STATE OF MAINE
KENNEBEC, SS

SUPERIOR COURT
CIVIL ACTION
DOCKET NO. CV-15-

STATE OF MAINE,	)	
	)	
Plaintiff	)	
	)	
v.	)	COMPLAINT
	)	(Injunctive Relief Requested)
AMGEN INC.,	)	
	)	
Defendant	)	

Plaintiff, State of Maine, by and through its Attorney General, brings this action against Defendant Amgen Inc. ("Defendant or Amgen") for violating 5 M.R.S. § 207 of the Unfair Trade Practices Act, 5 M.R.S. §§ 205-A through 214, seeking permanent injunctive relief, civil penalties, costs and attorney's fees.

PARTIES

1. Plaintiff, State of Maine (the "State"), is a sovereign state that brings this action by and through its Attorney General, Janet T. Mills, in the public interest pursuant to the authority granted her in 5 M.R.S. §§ 191 and 209 and the powers vested in her by common law.

2. Defendant Amgen Inc. is a Delaware corporation with a principal place of business at 1 Amgen Center Drive in Thousand Oaks, California 91320. At all relevant times, Amgen did business in the State of Maine by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

JURISDICTION AND VENUE

3. This Court has jurisdiction over Amgen pursuant to 14 M.R.S. § 704-A (2)(A) because Amgen has transacted business within the State of Maine at all times relevant to this

Complaint. This Court has jurisdiction over the subject matter of this action pursuant to 5 M.R.S. § 209 and 4 M.R.S. § 105.

4. Venue for this action properly lies in Kennebec County, Maine pursuant to 5 M.R.S. § 209.

COMMERCE

5. Amgen was, at all times relative hereto, engaged in trade or commerce in the State of Maine by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

ALLEGATIONS

Aranesp

6. Aranesp ® (darbepoetin alfa) is a biologic medication used to treat certain types of anemia by stimulating bone marrow to produce red blood cells. It belongs to a class of drugs called erythropoiesis-stimulating agents or ESAs.

7. Aranesp is approved to treat anemia caused by chronic renal failure (CRF) and chemotherapy-induced anemia (CIA) at a specified dose and frequency.

8. Aranesp's main competitor is Procrit, an ESA produced by Johnson & Johnson that has a shorter half-life and is dosed more frequently than Aranesp.

9. To better compete against Procrit, Amgen promoted Aranesp to treat anemia caused by CRF and CIA at dosing frequencies longer than the FDA approved label.

10. At the time Amgen promoted extended dosing frequencies, it lacked competent and reliable scientific evidence to substantiate the extended dosing frequencies.

11. Aranesp has never been approved by the FDA to treat anemia caused by cancer (Anemia of Cancer or AOC), which is distinct from anemia caused by chemotherapy.

12. Patients with AOC have active malignant disease and are not receiving chemotherapy or radiation.

13. Amgen promoted Aranesp to treat AOC even though it lacked competent and reliable scientific evidence to substantiate such use.

14. In 2001, when Amgen came on the market, Procrit was being used to treat AOC.

15. In order to compete with Procrit in the AOC market, Aranesp had to be reimbursable by insurance companies and federal programs.

16. The most common way to obtain reimbursement for an off-label use is to obtain a listing in a CMS recognized drug compendium.

17. A drug compendium is typically a non-profit reference book listing drug strengths, quality, and ingredients.

18. In 2003, there were two main compendia recognized by CMS: American Hospital Formulary Service (AHS) Drug Information and United States Pharmacopeia (USP) Drug Information.

19. AHS did not consider Phase 2 trial data, abstracts, open label studies, or special supplements, but USP did.

20. In October of 2003, after considerable lobbying by Amgen, USP accepted an AOC indication for Aranesp. To promote Aranesp off-label to treat AOC, Amgen distributed the USP monograph (a document which describes USP's approval of the off-label use), as well as various studies that encouraged off-label use of Aranesp to treat AOC.

21. In August and October of 2003, two large randomized controlled trials found increased death and possible tumor stimulation in cancer patients receiving ESAs that were not

approved in the United States.

22. In May of 2004, the FDA's Oncologic Drugs Advisory Committee met to discuss safety concerns of increased thrombotic events, tumor progression, and decreased survival seen in the 2003 studies as they applied to Aranesp and Procrit. The committee recommended large, randomized, controlled clinical trials with primary endpoints, including survival and transfusion rates to address the safety concerns.

23. Despite the growing concerns, Amgen promoted Aranesp to treat AOC.

24. In January of 2007, Amgen notified the FDA and health care professionals of the results of its pivotal 103 study in which patients receiving Aranesp for the treatment of AOC had a 28.5% increase in death and no significant reductions in transfusions or improvement in quality of life.

25. Shortly thereafter, the FDA required a black box warning on all ESAs that includes the warning, "ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers." It also explicitly states, "Discontinue following the completion of a chemotherapy course."

26. Aranesp's label also states, "Aranesp has not been shown to improve quality of life, fatigue, or patient well-being."

Enbrel

27. Enbrel® is Amgen's trade name for etanercept, a tumor necrosis factor (TNF) blocker for treatment of a number of conditions, including plaque psoriasis.

28. On November 2, 1998, the FDA approved Enbrel for its first indication, the

treatment of moderately to severely active rheumatoid arthritis.

29. On April 30, 2004, the FDA approved Enbrel for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

30. On February 18, 2005, the FDA sent a Warning Letter to Amgen stating that Amgen's direct-to-consumer television advertisement entitled "Freedom" overstated the effectiveness of Enbrel, failed to communicate the limitations of Enbrel's indication, thereby broadening the indication, and minimized the risks associated with Enbrel.

31. In March 2008, the FDA required a black box warning to be added to Enbrel's labeling. This warning informed prescribers and patients that infections, including serious infections that led to hospitalization or death, were observed in patients treated with Enbrel. These infections included cases of bacterial sepsis and tuberculosis.

32. In August 2009, the FDA required that Enbrel's black box warning be expanded to inform prescribers and patients that invasive fungal infections, as well as bacterial, viral, and other infections due to opportunistic pathogens were reported with the use of Enbrel. Additionally, the black box now warns that lymphoma and other malignancies, some fatal, have been observed in children and adolescent patients taking Enbrel.

33. Despite the black box warnings, the 2005 FDA Warning Letter, and Enbrel's limited approval for use in chronic moderate to severe plaque psoriasis, Amgen promoted Enbrel off-label for patients with mild plaque psoriasis from 2004 to 2011 and overstated Enbrel's efficacy in the treatment of plaque psoriasis.

VIOLATIONS OF LAW

34. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 33.

35. In marketing, promotion, selling, and distributing the biologic medications Aranesp® and Enbrel®, Defendant committed unfair or deceptive acts or practices by making misrepresentations about Aranesp® and Enbrel®, in violation of 5 M.R.S. § 207.

36. In marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, Defendant committed unfair or deceptive acts or practices by representing that Aranesp® and Enbrel® have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have, in violation of 5 M.R.S. § 207.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Pursuant to 5 M.R.S. § 209 and M.R. Civ. P. 65, permanently enjoin Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair, deceptive or misleading conduct, acts, or practices that violate 5 M.R.S. § 207 in the promotion and marketing of its biologic medications Aranesp® and Enbrel®;

B. Pursuant to 5 M.R.S. § 209, order Defendant to pay civil penalties of up to $10,000 for each intentional violation of 5 M.R.S. § 207;

C. Pursuant to 5 M.R.S. § 209 and 14 M.R.S. § 1522(1)(A), order Defendant to pay all costs for the prosecution and investigation of this action; and

D. Grant Plaintiff such other and further relief as the Court deems equitable and proper.

Dated: August 18, 2015

Respectfully submitted,

JANET T. MILLS
ATTORNEY GENERAL

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STATE OF MAINE
KENNEBEC, SS

SUPERIOR COURT
CIVIL ACTION
DOCKET NO. CV-15-145

STATE OF MAINE,

Plaintiff

v.

AMGEN INC.,

Defendant

CONSENT JUDGMENT

Plaintiff State of Maine has filed a Complaint against Defendant Amgen Inc. ("Amgen") concurrently with this Consent Judgment ("Judgment"). All parties having consented to the entry of this Judgment without trial or adjudication of any issue of fact or law, it is hereby ORDERED and ADJUDGED as follows:

I. FINDINGS

A. This Court has jurisdiction over the subject matter of this lawsuit and over the Parties.

B. The terms of this Judgment shall be governed by the laws of the State of Maine.

C. Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

D. The Parties have agreed to resolve the issues resulting from the Covered Conduct by entering into this Judgment.[1]

E. Amgen is willing to enter into this Judgment regarding the Covered Conduct in order to resolve the Signatory Attorney General's concerns under the State Consumer Protection Laws as to the matters addressed in this Judgment and thereby avoid significant expense, inconvenience, and uncertainty.

[1] This Judgment is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 4.

F. Amgen is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Amgen expressly denies. Amgen does not admit any violation of the State Consumer Protection Laws set forth in footnote 4, and does not admit any wrongdoing that was or could have been alleged by any Signatory Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Amgen. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

G. This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Amgen in any action, or of Amgen's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

H. It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Amgen in any respect other than in connection with the enforcement of this Judgment.

I. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

J. This Judgment (or any portion thereof) shall in no way be construed to prohibit Amgen from making representations with respect to any Amgen Product that are permitted under Federal

law or regulations or in Food and Drug Administration ("FDA") approved Labeling for the drug or biologic under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry, or permitted or required under any IND, NDA, sNDA, ANDA, BLA, or sBLA approved by the FDA, so long as the representation, taken in its entirety, is not false, misleading, or deceptive. Nothing in this Judgment shall prohibit Amgen from revising its procedures and policies to be consistent with then current Federal law under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), FDCA regulations, FDA Guidances, or other FDA interpretations.

K. Nothing in this Judgment shall:

1. require Amgen to take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") or any regulation promulgated thereunder, or by the FDA; or

2. require Amgen to fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA. Any written or oral Promotional claim subject to this Judgment which is the same, or materially the same, as the language required or agreed to by the Director of the Office of Prescription Drug Promotion, the Director of the Advertising and Promotional Labeling Branch, the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, or their authorized designees in writing shall not constitute a violation of this Judgment, unless facts are or become known to Amgen that cause the claim to be false, misleading, or deceptive; or

3. preclude Amgen from providing health care economic information to a formulary committee or similar entity or its members in the course of the committee or entity carrying out its responsibilities for the selection of drugs and biologics for managed care or other similar organizations pursuant to the standards of Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), as FDAMA may be amended or revised.

II. DEFINITIONS

The following definitions shall be used in construing this Consent Judgment:

A. "Amgen" shall mean Amgen Inc. including all of its subsidiaries, predecessors, and successors doing business in the United States.

B. "Amgen Marketing" shall mean Amgen personnel responsible for marketing an Amgen Product in the United States.

C. "Amgen Product" shall mean Erythropoietin Stimulating Agents (ESAs) and Enbrel.

D. "Amgen Sales" shall mean Amgen personnel responsible for Promoting an Amgen Product in the United States.

E. "Amgen Scientifically Trained Personnel" shall mean Amgen personnel who are highly trained experts with specialized scientific or medical knowledge whose roles involve the provision of specialized, medical or scientific information, scientific analysis and/or scientific information to HCPs but excludes anyone performing sales, marketing, or other primarily commercial roles.

F. "Aranesp" shall mean the biologic darbepoetin alfa.

G. "Clinically Relevant Information" shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding an Amgen Product.

H. "Compendium" (and "Compendia") shall mean any one of the compendia recognized by the U.S. Centers for Medicare & Medicaid Services (CMS) under Sections 1861(t) and 1927(g) of the Social Security Act that may be used in determining coverage of drugs and biologics for federal health care programs.

I. "Competent and Reliable Scientific Evidence" shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results, and that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

J. "Covered Conduct" shall mean Amgen's Promotional practices and dissemination of information regarding the biologics Aranesp® and Enbrel® in the United States through the Effective Date of the Judgment.

K. "Effective Date" shall mean the date on which a copy of this Judgment, duly executed by Amgen and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

L. "Enbrel" shall mean the biologic etanercept.

M. "Global Commercial Lead" shall mean the individual designated to represent the Amgen Global Commercial Operations (GCO) group with the Amgen Research & Development and Operations organizations during all stages of a product's life cycle.

N. "Health Care Professional" or "HCP" shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical or biologic products.

O. "Medical Information Responses" shall mean a scientific communication originating from Amgen Scientifically Trained Personnel to address an unsolicited request for medical information from HCPs regarding an Amgen Product relating to an Off-Label Use.

P. "Multistate Executive Committee" shall mean the Attorneys General and their staff representing Arizona, Florida, Illinois, Maryland, New York, North Carolina, Oregon, Pennsylvania, Texas, and Washington.

Q. "Multistate Working Group" shall mean the Attorneys General and their staffs representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii[2], Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah[3], Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

R. "Off-Label Use" shall mean a use or dose not consistent with the FDA-approved indication or other information in the FDA-approved U.S. Prescribing Information.

S. "Parties" shall mean Amgen and the Signatory Attorney General.

T. "Promotional," "Promoting," or "Promote" shall mean a representation about an Amgen Product intended to influence sales of that product, including attempts to influence prescribing practices and utilization of an Amgen Product, that would be deemed promotional labeling or

[2] Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

[3] With regard to Utah, the Utah Division of Consumer Protection is charged with administering and enforcing the Consumer Sales Practices Act, the statute relevant to this judgment/order. References to the "States," "Parties," or "Attorneys General," with respect to Utah, refers to the Utah Division of Consumer Protection.

advertising under the FDCA or any regulation promulgated thereunder, or by the FDA, under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry. These terms shall not include Medical Information Responses that comply with III.D or the provision of information to payors.

U. "Reprints" shall mean articles or reprints from a scientific or medical journal, as defined in 21 C.F.R. § 99.3(j), or reference publication, as defined in 21 C.F.R. § 99.3(i), describing an Off-Label Use of an Amgen Product.

V. "Signatory Attorney General" shall mean the Attorney General of Maine, or her authorized designee, who has agreed to this Judgment.

W. "Special Supplement" shall mean a manuscript for which Amgen has paid a journal for placement or publication (not including routine manuscript submission or preparation fees generally applicable to articles submitted for consideration for publication).

X. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.[4]

III. COMPLIANCE PROVISIONS

A. Compendia

The following subsection shall be effective for 5 years from the Effective Date of this Judgment.

1. Amgen shall not use a Compendium listing or publication to Promote any Amgen Product for any Off-Label Use to a Health Care Professional.

2. Amgen Marketing and Amgen Sales will not initiate any interactions with any Compendium relating to an Amgen Product and shall not determine the content of any materials for submission to a Compendium relating to an Amgen Product. Nothing in this Judgment,

[4] *See* 5 M.R.S. § 211 of the Maine Unfair Trade Practices Act, 5 M.R.S. §§ 205-A through 214.

however, shall prohibit Amgen Marketing and Amgen Sales from providing input into the decision-making process through the Global Commercial Lead.

3. Amgen shall not submit a Special Supplement to a Compendium in support of an Off-Label Use of an Amgen Product.

4. If Amgen submits information for a new listing relating to an Amgen Product to a Compendium, Amgen must inform the Compendium of any class effect that Amgen would be required to notify the FDA for inclusion in the Prescribing Information for an Amgen Product in accordance with 21 C.F.R. § 201.57(c)(6)-(7).

5. If Amgen requests any third party to provide specific information or comments to a Compendium regarding an Amgen Product, Amgen shall also request such third party to inform the Compendium that it is providing such information or comments at Amgen's request, provided, however, that if Amgen only notifies a third party of an opportunity to provide comments to a Compendium and does not suggest that the third party provide specific information, then the obligations of this section will not apply.

B. Promotional Activities

1. In Promoting an Amgen Product, Amgen shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive.

2. Amgen shall not represent that any Amgen Product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

The following paragraphs within this Section B shall be effective for 5 years from the Effective Date of this Judgment.

3. Amgen shall not make in a Promotional context an express or implied representation, not approved or permitted for use in the labeling or under the FDCA, that an Amgen Product is

better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by Competent and Reliable Scientific Evidence, whether or not such express or implied representation is made by comparison with another drug or treatment, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, a quotation, or other reference.

4. Amgen shall not Promote an Amgen Product by the use of Promotional Materials that:

a. contain a drug or biologic comparison that expressly or implicitly represents that an Amgen Product is safer or more effective than another drug or biologic in some particular when it has not been demonstrated to be safer or more effective by Competent and Reliable Scientific Evidence;

b. contain an express or implied representation that an Amgen Product is safer than it has been demonstrated to be by Competent and Reliable Scientific Evidence by selective presentation of information from a published article or other reference that report no side effects or minimal side effects with an Amgen Product or otherwise selecting information from any source in a way that makes an Amgen Product appear to be safer than has been demonstrated;

c. present information from a study in a way that implies that the study represents larger or more general experience with an Amgen Product than it actually does;

d. misleadingly present favorable information or conclusion(s) from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusion(s) for information that may be material to an HCP

prescribing decision when presenting information about a clinical study regarding an Amgen Product;

e. misleadingly use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity or misleadingly fails to reveal the range of variations around the quoted average results; or

f. use statistical analyses and techniques on a retrospective basis without adequate disclosures of their retrospective nature so as to misleadingly discover and cite findings not soundly supported by the study, or to misleadingly suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

5. Amgen shall not Promote Enbrel by misrepresenting any clinical treatment guideline in a manner that suggests Enbrel is approved for uses not consistent with the FDA-approved Prescribing Information.

C. Reprints

The following subsection shall be effective for 5 years from the Effective Date of this Judgment.

1. Reprints distributed by Amgen regarding an Amgen Product:

a. shall be accompanied by the FDA-approved Prescribing Information for the product, or a clearly and conspicuously described hyperlink that will provide the reader with such information;

b. shall contain a disclosure that is prominently displayed, which would include the first page or as a cover page where practicable, indicating that the article discusses unapproved new uses; and

c. shall not be referred to or used in a Promotional manner.

2. Amgen shall not use in a Promotional manner reprints of any Special Supplement that focuses primarily on an Off-Label Use of Aranesp.

D. Medical Information Responses

The following subsection shall be effective for 5 years from the Effective Date of this Judgment.

1. Amgen, through Amgen Scientifically Trained Personnel, shall have ultimate responsibility for developing and approving all Medical Information Responses regarding an Amgen Product. Additional approvals may be provided by the Amgen Law Department. Amgen shall not distribute any such materials unless:

a. Clinically Relevant Information is included in these materials to provide scientific balance;

b. data in these materials are presented in an unbiased, non-Promotional manner; and

c. these materials are clearly and conspicuously distinguishable from sales aids and other Promotional materials.

2. Nothing in this subsection shall prohibit Amgen Scientifically Trained Personnel from disseminating materials that are permitted to be distributed under then current Federal law, federal regulations, or FDA published guidance, whether in draft or final form, unless false, misleading, or deceptive.

3. Amgen Sales and Amgen Marketing shall not develop the medical content of Medical Information Responses regarding an Amgen Product.

4. Medical Information Responses regarding an Amgen Product may be disseminated only by Amgen Scientifically Trained Personnel to HCPs. Amgen Sales and Amgen Marketing shall not disseminate these materials to HCPs except in circumstances implicating public health and safety issues. In such circumstances, Amgen Sales and Amgen Marketing may disseminate

Medical Information Responses directly to HCPs when expressly authorized by leadership from the Amgen compliance, medical, and safety departments with advice and counsel from the Amgen Law Department.

IV. PAYMENT

No later than 30 days after the Effective Date of this Judgment, Amgen shall pay a total amount of $71 Million to be divided and paid by Amgen directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee.[5] Said payment shall be used by the States as attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, consumer protection enforcement funds, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for any lawful purpose, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

V. RELEASE

A. By its execution of this Judgment, the State of Maine releases and forever discharges Amgen and all of its predecessors, subsidiaries, successors, and assigns, and each and all of their current and former officers, directors, shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, disgorgement, fines, costs, attorneys' fees, remedies, and/or penalties that the Signatory Attorney General has asserted or could have asserted against the Released Parties under the above-cited consumer protection statutes, or any amendments thereto, or by common law claims concerning unfair, deceptive, or fraudulent trade practices or, if applicable, state

[5] The State of Maine's share is $790,731.01.

statutes equivalent to the federal Food, Drug, and Cosmetic Act that the Signatory Attorney General has the authority to release resulting from the Covered Conduct up to and including the Effective Date that is the subject of the Judgment.

B. Notwithstanding any term of this Judgment, specifically reserved and excluded from the release in Paragraph V.A as to any entity or person, including Released Parties, are any and all of the following:

1. any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of Maine.

2. any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Maine not expressly covered by the release in Paragraph V.A above, including, but not limited to, any and all of the following claims:

   a. state or federal antitrust violations;

   b. claims involving "best price," "average wholesale price," "wholesale acquisition cost," or any reporting practices;

   c. Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;

   d. state false claims violations; and

   e. actions of state program payors of the State of Maine arising from the purchase of an Amgen Product.

3. any liability under the State of Maine's above-cited consumer protection laws which any person and/or entity, including Released Parties, has or may have to individual consumers.

VI. DISPUTE RESOLUTION

A. For the purposes of resolving disputes with respect to compliance with this Consent Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Amgen has violated a provision of this Consent Judgment subsequent to the Effective Date, then such Signatory Attorney General shall notify Amgen in writing of the specific objection, identify with particularity the provisions of this Consent Judgment that the practice appears to violate, and give Amgen 30 days to respond to the notification.

B. Upon receipt of written notice from any of the Signatory Attorneys General, Amgen shall provide a good-faith written response to the Signatory Attorney General notification, containing either a statement explaining why Amgen believes it is in compliance with the Consent Judgment or a detailed explanation of how the alleged violation occurred and statement explaining how and when Amgen intends to remedy the alleged violation.

C. Except as set forth in Sections VI.D and E below, the Signatory Attorney General may not take any action concerning the alleged violation of this Consent Judgment during the 30 day response period. Nothing shall prevent the Signatory Attorney General from agreeing in writing to provide Amgen with additional time beyond the 30 days to respond to the notice.

D. Nothing in this Consent Judgment shall be interpreted to limit the State's Civil Investigative Demand (CID) or investigative subpoena authority, to the extent such authority exists under applicable state law, and Amgen reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

E. The Signatory Attorney General may assert any claim that Amgen has violated this Consent Judgment in a separate civil action to enforce compliance with this Consent Judgment, or may seek any other relief afforded by law for violations of the Consent Judgment, but only after providing Amgen an opportunity to respond to the notification as described above and to remedy the alleged violation within the 30 day response period as described above, or within any other period as agreed to by Amgen and the Signatory Attorney General. However, the Signatory Attorney General may take any action, including, but not limited to legal action to enforce compliance with the Consent Judgment, without delay if the Signatory Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

VII. GENERAL PROVISIONS

A. Amgen shall not cause or encourage third parties, nor knowingly permit third parties acting on its behalf, to engage in practices from which Amgen is prohibited by this Judgment.

B. This Judgment does not constitute an approval by any of the Signatory Attorneys General of Amgen's business practices, and Amgen shall make no representation or claim to the contrary.

C. Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this Judgment, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment.

D. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment and no prior versions of any of its terms that were not entered by the Court in this Judgment may be introduced for any purpose whatsoever.

E This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

F. This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

G. All Notices under this Judgment shall be provided to the following via email and Overnight Mail:

For Amgen Inc.:

General Counsel
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

For the State of Maine:

Carolyn A. Silsby
Assistant Attorney General
Consumer Protection Division
Office of the Maine Attorney General
111 Burton Cross Office Building, 6th Floor
Augusta, ME 04330
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H. To the extent that any provision of this Judgment obligates Amgen to change any policy(ies) or procedure(s) and to the extent not already accomplished, Amgen shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment.

FOR PLAINTIFF STATE OF MAINE:

JANET T. MILLS
ATTORNEY GENERAL

Date: August 18, 2015

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By:

Date: 8/12/15

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JUSTICE, MAINE SUPERIOR COURT