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ORIGINAL

UNITED STATES DISTRICT COURT
CENTRAL DISRICT OF CALIFORNIA

SEAL,

Plaintiffs,
Ex rel.

SEAL,

Plaintiff-Relator,

v.

SEAL,

Defendant.

GHK (SSx)

Civil Action No. CV 10-03165

COMPLAINT

Filed Under Seal pursuant to 31 U.S.C. §3730(b)(2) [Exempt From ECF]

DEMAND FOR JURY TRIAL

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ORIGINAL

UNITED STATES DISTRICT COURT
CENTRAL DISRICT OF CALIFORNIA

UNITED STATES OF AMERICA, the States of CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO,

Plaintiffs,
Ex rel.

BEVERLY BROWN,

Plaintiff-Relator,

v.

CELGENE CORPORATION,

Defendant.

GHK (SSx)

Civil Action No. CV 10-03165

COMPLAINT

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DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. On behalf of the United States of America and on behalf of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, the District of Columbia, and the City of Chicago, pursuant to the *qui tam* provisions of the Federal False Claims Act , 31 U.S.C. §§ 3729 *et seq.* and similar state law and municipal provisions, Plaintiff and "Relator" Beverly Brown files this *qui tam* Complaint against Defendant Celgene Corporation ("Celgene" or the "Company").

2. Celgene is a global biopharmaceutical company engaged in the development and sale of cancer and immune-modulatory related pharmaceuticals. In fiscal years 2008 and 2009, Celgene earned nearly $2.7 billion in total revenues, with blockbuster drugs Revlimid and Thalomid accounting for more than $1.7 billion and nearly $440 million in sales, respectively. Both Thalomid and Revlimid have consistently generated large revenues for the Company. From 2002 through 2009, Thalomid generated more than $2.7 billion in total sales. Similarly, from December 2005 (*i.e.*, Revlimid's inception) through 2009, Revlimid has accounted for more than $4.1 billion in revenues. According to Company estimates (*see* Celgene Q4 2008 Earnings Call (Jan. 29, 2009)), as well as industry analysis (*see* Credit Suisse Analyst Report (Apr. 1, 2009)), Medicare pays for the majority of Thalomid and Revlimid prescriptions.

3. As an FDA-regulated pharmaceutical company, Celgene is prohibited from marketing its drugs for off-label uses, that is, promoting its drugs as treatment for any diseases other than those specifically approved by the FDA, or in drug combinations, dosages, or other means not specifically enumerated in the FDA-approved use, or "indication." Federal law also prohibits Celgene from

paying kickbacks to induce drug sales or from making misrepresentations with regard to the safety and efficacy of drugs.

4. In 1998, after Celgene received FDA approval of Thalomid *solely* for treatment of an exceedingly rare skin disease, Celgene, in violation of FDA regulations, directed its employees to systematically off-label market Thalomid for a host of cancers, uses that were not approved. Similarly, when Revlimid was approved in 2005 for treatment of a relatively uncommon subtype of a blood disorder, Celgene dispatched its sales force to market Revlimid for other uses and in drug combinations other than those approved by the FDA. To further its off-label marketing activities, Celgene's wrongful scheme involved the systematic use of kickbacks and misbranding in order to boost sales of Thalomid and Revlimid at significant, and unwarranted, cost to government health care plans. Celgene's conduct has placed patients at risk for further physical injury and illness that will and have placed additional economic burdens on government health care plans.

5. Celgene deliberately transformed an FDA-mandated program designed to protect patients against the risks of horrific birth defects associated with Thalomid and Revlimid into a carefully orchestrated nationwide campaign to unlawfully market these drugs. In the late 1950s and early 1960s, Thalomid's pre-cursor, thalidomide, caused as many as 20,000 babies to be born with severe birth defects, including deformed, or all-together missing, limbs.[1] When Celgene sought Thalomid's (and later Revlimid's) approval, the FDA mandated that the Company implement a distribution system requiring physicians to follow specific procedures before prescribing these drugs. Under the guise of assisting physicians with these distribution systems, Celgene dispatched more than 100 agents across the country, operating under purposefully misleading titles,

[1] As discussed in more detail below, thalidomide was the impetus for many modern-day FDA regulations.

including Immunology Specialist and Hematology Oncology Consultant. Gaining access to doctors offices through this program, the Immunology Specialists and Hematology Oncology Consultants have carried out Celgene's unlawful marketing objectives. While these agents were purportedly in the business of implementing measures to prevent birth defects, they were and continue to be bonused based on (off-label and on-label) drug sales.

6. Celgene caused false claims to be submitted in violation of the law for payment by federal and state agencies or programs by:

- systematically engaging in illegal off-label marketing of its drugs, Thalomid (generic name "thalidomide"); and Revlimid (generic name "lenalidomide").

- furthering the unlawful off-label marketing of Thalomid and Revlimid through violations of continuing medical education ("CME") rules and regulations by directing and controlling physician speaker programs that purport to be unbiased;

- unlawfully promoting Thalomid and Revlimid in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Stark Law, 42 U.S.C. § 1395nn and 42 C.F.R. § 411.350 et seq., by providing cash and other incentives to induce doctors to promote and prescribe these drugs, including for off-label uses; and

- unlawfully tampering with Revlimid prescriptions to deceive Medicare, Medicaid, and other government-funded programs into believing that off-label prescriptions were for on-label indications.

7. During relevant time periods, Celgene's unapproved "off-label" marketing of Thalomid included proposed treatment of the following conditions:

(i) bladder cancer;

(ii) breast cancer;

(iii) brain cancer;

(iv) cervical cancer;

(v) colorectal cancer;

(vi) esophageal cancer;

(vii) kaposi sarcoma;

(viii) leukemia (including, but not limited to, chronic lymphocytic leukemia ("CLL"));

(ix) lung cancer;

(x) lymphoma;

(xi) melanoma (*i.e.*, skin cancer);

(xii) prostate cancer;

(xiii) pancreatic cancer;

(xiv) renal (*i.e.*, kidney) cancer;

(xv) thyroid cancer;

(xvi) multiple myeloma prior FDA's May 26, 2006 approval of Thalomid for the disease;

(xvii) multiple myeloma, ***not*** in combination with the drug, dexamethasone;

(xviii) relapsed or refractory multiple myeloma;

(xix) myelodysplastic syndromes;

(xx) ovarian cancer; and

(xxi) uterine cancer

8. Celgene's off-label marketing of Thalomid exposed patients to magnified risk of potentially fatal blood clots, potentially fatal skins conditions, severe nerve damage, and decreased white blood cell counts, and other side effects.

9. During relevant time periods, Celgene's unapproved "off-label" marketing of Revlimid included proposed treatment of the following conditions:

(i) brain cancer;

(ii) leukemia (including, but not limited to, CLL);

(iii) lymphoma;

(iv) myelofibrosis;

(v) myelodysplastic syndromes (all types);

(vi) multiple myeloma, prior to Revlimid receiving an FDA indication for the disease;

(vii) multiple myeloma, ***not*** in combination with the drug, dexamethasone;

(viii) newly-diagnosed multiple myeloma;

(ix) prostate cancer; and

(x) and stem-cell transplant maintenance therapy.

10. As with Thalomid, Revlimid exposed patients to risks of potentially fatal blood clots, potentially fatal skins conditions, severe nerve damage, and decreased white blood cell counts. In addition, Revlimid exposes patients to risk of potentially fatal hemorrhages.

11. In furtherance of its unlawful marketing scheme, Celgene trained and encouraged sales representatives to market these drugs for off-label uses with

full knowledge of the increased risks off-label uses might pose to patients, and without proper clinical evidence of their safety and/or efficacy for those off-label purposes. As a consequence of Defendant's wrongdoing, patients were placed at significant risk of physical and financial harm.

12. Relator Beverly Brown has knowledge of Celgene's national scheme to off-label and otherwise unlawfully market Revlimid and Thalomid. Relator was trained by Defendant to promote off-label uses for both Thalomid and Revlimid, and was specifically directed to market such off-label uses to physicians.

13. Relator was trained to "probe" physicians regarding whether the physicians treated various diseases for which Thalomid and Revlimid were not indicated, but for which Relator had been trained concerning Thalomid or Revlimid use. Additionally, Relator's superiors intermittently conducted ride-alongs on Relator's sales calls to assure that Relator was effectively communicating Celgene's off-label message.

14. Relator was directed and trained by Celgene to engage in a number of tactics to maximize off-label sales of Thalomid and Revlimid. These included: (1) using her job title, which suggested her visits were for a legitimate purpose, as an entry point to market drugs to physicians for off-label purposes; (2) "probing" physicians to lead conversations to off-label uses for the drugs; (3) encouraging physicians to order additional information from Celgene concerning off-label uses for Thalomid and Revlimid; (4) asking physicians for "guarantees" that they would prescribe Thalomid or Revlimid for various off-label uses; (5) paying physicians to discuss off-label uses of the drug at speaker's programs for other physicians; and (6) detailing off-label uses of these drugs by cherry-picking portions of studies to discuss with physicians.

15. Through illegal marketing activities such as these, Celgene exponentially expanded the markets for Thalomid and Revlimid, which

dramatically increased the Company's revenues at the expense of federal, state, and city governments. In addition to the federal healthcare dollars expended through Medicare and Medicaid, state governments spend money through Medicaid, as well as through their state workers' insurance plans. Furthermore, the city of Chicago expends municipal dollars to insure its own workers. Had federal, state, and city programs, including Medicare and Medicaid, known that such prescriptions were induced by illicit incentives or illegal off-label marketing to physicians for non-approved purposes, they would not have reimbursed claims for Thalomid or Revlimid.

16. Relator discovered Celgene's wrongful conduct while she was an "Immunology Specialist" and "Hematology Oncology Consultant" employed by Defendant. She conducted her own investigations in furtherance of a False Claims Act *qui tam* action and disclosed her findings to the United States Government and the State of California prior to filing this action.

II. JURISDICTION AND VENUE

17. Relator brings this action on behalf of herself and on behalf of the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733, and on behalf of the States for violations of the State False Claims Acts.

18. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 and supplemental jurisdiction over the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 1367.

19. This Court has personal jurisdiction over Celgene pursuant to 31 U.S.C. §3732(a) because Defendant can be found in and transacts business in this District. In addition, the acts prohibited by 31 U.S.C. §3729 occurred in this District.

20. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Celgene transacts business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

21. There has been no public disclosure of the allegations herein. To the extent that there has been a public disclosure unknown to the Relator, she is the "original source" under 31 U.S.C. § 3730(e)(4). Relator has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing this *qui tam* action based on that information. *See* 31 U.S.C. § 3730(e)(4).

III. PARTIES

22. Relator Beverly Brown has been employed by Celgene since 2001, working in Los Angeles, California and surrounding areas. Her job titles have included S.T.E.P.S. (System for Thalidomide Education and Prescribing Safety) Field Coordinator, Immunology Specialist and Hematology Oncology Consultant. Although she maintained these technical and science-related job titles, Relator is actually a pharmaceutical sales representative who received a base salary and bonuses based on both the on-label and off- label sales of Thalomid and Revlimid in her sales district. Relator is a top performer, winning commendations from Celgene for her sales performance. She is still employed by Celgene, and her current job title is Hematology Oncology Consultant, which she has held since in or about December 2004.

23. Defendant Celgene is a Delaware corporation, with its headquarters and principal place of business in Summit, New Jersey. Celgene engages in the global business of discovery, development, manufacturing, marketing, and sale of prescription drugs and other products for the prevention, diagnosis, and treatment of diseases.

IV. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO DEFENDANT CELGENE'S FALSE CLAIMS ACT VIOLATIONS

A. FEDERAL GOVERNMENT HEALTH PROGRAMS

24. The federal and state governments, through their Medicaid and Medicare programs, are among the principal purchasers of Celgene's pharmaceutical products.

25. Medicare is a federal government health program primarily benefiting the elderly that Congress created in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS").

26. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the federal government and those state governments choosing to participate in the program. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare.

27. Medicaid has broad coverage for prescription drugs, including self-administered drugs. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.

28. TRICARE is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated

hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

29. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

B. THE FALSE CLAIMS ACT

30. The Federal False Claims Act provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a) (1)(A),(B). Twenty-four states, the District of Columbia, and the City of Chicago have enacted analogous false claims act statutes that apply to Medicaid fraud.

31. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to prescribe a prescription drug for off-label for a person who seeks reimbursement from a federal government health program for the drug, or who causes another to do so, while certifying compliance with the Medicare Fraud & Abuse/AntiKickback Statute, the Medicaid Rebate Statute, and the Food, Drug and Cosmetics Act (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates state and federal False Claims Acts.

C. FDA REGULATIONS

32. The FDA regulates drugs based on the "intended uses" for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

33. The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drugs' intended uses are safe and effective. *See* 21 U.S.C. § 355. Once a drug is approved for a particular use, doctors are free to prescribe the drug for "non-indicated" or off-label purposes. While doctors may independently request information from drug manufacturers about such off-label uses, with very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting drugs for uses, *i.e.*, "indications" not approved by the FDA. As described above, "off-label" refers to-the marketing of an FDA-approved drug for uses that have not undergone FDA scrutiny and approval, *i.e.*, for purposes not approved by the FDA.

34. With the exception of purely scientific medical information provided by qualified medical professionals, sales and marketing presentations, promotions, or marketing to physicians for uses other than that approved by the FDA is considered off-label marketing or "misbranding" proscribed by the FDA. *See* 21 U.S.C. §§ 331(a)-(b), 352(a),(f). This includes any attempts by a pharmaceutical sales representatives to solicit discussions with physicians concerning off-label use.

35. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process, and removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

36. Pursuant to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, the Food and Drug Administration ("FDA") strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs.

37. FDA interprets "labeling" in its regulations broadly to include items that are "1) descriptive of a drug: 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel." 21 C.F.R. § 202.1. The FDCA defines both misleading statements and the failure to reveal material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n). Labeling includes, brochures, booklets, detailing pieces, literature, reprints, sound recordings, exhibits and audio visual material. 21 C.F.R. § 202.1 (l)(2).

38. The FDA regulations deem "advertising" to include media-based activities that appear in magazines, newspapers, professional journals and on television, radio, and telephone communications systems. *See* 21 C.F.R. § 202.1(l)(1). Courts have consistently held that oral statements made by a company's sales representative relating to a pharmaceutical product constitute commercial advertising or promotion. *See Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 10 (7th Cir. 1992) (interpreting the Lanham Act).

39. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301, 321, 331, 352, 360b, 371, 21 C.F.R. § 202.1(e)(6), (e)(7), 21 C.F.R. § 1.21.

40. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

- Minimize, understate, or misrepresent the risks, contra-indications, and complications associated with that drug;

- Overstate or misrepresent the risks, contra-indications, and complications associated with any competing drugs;

- Reference "off-label" uses of the drug — *i.e.,* those uses which are not indicated by the FDA — or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;

- Fail to reveal facts material in light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement;

- Contain representations or suggestions, not approved or permitted in the labeling, that is not demonstrated by substantial evidence or substantial clinical experience;

- Present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does;

- Use a quote or paraphrase out of context to convey a false or misleading idea; or

- Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

See 21 C.F.R. § 202.1 (e)(4)(5)(6), (7).

41. Oral statements and written materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's intended use. If these statements or materials promote a use inconsistent with the product's FDA-approved labeling, it is misbranded as it fails to provide adequate directions for all intended uses.

D. THE MEDICARE FRAUD & ABUSE/ANTI-KICKBACK STATUTE

42. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs, provides penalties for

individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years.

43. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals; paid as a result of the volume or value of any referrals or business generated. See 42 C.F.R. § 1001.952(f). Such remunerations are kickbacks when paid to induce or reward physicians' prescriptions. Kickbacks increase government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as physicians may prescribe drug products based on the physician's own financial interests rather than according to the patient's medical needs.

44. The Medicare Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. See 42 U.S.C. § 1320a-7(b)(3). None of the statutory exceptions or regulatory safe harbors protects the Defendant's conduct in this case.

45. The Balanced Budget Act of 1997 amended the Act to add administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. See 42 U.S.C. § 1320a-740(7).

46. More recently, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-

Kickback Statute or "Social Security Act," 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Id. at Sec. 6402(h).

47. As detailed below, Celgene's marketing of Thalomid and Revlimid repeatedly violated provisions of the Anti-Kickback Statute, which in turn violates the False Claims Act because Celgene's improper kickbacks and incentives induced physicians to prescribe Thalomid and Revlimid when they otherwise would not have and many of those prescriptions were paid for by Medicare, Medicaid and other government funded health insurance programs.

E. STARK LAW - THE MEDICARE/MEDICAID SELF-REFERRAL STATUTE

48. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn, *et seq.*, known as the "Stark" law, prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain "designated health services," including drug prescriptions, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. §1395nn(a)(1), (h)(6). The Stark law provides that the manufacturer shall not cause to be presented a Medicare or Medicaid claim for such prescriptions. Stark also prohibits payment of claims for prescriptions rendered in violation of its provisions. 42 U.S.C. §1395nn(a)(1), (g)(1).

49. Celgene's marketing of Thalomid and Revlimid repeatedly violated the Stark law, which in turn violates the False Claims Act, because Celgene's unlawful payments and services to prescribing physicians induced those physicians to prescribe these drugs when they otherwise would not have done so.

Many of those prescriptions were paid for by government funded health insurance programs.

V. SPECIFIC ALLEGATIONS OF CELGENE'S FALSE CLAIMS

A. CELGENE'S PRESCRIPTION DRUGS THALOMID AND REVLIMID

1. Thalomid's FDA-Approved Uses and Restrictions

50. Thalidomide, marketed by Celgene under the brand name Thalomid, was first approved by the FDA in 1998 for the treatment of erythema nodosum leprosum ("ENL"), a rare skin condition associated with leprosy. The drug is and was approved to treat "cutaneous manifestations of moderate to severe" ENL, as well as to prevent and suppress recurrences of ENL on human skin. ENL is an exceedingly uncommon skin condition that affects very few Americans each year. For instance, according to the Health Resources and Service Administration, a division of the United States Department of Health and Human Resources ("HHS"), there were a mere 137 new cases of leprosy in America in 2006. Thus, the number of patients suffering from ENL – a subset of the total leprosy population – is quite small.

51. From 1998 to the present day, Defendant marketed Thalomid for several other diseases, including bladder cancer, breast cancer, brain cancer, cervical cancer, colorectal cancer, esophageal cancer, kaposi sarcoma, leukemia (including, but not limited to, chronic lymphocytic leukemia ("CLL")), lymphoma, melanoma, prostate cancer, pancreatic cancer, renal (*i.e.*, kidney) cancer, thyroid cancer, multiple myeloma (prior to the FDA's May 26, 2006 approval of Thalomid for the disease), multiple myeloma, ***not*** in combination with the drug, dexamethasone, relapsed or refractory multiple myeloma, myelodysplastic syndromes, ovarian cancer, and uterine cancer.

52. In May 2006, the FDA issued an additional indication for Thalomid, when used in combination with the drug, dexamethasone, for treatment of newly diagnosed multiple myeloma ("MM"). MM is a cancer of the plasma cells found

in bone marrow, and a cancer of the blood, like leukemia. An MM patient's plasma cells grow uncontrollably in the bone marrow. MM can cause patients to experience bleeding, increased rates of infection, kidney damage, bone disease, and death.

53. Thalomid is approved only in combination with another drug, dexamethasone, for patients who have newly diagnosed MM. Thalomid has never been approved as a solo or "monotherapy" treatment for MM, meaning a drug administered by itself and not in combination with other drugs or in combination with any drug other than dexamethasone. In addition, Thalomid has never received FDA approval for treatment of patients with MM who have received a prior drug therapy.

54. While the price of Thalomid varies by dose and duration, Thalomid prescriptions can cost as much as $12,000 per year per patient.

2. Revlimid's FDA-Approved Uses and Restrictions

55. Lenalidomide, marketed by Celgene under the brand name Revlimid, was first approved by the FDA in December 2005 for an extremely narrow indication: the treatment of patients with transfusion-dependant anemia due to low or intermediate risk myelodysplastic syndrome ("MDS") *only when* associated with a deletion 5q cytogenic abnormality (*i.e.*, total deletion of the long arm of chromosome 5) with or without additional cytogenic abnormalities. MDS refers to a group of blood disorders that prevents human bone marrow from producing healthy blood cells. Although MDS includes a range of blood disorders, Revlimid is only indicated for the specific MDS-subtype of "low or intermediate risk" with "a deletion 5q cytogenic abnormality with or without additional cytogenic abnormalities." Stated differently, Revlimid is not indicated, and has never been indicated, for MDS patients (a) who ***do not*** have deletion 5q cytogenic abnormality or (b) who ***do not*** have low or intermediate risk MDS. Only about 20% to 30% of patients with MDS have deletion 5q cytogenic

abnormality. According to the Leukemia & Lymphoma Society, there are roughly 11,400 new cases of MDS each year, which equates to only 2,300 to 3,400 new cases of MDS with 5q cytogenic abnormality each year.

56. Despite Revlimid's narrow indication, Celgene marketed and continues to market the drug for all types of MDS, as well as a host of other off-label indications, including brain cancer, leukemia (including, but not limited to, CLL), lymphoma, myelofibrosis, myelodysplastic syndromes (all types), multiple myeloma, prior to Revlimid receiving an FDA indication for the disease, multiple myeloma not in combination with the drug, dexamethasone, newly-diagnosed multiple myeloma, prostate cancer, and stem-cell transplant maintenance therapy.

57. In June 2006, Revlimid received FDA approval, when taken in combination with dexamethasone, for MM patients who have received at least one prior therapy. Unlike Thalomid, Revlimid is not approved for newly diagnosed MM, but only for those who have already received another treatment other than Revlimid.

58. Revlimid is extremely expensive; prescriptions can cost as much as $120,000 per year per patient.

3. Safety Issue: FDA Warnings Concerning Potentially Fatal Side Effects of Thalomid and Revlimid

a. History of Thalomid

59. Thalodomide, which Celgene later marketed as Thalomid, was first manufactured by Chemie Grunenthal, a German pharmaceutical company, in 1957. Thalidomide is an antiangiogenic drug, which means that it inhibits the growth of new blood vessels. In 1958, thalidomide was being used throughout Europe and Canada to treat morning sickness in pregnant women. By 1961, however, thalidomide had been identified as the cause of between 10,000 and 20,000 serious birth defects, including severely deformed, or all-together missing, limbs. Thalidomide was not approved by the FDA during this period, and

samples of thalidomide were blamed for at least 17 cases of severe birth defects in America.

60. Thalidomide was the impetus for many modern-day FDA regulations. Specifically in response to the horror stories concerning thalidomide and birth defects, in 1962, Congress passed the Kefauver Harris Amendment, which for the first time required pharmaceutical companies to demonstrate a drug's efficacy *and* safety prior to FDA approval, and required drug advertisements to disclose information about potential side effects to consumers.

61. More than thirty years later, in 1998, when the FDA approved thalidomide (now marketed as Thalomid) for treatment of ENL, the FDA required Celgene to take multiple precautions to prevent Thalomid from, once again, causing severe birth defects. In addition to requiring Celgene to place a black-box warning on Thalomid's product labeling, the FDA required Celgene to take the remarkable step of creating a distribution system to prevent fetal exposure to Thalomid.

62. Specifically, as a condition of FDA approval, Celgene created the "System for Thalidomide Education and Prescribing Safety" ("S.T.E.P.S."), which requires all Thalomid-prescribing physicians to register with Celgene. It also requires all prescribing physicians to counsel patients on the risks of sexual activity during Thalomid use. Before a physician can prescribe Thalomid, the physician must notify Celgene through an automated system that he or she has counseled the patients on the risks of birth defects; then a Thalomid prescription is authorized by Celgene.

63. Revlimid is also an antiangiogenic drug. When the FDA first approved Revlimid in December 2005, it mandated a similar distribution system called RevAssist. As explained in more detail, *infra*, Celgene ultimately manipulated the cumbersome nature of RevAssist to cause Medicare, Medicaid,

and other government funded programs to cover the high-cost of off-label Revlimid prescriptions.

b. Thalomid's and Revlimid's Black Box Warnings Concerning Venous Thromboembolism

64. Cancer patients, including those with MM, have a high risk of developing venous thromboembolism ("VTE"), which are blood clots that form within the vein. According to a 2005 article entitled *Deep vein thrombosis in cancer: the scale of the problem and approaches to management*, and published in the Annals of Oncology, VTE is found at autopsy in at least 50% of cancer patients. Annals of Oncology, 16(5): 696-701 (May 2005).

65. VTEs can be either deep venous thromboses ("DVT"s), which are clots within the deep veins of the leg, the pelvic veins, or other veins, or can travel to the lungs where they are called pulmonary embolisms ("PE"s). PEs compromise lung function and can be fatal. *All* forms of VTEs are potentially fatal. Short of death, VTEs may cause heart complications, ulcers, and vein damage which can permanently impair blood flow.

66. Both Thalomid and Revlimid further exacerbate the risk of VTEs in cancer patients. After Thalomid received its MM indication in May 2006, the FDA required Celgene to add the following black-box warning:

> **The use of Thalomid® (thalidomide) in multiple myeloma results in an increased risk of venous thromboembolic events, such as deep venous thrombosis and pulmonary embolus. This risk increases significantly when thalidomide is used in combination with standard chemotherapeutic agents including dexamethasone. In one controlled trial, the rate of venous thromboembolic events was 22.5% in patients receiving thalidomide in combination with dexamethasone compared to 4.9% in patients receiving dexamethasone alone (p = 0.002). Patients and physicians are advised to be observant for the signs and symptoms of thromboembolism. Patients should be instructed to seek medical**

> **care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Preliminary data suggest that patients who are appropriate candidates may benefit from concurrent prophylactic anticoagulation or aspirin treatment.**

(emphasis in original).

67. Revlimid carries a similar black-box warning concerning risk of VTEs in MM patients, and due to the seriousness of the risk, Revlimid's product information includes an additional warning concerning VTEs and MM.

68. Since Thalomid was indicated solely for ENL from 1998 to 2006, Thalomid's product information never carried a black-box warning specifically concerning VTEs in MM patients. Moreover, since the only cancer for which Thalomid and Revlimid are approved is MM, neither drug carries warnings concerning the potential risks of VTEs in various forms of cancer.

69. In sum, doctors that prescribed Thalomid for MM prior to its receiving an MM indication in 2006 were never specifically warned of the risks of VTEs in MM patients taking Thalomid. Furthermore, at all relevant times, physicians prescribing Thalomid or Revlimid for cancers other than MM are not warned about the drugs' association with VTEs in various types of off-label cancers.

c. Thalomid's and Revlimid's Additional Safety Risks

70. In addition to the risk of potentially fatal blood clots, Thalomid and Revlimid can cause other serious side effects. Celgene's off-label marketing of Thalomid and Revlimid unnecessarily exposed patients to these risks.

71. Revlimid's package insert includes a black-box warning concerning neutropenia and thrombocytopenia.[2] Patients with neutropenia have low white blood cell counts, which can expose them to anemia and seriously compromise their ability to fight off infections. Thrombocytopenia sufferers, by contrast, have

[2] Thalomid's package insert also contains warnings concerning neutropenia.

low blood platelet levels, which can make it difficult for the blood to clot. Thrombocytopenia can cause patients to suffer hemorrhages, which can lead to death.

72. Revlimid and Thalomid can also cause peripheral neuropathy (*i.e.*, nerve damage), which can be severe and potentially permanent. Finally, both drugs can cause Stevens-Johnson Syndrome, a painful and dangerous condition causing skin to necrose and peel-off, as in a third-degree burn. Stevens-Johnson Syndrome can be fatal.

B. CELGENE STAFFED AND REWARDED A SALES FORCE THAT AGGRESSIVELY MARKETED THALOMID AND REVLIMID OFF-LABEL

73. When Relator was hired at Celgene in April 2001 she was immediately directed by Celgene to commence marketing Thalomid to physicians for off-label uses. To accomplish this task, Relator and other Celgene sales professionals were dispatched to physicians under false pretenses. As suggested above, when Relator joined Celgene in 2001, she was given the title "Immunology Specialist," which indicated to physicians that Relator was a medical professional, as opposed to a sales representative. Relator has no formal medical training at any level, nor has she ever studied immunology. Yet Celgene required Relator to hold herself out as competent to educate physicians and other medical practitioners in immunology.

74. Celgene also gave Relator the title "S.T.E.P.S. Field Coordinator" – a reference to Thalomid's FDA-mandated education, recordkeeping and distribution system – and dispatched her to medical practices under the guise of assisting physicians with the FDA-required S.T.E.P.S. program. But Relator's and other sales representative's purported assistance with S.T.E.P.S. was a "bait-and-switch," in that it merely provided Celgene with an opportunity to off-label market Thalomid to captive physicians who required help in complying with S.T.E.P.S.

75. More specifically, Relator and the other 100-plus S.T.E.P.S. Field Coordinators from across the country were dispatched to physicians' offices where they instructed physicians on procedures for registering themselves and their patients taking Thalomid with S.T.E.P.S. and the requirement to contact Celgene directly each time the physician wrote a Thalomid prescription. It was during these S.T.E.P.S. meetings with physicians that Relator marketed, at Celgene's direction, Thalomid for off-label uses.

76. Similarly, in or about December 2004, Celgene changed Relator's title from Immunology Specialist to Hematology Oncology Consultant ("HOC"). Relator's job duties stayed exactly the same, but since Thalomid was being marketed for both blood disorders (hematology) and cancers (oncology), Celgene believed the HOC title more accurately reflected the message its sales force was communicating to physicians. Again, while Relator has no formal medical training, Celgene required and continues to require her to hold herself out to physicians as learned in both hematology and oncology. In reality, Relator is a sales representative, and her compensation depends solely on her ability to market Thalomid and Revlimid to physicians.

77. Relator and other sales personnel were and are rewarded by Celgene for their off-label sales. Celgene's compensation and bonus structure incentivizes its sales force to meet or exceed certain benchmarks in drug sales. A March 23, 2003, Celgene memorandum from Dwight D'Iorio – Celgene's then-National Executive Director of Sales – distributed to Relator and other Celgene sales professionals states that Relator and her colleagues would have "the opportunity to earn additional bonus money with each additional sales level achieved," at a time when Thalomid was approved only for a single, rare indication.

78. Relator received Celgene stock options, cash bonuses, and vacations based on her off-label sales of Thalomid and Revlimid. In 2003 Relator was a member of the "Diamond Club" which, according to Celgene management,

"represents the pinnacle of success at Celgene." Diamond Club members are "in the top 15% of performers" based on drug sales and receive a Movado watch, which is enhanced with a diamond each additional year the salesperson remains a Diamond Club member.

79. Celgene holds an annual "Chairman's Challenge," which is a bonus program that rewards sales personnel for gross on-label and off-label Thalomid and Revlimid sales and each salesperson's ability to exceed certain sales benchmarks. A March 2003 Chairman's Challenge announcement from Dwight D'Iorio states, "As promised at the National Sales Meeting there will be an additional bonus opportunity if we achieve an even higher level of sales success."

C. CELGENE MARKETS THALOMID OFF-LABEL

80. From the beginning of Relator's tenure at Celgene, Relator and other sales representatives were systematically directed to market Thalomid for a variety of off-label cancers and other ailments. When Relator joined Celgene in April 2001, Thalomid was only approved for treatment of ENL and did not receive an additional indication until a full five years later, in May 2006. Nevertheless, Celgene never provided Relator any information or training concerning Thalomid's use in ENL. To this day, Relator has never been provided with any studies, pamphlets, or educational materials of any sort concerning the sole disease for which Thalomid, at the time, was indicated. In her nearly nine years at Celgene, Relator has never even met a physician who, to her knowledge, treats ENL. Furthermore, to Relator's knowledge, a mere twelve leprosy cases are treated in California each year, meaning ENL patients are virtually non-existent in her sales territory.

81. By contrast, since 2001, Celgene immersed Relator and other sales representatives in training materials concerning a litany of diseases – primarily cancers – for which Thalomid was not approved. Relator was provided stacks of studies by Celgene's national headquarters so that she could detail physicians on

these off-label uses. In addition, Celgene has off-label materials that are designed specifically to be used in sales calls.

82. Through discussions with fellow sales representatives, Relator has learned that Celgene began off-label marketing Thalomid almost immediately upon receiving FDA approval. For instance, a fellow West Region sales representative told Relator that in or about 1999 or 2000, Jerome Zeldis, Celgene's then-Medical Director, accompanied her on a sales call to a preeminent breast cancer physician in Texas, in order to convince the breast cancer doctor to prescribe Thalomid to all of his breast cancer patients.

83. Relator and her colleagues were directed to "probe" physicians on a variety of off-label uses for Thalomid. More specifically, Celgene directed Relator to ask physicians if they treated patients who suffered from a number of cancers and other diseases so that Relator could segue into Thalomid's use for these off-label purposes. For instance, Relator was directed by Celgene managers to ask physicians, "Do you treat any [off-label disease] patients?" If a physician responded "yes," Relator was told to highlight studies that purportedly showed strong data that supported Thalomid's use for the off-label indication. For example, a 2002 "Celgene Field Contact Report" written by Relator's then-district sales manager, Deanna Harding, directed Relator to "Identify your goal before walking into the office and establish an appropriate ***probe question*** to get you into a discussion."

84. But many of the studies Relator was required to emphasize to physicians were abstracts (*i.e.*, uncompleted studies), or contained insufficiently low numbers of patients to determine the efficacy of Thalomid in the particular disease. For instance, in or about 2001 or 2002, shortly after Relator began working for Celgene, she attempted to market Thalomid for smoldering MM (*i.e.*, early-stage, undeveloped MM) at the Ventura, California Hematology and Oncology Clinic. It is Relator's understanding that smoldering MM is *never*

treated, since it has not materialized into the full-blown disease. Nevertheless, Relator provided physicians at the Ventura facility with a study where 12 total patients were treated with Thalomid for smoldering MM. The head physician at the Ventura practice, Dr. Kelley, harshly scolded Relator for attempting to market Thalomid based on a woefully inadequate study.

85. Celgene also provided it sales force with a written off-label marketing plan for Thalomid in 2004 at a Celgene National Sales Meeting at the Lacosta Resort and Spa in Carlsbad, California, which was attended by the entire Celgene sales force from across the country, including Celgene's marketing department, and top-level Celgene management, including Sol J. Barer, then-President and COO, and then-CEO, John Jackson. At that meeting, Larry Bishop, the West Region Sales Director, provided the Celgene sales force with the "2004 Business Plan West Region (the "Plan")." The Plan focused "solely on Thalomid," and instructed sales personnel to, *inter alia*, "[e]mphasize MM, MDS and targeted solid tumor activity[3] on every [sales] call." In other words, although Thalomid was (a) not approved for MM[4] at the time the memorandum was distributed, (b) was and is not approved for MDS, and (c) was never approved for additional cancers, Celgene's senior management specifically directed Relator and her colleagues to market Thalomid for those diseases "on every call."

86. The 2004 Plan also provides a "Market Analysis Summary" which reported Celgene's West Region, through 2003, caused physicians to prescribe Thalomid to 230 brain cancer patients, 400 melanoma patients, 1000 MM patients, 730 MDS patients, 45 ovarian cancer patients, 250 prostate cancer patients, and 420 renal cell (i.e., kidney) cancer patients. Celgene's West Region

[3] "[T]arged solid tumor activity" refers to cancers.

[4] As stated above, Thalomid did not receive FDA approval for MM until May 2006. Even in 2006, however, Thalomid received the narrow indication for treatment of newly diagnosed MM, and only when it is taken in combination with the agent, dexamethasone.

was just one of Celgene's sales districts. The Plan also set "specific additional new patient goals, by malignancy."

87. The 2004 Plan encouraged Celgene sales representatives to use numerous off-label studies, journal articles and abstracts identified in the document when marketing Thalomid for off-label uses.

88. The Plan did nothing more than reiterate and memorialize management's previous (and continuing) directives to off-label market Thalomid. Relator's superiors, at times, referenced the Plan. For instance, in Relator's 2003 Performance Evaluation, completed in early 2004, Relator's then-district sales manager, Jeff Rowell ("Rowell"), instructed Relator to "Implement Larry Bishop's Regional Plan by targeting the selected tumors with the selected reference materials."

89. Relator successfully implemented the Plan. Every week, Celgene's national operations distributed spreadsheets summarizing Relator's and other sales representatives' sales data. Most of these sales report spreadsheets included a tab labeled "Indication and Duration Reports," which documented Relator's total Thalomid prescriptions for the current year as well as any "New [Thalomid] Patients" Relator successfully obtained. Each spreadsheet breaks these figures down by total numbers of patients and total Thalomid capsules prescribed. According to Relator's April 16, 2004 sales report, as of April 2004, Relator successfully caused physicians to prescribe 11,116 Thalomid capsules for MM patients, 504 for renal cell cancer patients, 1,148 for MDS patients, 196 for melanoma patients, 168 for prostate cancer patients, 112 for ovarian cancer patients, and 3,080 for patients suffering from "Other" ailments. Strikingly, ENL – the only disease for which Thalomid was indicated until May 2006 – is not listed on any of these Celgene-generated spreadsheets.

90. Similarly, at the end of certain quarters, Celgene distributed spreadsheets to Relator and her colleagues that included a tab labeled "Indication

Breakdown" and that provided the "Total Business" for Thalomid in specific diseases. According to the Celgene spreadsheet for the first quarter of 2004, from the first quarter of 2003 through the first quarter of 2004, Celgene's West Region sales force successfully caused physicians to prescribe: 131,702 Thalomid capsules for MM patients, 13,608 for MDS patients, and 1,484 for prostate cancer patients, and a total of 190,342 capsules for all patients combined. Critically, this same spreadsheet indicates that ***zero*** physicians in the region prescribed Thalomid for ENL.

1. CELGENE DIRECTED ITS SALES FORCE TO SECURE OFF-LABEL MEDICAL REQUEST FORMS TO PROVIDE COVER FOR THE COMPANY

91. Celgene, like other pharmaceutical companies, used "medical information request forms" to memorialize physician requests for off-label information. Believing that a physician's unsolicited or voluntary request directly to the company for such information generally is not considered evidence of company's intent to "misbrand" or off-label market a drug, Celgene subverted the "medical information request" process by requiring its sales force to verbally discuss off-label uses of its drugs during visits with physicians and *then* encourage physicians to order materials from Celgene, using "medical information request" forms. The forms, which were filled out by sales representatives and signed by physicians were designed to make it appear as though a physician's request for off-label information from Celgene's medical services department was entirely voluntary and unsolicited.

92. In complying with Celgene's directives, Relator routinely encouraged physicians to order off-label information from Celgene's medical services department during her sales pitches. If the physician agreed, Relator commonly filled out the form for the physician and then asked the physician sign. Relator sent the signed medical information request forms to Celgene's

headquarters in Summit, New Jersey, which in turn sent the information to the physician.

93. Celgene put intense pressure on Relator and other sales personnel to secure as many medical information request forms as possible. Relator's 2003 Performance Evaluation directed Relator to "obtain a signed Medical Services Request form on each call." Furthermore, Relator and other sales representatives who failed to secure sufficient numbers of these medical information request forms were routinely admonished by their superiors.

94. Moreover, at almost every national sales meeting, a member of Celgene's marketing department would stand and commend the Celgene regional sales force that secured the greatest number of medical information request forms during the previous year. Some of Celgene's highest level management, including Sol J. Barer (Celgene's current CEO), who were present at these meetings, joined in applauding the regional team that secured the most off-label request forms.

95. Celgene's directive to circumvent the "medical information request" process not only furthered its goal to unlawfully increase its sales of Thalomid and Revlimid, but provided needed cover were regulators to learn that the company had unlawfully distributed materials outside the drugs' labeling.

2. CELGENE DIRECTED ITS SALES FORCE TO "PUSH THE DOSE" WITH THALOMID

96. Thalomid grows more expensive the higher the dose.[5] Accordingly, Celgene directed sales representatives, including Relator, to encourage physicians to prescribe high doses of Thalomid, and sales representatives received larger bonuses based on higher dosages. Celgene's marketing strategy focused on diseases where patients in a study were given very high doses of Thalomid. For

[5] By contrast, a supply of Revlimid costs roughly the same amount regardless of the dosage.

example, Celgene's managers directed Relator to target physicians who treated renal cell (*i.e.*, kidney) cancer, because there existed published studies where renal cell cancer patients were treated with up to 1200mg of Thalomid per day. Relator was provided stacks of these and other studies to distribute directly to physicians by Allison Tozer, a Medical Information Specialist at Celgene's headquarters in New Jersey. Celgene directed Relator to detail physicians concerning these studies and related off-label uses of Thalomid.

97. Relator also targeted physicians that treated glioblastoma (*i.e.*, brain cancer) patients, because other studies used extremely high Thalomid dosage levels in treatment. In an effort to target these physicians, Celgene's national sales operations, provided Relator and other sales representatives a list of physicians in their areas that prescribed Temodar, a popular brain cancer medication. Celgene closely tracked physicians that prescribed Temodar.

98. Notwithstanding Celgene's efforts to target brain and kidney cancer specialists, Relator and other representatives often encountered resistance from physicians related to "pushing the dose," because many patients could not tolerate high dosage levels of Thalomid. Elevated doses of Thalomid can cause conditions such as pathological blood clots (which are potentially fatal), peripheral neuropathy, neutropenia, and constipation.

3. CELGENE BROUGHT SALES REPRESENTATIVES TO ITS HEADQUARTERS TO LEARN TO OFF-LABEL MARKET THALOMID

99. Celgene sent its sales force to the Company's headquarters in Summit, New Jersey to participate in routinely conducted off-label training sessions. In or about 2004, Larry Bishop, who authored the 2004 marketing Plan, conducted a "Phase II Training" to assist Celgene's sales force in marketing Thalomid for a number of off-label uses. The Phase II Training materials discussed Thalomid use in the following cancers: prostate, ovarian, melanoma, renal, colorectal, brain, pancreatic, bladder, esophageal, gastric, testicular,

cervical, uterine, breast, and thyroid. The Phase II materials conclude with five pages of questions concerning Thalomid's purported effectiveness in cancers. Following the Phase II training session, Bishop circulated a number off-label studies (concerning these diseases) to sales representatives for use in detailing physicians. Mandatory training seminars similar to Bishop's Phase II Training were routinely conducted at Celgene's headquarters in Summit, New Jersey.

4. CELGENE UTILIZED NATIONAL SALES MEETINGS TO TRAIN AND ENCOURAGE SALES PERSONNEL TO OFF-LABEL MARKET THALOMID

100. Celgene held annual national sales meetings throughout the country, where Relator and other sales representatives were also trained and encouraged to off-label market Thalomid. These meetings were attended by up to 500 Celgene employees (depending on whether Celgene's international divisions attended), including employees in Celgene's sales and marketing departments as well as Celgene's top executive officers, including John Jackson and Sol J. Barer.

101. At the 2003 and 2004 national meetings, Larry Bishop, then-West Regional sales director, conducted trainings to assist Celgene's sales force in marketing Thalomid for various off-label uses. Following these sessions, Bishop circulated a number of off-label studies concerning a variety of diseases to sales representatives. As discussed above, Bishop's Plan was distributed and discussed in training sessions at Celgene's 2004 national meeting.

102. At national sales meetings, Celgene used individuals being treated with Thalomid who suffered from life-threatening diseases, which were outside Thalomid's label, to attest to the drug's efficacy. These individuals were introduced to the sales force both informally and on-stage. Specifically, at the 2003 National Sales meeting in West Palm Beach, a Celgene employee introduced a patient suffering from melanoma, who spoke about her success on Thalomid. Relator also recalls a patient taking Thalomid as a single agent for multiple myeloma speaking at a national meeting. Following

these patient presentations, a Celgene employee routinely closed the meeting by emphasizing the importance of providing off-label information to physicians so that similar patients could receive Thalomid therapy.

5. MANAGEMENT ACCOMPANIED RELATOR AND OTHER SALES REPRESENTATIVES ON SALES CALLS

103. Managers joined Relator and other sales representatives on their sales calls at least once every three months to ensure that sales representatives were effectively marketing Thalomid off-label. During Relator's first four months at Celgene, in or about July 2001, Relator's then-district sales manager, Deana Harding, accompanied Relator on a full day of sales calls. After those calls, in Relator's "Celgene Field Contact Report," Harding wrote, "I would like to hear you articulate the newly diagnosed [MM] data next time we are together; as well as the thought leaders [sic] dosing guidelines to move your MDs forward." Similarly, in a 2002 report, Harding instructed Relator to "Brush up on your MDS and Figg data so that after Myeloma you have an alternative message." "Figg data" refers to a study concerning Thalomid use in prostate cancer. Relator memorized portions of the Figg study in an effort to promote Thalomid in prostate cancer.

104. In Relator's 2003 performance evaluation, Relator's then-district sales manager, Jeff Rowell, commented on a ride-along he had had with Relator, writing, "You are not afraid to seek to seek additional uses of Thalomid beyond Multiple Myeloma as evidenced by seeing you discuss data on MDS, Renal Cell Carcinoma, Prostate Cancer. Colorectal Cancer, Melanoma, and other tumor types [with physicians]."[6] Based on this, and other performance measures, Rowell rated Relator's 2003 job performance "EE" for "Exceeds Exceptions."

[6] As Harding's and Rowell's words plainly show, years before Celgene received approval for treatment of newly diagnosed MM, Celgene already considered Thalomid an MM medication. In a 2003 letter from Barer – Celgene's current CEO – to Relator, Barer warned of the competition that Thalomid could face for treatment of MM: "[o]ur commercial force will face competition: Velcade will be

105. Moreover, Relator's managers conducted ride-alongs after Relator and other sales representatives had secured signed off-label medical information request forms. When Relator returned with her manager, she asked the physician whether he or she had received the off-label information requested. Relator then often asked the physician for assurances that he or she would prescribe Thalomid for that specific off-label use. This would show Relator's manager that, not only was she securing off-label information requests, but that she was succeeding in securing new prescriptions.

106. Celgene's highest level management, stationed in New Jersey, also conducted ride-alongs with Relator and other sales representatives. In 2001, Celgene's Vice President of Sales, Dwight D'Iorio, rode along with Relator. Moreover, Relator is aware of John Jackson, Celgene's former CEO, performing a ride-along with at least one representative, Jackie Qwon – a representative in the Rockville, Maryland area – in or about 2003 or 2004.

6. RELATOR AND OTHER SALES REPRESENTATIVES WERE REQUIRED TO CONDUCT TRAINING SESSIONS CONCERNING THALOMID'S OFF-LABEL USES

107. Despite Relator's lack of formal medical training, she and other Celgene sales representatives were required to present information to fellow sales personnel concerning Thalomid's use in various off-label diseases. Celgene required that these presentations not only convey medical information to be communicated to physicians, but that they provide strategies for encouraging physicians to prescribe for the off-label uses.

108. For example, in or about 2003, two of Relator's fellow sales representatives, Alana Torgelson and Suzanna Zalutko, conducted training on

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approved sometime this year for ***myeloma***. While we believe that it will be relegated to a salvage role and doesn't have the wealth of evidence Thalomid has[,] it is important to remember ***that we will for the first time have competition***." Thalomid did not receive an MM indication for more than three years after Barer's letter.

Thalomid's use in colorectal cancer. The colorectal cancer training materials provided "Selling points of Thalomid use" in colorectal cancer, as well as "Potential Probes" for physicians, including "What is your treatment regimen for [colorectal cancer] [patients] ?" Another of Relator's colleagues, Hank Schwarz, conducted a "Kidney Cancer" training session in or about 2004, which included similar hypothetical "probe" questions. In or about 2003 or 2004, Relator conducted a training session concerning Thalomid's use in prostate cancer. Relator felt uncomfortable giving this presentation, as she had no formal medical training, let alone training concerning prostate cancer.

7. CELGENE MANIPULATED CONTINUING MEDICAL EDUCATION PROGRAMS TO OFF-LABEL MARKET THALOMID

109. To further its off-label marketing of Thalomid, Celgene utilized multiple continuing medical education ("CME") programs led by speakers paid by Celgene to tout the benefits of using Thalomid for non-indicated diseases. Relator and other sales representatives were required to bring CME programs to physicians' practices in her area, in order to encourage physicians to prescribe Thalomid for off-label uses.

110. In or about 2004, Celgene provided educational grants for various CME programs concerning Thalomid treatment in MM, MDS, and renal cell carcinoma, among other diseases. These CMEs consisted of speakers paid by Celgene to promote Thalomid's off-label uses. In or about 2003 or 2004, Howard A. Burris, III ("Burris") performed Celgene-sponsored speeches concerning "Recent Developments and Future Directions in the Treatment of Renal Cell Carcinoma." At the time, Burris was both a paid Celgene consultant and a member of Celgene's Speakers Bureau.

111. Relator and other sales representatives were pressured to bring Burris and other CME presenters to medical practices to encourage off-label Thalomid use. Relator kept "Oncology Profiling Notes" which tracked her experiences at various physicians' practices where she promoted Thalomid. In

one set of Relator's notes from 2004 (*i.e.*, while Thalomid was still indicated *solely* for ENL), Relator described how she considered bringing Dr. Burris to one medical practice, Kaiser Woodland hills, to present a renal cell cancer CME, but decided to conduct a CME concerning Thalomid for MM, since that practice treated a greater number of MM patients: "Met with CME coordinator to bring Dr. Bargolie to Kaiser Woodland Hills for the morning tumor boards . . . I originally planned on Dr. Burris for renal cell, but Woodland Hills has more MM."

8. CELGENE TEMPORARILY CHANGED COURSE IN PREPARATION FOR REVLIMID'S ANTICIPATED FDA APPROVAL

112. At the 2005 National Sales Meeting, Celgene's Senior Vice President of Sales and Marketing, Francis Brown ("Brown"), told Celgene's sales force that they would no longer be compensated for Thalomid sales. In 2005, Celgene was anticipating FDA approval of Revlimid, and the Company was worried that the FDA would question Thalomid's high volume sales because Thalomid was only approved for ENL at the time. Brown said that Celgene intended to tell the FDA that Celgene's sales force was paid for administering the S.T.E.P.S. distribution system, and not for Thalomid sales. This would indicate to the FDA that Celgene's sales force was not paid or incentivized to market Thalomid off-label.

113. Brown also told Celgene sales personnel that not providing bonuses for off-label sales would show the FDA that sales representatives were not being encouraged to off-label market. Brown said it would "protect" the sales representatives and Celgene and shows the FDA that the Company was not "out of line."

114. In reality, Celgene had off-label marketed Thalomid for years, and rewarded its sales force handsomely for their off-label sales.

D. CELGENE MISBRANDED THALOMID BY MAKING REPRESENTATIONS UNSUPPORTED BY THALOMID'S FDA-APPROVED PRESCRIBING INFORMATION

115. In addition to marketing Thalomid off-label, Celgene routinely made false statements to physicians concerning Thalomid's effectiveness in certain patient populations. These representations constituted illegal misbranding, because they were unsupported by Thalomid FDA-approved prescribing information.

116. For instance, Thalomid's FDA-approved prescribing information does not carry information concerning Thalomid use in patients with renal (*i.e.*, kidney) impairment or insufficiency.[7] But since Thalomid is processed in the kidneys, there is a question of whether Thalomid works in patients with poorly functioning kidneys. Since, a large number of MM patients suffer from renal insufficiency, Celgene worried that doctors might not prescribe Thalomid to this population of patients. A March 30, 2004, email from Alison Tozer, then manager of Celgene's Medical Services, to Celgene's national sales force states, "some of your prescribers have the misconception that thalidomide cannot be used in patients with impaired renal function." The letter continues, "**You can let prescribers know that:** . . . although thalidomide has not been fully investigated in patients with renal impairment, existing data would not suggest that dosage adjustment should be necessary in patients with renal dysfunction." To support this claim, Celgene cites a study that evaluated a mere 40 MM patients with renal impairment.

117. By representing to physicians that Thalomid was effective in patients with renal impairment without FDA-approval of those representations, Celgene unlawfully misbranded Thalomid to physicians.

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[7] While Thalomid's prescribing information currently includes information concerning Thalomid use in renally-impaired patients undergoing dialysis, the FDA has never approved prescribing information concerning Thalomid use in the larger renally-impaired population.

E. CELGENE MARKETS REVLIMID FOR OFF-LABEL USES

1. MDS

118. When Revlimid was launched in December 2005, it was approved solely for treatment of transfusion-dependant anemia due to low or intermediate risk MDS associated with a deletion 5q cytogenic abnormality.[8] As previously alleged, 5q cytogenic abnormality is relatively uncommon, as only 20% to 30% of MDS patients suffer from the condition. Nevertheless, Celgene immediately began directing Relator and other sales representatives to market the drug off-label for ***all*** types of MDS, including "high risk" MDS, and MDS without the 5q cytogenic abnormality.

119. Subsequent to Revlimid's launch, Celgene provided Relator and other sales representatives information concerning Revlimid use in non-indicated forms of MDS. One particular document Celgene provided to Relator includes a "Field question/objection addressed: Doesn't Revlimid only work in those patients with a del5q abnormality" and provides study results that Relator can recite to a physician to suggest Revlimid's purported efficacy in general MDS. Relator would probe physicians as to whether they treat general MDS, and then provide this information. Moreover, Relator memorized portions of a study in the *New England Journal of Medicine* that included partial findings concerning Revlimid's efficacy in general MDS. To this day, Relator provides this information to physicians.

120. As with Thalomid, Relator was pressured to secure off-label medical requests forms for Revlimid. And, based on Relator's ability to effectively market Revlimid for general MDS, Relator was able to routinely secure these forms for general MDS.

[8] To this day, Revlimid is still not FDA-approved for any other type of MDS.

121. Similarly, as with Thalomid, Relator's managers continue to conduct routine ride-alongs to ensure that Relator effectively markets Revlimid for off-label uses.

2. MM

122. While Revlimid was launched in December 2005, it was not until June 2006 that the drug received FDA approval for treatment of MM. Moreover, Revlimid's June 2006 approval was only for MM patients who have received at least one prior therapy *and* only when Revlimid is taken in combination with the drug, dexamethasone.[9] Not surprisingly, however, upon Revlimid's December 2005 launch, Relator was immediately instructed to begin marketing Revlimid for MM.

123. Furthermore, despite the narrow MM indication for which Revlimid was eventually approved, at all relevant times since Revlimid entered the market, Relator was directed to market Revlimid for the following off-label uses (a) newly-diagnosed MM (*i.e.,* MM patients who have not received at least one prior therapy, (b) monotherapy for MM; and (c) in combination with drugs other than dexamethasone for MM.

124. Continuing to the present day, Celgene provides studies to Relator and other sales representatives concerning non-indicated Revlimid uses for MM. These compilations provided to Relator include studies concerning Revlimid use in combination with drugs other than dexamethasone, including Bortezomib and Melphalan. Additionally, the materials provided to Relator include studies concerning "Monotherapy with Revlimid", and "Newly Diagnosed [MM] and Revlimid.

[9] As noted above, Revlimid is still only approved for this narrow MM indication.

3. LIKE THALOMID, CELGENE OFF-LABEL MARKETED REVLIMID FOR A VARIETY OF CANCERS AND OTHER AILMENTS

125. Sales representatives have been directed to off-label market the drug for a host of cancers, and Celgene is still at least implicitly encouraging Relator to off-label market Revlimid for a wide array of other diseases.

126. Specifically, upon Revlimid's launch, Celgene provided Relator with "Revlimid Standard Letters" or a list and compilation of studies concerning off-label uses for Thalomid. These compilations include studies concerning Revlimid use in a host of off-label cancers, as well as off-label treatments for MM and MDS.

F. CELGENE DIRECTS SALES REPRESENTATIVES TO ENCOURAGE PHYSICIANS TO SWITCH PATIENTS FROM THALOMID TO REVLIMID REGARDLESS OF WHETHER THE PATIENTS ARE HEALTHY AND STABLE

127. Since Revlimid is considerably more expensive than Thalomid, ($10,000 per month for Revlimid, compared to up-to $1,000 per month for Thalomid) Relator and other sales personnel have been pressured to move stable, relatively health patients taking Thalomid, to Revlimid. This practice, which serves no medical purpose, places patients at risk of potentially fatal VTE and peripheral neuropathy, among other serious ailments. Furthermore, this practice causes the federal, state, and city governments to expend significant, additional funds to cover the far higher cost of Revlimid. And as explained in more detail below, Celgene provides free Revlimid prescriptions to patients. Since Revlimid is far more expensive than Thalomid, these free prescriptions induce patients to switch from Thalomid to Revlimid—prescriptions that are ultimately paid for by Medicare and other government-funded insurance.

128. In a February 11, 2008, email from Shawn Tomasello, Celgene's Vice President of Sales, Tomasello refers to the need to "crack" physicians who have prescribed Thalomid but not Revlimid. In the February 2008 email, Tomasello circulates a list of physicians that have prescribed Thalomid but not

Revlimid and writes "Let's get a plan together on what we need to convert these docs . . . I am sure there are nuances for some that we will not crack but other should be ready for 'cracking.'"

129. Similarly, Celgene holds "Rev/Dex" contests, which award the sales representatives and sales teams that successfully moves the most MM patients from Thalomid to Revlimid. A November 7, 2008 email from Tomasello to Celgene's sales force and sales and marketing departments states, "Looks like Atlantic Central is leading the way in quarterly standings with an average of 6.10 patients converting from Thalomid MM to Revlimid MM . . . Keep up the great work with our customers!" Representatives who are successful in converting physicians from Thalomid to Revlimid earn points that can be exchanged for gifts, including airline tickets, vacations, clothing, appliances, jewelry. In 2009, Relator used her Rev/Dex contest points to purchase airfare.

130. Relator and other sales representatives were trained on moving physicians from Thalomid to Revlimid. Relator participated in Phase III training at Celgene's corporate headquarters in New Jersey where she was required to "Identify 10 prescribers that have written Thalomid MM but not Revlimid MM" and then list, "tactics you will employ with these prescribers" and "probing questions you might ask."

131. Celgene accomplished these goals, in part, by misbranding Revlimid. Specifically, Celgene directed Relator to make unsubstantiated claims concerning the supposed superiority of Revlimid to Thalomid. While there are no head-to-head trials comparing Revlimid's versus Thalomid's efficacy in, for instance, MM patients, Relator was specifically instructed to make claims to physicians that Revlimid is a more effective medication for the disease. These representations constituted unlawful misbranding since they were not supported by Revlimid's FDA-approved labeling.

132. Lastly, Celgene marketed Revlimid to physicians in this fashion *prior* to receiving FDA approval for the drug, in an effort to begin convincing physicians that they would want to change switch their patients from Thalomid to Revlimid.

G. CELGENE PAYS KICKBACKS TO PHYSICIANS TO PRESCRIBE REVLIMID AND TO ENCOURAGE OTHER PHYSICIANS TO PRESCRIBE THE DRUG

133. The federal anti-kickback statute makes it unlawful to pay remuneration in any form to induce the generation of business reimbursable by Medicare, Medicaid, or any other government-funded insurance program.

134. Immediately after Revlimid's launch, Relator and other sales representatives began receiving intense pressure to find physicians Celgene could pay to promote Revlimid. In addition, Celgene sales representatives were forced to take these physicians to other medical practices where the physicians could promote Revlimid use. These practices constitute illegal kickbacks meant to directly and/or indirectly encourage the writing of Revlimid prescriptions.

135. More specifically, Celgene designates certain physicians as "Thought Leaders." A Thought Leader is an experienced, respected physician with a high volume of Revlimid prescriptions. After Celgene designates a physician as a Thought Leader, the Thought Leader is connected with a company called Envision, which trains the Thought Leaders to give presentations, and facilitates Thought Leader programs. Celgene refers to the programs as "Envision Programs." Envision programs can take nearly any form. More specifically, an envision program can be a one-on-one, in-office conversation between a Thought Leader and another physician or a breakfast, lunch or dinner presentation either within or outside of a physician's practice. Physicians are typically paid anywhere from $1,600 to $4,000 for each Envision Program he or she conducts. Certain physicians were paid even more. For example, Relator is

aware of a Dr. Berenson in California who receives upwards of $10,000 to conduct Envision Programs.

136. From 2006 through 2009, Relator was generally required to facilitate 15 or 16 Envision Programs per year. Within Relator's sales district, total Envision Program goals are generally to exceed 150 programs per year. Tellingly, Celgene strongly encourages Relator and other sales representatives to hold Envision Programs at physicians practices where Celgene can get the most bang for its buck. Multiple emails from Relator's manager ordered Relator and her fellow sales representatives to "target" physicians who are high Dacogen (an MDS drug) and Velcade (an MM drug) prescribers in an effort to convert those physicians to Revlimid.[10]

137. For instance, an August 31, 2009 email from Relator's current district sales manager, Shawn Gormish, to Relator and other sales representatives stated that sales representatives should focus on "opportunities in high Velcade or Dacogen accounts" and to "capitalize on ROI" (*i.e.*, return on investment). For 2009, Celgene's budget for Envision Programs was $5 million. In 2008, Relator alone facilitated more than $45,000 in Envision Programs.

138. Relator and other sales representatives were praised for holding high numbers of Envision Programs and, likewise, were penalized for failing to meet certain quotas. In Relator's 2006 Performance Evaluation, Gormish praised Relator for developing Thought Leaders and utilizing Envision Programs, writing "You developed the following advocates: Dr. George Somlo and Dr. Amrita Krishnan, both attended MM speaker training and Dr. Somlo also attended the

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[10] Dacogen is FDA-approved for treatment all types of MDS, while Velcade is indicated for *all* types of MM. As stated throughout the Complaint, Revlimid is indicated *solely* for low to intermediate risk MDS with deletion 5q cytogenic abnormality, and previously treated MDS. By encouraging sales representatives to target Dacogen and Velcade prescribers and market Revlimid as a competitor drug, Celgene further caused its sales representatives to off-label market Revlimid.

MDS advisory board . . . Bev, I am especially proud of this effort . . . [T]he envision programs worked for you." Relator was similarly praised in her 2008 Performance Evaluation: "[O]f particular note of Business management is your ability to use your envision promotional programs which you have completed 16 envision programs . . . In 2009, continue to analyze your business needs and place your envision programs."

139. An August 25, 2008 email from Gormish praised Relator and two other sales representatives who had "planned or executed the most" Envision Programs. The email continues by encouraging other sales representatives to do more programs: "Per the guidance on our last Conference call, I would like everyone to end up with at least 16, those who have 12 or more, please keep planning and executing where your territory needs . . . The district average per territory, should at least [sic] 16 programs per HOC. That would place the great Hollywood district at 160 for the year."

H. CELGENE DIRECTLY TARGETS FEDERAL AND STATE HEALTHCARE DOLLARS

140. Throughout Relator's tenure at Celgene, she and other sales representatives have been immersed in educational materials concerning government insurance programs. In or about 2006 Relator received a booklet from Celgene entitled "Reimbursement in the Oncology Market." The booklet contains a section entitled "Key Payers for Chemotherapeutic Drugs," that states "Because the average age of a multiple myeloma patient is 65 or greater, Medicare is the primary payer for most patients and is therefore essential to Celgene's business." The booklet continues with a discussion of, *inter alia*, Medicare and Medicaid.

141. Moreover, due to the high cost of Thalomid and Revlimid, Celgene knew it could raise the volume of Thalomid and Revlimid prescriptions by assuring doctors that government programs could mitigate the costs of the drugs. For example, in or about 2006, Relator was provided with a DVD entitled

"Medicare Part D and Beyond: Facilitating Patient Access to Novel Therapeutics in Oncology." Relator was directed to provide this DVD to physicians to help them better understand how Medicare could pay for Thalomid and Revlimid. Similarly, in 2008, Relator was praised by Gormish for *her* "thorough understanding of Reimbursement for Medicare [P]art D," which she was able to effectively communicate to physicians.

142. As suggested above, a large percentage of Revlimid and Thalomid prescriptions are paid for by Medicare. As Celgene's President and Chief Operating Officer, Robert J. Hugin, stated on January 29, 2009 Earnings Conference Call, a majority of [Revlimid] patients are most likely Medicare." Similarly, an April 1, 2009, Credit Suisse analyst report states that "Medicare . . . patients account for the lion's share of [Celgene's] revenue."

1. CELGENE CREATED A POSITION, THE PATIENT SUPPORT COORDINATOR, TO ASSIST PATIENTS IN OBTAINING GOVERNMENT FUNDING FOR THESE DRUGS

143. In 2006, Celgene created the Patient Support Coordinator (the "PSC").[11] The PSC provides "reimbursement assistance" to patients prescribed Thalomid, Revlimid and other Celgene drugs. The program consists of individuals called Patient Support Specialists ("PSS"s) who assist patients in enrolling in Medicare or Medicaid, and help patients receive reimbursement from government-funded insurance. The primary PSS responsible for Relator's sales district is Samuel Vasquez ("Vasquez"). Essentially, a sales representative, such as Relator, informs a physician about the PSC anticipating that the physician will then refer his or her patient to the program. The PSC has caused Medicare and Medicaid to pay for a greater number of off-label Thalomid and Revlimid prescriptions.

[11] Celgene recently changed PSC's name to "Celgene Patient Support," to "revitalize[e]" the programs image.

144. Celgene sales representatives touted the PSC to physicians in order to encourage them to prescribe Thalomid and Revlimid. Moreover, at a recent Celgene National Sales meeting in 2009 in Scottsdale, Arizona, sales representatives were told to encourage physicians to enroll as many patients as possible in the PSC. A prime example of Celgene efforts with the PSC is contained in a November 17, 2009 email sent by Katherine Stultz ("Stultz") – Celgene Director of Patient Support and Reimbursement Services – to Celgene's national sales force in which Stultz directs Celgene's sales force to distribute PSC materials concerning Medicare enrollment to physicians. Specifically, Stulz writes the following:

> Next week each of you will receive an auto shipment of the ***"Reminder Medicare Part D enrollment cards"*** . . . Please utilize these cards to remind your office this is the only time of year to enroll patients in Medicare Part D . . . Most important – these cards are a trigger to come to our team for assistance if they or their patients have questions about coverage of a Celgene product in any Medicare Part D plan.

(emphasis in original).

145. Celgene's efforts have been very successful. A September 28, 2009 email from Vasquez states that "there is a rise in the number of cases I am currently handing . . . due to the Patient Support initiative to enroll patients into Medicare Part D." Vasquez's email includes a chart showing Thalomid and Revlimid patients for whom Vasquez is assisting with Medicare and Medicaid. Prior to the surge in enrollment, roughly one-third of Revlimid and Thalomid takers were enrolled in the PSC.

2. CELGENE TARGETED VETERANS ADMINISTRATIONS AND TRICARE

146. In addition to directly targeting Medicare and Medicaid dollars, Celgene targeted Veterans Administration ("VA"s) whose patients are insured by

the federal military insurance program, TRICARE. A 2007 Company newsletter titled, "What's Up In Summit?" (a reference to Celgene's headquarters in Summit, New Jersey) provides "Tips for Working a VA" for sales representatives who are "having trouble meeting with [their] VA Hematologists/Oncologists."

147. Moreover, at all relevant times, Relator promoted Thalomid and Revlimid for off-label uses at the North Hills VA in North Los Angeles County, CA.

148. In or about 2004, Relator learned that the North Hills VA treated many MM patients, but with VAD, a combination of chemotherapy drugs.[12] Around that time, Celgene informed Relator that Tri-Care offered a minimal $5 co-pay on the otherwise expensive Thalomid. Relator, however, experienced great difficulties penetrating this VA, notwithstanding that she had informed physicians of patients' mere $5 co-pay for their Thalomid prescriptions. Accordingly, at a 2004 Diamond Club Meeting, Relator approached then-COO, Barer, concerning her difficulties persuading VA physicians to prescribe Thalomid for MM. Barer agreed with Relator that it was an interesting problem, and then allowed other sales reps to interject and offer their strategies for penetrating VAs. Barer told Relator that he would have to contemplate the issue and see if he could come up with any solutions.

I. CELGENE PAYS PATIENTS KICKBACKS TO INDUCE REVLIMID PRESCRIPTIONS

149. As explained above, the federal Anti-Kickback Statute makes it unlawful to pay remuneration in any form to induce the generation of business reimbursable by Medicare, Medicaid, or any other government-funded insurance program. Furthermore, in 2005, HHS and the Office of the Inspector General ("OIG") issued guidance concerning, *inter alia*, inducements paid to Medicare and Medicaid patients (or potential patients) that could induce prescriptions. 70

[12] In 2004, Thalomid was not indicated for MM.

Fed. Reg. 224 (Nov. 22, 2005). More specifically, according to the OIG, when pharmaceutical companies provide free drugs that may generate additional prescriptions, those free drugs can constitute unlawful kickbacks.

150. Currently, Revlimid provides free Revlimid and Thalomid prescriptions to patients who are not insured under Medicare Part D but who are eligible for the program. Since patients can enroll in Medicare Part D only from November 15 through December 31 of each year, many patients who are eligible for Medicare do not have access to health insurance until the end of the year enrollment period. Due to Revlimid's and Thalomid's high cost (up to $10,000 and $1,000 per month, respectively) many patients are unable to afford the drugs until they can enroll in Medicare. Accordingly, these patients may opt for alternative and less expensive drug regimens. To either procure or retain this potentially lost business, Celgene supplies these patients with free Revlimid and Thalomid prescriptions. *See* Celgene Patient Support, http://www.celgenepsc.com/pat_free.aspx. Since these patients would otherwise undergo less expensive therapies, and instead are induced by Celgene to take Revlimid or Thalomid (the high cost of which is shouldered by Medicare when the patient ultimately enrolls), these free prescriptions constitute illegal kickbacks.

151. Additionally, when a patient is enrolled in Medicare or Medicaid, Celgene will enroll the patient in a foundation that assists with the patient's out of pocket expenses, or co-pay, for Revlimid or Thalomid. This conduct constitutes an illegal kickback as well, since it has the effect of keeping the patients on the expensive drug, the high cost of which is ultimately shouldered by government-funded insurance.

J. CELGENE MANIPULATES REVASSIST TO CAUSE MEDICARE AND MEDICAID TO PAY FOR OFF-LABEL REVLIMID PRESCRIPTIONS

152. As explained in section V. A. 3., *supra*, due to the high risk of birth defects with Thalomid and Revlimid, the FDA requires Celgene to implement

strict distribution systems for each drug. Revlimid prescribers must comply with the RevAssist system, which operates in the following manner.

153. First, the physician uses RevAssist software (loaded onto computer via CD and accessible online) to create a Patient-Physician Agreement Form ("PPAF"). The PPAF has a patient information page, where the physician selects the patient's "Diagnosis" from a "drop-down" menu of ICD-9 codes, which are three to five digit codes indicating the disease for which a patient is receiving Revlimid. This is a one-time process for each new Revlimid patient.

154. The physician then completes a survey either online or via telephone, where he or she warrants that the patient has been counseled about the risk of birth defects and the need to engage in protected sex while taking Revlimid. After completing the survey, the physician receives an authorization number from Celgene that allows him or her to write the prescription. A physician must complete this survey every time he or she writes a prescription. Physicians may only write a prescription for a one-month or less supply of Revlimid, and may not include refills in any prescription. Thus, for a patient who takes Revlimid long-term, a physician must write a new prescription every month.

155. Once the physician writes a prescription, RevAssist requires the physician to fill-out a dedicated RevAssist prescription form. This form can be generated through RevAssist software, be faxed to the physician from Celgene, or downloaded from the Celgene's website. The form has a blank field for the "Patient's Diagnosis Code (ICD-9 Code)."

156. The physician is then required to submit the prescription to a "specialty pharmacy" which must be specifically licensed to supply Revlimid. When the specialty pharmacy receives the prescription form, the pharmacist must contact Celgene and confirm the physician's authorization code.

157. In or about 2006, shortly after Revlimid's launch, Relator's manager, Gormish, directed Relator and other sales representatives to "change the [ICD 9]

codes" on Revlimid prescriptions that were written for off-label indications to reflect that the prescriptions were for on label uses. These specific directives continued until as recently as March of February of 2009. At the 2009 national sales meeting in Scottsdale, Arizona, during a "district break-out session," the manager of the West Region's PSC, Tom Girrardi, directed the West Region sales representatives to change the codes on physicians' Revlimid prescriptions.

158. Relator has refused to take part in the scheme. In October 2008, Relator wrote a letter to Celgene stating that she understood changing ICD-9 codes was unlawful. Moreover, Relator participated as a third party in a deposition brought by a former Celgene sales representative who claimed unlawful discharge in the summer of 2009. During the deposition, Relator reiterated her position concerning changing ICD-9 codes.[13]

159. Since Relator has stalwartly refused to participate in Celgene's unlawful code-changing practice, she has never inquired as to *how* she could change physicians' prescription forms. Nevertheless, from 2006 to the present day, Relator has observed activities within Celgene that suggest the various ways Celgene personnel accomplish this task.

[13] In response to her opposition to Celgene's violations outlined in this Complaint, Relator has, for the first time in her career at Celgene, received poor performance reviews that she believes may later serve as a basis for her termination. For instance, during the week of March 6, 2010, Gormish provided Relator with her 2009 performance evaluation, which stated that Relator "needs improvement." When Relator inquired about the basis for her poor performance review, Gormish provided very little explanation. Furthermore, Relator asked Gormish for her current "ranking" among Celgene's sales force. Gormish was initially unable to provide Relator her current ranking, instead telling her that her rank fell somewhere between 80 and 100 out of 102 total sales representatives. On March 10, 2010, Gormish forwarded to Relator an email from a member of Celgene's West Region that stated that Relator is currently the 98th ranked (out of 102) sales representatives within the Company. According to Relator, this sales rank is incorrect, as she continues to out-perform many of her peers within the Company.

160. Without FDA approval, Celgene has modified its RevAssist program under the guise of "assisting" physicians with RevAssist's cumbersome process. With RevAssist, Celgene is supposed to require physicians to use a specific RevAssist prescription form provided by the Company. But Celgene now allows at least one specialty pharmacy, PharmaCare Specialty Pharmacy ("PharmaCare"), to create its own prescription form for physicians who write Revlimid prescriptions. This new prescription form requires the physician to check one of two boxes that include a corresponding on-label ICD-9 code for either MDS or MM. The physician can also check a box for "Other" which is adjacent to a blank line.

161. The PharmaCare prescription form is laid-out in this manner to encourage physicians to check a box that corresponds to an on-label ICD-9 code, regardless of whether the prescription is off-label. Moreover, Relator believes that PharmaCare specialty pharmacists may "doctor" prescriptions where the "Other" box is checked, and fill-in an on-label ICD-9 code. These prescription forms are then submitted to Medicare, Medicaid, or other government insurers. Relator and her fellow sales representatives have received intense pressure from Gormish to encourage physicians to send all prescriptions to PharmaCare, which distributes this alternate prescription form.

162. Similarly, Relator has recently learned that shortly before a patient's prescription ends, PharmaCare may be sending physicians pre-prepared prescription forms that merely require the physician to sign for a patient's refill. These forms contain on-label ICD-9 codes, which most physicians will not bother to change.

163. Additionally, Relator is aware of at least one practice in the Los Angeles area that has had its Revlimid prescriptions for prostate cancer patients changed to on-label, MDS ICD-9 codes. Specifically, the Compassionate Oncology Medical Group in Los Angeles, run by Dr. Bob Liebowitz,

predominately treats prostate cancer patients. Celgene's records indicate that Dr. Liebowitz is one of the highest-volume prescribers of Revlimid for MDS. On information and belief, Dr. Liebowitz's off-label Revlimid prescriptions have, in fact, been unlawfully altered.

COUNT ONE
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)[14]

164. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

165. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1).

166. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to Medicaid, Medicare, and other Government funded health insurance programs false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

167. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed.

168. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

[14] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *.e.g.*, 31 U.S.C. § 3729(a)(1)

COUNT TWO
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)[15]

169. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

170. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(2).

171. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be made or used false records or statements that caused false claims to be paid or approved by the United States Government.

172. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed.

173. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT THREE
California False Claims Act., Cal. Gov't Code § 12651 et seq.

174. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

175. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 et seq.

176. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent

[15] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *.e.g.*, 31 U.S.C. § 3729(a)(2)

claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

177. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

178. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FOUR
Connecticut False Claims Act., Conn. Gen. Stat. § 17b-301b et seq.

179. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

180. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301b, et seq.

181. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid.

182. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

183. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIVE
Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 et seq.

184. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

185. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 et seq.

186. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid.

187. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

188. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIX
Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.

189. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

190. This is a claim for treble damages and civil penalties under the Florida False - Claims Act. Fla. Stat. Ann. § 68.081 et seq.

191. By virtue of, the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

192. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

193. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVEN
Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 et seq.

194. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

195. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 et seq.

196. By virtue of, the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

197. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

198. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHT
Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 et seq.

199. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

200. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22 et seq.

201. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

202. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

203. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT NINE
Illinois Whistleblower Reward and Protection Act, 740 III. Comp. Stat. 175/1 et seq.

204. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

205. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 111. Comp. Stat. 175/1 et seq.

206. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

207. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

208. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TEN
Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5

209. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

210. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

211. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

212. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT ELEVEN
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann. § 46:439.1 et seq.

213. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

214. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1 et seq.

215. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off label uses of Thalomid and Revlimid.

216. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

217. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWELVE
Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(0)

218. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

219. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A)-(0).

220. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

221. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

222. By reason of these payments, the Massachusetts Medicaid Program has been

damaged, and continues to be damaged in a substantial amount.

COUNT THIRTEEN
Michigan Medicaid False Claims Act, MCLS § 400.601 et seq.

223. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

224. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLS § 400.601 et seq.

225. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Michigan Medicaid Program false or fraudulent claims for the

improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

226. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

227. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FOURTEEN
Montana False Claims Act, Mont. Code Anno §17-8-401 *et seq.*

228. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

229. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Anno. § 17-8-401 *et seq*.

230. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

231. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

232. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIFTEEN
Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.*

233. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

234. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. §357.010 et seq.

235. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

236. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

237. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIXTEEN
New Hampshire Medicaid Fraud and False Claims, N.H. Rev. Stat. Ann. § 167:61 *et seq.*

238. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

239. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. § 167:61, et seq.

240. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

241. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

242. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVENTEEN
New Jersey False Claims Act, N.J. Stat. §2A:32 C-1 *et seq*.

243. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

244. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act. N.J. Stat. § 2A:32C-1 *et seq*.

245. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

246. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

247. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHTEEN
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*

248. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

249. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1 et seq.

250. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

251. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

252. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT NINETEEN
New York False Claims Act, N.Y. CLS St. Fin. § 186 et seq.

253. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

254. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. CLS St. Fin. § 186 et seq.

255. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

256. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

257. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY
North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*

258. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

259. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.

260. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the North Carolina Medicaid program for false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

261. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

262. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-ONE
Oklahoma Medicaid False Claims Act, 63 Okl. St. §5053 *et seq.*

263. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

264. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act. 63 Okl. St. § 5053 *et seq*.

265. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

266. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

267. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-TWO
Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1-1 *et seq.*

268. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

269. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq.*

270. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

271. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

272. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-THREE
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* and Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

273. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

274. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181 et seq.; Tenn. Code Ann. § 4-18-101 et seq.

275. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

276. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

277. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-FOUR
Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

278. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

279. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001 et seq.

280. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Texas Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

281. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

282. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-FIVE
Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216 *et seq.*

283. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

284. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-21.6 et seq.

285. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

286. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

287. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-SIX
Wisconsin False Claims Act, Wis. Stat. §20.931 *et seq.*

288. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

289. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act. Wis. Stat. § 20.931 *et seq*.

290. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

291. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

292. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-SEVEN
District of Columbia False Claims Act, D.C. Code § 2-308.03 *et seq.*

293. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

294. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03 *et seq*.

295. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

296. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

297. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-EIGHT
City of Chicago False Claims Act, Chicago Mun. Code Chapter 1-22 *et seq.*

298. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

299. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act, Chicago Municipal Code Chapter 1-22, et seq.

300. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the City of Chicago false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Thalomid and Revlimid.

301. The City of Chicago, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

302. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Relator requests that judgment be entered against Defendant, ordering that:

(i) Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, et seq., and the State False Claims Acts;

(ii) Defendant pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendant's actions, plus the appropriate amount to the States under similar provisions of the state false claims acts;

(iii) The Relator be awarded the maximum "relator's share" allowed pursuant to 31U.S.C. § 3730(d) and similar provisions of the state false claims acts;

(iv) The Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

(v) Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

(vi) Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

(vii) The United States, the States, and the Relator recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

DATED: April 27, 2010

Respectfully submitted,

BY: 

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CERTIFICATE OF SERVICE

On April 27, 2010, I hereby certify that a copy of Relator's Complaint (file-stamped) pursuant to the Federal False Claims Act will be served promptly on the following after Relator's Counsel receives a file-stamped copy of the Complaint from the Clerk's office and in accordance with Fed. R. Civ. P. 4.

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