Aegerion discussed an NDA limited to HoFH.

56. In February 2012, Aegerion submitted an NDA limited solely to HoFH.

57. In October 2012, the FDA convened an Advisory Committee Meeting to discuss whether the FDA should approve Juxtapid. Despite recommending approval by a vote of 13-2, panelists strongly urged the FDA to restrict use of Juxtapid to patients with HoFH and to "avoid the slippery slope" of using the drugs in HeFH or in patients with resistant hypercholesterolemia. The most pointed comments came from Sidney Wolfe, MD, Founder and Senior Adviser of Public Citizen's Health Research Group. Dr. Wolfe stated:

> Given the enthusiastic response by Wall Street when these documents came up, and if you add up all the number of people in this country and know that only a small fraction are going to be able to afford it, it is at least likely -- even if company doesn't intend that because they repeatedly said we're limiting this only to HoFH -- that ***glowing financial predictions ultimately depend on sales for off-label use*** to treat elevated cholesterol in the larger number of patients who do not have HoFH. So I think that in view of that, there needs to be some sharpening up of the risk management to more explicitly make sure that ***only people with HoFH*** get included in the trials… If it's approved, however, a serious rethinking of the risk management program to more definitively exclude the possibility, if it's proven to be too dangerous to use on patients ***who do not have HoFH***, is urgently needed.

58. The FDA approved Juxtapid (lomitapide) in December 2012 to treat homozygous familial hypercholesterolemia (HoFH). Because of its orphan designation, Juxtapid was permitted to prove safety and efficacy with 2 small studies that were neither double-blind nor placebo-controlled. The total number of subjects from both studies was 36.

59. Aside from HoFH, there are no other "medically accepted indications" for Juxtapid as that term is defined under Medicare or Medicaid. There are no citations in Drugdex supporting any other use for Juxtapid aside from treating HoFH.

## VI. JUXTAPID REMS PROGRAM

60. A key component of the Juxtapid approval was the institution of a Risk Evaluation and Mitigation Strategy ("REMS"). Section 505-1 of the Food, Drug and Cosmetic Act ("FDCA") authorizes the use of REMS requirement if the FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks. The REMS program for Juxtapid was found to be necessary to "assure safe use" of Juxtapid and to "ensure that the benefits of the drug outweigh the potential risk of hepatotoxicity."

61. The stated goals of the Juxtapid REMS program are: (a) to "educate" prescribers about (i) the black box warning of the "risk of hepatotoxicity associated with the use of Juxtapid" and (ii) the need to monitor patients during treatment with Juxtapid as per product labeling; and (b) to "restrict access to therapy with Juxtapid to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)." In short, the purpose of this REMS program is to make sure doctors understand and properly address the risks of the drug, and to limit the use of the drug to the on-label population, as that is the only population for which the FDA has evaluated and approved of the risk-benefit ratio.

62. The Juxtapid REMS program requires that each physician who prescribes Juxtapid first enroll in the program, undergo training, and obtain special certification.

63. Each new prescription of Juxtapid requires completion of a REMS prescription authorization form, which contains the following attestation: "I affirm that my patient has a clinical or laboratory diagnosis consistent with HoFH." These procedures are necessary for a patient to receive the drug. Juxtapid is only available through one specialty pharmacy: Centric Health Resources, Inc. ("Centric"), which is located at 221 Bolivar Street in Jefferson City, Missouri. Centric receives and processes all prescriptions for Juxtapid.

64. Additionally, Aegerion is required to maintain a secure database of all certified prescribers.

## VII. AEGERION

65. Aegerion was incorporated in 2005 as a Delaware corporation. Initially, it was a privately-held company with its principal executive offices located in Bridgewater, New Jersey. In 2007 and 2008, Aegerion twice tried unsuccessfully to go public.

66. In August 2008, its original CEO Jerry Wisler abruptly left the company. He was replaced on an interim basis by Peter Garrambone, who abruptly resigned in September 2010, along with Chief Medical Officer and Executive Vice President, Dr. William Sasiela.

67. Marc D. Beer became the new CEO in September 2010.

68. In October 2010, Aegerion completed its first public offering and had its stock listed on NASDAQ (ticker symbol: AEGR). On its first day, shares finished

trading at $10.80 per share. In the S-1 Registration Statement filed with the SEC on August 10, 2010, Aegerion stated:

> We believe that lomitapide may also be useful for the treatment of elevated lipid levels in broader patient populations, such as those suffering from heterozygous familial hypercholesterolemia, patients who are statin intolerant and patients with severe hypertriglyceridemia that is brought on by factors other than FC. If we elect to develop lomitapide for broader patient populations, we would plan to do so selectively either on our own or by establishing alliances with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs and our available resources.

69. In January 2011, Aegerion changed its logo and moved its corporate headquarters to 101 Main Street in Cambridge, Massachusetts.

70. Aegerion's executive officers are currently as follows:

- Marc Beer - CEO
- Mark Sumeray - Chief Medical Officer
- Martha Carter - Chief Regulatory Officer
- Anne Marie Cook - General Counsel, Senior VP, and Secretary
- Mark Fitzpatrick - Chief Financial Officer
- Massimo Boriero - President (Europe)
- Craig Fraser - President (U.S.; Commercial and Global Marketing and Supply Chain)
- Mary Weger – Senior VP, Human Resources
- Sarah L. Whipple - VP, Chief Compliance Officer

71. The following individuals comprise Aegerion's current Board of Directors:

- David Scheer, Chairman (President, Scheer & Company, Inc.)
- Marc Beer (CEO, Aegerion Pharmaceuticals)
- Dr. Sol J. Barer, Ph.D. (former Chairman and CEO, Celgene)
- Dr. Antonio M. Gotto Jr., M.D. (Weill Medical College, Cornell )
- Sandford ("Sandy") D. Smith (Former Executive VP, Genzyme)
- Paul G. Thomas (CEO, Roka Bioscience)
- Anne M. VanLent (President, AMV Advisors)

72. Aegerion has divided the country into four Sales Regions. Greg Fenner is the Director for the East Region; William Dull is the Director for the Southeast Region; Monte Washington is the Director for the West Region; and Johanna Sealscott is the Director for the East Region. The latter two were hired in September 2013 as part of Aegerion's Commercial Leadership Team expansion.

73. Each region is then divided into roughly a dozen sales areas, each with its own LSM. In total, Aegerion has 55 LSMs.

74. The Relators were the LSMs for the New York, Boston, and Ohio Valley areas.

## VIII. DEFENDANTS HAVE MISBRANDED JUXTAPID AND HAVE KNOWINGLY CAUSED FALSE CLAIMS FOR PAYMENT

75. Defendants' conduct in this case has caused Medicare and Medicaid (and/or other government healthcare programs cited above) to pay for prescriptions

that were off-label and ineligible for reimbursement, and that would not otherwise have been presented for payment.

**A. Marketing Strategies**

76. As set forth below, Aegerion markets and promotes Juxtapid for the following off-label uses: (a) people with a signs and symptoms consistent with HoFH, but who do not have HoFH; (b) people with heterozygous familial hypercholesterolemia (HeFH) (only one parent with the genetic disorder), but who do not have HoFH; (c) people with a family history of high cholesterol, but who do not have HoFH; (d) people with moderately high LDL-C (greater than 200 mg/dL), but who do not have HoFH; and (e) people with elevated LDL-C (greater than 150 mg/dL), but who do not have HoFH.

77. This promotion is illegal, and it is contrary to the FDA-approved label, the drug's orphan designation, the REMS program, and assurances that Aegerion and Dr. Rader have made to the FDA.

78. No citations in any of the designated compendia, including Drugdex, support any use of Juxtapid beyond HoFH, and none of the off-label uses identified above are "medically accepted indications" for Juxtapid allowing them to be eligible for coverage under federal drug reimbursement programs. Additionally, BMS, Drs. Rader and Cuchel, and/or Aegerion have conducted multiple clinical trials that show that Juxtapid was neither safe nor effective to treat any condition beyond HoFH. The FDA has rejected Aegerion's attempt to redefine HoFH with a "functional definition," which the FDA observed was similar to the severe refractory HeFH population. The FDA has

told Aegerion that use of Juxtapid by patients with HeFH would adversely alter the risk-benefit ratio, and accordingly any attempt to broaden the indication would be rejected. Finally, the FDA has mandated a REMS program, which among other things, is intended to ensure that Juxtapid's use is limited to patients with HoFH.

79. Despite this knowledge, Aegerion is marketing Juxtapid precisely in the off-label manner that the FDA feared.

80. First, Aegerion encourages doctors to "data mine" for candidates for therapy with Juxtapid by ignoring the FDA-approved indication, and instead using some version of the proposed indication that the FDA has consistently rejected. These data mining operations range from a personal review of patient files to electronic data mining on a grand scale.

81. The data mining consists of searching for patients using the functional definition of HoFH, *e.g.* high LDL-C values, which the FDA has disallowed. Of course, HoFH is so rare and deadly, a doctor would not need to "data mine" for patients. But this is all unnecessary, because like a 1926 Buffalo Nickel, you know when you have one. Indeed, Marc Beer publicly stated on October 18, 2012[2] that most HoFH patients are diagnosed between 2 and 5 years of age, and thus these patients have already been identified; no data mining is necessary to find them. Aegerion is therefore encouraging

[2] *See* http://www.bloomberg.com/video/aegerion-ceo-on-cholesterol-drug-lomitapide-HHP_eZBfSX~kF3MxrMVCLw.html.

doctors to search for patients who do not have the HoFH genotype but are more likely Severe Refractory Lipid patients ("S/R HeFH").

82. Second, Aegerion violates The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") by causing doctors or their nurses to identify patients by name to Aegerion, absent or in advance of patient consent.

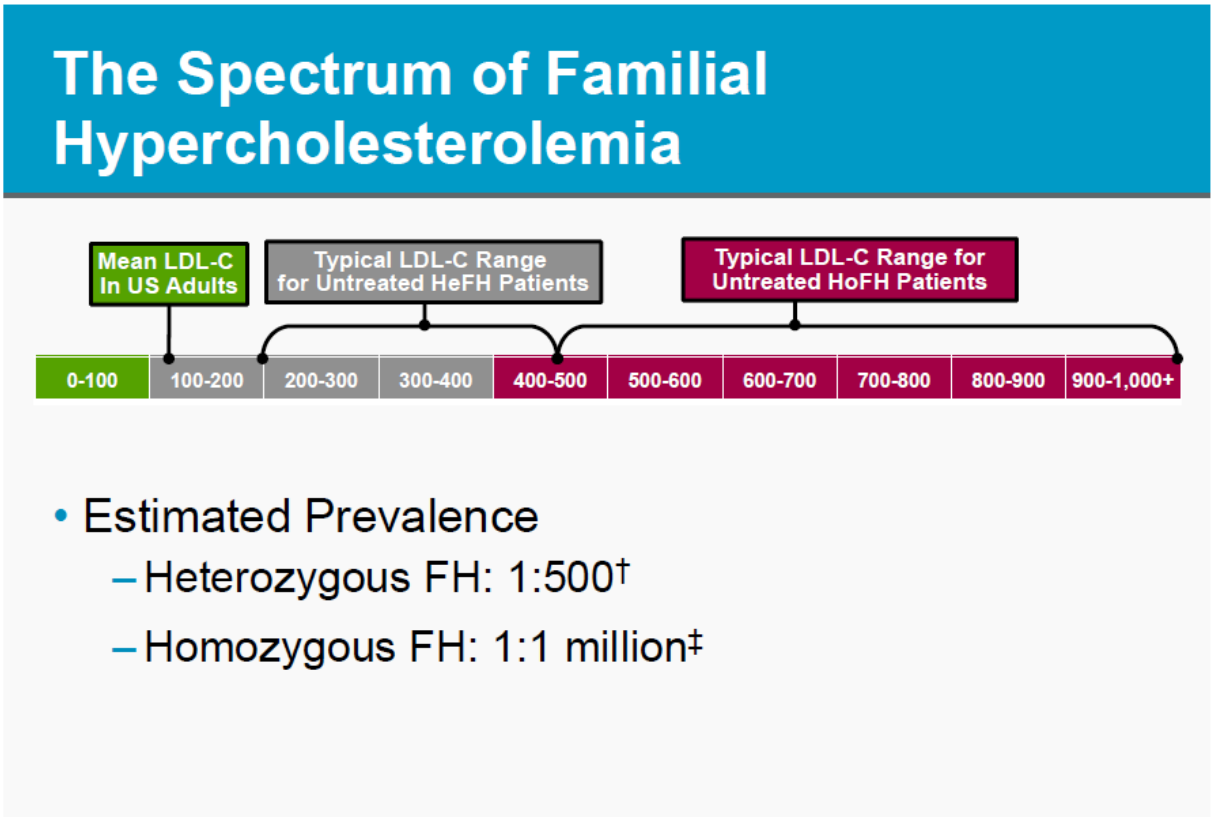
83. A key aspect of the marketing involves Aegerion's learning the patient's name. This information prompts the Aegerion LSM to open the dialogue with the doctor that this may be a possible candidate for Juxtapid treatment; to REMS certify the physician; and to obtain the necessary prescription authorization form. Aegerion is not permitted to know the patient's name until the patient has consented. However, in most cases, Aegerion learns of the patient's name *before* the consent, and even supplies the form to the doctor with pre-populated data entered by the LSMs—a HIPAA violation on its face. Aegerion also learns the of names of patients who never consented to the release of their names and protected information by encouraging LSMs to perform or assist in the actual data mining at the doctor's office, whether by electronic medical record (EMR) searches or chart reviews. Such data mining necessarily entails that sales reps review raw patient data, neither masked nor redacted, at a doctor's office. This is also a HIPAA violation.

84. Third, Aegerion helps doctors navigate any obstacles to a patient's being placed on Juxtapid therapy. In some cases, this involves brief and incomplete REMS training to allow the doctor to achieve REMS certification. Aegerion LSMs often complete the prescription authorization forms, including filling in the patient's name.

Aegerion also instructs doctors on how to avoid bureaucratic obstacles to payment, including coaching them on using the ICD-9 code 272.0 (pure hypercholesterolemia), rather than 272.9 (unspecified disorder of lipoid metabolism), which is more commonly used for the patients, to facilitate insurers (including Medicare and Medicaid) paying for the claim.

85. A key ingredient of Aegerion's off-label marketing is "Not 'defining' HoFH patients," in order to "open minds." Rather than defining HoFH, or even mentioning it, Aegerion instructs its sales representatives to market Juxtapid to patients based on their LDL-C levels. This is the "functional definition" of HoFH that the FDA has rejected.

86. Aegerion's marketing and training materials suggest that anyone with elevated LDL-C levels could have FH. The following slide is taken from Aegerion's presentation to the FDA dated October 17, 2012, here Aegerion expressly embraces (for FDA purposes) the 1-in-a-million patient population:



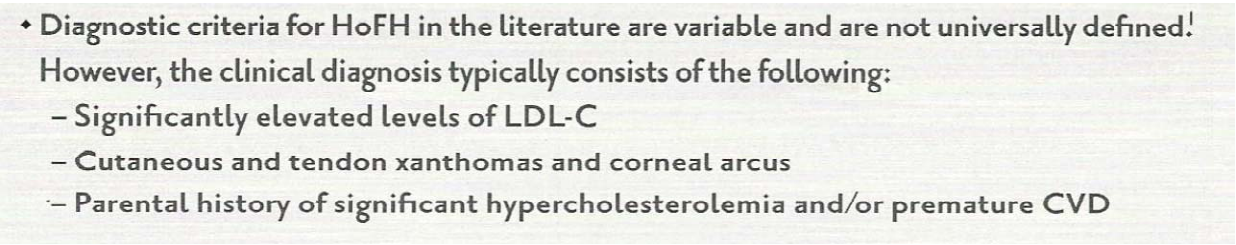

87. Another element of Aegerion's marketing strategy is to blur the distinction between HoFH and HeFH. Aegerion's marketing materials routinely combine HoFH and HeFH into one large category of "Familial Hypercholesterolemia," or "FH." The goal of this is to convince physicians who would consider using Juxtapid for HoFH to also consider for HeFH, a condition which is 2,000 times more common and which the FDA never has approved Juxtapid to treat.

88. To this end, Aegerion sponsors The FH Foundation, an organization purportedly dedicated to helping the 660,000 people with HeFH and the 300 people with HoFH who, combined, have "FH." The goal of the sponsorship is in part to convince doctors and patients that FH is a specific, singular diagnosis so that a treatment for one will be considered a treatment for the other.

89. Indeed, on its website, The FH Foundation's website refers to HoFH as "the most severe form of FH," which deceptively suggests that any treatment that is effective to treat HoFH will also be effective to treat the less severe form. By no coincidence, Dr. Rader is on the Scientific Advisory Committee of The FH Foundation. Dr. Rader is listed on the FH Foundation's website, but there is no disclosure of his commercial ties to Aegerion.[3]

90. As will be seen, Relators were all directed by Aegerion to avoid using the term HoFH, but rather to talk in generalities about difficult-to-treat patients with high cholesterol. For example, in early May 2013, Fenner lead a conference call with the sales force and instructed them to line up a leading physician to speak on HoFH. However, Fenner cautioned the sales reps that they must chose speakers "who believe in our definition of HoFH."

91. Indeed, Aegerion did have its own definition of HoFH. In 2013, the company produced a detail piece to be handed to healthcare providers entitled the "HoFH flashcard" in which it summarized a variety of scientific articles with divergent definitions of HoFH. The flashcard then sets out the company's homespun definition:




[3] *See* http://thefhfoundation.org/about-us/scientific-advisory-board/.

92. This last component—"parental history"—rewrites the approved label for Juxtapid by glossing over the label's requirement that *both* parents have hypercholesterolemia; and as a result, Aegerion improperly expands the patient population for Juxtapid from 1 in 1 million (HoFH) to 1 in 500 (HeFH).

93. Because the population of patients with HoFH is so tiny, any ability to broaden the definition will have a significant impact. For example, adoption of the "phenotypic HoFH" definition, the functional definition the FDA has rejected, presents a pool of "addressable patients" that is 800% larger than the size estimate for the FDA-approved population (780[4] adults vs. 85 adults):

Range in Number of Addressable Patients

| Patient Segments | | HeFH Prevalence 1/500 | 1/450 | 1/400 | 1/350 | 1/300 |
|---|---|---|---|---|---|---|
| Classic HoFH | | ~85 (adults) ~75 (ped.) | ~110 (adults) ~90 (ped.) | ~140 (adults) ~115 (ped.) | ~180 (adults) ~150 (ped.) | ~245 (adults) ~200 (ped.) |
| Phenotypic HoFH | Complex Genetics | ~110 | ~135 | ~165 | ~215 | ~285 |
| | Other FH Patients | ~670 | ~745 | ~840 | ~955 | ~1.1 K |
| Severe-Refractory HeFH | 2°P | ~4.8 K | ~5.3 K | ~6.0 K | ~6.9 K | ~8.0 K |
| | 1°P | ~1.2 K | ~1.3 K | ~1.5 K | ~1.7 K | ~2.0 K |
| Total Patient Numbers (Excluding Pediatric) | | ~6.9 K | ~7.7 K | ~8.7 K | ~9.9 K | ~11.7 K |

[4] This figure is derived from adding the approximately 110 patients with "phenotypic HoFH" who have "complex genetics" to the approximately 670 patients with "phenotypic HoFH" who do not have "complex genetics." All of these figures are retrieved from the column of figures using the rarest prevalence of HeFH.

94. In its marketing and public disclosures, Aegerion uses these inflated estimates of the size of the HoFH market to conceal its off-label marketing of Juxtapid. Otherwise, an alert observer would realize that the company would very soon saturate the U.S. market and have no room for growth. Indeed, Aegerion already has exceeded the total on-label market in the U.S. of 300 patients. Aegerion has side stepped this problem by grossly inflating the estimates of HoFH and exaggerating the prevalence of the disease. For example on January 23, 2013, CEO Marc Beer appeared on CNBC's *Fast Money* (http://video.cnbc.com/gallery/?video=3000142358) where he made the following claim: "*You know with all the rare diseases, we don't know exactly how many patients are out there until we have an effective therapy that comes to the market. We have studied it carefully in the last two years and we think there's about 3,000 patients in the U.S. and 3,000 in Europe.*" In the same interview, Beer remarks: "*If you're on an effective diet, this drug brings down your cholesterol rapidly, effectively and safely,*" without any qualification that might be appropriate for a drug with a checkered safety history and which carries a black box warning.

95. On June 5, 2013, Marc Beer made another appearance on *Fast Money*. Beer was asked directly how the company gauges the size of the patient population for Juxtapid. Beer replied: "*So we've studied this for about the last two years, how many patients are out there, and we've gone out there and we've talked to cardiologists and the specialty within that area, lipidologists, and we've asked them 'If this product could do this to your patients, how many patients do you have that would be candidates? And our best estimate is about 3,000 in the US and about 15,000 in the developed countries.*" In effect, Beer admits that rather than

marketing Juxtapid for HoFH, the sales force has promoted the drug for the reduction of cholesterol in the general population and there are at least 3,000 of *those* patients (as opposed to HoFH patients).

96. Although Beer claims that the company has "studied" the numbers carefully, none of the Relators—nor anyone within the company with whom the Relators have spoken—knows how the 3,000 U.S. patient number is derived. Certainly, Beer never has explained the genesis of the 3,000 number.

97. Craig Fraser attempted to address the question in an email on June 28, 2012, although the statistical support he cites seems far from clear:

> The 1 in 1 million is a mathematical equation from the 1 in 500 FH assumption. That's it. So the 1 in 500 came from (only) a 1973 study which looked at hyperchol. incident rates at that time. It's simply been repeated over and over. Now think about 1973…. How many people were being tested for lipids? Generally, post MI patients, etc. For this and other recent reports and reasons, the general thinking is becoming FH is 1 in 350 or so. When you draw a range then, all the downstream numbers (including HoFH) go up of course. Now the 1 in a million (or perhaps 1 in 700,000 as described above) is for classic, genotypical HoFH (show up as kid with LDLs >400+ untreated). Then there is phenotypical / clinical HoFH which is that general consensus of >300LDL (with very poor response because of two mutations). This is at least 4 times bigger.

98. The inflated HoFH numbers help on Wall Street. Although in its regulatory interactions, Aegerion does not dispute that there are likely only 300 people in the United States with HoFH, it publicly claims to the investment community that there are actually 3,000 potential patients, a 10-fold increase. This small difference, however, has a significant effect on the company's bottom line. If Aegerion could

achieve 50% market penetration of the 3,000 people it claims are candidates for treatment (versus the 300 the FDA estimates), its annual revenue would be $440 million (versus $44 million). Aegerion addressed the difference between its view of prevalence and the FDA's as one of several "risk factors" discussed in its Form S-1 Registration Statement filed with the SEC prior to FDA approval of Juxtapid.[5]

99. Specifically, Aegerion admitted that the "numbers of patients suffering from HoFH … are small and have not been established with precision." Aegerion's Registration Statement admitted that "the FDA has stated that our functional HoFH definition of patients with average fasting LDL-C greater than 300 mg/dL on maximally tolerated lipid lowering therapy closely resembles the severe refractory heterozygous familial hypercholesterolemia population. This means that these patients may ultimately be considered to be outside the HoFH population," *i.e.* an overstatement. Nevertheless Defendants publicly proclaim the accuracy of the inflated patient numbers. On October 2, 2013, Beer spoke at an investor conference organized by the investment bank Leerink Swann & Co. Beer reiterated his confidence in the 3,000 number: *"I feel more comfortable than ever that it is 3,000 plus now that I have the clinical utility of the usage, compare that back to my market research and all the data we purchased, I feel more comfortable than ever that it is 3,000 plus patients. I'm not comfortable taking that total market available up yet. When we have enough data we will inform you that we think it's 4,000 or 5,000 or whatever that number points to but I think you can count on, comfortably now more*

[5] *See* Aegerion Form S-1/A filed June 20, 2011: https://www.sec.gov/Archives/edgar/data/1338042/000119312511168258/ds1a.htm

*than ever, that there's 3,000 plus patients out there that we believe meet the combination of our label and the REMS attestation that the physician has to write."* Contrary to Beer's assertions, there is no scientific support for such a large HoFH patient population.

100. These claims were propped up by buy-side investment analysts, such as Nicholas Bishop of Cowen & Co., who dismissed concerns that the market might only be 300 patients:

> To better understand lomitapide's addressable market size, we conducted a survey of 9 LDL- apheresis center physicians and 18 other lipidologists. Results suggest there may be 2,400 diagnosed functional HoFH patients in the U.S. (under a restrictive label scenario) or as many as 4,000+ patients (under a more liberal label). We believe sell-side expectations vary from 300-3,000 patients.

Bishop then proceeded to claim that the label matches the "less restrictive" definition. This claim is false, because the FDA repeatedly and unequivocally has rejected the broader "functional definition" for HoFH.

101. As mentioned above, Aegerion routinely violates HIPAA by obtaining and further disclosing patient names without appropriate consents. In many cases, Aegerion reviews patient data in bulk through attempts to mine for data. Aegerion also violates HIPAA by learning of specific patients who have not yet consented, or who in some cases never consent, to having their names divulged.

### B. Specific Instances of Off-Label Marketing

102. Off-label marketing is a critical component of Aegerion's corporate strategy.

103. When Relator Clarke first interviewed with Aegerion on March 26, 2012, she met Paul Merrigan (Director of Global Marketing). In that first interview, Merrigan mentioned that the company was counting on at least 40% of sales in the off-label market. To illustrate his point, he drew a large circle, which he designated "HE" (heterozygous hypercholesterolemia). Next to it, but overlapping with the big circle, he drew a small circle designated "HoFH," as if the narrow HoFH label indication gave the company an entrée into the more mainstream HE market. This strategy was very quickly rolled out in a training module for Aegerion's LSM sales force.

104. Relator Clarke has handwritten notes from October 2012 (prior to FDA approval) which evidence that the company's target patient population was always intended to be "*severe refractory LDL 200-300 on MTT* [maximum tolerated therapy] *with documented coronary heart disease*" (as opposed to HoFH) as Craig Fraser, President of U.S. Commercial Operations put it. Fraser further stated that with these parameters, the Juxtapid patient population "*target is 3750 patients on and off label*."

105. All three Relators attended a National Sales Meeting/ Juxtapid Launch Meeting in Cabo San Lucas, Mexico between January 14 and 18, 2013. There, Craig Fraser made a presentation on "The Art of Not Defining HoFH." At this meeting, the sales reps repeatedly were told that there was no definition of HoFH, instead the doctors should decide for themselves what constitutes HoFH by patient observation (Aegerion also discourages genetic testing). The pitch would continue with the observation that one patient in the company's FDA approved study had LDLs as low as 152. Fraser indicated that it was an easy sell to pose the rhetorical question: "Doctor,

do you have a patient with LDLs of 152 who is not improving despite taking a statin?" Fraser also spoke to small breakout groups and, when huddled together, Fraser would suggest a pitch of the following nature: "Doctor, I'd like to talk to you about your severe refractory lipid patients because that's exactly what we studied in an HoFH study." When Relator Szudlo asked about the label restriction that the patient's parents would also both have to have hypercholesterolemia, Fraser's reply was that "sometimes not everything will line up!"

106. Aegerion also made sure that the LSMs were incentivized to achieve their onerous sales targets. In addition to a base salary of approximately $140,000 (plus car allowance), LSMs were rewarded with a one-time bonus of $9,000 per new prescription. From May 3 to May 9, 2013, there was a post-POA "kicker contest" in which each new prescription generated an additional $3,500 with shipment. This contest was repeated with a "kick to the close" quarter-end contest which ran from June 3 to June 14, 2013, during which there was an additional tiered bonus (in addition to the $9,000 per patient) of $1,500 per prescription if 2 prescriptions were generated; $2,000 per prescription if 3 prescriptions were generated; and an additional $2,500 per prescription if 4+ prescriptions were generated. This "kick to close" quarter-end contest was rerun between August 26, 2013, and September 13, 2013, and it proved to be an effective incentive arrangement. On September 16, 2013, Fraser announced 31 new prescriptions in the previous week (when the extra sales incentives were in effect).

107. Relator Szudlo found that when she visited doctors' offices and explained that Juxtapid was a newly-approved drug for HoFH, the doctors would politely hand

her card back and end the meeting explaining that they did not have any patients with HoFH. Some doctors remarked that they had never seen a patient with HoFH.

108. When Szudlo shared her experience with Greg Fenner (National Sales Director East), he told her: "You do not mention HoFH." Fenner explained that the term HoFH was the ultimate *faux pas*. Instead, he instructed Relator Szudlo that she should talk in terms of generalities about a "breakthrough" lipid treatment for refractory patients with high cholesterol. When the doctor showed interest, he instructed, she should then invite them to lunch where they could discuss the matter further and see what patients might be helped with this new wonder drug. However, as Relator Szudlo soon learned, if after one of these initial meetings, a doctor identified a likely candidate but changed his mind, Aegerion would pressure both the LSM and the doctor into a different course of action.

109. The tactic to avoid any association between Juxtapid and HoFH is now official company strategy and is reinforced in emails, conversations, and slide presentations. For example in the "Western Region Execution Review" slide presentation of May 16, 2013, LSMs were cautioned in these terms: "Do not lead with HOFH; stop presentation after results (50% reduction in LDL-C) and probe for patients." In the "What's Working" section of the presentation, the Western Region found "Not defining HOFH" to be helpful. The Eastern Region concurred, observing in a discussion of "What's Not [Working]" that "Opening calls with HOFH" was a mistake. The tactic of avoiding any mention of the FDA-approved use of Juxtapid dovetailed nicely with Aegerion's express strategy of discouraging genetic testing.

Indeed, in the Western Region Review referenced above, Aegerion expressly identified "Academic 'purist' + genetic testing" as being a threat to Juxtapid sales. Thus, Aegerion undeniably was far more interested in the commercial sales of Juxtapid than in the hard science that would justify its being prescribed. Put another way, Aegerion was concerned that genetic testing would yield results that undermined sales of Juxtapid – *i.e.*, that such testing would confirm that patients did *not* have HoFH, and therefore were *not* suitable patients for Juxtapid.

110. Relator Szudlo met "Dr. M" in early January 2013. The doctor was familiar with HoFH and Juxtapid and told relator Szudlo that he would start four patients on the new therapy. The two met on March 29, 2013 to complete the enrollment of the four patients he had identified. In the meantime, the doctor had attended an independent educational program and began to have doubts about the diagnosis of HoFH and the risks attendant with Juxtapid. After a full review of the patients' charts, Dr. M decided that these patients were not in fact HoFH patients. When Relator Szudlo related this back to management at Aegerion, Greg Fenner would not accept losing these potentially lucrative patients. Instead, others at the company called the doctor repeatedly to get him to change his mind. Fenner told Relator Szudlo that the CEO already had reported those four prescriptions to Wall Street as revenue. Relator Szudlo thereafter was punished for the loss of these off-label patients at each subsequent performance review. History repeated itself when another doctor ("Dr. S") also reevaluated two patients whom he had planned to prescribe Juxtapid. Dr. S.

decided that the two patients did not have HoFH. Again, Aegerion punished Relator Szudlo for not somehow changing the doctor's mind.

111. Relator Mullins also has witnessed first-hand the company's relentless push into off-label marketing. Mullins is the Aegerion sales rep (LSM) in New York City and she calls on many extremely well-informed cardiologist and lipidologist thought-leaders, the very sort of "academic purists" Aegerion fears. Not surprisingly, this has made her job all the harder, because the better informed the doctor, the harder it is to persuade him that he has an HoFH patient. On April 4, 2013, Mullins and Greg Fenner called on "Dr. U," a noted lipidologist, with whom Mullins had regular meetings to identify patients. Dr. U explained that he assiduously had been screening his patients for any who might be considered appropriate for Juxtapid therapy. The doctor had identified no willing candidates. Unwilling to take "No" for an answer and knowing that the doctor had no "on-label patients," Fenner explained in a live meeting to "Dr. U" and Relator Mullins that Dr. U needed to start prescribing Juxtapid to gain clinical experience as soon as possible, otherwise the company would not be able to engage the doctor as a speaker.

112. Aegerion LSMs have come under such intense pressure to sell Juxtapid that all three Relators – each with decades of drug sales experience – have never known anything like it. For example, CEO Marc Beer became an Aegerion sales rep for a day to show the sales force how it should be done.

113. On February 27, 2013, CEO Beer, Greg Fenner (Director of Sales East) and Craig Fraser (President) set out on a hunting competition. The aim of the hunt was to

sell prescriptions for Juxtapid and, by real time email updates, teach the sales force to be equally aggressive. An email entitled "Game On" was circulated at 9:10 a.m. announcing: "clock has just started ticking." Five minutes later, the first prescription (possibly two) was claimed by CEO Beer who boasted that, before his flight had even landed that morning, he had a customer: "*Sitting next to an Atlanta CV physician on the plane..."script number one" achieved...possibly two...fill you in when I land Natalia!! Clarke and Frigge...whattaya got!!:)*" This braggadocio simultaneously was broadcast to the LSMs involved, as well as Marc Beer's administrative assistant, Mary Landers, and the Commercial team's administrative assistant, Ally Leonard; and it continued throughout the day among the three men. By 10:31 a.m., Craig Fraser claimed two prescriptions and added: "Sorry.... Jim and I have been too busy selling. We just had mccoullgh [*sic*] (head of cardio) agree to not only treatments for two patients, [*sic*] But have his research nurse do an EMR run for ascension healthcare's 1,400 facilities (and 20% of Michigan's lives) to work on a mail / education campaign." At 12:42 p.m., Jim Frigge claimed another prescription. Greg Fenner claimed another two by 3:26 p.m. The day ended with the sale of 6 or 7 prescriptions and Marc Beer celebrated by circulating the following picture of new prescriptions scattered at his feet:

114. There are approximately 23,000 cardiologists in the United States. Assuming a total HoFH population (including children) in the country of 300 (1 per million), one would expect on average to screen about 77 cardiologists to locate a single HoFH patient. Therefore, it is highly unlikely that Marc Beer was lucky enough to be seated on an airplane next to a cardiologist with a true HoFH patient, and far more likely that the Aegerion CEO pitched the drug to the doctor off label. Furthermore, even assuming, *arguendo*, that the email from CEO Beer was misleading and he did not truly achieve any genuine sales of Juxtapid, the message to the sales force still would be (and was) clear: *Regulations be damned! Sell this drug!* As Greg Fenner stated in an email on May 8, 2013, announcing a bonus incentive program: "LSMs, not to be outdone, Frigge kicked in 1 new RX yesterday and he has two patient onboardings today. Don't

let these chickens get away, the grease is hot, fry 'em up!!!" Even so, the company needed targets.

115. On May 17, 2013, Bart Sladovnik, the LSM for the Omaha area, performed data mining of the "entire patient database" for Heart Consultants, a large cardiology practice in Omaha. "Dr. H" of Heart Consultants provided Sladovnik with a laptop and a conference room, and the two of them ran queries, first looking for patients with LDL-C greater than 250, and then looking for patients with LDL-C greater than 160. Then, Dr. H left Sladovnik alone to review electronic charts to determine whether there were clinical findings "consistent" with HoFH. This process yielded 8 patients, none of whom had a clinical diagnosis or genetic test indicating HoFH. Dr. H then agreed to consider these patients for Juxtapid therapy, and even agreed to schedule several of them in one day—to be called a "Juxtapid consult day," where Sladovnik could meet the patients and try to convince them to agree to the therapy.

116. This unlawful data mining was not simply tolerated by Aegerion, it was positively encouraged. Sladovnik's success that day was trumpeted in company emails to the sales reps, evoking high praise from Craig Fraser: "Great story and opportunity! Team, thanks for all your great work identifying patients in nearly every practice we visit." This improper hands-on approach to patient files is also embraced within Compass, Aegerion's in-house patient support program.

117. In order to enroll with Compass, a patient must sign a consent form that grants access to his/her personal medical and insurance information. The consent form gives Compass permission to pro-actively call, email, and/or send a text message to a

patient, a tactic used to persuade undecided patients to start therapy. Compass assigns an individual case manager to each enrolled patient and that case manager helps with, among other things, insurance reimbursement. Compass purports to be a patient advocacy service but its true purpose is to ensure that Aegerion receives payment for Juxtapid, a far cry from its patient-centric image. Compass case managers understand and are instructed that when they review the paperwork sent in from a prescribing physician, the Statement of Medical Necessity ("SMN") must carry the diagnosis code 272.0 and words to the effect of "clinical signs and symptoms *consistent with* HoFH," even if this clearly was not what the prescribing physician had indicated when filling out the paperwork.

118. For example, Relator Szudlo called on "Dr. G" in Cincinnati who decided to put "Patient J" on Juxtapid. However, rather than complete the required SMN, the doctor faxed the patient record in its entirety to Centric, the specialty pharmacy. Centric could not process the prescription because the doctor had not filled in the SMN and it contacted Compass to liaise with the doctor's office to review the paperwork. The Compass case manager instructed a staff member at Dr. G's office how to complete the SMN and to change the diagnosis code from 272.9 to 272.0 (HoFH). In this way, Compass was able to obtain the paperwork needed to pass muster and the prescription was processed. Dr. G did not know of the change in diagnosis code until subsequently informed about it by Relator Szudlo. When Patient J later found out that she had been "diagnosed" with HoFH, she was extremely concerned and planned to talk with her doctor about the situation.

119. Relator Mullins also was instructed by Aegerion to make sure that any SMNs and Prior Authorization forms carry the 272.0 diagnosis code as well as language that the patient has "signs and symptoms consistent with HOFH"; she further was instructed to ensure that doctors' offices understood this. On April 16, 2013, Aegerion's Director of Marketing, Sachiyo Minegeshi, explained this to her. Relator Mullins was uncomfortable with influencing the content of any Prior Authorization forms or SMNs and asked Ms. Minegeshi why they were doing this. The response was simply that Aegerion's Robin Goldwater, Senior Director Reimbursement and Distribution Services, wants it this way and this is the easiest way to get Juxtapid prescriptions approved. Relator Mullins later learned at the Las Vegas POA meeting that about half of Aegerion sales reps personally fill in patient information on the Prior Authorization forms, Prescription forms, and SMNs in order to facilitate Juxtapid prescriptions.

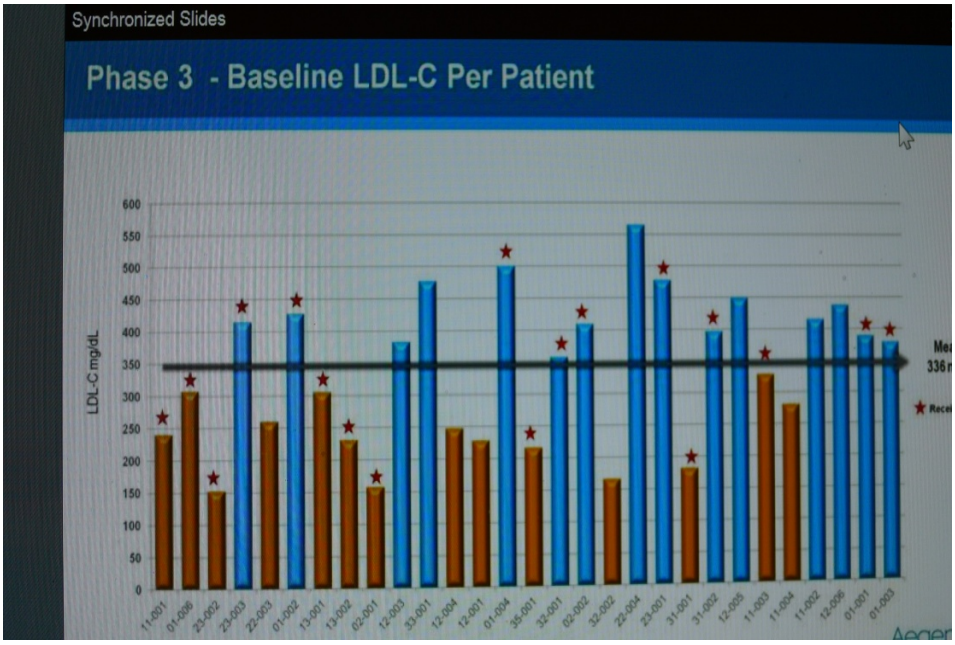
120. On approximately June 13, 2013, Relator Mullins was contacted by a Compass case manager and told that there was a problem with one of her prescriptions. The case manager suggested that she have the diagnosis code changed from 272.9 to 272.0 (HoFH). However, the prescribing doctor was out of the country and Relator Mullins refused to call the office in his absence and have changes made. The need to change the diagnosis message was reinforced by Case Manager Stephanie Rogers-Madrid and Sachiyo Minegeshi, who emphasized to Relator Mullins that the SMN must read 272.0 and carry the phrase "signs and symptoms consistent with HoFH." The strategy of avoiding a definition of HoFH while insisting on its specific identification in

medical forms reached its highest point to date at the recent meeting of the National Sales Meeting in Las Vegas.

121. The Aegerion National Sales Meeting was held in Las Vegas between April 29, 2013 and May 2, 2013. The meeting served as a platform for Aegerion's off-label strategy. In his "Lessons Learned" presentation, Greg Fenner, spoke on the subject of "not 'defining' HOFH patients – opening up minds." The slide also illustrates the company's focus on "EMR patient mining." Relator Mullins took a photograph of the slide with her cell phone:


122. Another tactic Defendants have employed in order to "open up minds" is conveying the false impression that patients in the Phase III study for Juxtapid entered the study with relatively normal LDL levels. This simply is not true. For example, as

the following slide indicates, at the start of the trial only 4 of 29 patients had LDL levels below 200. Furthermore, of those four, three were on apheresis treatment (indicated by a star), meaning that their blood was regularly filtered to keep their LDL levels artificially low:




123. Nevertheless, during the Leerink Swann & Co. investor conference discussed previously, CEO Beer made the following misrepresentation: "*One of the things it's important to keep in mind is that it is not an LDL only disease, eight, eight out of, eight out of twenty three patients in our phase three trial had an LDL below 200 and, and er, were genotyped confirmed with two defective alleles, so they were genotyped confirmed patients that you know still had an LDL of between 150 and 200, so, it's important to not just look at LDLs.*"

124. In misstating the data, Beer gave the false impression that 8 out of 23, or 34%, of patients enrolled in the pivotal Phase Three study started out with LDL levels

under 200, whereas the true number is 4 out of 29, or 14%. Overlooking the fact that Beer did not mention that the reason why their LDL levels were under 200 (because they were receiving apheresis treatment), here the CEO lied to investors and physicians about the target patient population in order to convey the false impression that HoFH is not really so rare a disease after all. The aim, as Aegerion speaker Dr. Seth Baum put it at another investor conference on November 7, 2013, was (and continues to be) to convey the impression that the "data points to a potentially bigger opportunity than anyone expected."

125. Marc Beer's misleading hyperbole has not gone unnoticed. On November 8, 2013, the FDA sent Aegerion a warning letter. Referring to Beer's statements during *Fast Money* on June 5, 2013, and October 31, 2013, the FDA forcefully stated: "*The statements provide evidence that Juxtapid is intended for new uses, for which it lacks approval and for which its labeling does not provide adequate directions for use, which renders Juxtapid misbranded within the meaning of the Federal Food Drug and Cosmetic Act (FD&C Act) and makes its distribution violative of the FD&C Act.*" The letter also instructed the company to correct the false impressions made by means of a "*comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed*."

### C. Damages Caused by Off-Label Marketing

126. At Aegerion's National Sales Meeting in Baltimore in the Fall of 2013, Paul Schneider, the new VP of Patient and Market Access, announced to a gathering of virtually the entire company, that Aegerion had over *90 Medicare patients* on Juxtapid.

According to Jane Pitluck, an LSM who spoke with Relator Clarke, this information was received with delight and was an apparent cause for celebration.

127. The vast majority of the Medicare patients taking Juxtapid are over 65 years of age; and, consequently, they are extremely unlikely to have HoFH because the life expectancy of an HoFH patient is 30 years. Assuming that no further Medicare prescriptions were obtained beyond the Fall of 2013 (*i.e.*, when 90 or so Medicare patients existed), the federal government is suffering monetary damages of $28 million per year (*i.e.*, 90 x $311,000).

128. Aegerion's actions detailed herein have caused the submission of false and fraudulent claims to the United States government and to the Plaintiff States and the District. The United States, the Plaintiff States, and the District have sustained monetary damages as a result of Aegerion's actions, which also have endangered patient lives.

## IX. RETALIATION AGAINST RELATOR MULLINS

129. Relator Tricia Mullins began working for Aegerion on September 10, 2012, as an LSM in the New York area. Prior to joining Aegerion, Relator Mullins had enjoyed a successful career spanning nineteen years in the pharmaceutical/biotech industry. However, she quickly learned that working at Aegerion would be very different because drug sales were demanded by Aegerion regardless of patient suitability for Juxtapid. On January 21, 2013, less than a month after Juxtapid's approval, her direct supervisor, Greg Fenner, sent an email to the East Coast sales team setting out unrealistic sales goals. Sales representatives were asked to "reset your

ethical compass everyday." Given Relator Mullins nineteen-year track record and the high ethical standards she observes, she was disturbed by this directive. Upon the return from the Cabo San Lucas Launch Meeting, an email from Craig Frasier was sent out to the sales force on January 20, 2013 reminding them of the factors for success. Relator Mullins was appalled that employees were told to "hunt" for these terribly sick patients as if they were game to be preyed upon. In addition, Frasier instructed LSMs to make the doctors see the possibility of using Juxtapid for their severe refractory lipid patients. Relator Mullins was immediately concerned that a member of senior management was suggesting that sales representatives target patients who do not necessarily have HoFH.

130. As could be expected, Relator Mullins found that New York was an extremely tough market to achieve sales, despite its concentration of expert lipidologists. Contrary to Fenner's view that New York was "no different than Kansas," Relator Mullins found that the city's lipidologists knew very well whether or not they had an HoFH patient. And, the vast majority did not. On February 27, 2013, Beer, Fraser, and Fenner conducted their much-publicized "hunt" for patients to demonstrate that sales could be achieved regardless of the rarity of HoFH. Fenner, in particular, pushed Relator Mullins to broaden her marketing message and to think beyond the FDA label and HoFH patients. By February 21, 2013, this pressure had translated into a specific goal for Relator Mullins and other LSMs to have three patients on drug by the end of the company's first quarter post-launch and finish March 2013 with five or more prescriptions. The pressure increased again in the second quarter: the goal more than

doubled to eight prescriptions. Relator Mullins verbally disagreed with Fenner's instructions to market Juxtapid beyond its label; and, as a consequence, Fenner treated her in a hostile and demeaning manner, warning her that she had better "get on board" with Aegerion's definition of HoFH or "you're done, I can only hold them off for so long."

131. On April 16, 2013, Relator Mullins had a conversation with Director of Marketing, Sachiyo Minegeshi, which revealed the extent of the company's off-label marketing strategy. Ms. Minegeshi explained that regardless of the true nature of the patient, Relator Mullins should ensure that the SMNs contain the "right" language and most importantly, that the diagnostic code should be 272.0. When Relator Mullins expressed her concern about influencing the contents of medical paperwork, Ms. Minegeshi told her that it would make reimbursement easier.

132. Between April 29, and May 2, 2013, Relator Mullins attended a sales meeting in Las Vegas, Nevada at which Fenner spoke of the "art of not defining HoFH." There, it became apparent to Relator Mullins that other LSMs were achieving their sales goals (and exceeding them) by engaging in the off-label promotion of Juxtapid and questionable activities (*e.g.* LSMs buying fish oil vitamins, going to patients homes of non-consented patients , filling out prescriptions, and managing patients labs). On the final day of the Las Vegas POA meeting, Relator Mullins spoke out openly against the unlawful tactics being promoted there. Relator Mullins vocalized her concerns in front of her peers and Fenner during a roundtable case-based break out session. This did not

go unnoticed, as Fenner referred to Relators Mullins's table as the "problem table" as she discussed her concerns with her table and ultimately the group.

133. On May 6, 2013, Relator Mullins received a letter from Fenner criticizing her supposedly disappointing "performance delivery." When she confronted Fenner about the letter, he assured her that it was routine and that all LSMs at her level and below had received the same letter. That was not true. In fact, only one other LSM had received such a letter—Relator Clarke. Management sent the letters on May 6th and May 7th, almost two months before the end of the quarter.

134. As it turned out, Relator Mullins did reach her performance expectations that quarter, achieving sales of eight Juxtapid prescriptions. Nevertheless, she received a second warning letter on June 21, 2013—again before the end of the quarter—acknowledging that she had "reached the 8 scripts we targeted for you." Confusingly, the letter further stated that "overall we would have expected a higher level of performance at this time." The letter gave Relator Mullins just thirty days to "achieve a much higher level of performance" without stating precisely what was expected. The letter caused Relator Mullins much distress and by June 28, 2013, she was under the care of her doctor for a medical condition exacerbated by stress, forcing her to take time off work.

135. Aegerion used Relator Mullins' legitimate absence from work as a pretext upon which to further retaliate against her. On July 11, 2013, Mary Weger, Senior Vice President of Human Resources, emailed Relator Mullins to complain that the doctor's note she had provided supposedly was insufficient. Ms. Weger demanded that she

complete certain medical forms by July 22, 2013, but failed to provide those forms. On the same day, Fenner sent another email to Relator Mullins in which he unfairly criticized her job performance.

136. On July 17, 2013, Relator Mullins wrote to CEO Marc Beer regarding her compliance concerns in order to ensure that the message got through at the highest level of management. In her email, she informed Beer that "*the company is promoting the off-label use of Juxtapid for a population it was not approved for, which is a fraud on that patient population and on the government*." Relator Mullins received no response to this letter—not even an acknowledgement from the CEO. On July 18, 2013, Ms. Weger wrote again to Relator Mullins, this time taking the position that the medical forms had been due on July 17. The following day, Ms. Weger informed Relator Mullins, without reference to her treating physician, that she did not qualify for FMLA leave and that if she did not return to work by the end of July, then it would be regarded as job abandonment. On or about December 24, 2013 Relator Mullins was taken off all corporate emails, and was no longer receiving notice of any changes in health benefits, blackout periods (re stock options or the like). As of the date of this First Amended Complaint Relator Mullins remains in professional limbo with Aegerion.

## X. RETALIATION AGAINST RELATOR CLARKE

137. Relator Michele Clarke began work for Aegerion in April 2012, initially as a part-time LSM when the company was a startup operation. On August 1, 2012, she became a full-time employee with responsibility for training new LSMs and liaising between the home office and the national sales team.

138. As a pharmaceutical sales rep with twenty-five years of experience, Relator Clarke was familiar with the distinction between doctors lawfully prescribing off-label (which may be motivated by a specific clinical judgment) and drug companies illegally marketing a drug for off-label uses or even misinforming doctors about a drug's FDA indication. Relator Clarke recalls that even as early as her initial interview, Craig Fraser told her that the on-label patient population for Juxtapid in the United States was around 300, but that Aegerion calculated that it could net thousands of "severe refractory patients" for an estimated market of 3,750—"both on and off label." In retrospect, this was an early sign that the company was not simply aware that off-label prescriptions would be written, but that the off-label market was the heart of the company's business model.

139. Relator Clarke attended Aegerion's national sales training in Cabo San Lucas in January 2013 (as did her Co-Relators).

140. Relator Clarke, who then attended the Las Vegas sales meeting at the end of April, realized that sales reps were filling out SMNs on behalf of their doctors and upon rehearing Fenner's "art of not defining HoFH" pitch, she began to raise her concerns with Greg Fenner. Those concerns fell on deaf ears.

141. On May 7, 2013, Relator Clarke had a further conversation with Fenner in which she also raised HIPAA compliance issues and her concerns that sales reps were filling out SMNs on behalf of doctors. Specifically, Relator Clarke grew concerned when Melanie Detloff, LSM for New Orleans, was asked to present "best practices" to the entire LSM team while Greg Fenner, Bill Dull, Craig Fraser, Sachiyo Minegeshi, and

various other Aegerion management looked on. Ms. Detloff talked to the group about going to patient's homes to get them to sign the consent forms, indicating quite clearly that she already had the patient's names or addresses—a HIPAA violation. Ms. Detloff also talked about discussing the fact that HoFH is genetic and getting other family members that she thought had HoFH at the home to sign consents and/or discuss seeing the doctor. Aegerion even used some of Ms. Detloff's SMN's on the screen as an example how they should be filled out, and it appeared to Relator Clarke and others that Ms. Detloff had filled them out herself. This would require her to have knowledge of privileged patient information—another HIPAA violation. Relator Clarke expressed her concerns about the apparent HIPAA violations being touted as "best practices," but neither Fenner, Dull, Fraser, nor Minegeshi did anything to correct or clarify proper behavior.

142. Later on May 7th—after Relator Clarke had confronted Fenner about the apparent HIPAA violations, Fenner emailed her a warning letter stating: "It is critical to our goals that you immediately improve your performance delivery." As noted above, the only other LSM to receive such a warning letter was Relator Mullins; and just like her, Relator Clarke was told her sales goal was eight Juxtapid prescriptions by the end of the second quarter. Like Relator Mullins, Relator Clarke also reached and in fact exceeded the target with a total of ten prescriptions before the deadline. Nevertheless, on June 26, 2013, Fenner sent a second warning letter to Relator Clarke. In terms reminiscent of the second warning letter to Relator Mullins, he advised Relator Clarke: "I note that you reached the 8 scripts we targeted for the end of June." His letter then

inexplicably demanded a "much higher level of overall performance over the next 30 days." Relator Clarke asked Greg Fenner to tell her specifically what her sales goal was since the warning letter did not include any measurable goals as was standard practice. Fenner responded, "I can't tell you." On June 27th, Relator Clarke sent an email to Greg Fenner once again requesting clarification of her performance goals.

143. On July 11th, Fenner finally responded with an email that was condescending, degrading, and still did not answer Relator Clarke's questions. Fenner told Clarke that the goals were "qualitative assessments," and refused to provide any objective sales targets.

144. Relator Clarke was very distressed by Fenner's letter and the seeming impossibility of satisfying him and Aegerion, even when reaching her sales goals. Her health began to deteriorate and she was forced by Aegerion to take a leave of absence beginning on July 10, 2013, despite her physician's initial request that she take only three days off to recuperate. Relator Clarke's nurse wrote to Aegerion's Mary Weger to explain the absence. The nurse's note supposedly was insufficient for Ms. Weger, who disputed the adequacy of the explanation, commencing protracted correspondence and exacerbating Relator Clarke's condition. On July 16, 2013, Relator Clarke wrote to Fenner regarding her condition and highlighting her concerns with Aegerion's lack of compliance: "*I have been singled out and mistreated by Aegerion immediately after expressing my concerns regarding several HIPAA violations, possible fraud on the government, ethical violations, and off label promotions I had witnessed*." In addition to the harassment Relator Clarke suffered from Greg Fenner, she was also continuously harassed during her

medical leave by Mary Weger and Craig Fraser. Both Weger and Fraser insisted on meeting with Clarke in person despite her physician's instruction not to work. Mary Weger was insistent that Relator Clarke meet her at a hotel, located immediately next to the corporate office where many of the Aegerion employees stay. Relator Clarke expressed her discomfort due to the likelihood of running into her Manager but Weger persisted. Relator Clarke also received multiple phone calls and texts from Craig Fraser. Aegerion did not cease direct communications with Relator Clarke until August 28, 2013, when the physician who did an independent medical exam at Aegerion's request stated that Relator Clarke should have "no communications from Aegerion" to give her time "to address her multiple medical conditions without interruption." Relator Clarke continued her tenure as an unpaid employee until December 16, 2013 when she was terminated. Despite the fact that Relator Clarke was terminated while on disability leave, Aegerion has wrongfully prevented her from exercising her rights under the Stock Option and Incentive Plan. Relator Clarke has even been deprived of unemployment benefits; after filing for unemployment in the state of Massachusetts she learned that Aegerion had not paid into the state of Massachusetts, but rather to the state of New Hampshire (where she formerly lived). When Relator Clarke filed for benefits in New Hampshire, Aegerion disrupted her rights to unemployment and Relator Clarke was not granted unemployment benefits of any kind.

**FIRST CAUSE OF ACTION**
VIOLATION OF 31 U.S.C. § 3729 (a)(1)(A)

145. Relators repeat and reallege the allegations set forth in Paragraph 1 through 144 as though set forth herein.

146. As described in detail above, Defendants have caused the presentation of numerous false claims to the United States through the Medicare and Medicaid programs and other federal health insurance programs for reimbursement of prescriptions of Juxtapid caused by off-label marketing for unapproved uses. The uses in question are ones that the FDA specifically has refused to allow Defendants to market, and there are no citations or supporting references in any of the federally-recognized compendia.

147. Through its various marketing activities and its LSM sales representatives, Defendants encourage doctors to prescribe Juxtapid for off-label uses, knowing that patients are reasonably likely to have Medicare or Medicaid coverage. Thus at all times, Defendants know and have known that their marketing would cause Medicare and Medicaid to pay for unapproved uses of Juxtapid.

**SECOND CAUSE OF ACTION**
VIOLATION OF 31 U.S.C. § 3729(a)(1)(B)

148. The Relators repeat and reallege all of the allegations set forth in paragraphs 1 through 147 as though set forth herein.

149. In the regular course of its marketing, Defendants make false statements to physicians that cause claims to be presented to Medicare, Medicaid and other federal health insurance programs, and are material to the decisions to pay those claims.

Specifically, Defendants falsely state that the definition of HoFH is based on the phenotype, not the genotype, and that patients who do not have confirmed diagnosis of HoFH based on a genetic test nevertheless have HoFH based on a functional diagnosis that the FDA has rejected. Such statements are false and Defendants know they are false. They are made for the express purpose of soliciting and causing off-label prescriptions that will result in the presentation of false claims to the government.

150. Defendants' false statements were material to false or fraudulent claims. Had Defendants informed their customers that Medicare, Medicaid and the federal health insurance programs would not consider the prescriptions to be within the labeling, then prescribing doctors would likely not have prescribed Juxtapid to their Medicare or Medicaid patients.

151. As a result of the false statements, millions of dollars has been and/or will be spent by Medicare, Medicaid, and the other federal healthcare programs for unapproved uses of Juxtapid that are not reimbursable under federal rules and regulations.

**THIRD CAUSE OF ACTION**
California False Claims Act
Cal. Gov't. Code §§ 12650 *et seq.*

152. Relators repeat and reallege the allegations set forth in paragraphs 1 through 151 as if fully set forth herein.

153. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of the State of California or of any

political subdivision thereof, a false claim for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

154. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false claim paid or approved by the State of California or by any political subdivision, in violation of Cal. Gov't Code § 12651 (a)(2).

155. California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

157. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**FOURTH CAUSE OF ACTION**
Colorado Medicaid False Claims Act
CRS §§ 25.5-4-304 *et seq.*

158. Relators repeat and reallege the allegations set forth in paragraphs 1 through 157 as if fully set forth herein.

159. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a Colorado agency a false claim for payment or approval, in violation of CRS §25.5-4-305(a).

160. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Colorado agency, in violation of CRS §25.5-4-305(b).

161. Colorado, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

162. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

163. Pursuant to CRS §25.5-4-305(a), the State of Colorado is entitled to three times actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**FIFTH CAUSE OF ACTION**
Connecticut General Statutes, §17b-301a *et seq.*
Connecticut False Claims Act

164. Relators repeat and reallege the allegations set forth in paragraphs 1 through 163 as if fully set forth herein.

165. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a Connecticut agency a false claim for payment or approval, in violation of Conn. Gen. Stat. § 17b-301b(a)(1).

166. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Connecticut agency, in violation of Conn. Gen. Stat. § 17b-301b(a)(2).

167. Connecticut, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

168. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

169. Pursuant to Conn. Gen. Stat. § 17b-301b(a), the State of Connecticut is entitled to three times actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**SIXTH CAUSE OF ACTION**
Delaware False Claims And Reporting Act
6 Del. C. §§ 1201 *et seq.*

170. Relators repeat and reallege the allegations set forth in paragraphs 1 through 169 as if fully set forth herein.

171. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, directly or indirectly, to an officer or employee of Delaware a false or fraudulent claim for payment or approval, in violation of 6 Del. C. § 1201(a)(1).

172. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved by Delaware in violation of 6 Del. C. § 1201(a)(2).

173. Delaware, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

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

175. Pursuant to 6 Del. C. § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**SEVENTH CAUSE OF ACTION**
Florida False Claims Act
Fla. Stat. §§ 68.081 *et seq.*

176. Relators repeat and reallege the allegations set forth in paragraphs 1 through 175 as if fully set forth herein.

177. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a Florida agency a false claim for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

178. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Florida agency, in violation of Fla. Stat. § 68.082(2)(b).

179. Florida, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

181. Pursuant to Fla. Stat. § 68.082(2)(g), the State of Florida is entitled to three times actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**EIGHTH CAUSE OF ACTION**
Georgia State False Medicaid Claims Act
O.C.G.A. § 49-4-168

182. Relators repeat and reallege the allegations set forth in paragraphs 1 through 181 as if fully set forth herein.

183. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer, employee, fiscal intermediary grantee or contractor of the Georgia Medicaid Program a false claim for payment or approval, in violation of O.G.C.A. § 49-4-168.1(a)(1).

184. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program, in violation of O.G.C.A. § 49-4-168.1(2)(b).

185. The Georgia Medicaid program, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

186. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

187. Pursuant to O.G.C.A. § 49-4-168.1(a), the State of Georgia is entitled to three times actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used or caused to be made or used by Defendants.

**NINTH CAUSE OF ACTION**
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21 *et seq.*

188. Relators repeat and reallege the allegations set forth in paragraphs 1 through 187 as if fully set forth herein.

189. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(1).

190. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

191. The State of Hawaii, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

193. Pursuant to Haw. Rev. Stat. § 66l-21(a)(8) the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TENTH CAUSE OF ACTION**
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §§ 175/1 *et seq.*

194. Relators repeat and reallege the allegations set forth in paragraphs 1 through 193 as if fully set forth herein.

195. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

196. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

197. Illinois, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

199. Pursuant to 740 Ill. Comp. Stat. § 175/3(a)(7), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**ELEVENTH CAUSE OF ACTION**
Indiana False Claims and Whistleblower Protection Act
Ind. Code. §§ 5-11-5.5 *et seq*.

200. Relators repeat and reallege the allegations set forth in paragraphs 1 through 199 as if fully set forth herein.

201. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Indiana a false or fraudulent claim for payment or approval in violation of Ind. Code §§ 5-11-5.5-2(b)(1) and (8).

202. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana, in violation of §§ 5-11-5.5-2(b)(2) and (8).

203. Indiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

205. Pursuant to § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWELFTH CAUSE OF ACTION**
Iowa Medicaid False Claims Act
Iowa Code § 685 *et seq.*

206. Relators repeat and reallege the allegations set forth in paragraphs 1 through 205 as if fully set forth herein.

207. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a Iowa agency a false claim for payment or approval, in violation of Iowa Code § 685.2.1.a.

208. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Iowa agency, in violation of Iowa Code § 685.2.1.b.

209. Iowa, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

210. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

211. Pursuant to Iowa Code § 685.2.1, the State of Iowa is entitled to three times actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**THIRTEENTH CAUSE OF ACTION**
Louisiana False Claims Act/Medical Assistance Programs Integrity Law
46 La. Rev. Stat. Ch. 3 §§ 437.1 *et seq.*

212. Relators repeat and reallege the allegations set forth in paragraphs 1 through 211 as if fully set forth herein.

213. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to Louisiana false or fraudulent claims, in violation of 46 La. Rev. Stat. Ch. 3 §438.3(A).

214. By virtue of the acts described above, Defendants knowingly engaged in misrepresentation to obtain, or attempt to obtain, payment from Louisiana medical assistance programs funds, in violation of 46 La. Rev. Stat. Ch. 3 § 438.3(B).

215. Louisiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants alleged herein.

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

217. Pursuant to 46 La. Rev. Stat. Ch. 3 § 438.5 and § 438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**FOURTEENTH CAUSE OF ACTION**
Maryland False Health Claims Act
Md. Code Ann., Health-Gen §2-601 *et seq.*

218. Relators repeat and reallege the allegations set forth in paragraphs 1 through 217 as if fully set forth herein.

219. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a Maryland agency a false claim for payment or approval, in violation of Md. Code Ann., Health-Gen §2-602(a)(1).

220. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Maryland agency, in violation of Md. Code Ann., Health-Gen §2-602(a)(2).

221. Maryland, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

222. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

223. Pursuant to Md. Code Ann., Health-Gen §2-602(b), the State of Maryland is entitled to three times actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**FIFTEENTH CAUSE OF ACTION**
Massachusetts False Claims Law
Mass. Gen. Laws Ch. 12 §§ 5A *et seq.*

224. Relators repeat and reallege the allegations set forth in paragraphs 1 through 223 as if fully set forth herein.

225. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented to the Commonwealth of Massachusetts, a false or fraudulent claim for payment or approval, in violation of M.G.L. ch. 12 § 5B(l).

226. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to obtain payment or approval of a claim by the Commonwealth of Massachusetts or any political subdivision thereof, in violation of M.G.L. ch. 12 § 5B(2).

227. Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

228. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

229. Pursuant to M.G.L. ch. 12 § 5B(9), the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**SIXTEENTH CAUSE OF ACTION**
Michigan Medicaid False Claim Act
M.C.L. §§ 400.601 *et seq.*

230. Relators repeat and reallege the allegations set forth in paragraphs 1 through 229 as if fully set forth herein.

231. By virtue of the acts described above, Defendants knowingly caused to be presented to Michigan, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of M.C.L. § 400.603(l).

232. By virtue of the acts described above, Defendants knowingly caused to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit under the Michigan Medicaid program, in violation of M.C.L. § 400.603(2).

233. Michigan, unaware of the falsity of the statements and claims caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

235. Pursuant to M.C.L. § 400.612, the State of Michigan is entitled to three times the amount of actual damages, forfeiture of all amounts received by Defendants and the maximum penalty of $10,000 for each and every false or fraudulent claim made, used, presented or caused to be made, used or presented by Defendants.

**SEVENTEENTH CAUSE OF ACTION**
Minnesota False Claims Act
M.S.A. § 15C.01 *et seq.*

236. Relators repeat and reallege the allegations set forth in paragraphs 1 through 235 as if fully set forth herein.

237. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a Minnesota agency a false claim for payment or approval, in violation of M.S.A. § 15C.02(a)(1).

238. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Minnesota agency, in violation of M.S.A. § 15C.02(a)(2).

239. Minnesota, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

240. By reason of Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

241. Pursuant to M.S.A. § 15C.02(a), the State of Minnesota is entitled to three times actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**EIGHTEENTH CAUSE OF ACTION**
Montana False Claims Act
Mont. Code Ann. §§17-8-401 *et. seq.*

242. Relators repeat and reallege the allegations set forth in paragraphs 1 through 241 as if fully set forth herein.

243. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented to an officer or employee of a Montana governmental entity, a false or fraudulent claim for payment or approval, in violation of Mont. Code Ann. § 17-8-403(l)(a).

244. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to obtain payment or approval of a claim by governmental entities of Montana, in violation of Mont. Code Ann. § 17-8-403(l) (b).

245. Montana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

247. Pursuant to Mont. Code Ann. § 17-8-403(2), the State of Montana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**NINETEENTH CAUSE OF ACTION**
Nevada False Claims Act
Nev. Rev. Stat. §§ 357.010 *et seq.*

248. Relators repeat and reallege the allegations set forth in paragraphs 1 through 247 as if fully set forth herein.

249. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to Nevada a false claim for payment or approval, in violation of Nev. Rev. Stat. §357.040(1)(a).

250. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, a false record or statement to obtain payment or approval by Nevada of a false claim, in violation of Nev. Rev. Stat. § 357.040(1)(b).

251. Nevada, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

253. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTIETH CAUSE OF ACTION**
New Jersey False Claims Act
N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*

254. Relators repeat and reallege the allegations set forth in paragraphs 1 through 253 as if fully set forth herein.

255. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented to an employee, officer or agent of New Jersey or any contractor, grantee or recipient of New Jersey state funds, a false or fraudulent claim for payment or approval, in violation of N.J. Stat. Ann. § 2A:32-C3a.

256. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid by New Jersey, in violation of N.J. Stat. Ann. § 2A:32-C3b.

257. New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

258. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

259. Pursuant to N.J. Stat. Ann. § 2A:32-C3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-FIRST CAUSE OF ACTION**
New Mexico False Claims Act
N.M.S.A §§ 27-14-1 *et seq.*

260. Relators repeat and reallege the allegations set forth in paragraphs 1 through 259 as if fully set forth herein.

261. By virtue of the acts described above, Defendants presented, or caused to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent, in violation of N.M.S.A. § 27-14-4(A).

262. By virtue of the acts described above, Defendants made, used or caused to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false, in violation of N.M.S.A. § 27-14-4(C).

263. New Mexico, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

265. Pursuant to N.M.S.A. § 27-14-4, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty which may be applicable for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-SECOND CAUSE OF ACTION**
New York False Claims Act
N.Y. Fin. Law §§ 187 *et seq.*

266. Relators repeat and reallege the allegations set forth in paragraphs 1 through 265 as if fully set forth herein.

267. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to employees, officers or agents of New York or New York local governments, false or fraudulent claims for payment or approval, in violation of N.Y. Fin. Law § 189.1(a).

268. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by New York or a New York local government, in violation of N.Y. Fin. Law § 189.1 (b).

269. New York, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

270. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

271. Pursuant to N.Y. Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-THIRD CAUSE OF ACTION**
North Carolina False Claims Act
N.C.G.S. §1-605 *et seq*.

272. Relators repeat and reallege the allegations set forth in paragraphs 1 through 271 as if fully set forth herein.

273. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of a North Carolina agency a false claim for payment or approval, in violation of N.C.G.S. § 1-607(a)(1).

274. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a North Carolina agency, in violation of N.C.G.S. § 1-607(a)(2).

275. North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

276. By reason of Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

277. Pursuant to N.C.G.S. § 1-607(a), the State of North Carolina is entitled to three times actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-FOURTH CAUSE OF ACTION**
Oklahoma Medicaid False Claims Act
Okla. Stat. § 63-5053 *et seq.*

278. Relators repeat and reallege the allegations set forth in paragraphs 1 through 277 as if fully set forth herein.

279. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to Officers or employees of the State of Oklahoma a false claim for payment or approval, in violation of Okla. Stat. § 63-5053.1B1.

280. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, a false record or statement to obtain payment or approval by Oklahoma of a false claim, in violation of Okla. Stat. § 63-5053.1B2.

281. Oklahoma, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

282. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

283. Pursuant to Okla. Stat. § 63-5053.1B, the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-FIFTH CAUSE OF ACTION**
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1 *et seq.*

284. Relators repeat and reallege the allegations set forth in paragraphs 1 through 283 as if fully set forth herein.

285. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to officers or employees of Rhode Island false claims for payment or approval, in violation of R.I. Gen. Laws §§ 9-1.1-3(a)(1).

286. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false records or statements to obtain payment or approval by Rhode Island of false claims, in violation of R.I. Gen. Laws §§ 9-1.1-3(a)(2).

287. Rhode Island, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

288. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

289. Pursuant to R.I. Gen. Laws §§ 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-SIXTH CAUSE OF ACTION**
Tennessee Medicaid False Claims Act
Tenn. Code §§ 71-5-181 *et seq.*

290. Relators repeat and reallege the allegations set forth in paragraphs 1 through 289 as if fully set forth herein.

291. By virtue of the acts described above, Defendants presented, or caused to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent, in violation of Tenn. Code § 71-5-182(a)(l)(A).

292. By virtue of the acts described above, Defendants made, used, or caused to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false, in violation of Tenn. Code § 71-5-182(a)(1)(B).

293. Tennessee, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

295. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-SEVENTH CAUSE OF ACTION**
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code §§ 36.001 *et seq.*

296. Relators repeat and reallege the allegations set forth in paragraphs 1 through 295 as if fully set forth herein.

297. By virtue of the acts described above, Defendants knowingly presented or caused to be presented false or fraudulent claims to the State of Texas for payment or approval, in violation of Tex. Hum. Res. Code § 36.002.

298. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce Texas to approve and pay such false and fraudulent claims, in violation of Tex. Hum. Res. Code § 36.002.

299. Texas, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

301. Pursuant to, in violation of Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-EIGHTH CAUSE OF ACTION**
Virginia Fraud Against Taxpayers Act
Va. Code §§ 8.01-216.1 *et seq.*

302. Relators repeat and reallege the allegations set forth in paragraphs 1 through 301 as if fully set forth herein.

303. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee of the Commonwealth of Virginia a false or fraudulent claim for payment or approval, in violation of Va. Code § 8.01-216.3(A)(l).

304. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Virginia in violation of Va. Code § 8.01-216.3(A)(2).

305. Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

306. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

307. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of

$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**TWENTY-NINTH CAUSE OF ACTION**
Washington Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.020 *et seq.*

308. Relators repeat and reallege the allegations set forth in paragraphs 1 through 307 as if fully set forth herein.

309. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee or agent of Wisconsin a false claim for medical assistance in violation of Wash. Rev. Code §§ 74.66.020 (1)(a).

310. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance by the State of Wisconsin in violation of Wash. Rev. Code §§ 74.66.020 (1)(b).

311. Washington, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

312. By reason of Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

313. Pursuant to Wash. Rev. Code §§ 74.66.020 (1), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of

$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**THIRTIETH CAUSE OF ACTION**
Wisconsin False Claims For Medical Assistance Law
Wis. Stat. §§ 20.931 *et seq.*

314. Relators repeat and reallege the allegations set forth in paragraphs 1 through 313 as if fully set forth herein.

315. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee or agent of Wisconsin a false claim for medical assistance in violation of Wis. Stat. § 20.931(2)(a).

316. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance by the State of Wisconsin in violation of Wis. Stat. § 20.931(2)(b).

317. Wisconsin, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

318. By reason of Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

319. Pursuant to Wis. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for

each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**THIRTY-FIRST CAUSE OF ACTION**
District of Columbia False Claims Act
D.C. Code §§ 2-308.03 *et seq.*

320. Relators repeat and reallege the allegations set forth in paragraphs 1 through 319 as if fully set forth herein.

321. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to an officer or employee of the District of Columbia a false claim for payment or approval, in violation of D.C. Code § 2-308.14(a)(1).

322. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false claim paid or approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

323. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

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

325. Pursuant to D.C. Code § 2-308.14(a), the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**THIRTY-SECOND CAUSE OF ACTION**
VIOLATION OF 31 U.S.C. §3730(h)
PLAINTIFF/RELATOR MULLINS AGAINST AEGERION

326. Relator Mullins repeats and realleges each of the allegations set forth in paragraphs 1 through 325 as if fully set forth herein.

327. As set forth in detail above, Aegerion threatened, harassed and otherwise discriminated against Relator Mullins because of her lawful acts involving a potential violation(s) of the False Claims Act by her employer, Aegerion. By these actions, Aegerion violated the False Claims Act, 31 U.S.C. § 3730(h).

328. Aegerion retaliated against Relator Mullins because she refused to engage in off-label promotion and attempted to stop practices that led to the presentation of false claims to the United States. Any other ground for dismissing or disciplining Relator Mullins was pretextual. Accordingly, Aegerion discharged, harassed, and discriminated against Relator Mullins on account of conduct protected by 31 U.S.C. § 3130(h). Such conduct constitutes retaliatory conduct in violation of said statute.

329. Relator Mullins has been damaged as a direct result of these illegal actions. She has suffered economic harm, loss of income, benefits future earnings, and emotional injury.

**THIRTY-THIRD CAUSE OF ACTION**
VIOLATION OF 31 U.S.C. §3730(h)
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

330. Relator Clarke repeats and realleges each of the allegations set forth in paragraphs 1 through 329 as if fully set forth herein.

331. As set forth in detail above, Aegerion threatened, harassed and otherwise discriminated against Relator Clarke because of her lawful acts involving a potential violation(s) of the False Claims Act by her employer, Aegerion. By these actions, Aegerion violated the False Claims Act, 31 U.S.C. § 3730(h).

332. Aegerion retaliated against Relator Clarke, and ultimately fired her, because she refused to engage in off-label promotion and attempted to stop practices that led to the presentation of false claims to the United States. Any other ground for dismissing or disciplining Relator Clarke was pretextual. Accordingly, Aegerion discharged, harassed, and discriminated against Relator Clarke on account of conduct protected by 31 U.S.C. § 3130(h). Such conduct constitutes retaliatory conduct in violation of said statute.

333. Relator Clarke has been damaged as a direct result of these illegal actions. She has suffered economic harm, loss of income, benefits, future earnings, and emotional injury.

**THIRTY-FOURTH CAUSE OF ACTION**
WRONGFUL TERMINATION IN VIOLATION OF PUBLIC POLICY
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

334. Ms. Clarke repeats and realleges the allegations set forth in paragraphs 1 through 333 as if fully set forth herein.

335. Aegerion has wrongfully terminated Ms. Clarke's employment in retaliation for engaging in activity required by the law and/or for refusing to what the law forbids all in violation of public policy.

336. Aegerion's conduct has caused damage to Ms. Clarke in the form of, inter alia, lost salary, lost benefits, punitive damages and emotional distress.

**THIRTY-FIFTH CAUSE OF ACTION**
VIOLATION OF MASS. GEN. LAWS CH. 149 § 185B
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

337. Ms. Clarke repeats and realleges the allegations set forth in paragraphs 1 through 336 as if fully set forth herein.

338. Ms. Clarke disclosed to her supervisor in writing an activity that she reasonably believed to be in breach of a law, rule or regulation promulgated by law and which she reasonably believed to pose a risk to public health, safety or the environment. In so reporting the activity Aegerion had a reasonable opportunity to correct the activity.

339. Ms. Clarke reasonably believed that reporting the activity was an emergency because the lives of patients were at stake.

340. Aegerion has taken retaliatory action against Ms. Clarke in violation of M.G.L. ch. 149 § 185(b).

341. Aegerion's conduct has caused damage to Ms. Clarke in the form of, inter alia, lost salary, lost benefits, punitive damages (if available) and emotional distress.

**THIRTY-SIXTH CAUSE OF ACTION**
BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

342. Ms. Clarke repeats and realleges the allegations set forth in paragraphs 1 through 341 as if fully set forth herein.

343. Every contract contains an implied term of good faith and fair dealing between the parties.

344. Ms. Clarke reported what she reasonably believed to be unlawful activity to her supervisor at Aegerion. In response Aegerion retaliated against Ms. Clarke for reporting such activity and thereby breached the implied term of good faith and fair dealing.

345. Aegerion's conduct has caused damage to Ms. Clarke in the form of, inter alia, lost salary, lost benefits and emotional distress.

**THIRTY-SEVENTH CAUSE OF ACTION**
BREACH OF THE FAMILY MEDICAL LEAVE ACT (FMLA) OF 1993
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

346. Ms. Clarke repeats and realleges the allegations set forth in paragraphs 1 through 345 as if fully set forth herein.

347. Ms. Clarke informed Aegerion that she may have been eligible for FMLA leave. This was Ms. Clarke's first request to take leave under the FMLA in Aegerion's twelve-month leave year.

348. Aegerion failed to provide Ms. Clarke with FMLA eligibility notice and eligibility status in writing within five business days. After designating Ms. Clarke's leave, Aegerion failed to provide her notice in writing, within five business days, of having enough information to determine whether the leave qualified as FMLA leave. Aegerion's failures constitute interference with, restraint or denial of the exercise of Ms. Clarke's rights under the FMLA.

349. Aegerion's conduct has caused damage to Ms. Clarke in the form of, inter alia, lost salary, lost benefits and emotional distress.

**THIRTY-EIGHTH CAUSE OF ACTION**
BREACH OF MASS. GEN. LAWS CH. 151B § 4 AND
THE AMERICANS WITH DISABILITIES ACT OF 1990
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

350. Ms. Clarke repeats and realleges the allegations set forth in paragraphs 1 through 349 as if fully set forth herein.

351. Aegerion is an employer covered by both M.G.L. ch. 151B § 4 and the Americans with Disabilities Act.

352. Ms. Clarke was an employee of Aegerion with a medically-diagnosed physical impairment that can substantially limit one or more major life activities but still able to perform the essential functions of her employment.

353. Aegerion knew of Ms. Clarke's impairment and her need for accommodation in the workplace but failed to provide any reasonable accommodation.

354. Aegerion's conduct has caused damage to Ms. Clarke in the form of, inter alia, lost salary, lost benefits and emotional distress.

**THIRTY-NINTH CAUSE OF ACTION**
BREACH OF CONTRACT
PLAINTIFF/RELATOR CLARKE AGAINST AEGERION

355. Ms. Clarke repeats and realleges the allegations contained in paragraphs 1 through 354.

356. Aegerion and Ms. Clarke are parties to a contract entitled the "Stock Option and Incentive Plan" (the "Plan"). Under the terms of the Plan, Ms. Clarke's

outstanding stock options should have become fully exercisable. Aegerion prevented Ms. Clarke from exercising her rights under the Plan and so breached the contract between them.

357. As a result of Aegerion's breach, Ms. Clarke has suffered monetary damages.

**FOURTIETH CAUSE OF ACTION**
BREACH OF THE FAMILY MEDICAL LEAVE ACT OF 1993
PLAINTIFF/RELATOR MULLINS AGAINST AEGERION

358. Ms. Mullins repeats and realleges the allegations set forth in paragraphs 1 through 357 as if fully set forth herein.

359. Ms. Mullins informed Aegerion that she may have been eligible for FMLA leave. This was Ms. Mullins' first request to take leave under the FMLA in Aegerion's twelve-month leave year.

360. Aegerion failed to provide Ms. Mullins with FMLA eligibility notice and eligibility status in writing within five business days. After designating Ms. Mullins' leave, Aegerion failed to provide her notice in writing, within five business days, of having enough information to determine whether the leave qualified as FMLA leave. Aegerion's failures constitute interference with, restraint or denial of the exercise of Ms. Mullins' rights under the FMLA.

361. Aegerion's conduct has caused damage to Ms. Mullins in the form of, inter alia, lost salary, lost benefits and emotional distress.

**FORTY-FIRST CAUSE OF ACTION**
BREACH OF THE AMERICANS WITH DISABILITIES ACT OF 1990
PLAINTIFF/RELATOR MULLINS AGAINST AEGERION

362. Ms. Mullins repeats and realleges the allegations set forth in paragraphs 1 through 361 as if fully set forth herein.

363. Aegerion is an employer covered the Americans with Disabilities Act.

364. Ms. Mullins was an employee of Aegerion with a medically-diagnosed physical impairment that can substantially limit one or more major life activities but still able to perform the essential functions of her employment.

365. Aegerion knew of Ms. Mullins' impairment and her need for accommodation in the workplace but failed to provide any reasonable accommodation.

366. Aegerion's conduct has caused damage to Ms. Mullins in the form of, inter alia, lost salary, lost benefits and emotional distress.

**FORTY-SECOND CAUSE OF ACTION**
BREACH OF THE NEW YORK CITY HUMAN RIGHTS' LAW (NYCHRL)
PLAINTIFF/RELATOR MULLINS AGAINST AEGERION

367. Ms. Mullins repeats and realleges the allegations set forth in paragraphs 1 through 366 as if fully set forth herein.

368. Ms. Mullins is a qualified individual with a disability under the NYCHRL.

369. Aegerion breached the NYCHRL in failing to engage in a good faith discussion with Ms. Mullins regarding her requested accommodation which would have enabled her to fulfill her duties. Any such accommodation would have been reasonable and would not have created undue hardship for Aegerion.

370. Aegerion's conduct has caused damage to Ms. Mullins in the form of, inter alia, lost salary, lost benefits and emotional distress.

**FORTY-THIRD CAUSE OF ACTION**
BREACH OF CONTRACT
PLAINTIFF/RELATOR MULLINS AGAINST AEGERION

371. Ms. Mullins repeats and realleges the allegations contained in paragraphs 1 through 370.

372. Aegerion and Ms. Mullins are parties to a contract entitled the "Stock Option and Incentive Plan" (the "Plan"). Under the terms of the Plan, Ms. Mullins' outstanding stock options should have become fully exercisable. Aegerion prevented Ms. Mullins from exercising her rights under the Plan and so breached the contract between them.

373. As a result of Aegerion's breach, Ms. Mullins has suffered monetary damages.

**FORTY-FOURTH CAUSE OF ACTION**
WRONGFUL TERMINATION IN VIOLATION OF PUBLIC POLICY
PLAINTIFF/RELATOR MULLINS AGAINST AEGERION

374. Ms. Mullins repeats and realleges the allegations set forth in paragraphs 1 through 373 as if fully set forth herein.

375. Aegerion has effectively terminated Ms. Mullin's employment in retaliation for engaging in activity required by the law and/or for refusing to do what the law forbids, all in violation of public policy.

376. Aegerion's conduct has caused damage to Ms. Mullins in the form of, *inter alia*, lost salary, lost benefits, punitive damages and emotional distress.

## CONCLUSION

**WHEREFORE,** the Relators, on behalf of the United States, the Plaintiff States, and the District, hereby pray that this Court:

1. Enter judgment against Defendants holding them liable for a civil penalty of $11,000 for each violation of the False Claims Act committed by Defendants;
2. Enter judgment against Defendants holding them liable for three times the amount of damages sustained by the United States because of the acts of Defendants;
3. Enter judgment against Defendants holding them liable for the maximum civil penalties permitted for each violation of the false claims acts of the Plaintiff States and the District pled herein;
4. Enter judgment against Defendants holding them liable for the damages sustained by the Plaintiff States and the District because of the acts of Defendants described herein, multiplied, as permitted, under the false claims acts of the Plaintiff States and the District;
5. Enter judgment against Defendants awarding the Relators a percentage of the proceeds recovered by the United States as a result of this action in accordance with 31 U.S.C. § 3730(d);

6. Enter judgment against Defendants awarding the Relators a percentage of the proceeds recovered by the Plaintiff States and the District as a result of this action in accordance with the false claims acts of the Plaintiff States and the District;
7. Enter judgment against Defendants awarding the Relators their costs and reasonable attorneys' fees for prosecuting this action in accordance with 31 U.S.C. § 3730(d) and similar provisions in the false claims acts of the Plaintiff States and the District;
8. With respect to the 31 U.S.C. § 3730(h) claims of Relators Clarke and Mullins, enter judgment against Defendant Aegerion awarding Relators Clarke and Mullins, respectively, all available damages and relief against Aegerion including, without limitation, two times the amount of back pay each would have earned but for the retaliation, with interest on that award; compensation for all special damages each has sustained as a result of Aegerion's discrimination and harassment; and costs and reasonable attorneys' fees for prosecuting each one's personal "h" claims;
9. With respect to the state law claims of Relators Clarke and Mullins, enter judgment against Defendant Aegerion awarding all available damages and relief against Aegerion including, without limitation, back pay, front pay, damages for emotional distress, damages for loss of stock options, compensation for all special damages each has sustained

as a result of Aegerion's discrimination and harassment, with interest as well as reasonable attorneys' fees and costs; and

10. Enter judgment against Defendants awarding any and all other relief that the Court finds to be just and equitable.

Respectfully submitted,

Dated: March 14, 2014

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**CERTIFICATE OF SERVICE**

I, Royston H. Delaney, hereby certify that on March 14, 2014, a copy of the foregoing was served on the list of persons below via United States mail postage prepaid.

Dated: March 14, 2014

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