STATE OF MAINE
KENNEBEC, ss.

SUPERIOR COURT
CIVIL ACTION
Docket No. CV-17-218

STATE OF MAINE,	)	
	)	
Plaintiff	)	
	)	
v.	)	**CONSENT JUDGMENT**
	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	)	
	)	
Defendant	)	

Plaintiff, State of Maine, has filed a concurrent Complaint for a permanent injunction and other relief in this matter pursuant to 5 M.R.S. § 209 of the Maine Unfair Trade Practices Act, and Plaintiff, by its counsel, and Defendant Boehringer Ingelheim Pharmaceuticals, Inc., by its counsel, have agreed to the entry of this Consent Judgment (the "Judgment") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind.

NOW THEREFORE, IT IS HEREBY ORDERED THAT:

1. PARTIES

1.1 Plaintiff, State of Maine, is represented by its Attorney General, Janet T Mills, who is charged with the responsibility for enforcing the Maine Unfair Trade Practices Act, 5 M.R.S. §§ 205-A through 214.

1.2 Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), is a Delaware corporation with its principal place of business at 900 Ridgebury Road in Ridgefield, Connecticut. At all relevant times, BIPI did business in the State of Maine by marketing, selling,

and Promoting the drugs Aggrenox, Atrovent, Combivent, and Micardis (the "Covered Products").

2. PREAMBLE

2.1 Prior to the execution of this Judgment, BIPI represents that it voluntarily established a compliance program that is applicable to all BIPI employees.

2.2 BIPI further represents that its compliance program includes a Compliance Officer; a Code of Conduct; written policies and procedures; education and training initiatives; a disclosure program that allows for confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures; and regular internal auditing procedures.

3. FINDINGS

3.1 This Court has jurisdiction over the subject matter of this lawsuit and over all parties.

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

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

3.4 The parties have agreed to resolve the issues resulting from the Covered Conduct by entering into this Judgment.

3.5 BIPI 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.

3.6 BIPI 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, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, including allegations in the Complaint, all of which BIPI expressly denies. BIPI does not admit any violation of law, and does not admit any wrongdoing that was, or could have been, alleged by the Signatory Attorney General before the date of the Judgment. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by BIPI.

3.7 This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to BIPI in any action, or of BIPI'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. Nothing in this Judgment shall waive, release, or otherwise affect any claims, defenses, or positions BIPI may have in connection with any investigations, claims, or other matters the State of Maine is not releasing hereunder. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. It is the intent of the parties that this Judgment shall not be binding or admissible in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Judgment. Unless otherwise provided under state law, 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. Notwithstanding the foregoing, the State of Maine may file an action to enforce the terms of this Judgment.

3.8 This Judgment (or any portion thereof) shall in no way be construed to prohibit, limit, or restrict BIPI from making representations with respect to the Covered Products that are permitted or authorized under federal law, the Federal Food, Drug & Cosmetic Act (the

"FDCA," 21 U.S.C. § 301 et seq.), U.S. Food and Drug Administration (the "FDA") regulations, or FDA Guidances for Industry, currently issued or as revised. Further, the Judgment shall in no way prohibit, limit, or restrict BIPI from making representations with respect to the Covered Products that are required or authorized by, or consistent with the FDA-approved Labeling or prescribing information, or by any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application filed with the FDA so long as the representation, taken in its entirety, is not false, misleading or deceptive.

3.9 Nothing in this Judgment shall require BIPI to:

(a) take any action that is prohibited by the FDCA or any regulation promulgated thereunder, or by the FDA; or

(b) fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA.

4. DEFINITIONS

The following definitions shall be used in construing this Judgment:

4.1 "BIPI" means Boehringer Ingelheim Pharmaceuticals, Inc., including all of its past and present subsidiaries, predecessors, successors, and assigns.

4.2 "BIPI Marketing" shall mean BIPI personnel responsible for marketing Covered Products in the United States.

4.3 "BIPI Medical" shall mean BIPI 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 commercial roles.

4.4 "BIPI Sales" shall mean the BIPI sales force responsible for sales of Covered Products in the United States, including, but not limited to, the field force and all management personnel such as district managers, regional managers, vice president(s) over sales, and president over sales.

4.5 "Clear(ly) and Conspicuous(ly)" shall mean, with respect to a disclosure or information presented, that such information meets requirements of the FDCA, the requirements of FDA regulations, and the recommended actions in FDA Guidances for Industry, including FDA's "Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion," or as revised.

4.6 "Covered Conduct" shall mean BIPI's Promotional and marketing practices, and dissemination of information and remuneration to HCPs regarding the Covered Products through the Effective Date of the Judgment.

4.7 "Covered Product(s)" shall mean BIPI's drugs Aggrenox, Atrovent, Combivent, and Micardis, which have all been approved by FDA.

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

4.9 "FDA Guidances for Industry" shall mean documents, as currently drafted or as revised, issued by the FDA, pursuant to 21 U.S.C. § 371(h), that represent the FDA's current thinking on a topic.

4.10 "HCP" shall mean any physician or other health care practitioner, who is licensed to provide health care services or to prescribe pharmaceutical products.

4.11 "Labeling" shall mean all labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

4.12 "Medical Information Response(s)" shall mean a non-Promotional, scientific communication to address an Unsolicited Request for medical information from a HCP.

4.13 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, the District of Columbia, Illinois, Indiana, Kansas, Nevada, Pennsylvania, Tennessee, and Texas.

4.14 "Multistate Working Group" shall mean the Attorneys General and their staffs representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii[1], Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah[2], Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

4.15 "Off-Label" shall mean a use, including indication, dosage, population, and/or method of administration, not consistent with the use approved by the FDA in the Labeling for a Covered Product at the time information regarding such use was communicated, or at the time the conduct occurred.

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[1] 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.

[2] The Utah Attorney General's Office represents the Utah Division of Consumer Protection (Division), the state agency charged with enforcement of the Consumer Sales Practices Act, in this action, but is not a party itself. As to Utah, the definition of "Attorneys General" means the Utah Attorney General as counsel to the Division.

4.16 "Promotional," "Promoting," or "Promote" shall mean representations made to HCPs, patients, consumers, payors, and other customers, about a Covered Product and other practices intended to increase sales in the United States, or that attempt to influence prescribing practices of HCPs in the United States, including direct-to-consumer.

4.17 "Promotional Materials" shall mean any item used to Promote a Covered Product.

4.18 "Promotional Speaker(s)" shall mean a HCP speaker engaged by or on behalf of BIPI to Promote a Covered Product in the United States.

4.19 "Reprints Containing Off-Label Information" 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 a Covered Product.

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

4.21 "State Consumer Protection Laws" shall mean the Maine Unfair Trade Practices Act.

4.22 "Unsolicited Request" shall mean a request for information communicated to an agent of BIPI that has not been prompted by or on behalf of BIPI.

4.23 Any reference to a written document shall mean a physical paper copy of the document, an electronic version of the document, or electronic access to such document.

5. COMPLIANCE PROVISIONS

The following Compliance Provisions, Paragraphs 5.3 through 5.24, shall apply for five (5) years from the Effective Date of this Judgment.

Promotional Activities

5.1 BIPI shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any Covered Product.

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

5.3 BIPI shall not promote any Covered Product for any Off-Label use.

5.4 In Promotional Materials for Covered Products, BIPI shall Clearly and Conspicuously disclose the risks associated with the Covered Products as set forth in the products' Labeling and shall present information about effectiveness and risk in a balanced manner.

5.5 BIPI shall require that all Promotional Speakers for any Covered Product comply with BIPI's obligations contained in this Judgment.

5.6 BIPI shall notify BIPI Sales promptly of any warning letter received from the FDA that affects the conduct of any sales representative in Promoting the relevant Covered Product and shall promptly disseminate a description of the concerns described in the warning letter.

5.7 BIPI shall not Promote a Covered Product by misrepresenting any clinical treatment guideline in a manner that suggests a Covered Product is approved for uses not consistent with the FDA-approved prescribing information.

Product Sampling

5.8 BIPI shall provide samples of a Covered Product only to those HCPs whose clinical practice is consistent with the product's FDA-approved Labeling.

5.9 If a HCP whose clinical practice is inconsistent with a Covered Product's Labeling requests samples of that Covered Product, BIPI personnel shall refer the HCP to BIPI Medical where the HCP can speak directly with a BIPI Medical representative who will provide answers to the HCP's questions about the Covered Product, and BIPI may provide him/her with

samples only if appropriate (i.e., if the HCP requests the samples for an FDA-approved [on-label] use).

Financial Incentives to BIPI Sales and/or BIPI Marketing

5.10 BIPI's financial incentives shall be designed to ensure that BIPI Sales and/or BIPI Marketing are not motivated to engage in improper Promotion, sales, and marketing of Covered Products.

5.11 BIPI's financial incentives shall not include mechanisms to provide incentive compensation for sales that may indicate Off-Label use of any Covered Product.

Dissemination and Exchange of Medical Information

5.12 The content of BIPI's communications concerning Off-Label uses of a Covered Product shall not be false, misleading, or deceptive. BIPI shall not knowingly disseminate any Medical Information Response, including one that describes any Off-Label use of a Covered Product, unless such information and materials comply with the standards in applicable FDA regulations and with recommendations in FDA Guidances for Industry.

5.13 BIPI Sales and BIPI Marketing shall not develop Medical Information Responses regarding a Covered Product.

5.14 Medical Information Responses to Unsolicited Requests for Off-Label information regarding a Covered Product may be disseminated only by BIPI Medical, except in circumstances implicating public health or safety issues.

5.15 BIPI Medical shall have ultimate responsibility for developing and approving all Medical Information Responses regarding a Covered Product. Additional approvals may be provided by BIPI's legal department. BIPI 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.

5.16 Nothing in this subsection shall prohibit BIPI Medical from disseminating materials that are permitted to be distributed under Federal law, Federal regulations, or FDA published Guidance, unless false, misleading, or deceptive.

Responses to Unsolicited Requests for Off-Label Information

5.17 If BIPI elects to respond to an Unsolicited Request for Off-Label information regarding a Covered Product, BIPI Medical shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote a Covered Product for any Off-Label use.

5.18 Any written BIPI response to an Unsolicited Request for Off-Label information regarding a Covered Product shall be a Medical Information Response and shall include:

(a) a copy of the FDA-required Labeling, if any, for the Covered Product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient Labeling);

(b) a prominent statement notifying the recipient that the FDA has not approved or cleared the Covered Product as safe and effective for the Off-Label use addressed in the accompanying materials;

(c) a prominent statement disclosing the uses for which FDA has approved or cleared the Covered Product; and

(d) a report containing the results of a reasonable literature search using terms from the request.

5.19 BIPI Sales and BIPI Marketing may respond orally to an Unsolicited Request for Off-Label information regarding a Covered Product only by offering to refer the request to BIPI Medical, or by offering to put the HCP in touch with BIPI Medical.

Reprints Containing Off-Label Information

5.20 BIPI shall not disseminate information describing any Off-Label or unapproved use of a Covered Product, unless such information and materials comply with the standards in applicable FDA regulations and with recommendations in FDA Guidances for Industry, including FDA's "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" and FDA's "Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices," or as revised.

5.21 BIPI Medical shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding a Covered Product.

5.22 Reprints Containing Off-Label Information regarding a Covered Product:

(a) shall be accompanied by the FDA approved Labeling for the Covered Product or a prominently displayed and Clearly and Conspicuously described hyperlink that will provide the reader with such information;

(b) shall contain a Clear and Conspicuous disclosure in a prominent location, which would include the first page or as a cover page where practicable, indicating that the article discusses Off-Label information; and

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

5.23 Reprints Containing Off-Label Information regarding a Covered Product may only be disseminated if approved by BIPI Medical to HCPs.

5.24 This section of the Judgment does not apply to reprints containing only incidental references to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall contain the disclosures required by Paragraphs 5.22(a) and 5.22(b) in a prominent location, as defined above, and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Paragraph 5.22(c).

6. PAYMENT

6.1 No later than 30 days after the Effective Date of this Judgment, BIPI shall pay a total amount of Thirteen Million Five Hundred Thousand Dollars ($13,500,000) to be divided and paid by BIPI 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. 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, the consumer protection enforcement fund, 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 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.

7. RELEASE

7.1 By its execution of this Judgment, the State of Maine releases BIPI and all of its past and present subsidiaries, predecessors, successors, assigns, parents, affiliates, each of their current and former officers, directors, shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties") from the following: all civil claims, *parens patriae* claims, causes of action, damages, restitution, fines, attorney's fees, costs, and penalties that the Maine

Attorney General has asserted or could have asserted against the Released Parties under the above-cited consumer protection statutes or any common law claims concerning unfair, fraudulent, or deceptive trade practices other than those described in Paragraph 7.2 resulting from the Covered Conduct up to and including the Effective Date.

7.2 Notwithstanding any term of this Judgment, specifically reserved and excluded from the release in Paragraph 7.1 as to any entity or person, including Released Parties, are any and all of the following:

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

(b) 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 7.1 above, including, but not limited to, any and all of the following claims:

(i) state or federal antitrust violations;

(ii) claims involving "best price," "average wholesale price," "wholesale acquisition cost," or any price-reporting practices;

(iii) 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;

(iv) state false claims violations; and

(v) actions of state program payors of the State of Maine arising from the purchase of a Covered Product, except for the release of civil penalties under the Maine Unfair Trade Practices Act.

(c) any claims individual consumers have or may have under the State of Maine's above-cited consumer protection law, and any common law claims individual consumers may have concerning unfair, fraudulent or deceptive trade practices, against any person and/or entity, including Released Parties.

8. DISPUTE RESOLUTION

8.1 For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that BIPI has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify BIPI in writing of the specific objection, identify with particularity the provision of this Judgment that the practice appears to violate, and give BIPI 30 days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, BIPI shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why BIPI believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how BIPI intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the state's or Attorney General's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and BIPI reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

8.2 Upon giving BIPI 30 days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy

relevant, non-privileged, non-work product records and documents in the possession, custody, or control of BIPI that relate to BIPI's compliance with each provision of this Judgment pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to BIPI.

8.3 The Signatory Attorney General may assert any claim that BIPI has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing BIPI an opportunity to respond to the notification described in Paragraph 8.1 above; provided, however, that the Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

9. GENERAL PROVISIONS

9.1 BIPI shall not cause third parties, acting on its behalf, to engage in practices from which BIPI is prohibited by this Judgment.

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

9.3 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. 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.

9.4 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.

9.5 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.

9.6 To the extent that any provision of this Judgment obligates BIPI to change any policy(ies) or procedure(s) and to the extent not already accomplished, BIPI shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 90 days after the Effective Date of this Judgment.

9.7 The parties agree that neither of them shall be deemed the drafter of this Judgment and that, in construing this Judgment, no provision hereof shall be construed in favor of one party on the ground that such provision was drafted by the other.

9.8 All notices under this Judgment shall be provided to the following via email and Overnight Mail:

For the State of Maine:

Linda J. Conti, Chief
Consumer Protection Division
Office of the Maine Attorney General
Burton Cross Office Building, 6th Floor
111 Sewall Street
Augusta, ME 04330
linda.conti@maine.gov

For Boehringer Ingelheim Pharmaceuticals, Inc.:

Wick Sollers
King & Spalding LLP
1700 Pennsylvania Avenue, N.W.
Washington, DC 20006
wsollers@kslaw.com

IT IS SO ORDERED, ADJUDGED AND DECREED.

Dated: 12-27-2017

JUSTICE
Maine Superior Court

JOINTLY APPROVED AND SUBMITTED FOR ENTRY BY:

Plaintiff State of Maine:

JANET T. MILLS
ATTORNEY GENERAL

Date: 12/20/17

Carolyn A. Silsby, Maine Bar No. 3030
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FOR BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

Date: December 19, 2017

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FOR BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

By: _____ Date: 12/18/17

J. Sedwick Sollers, III, Esq.
Mark Jensen, Esq.
Brandt A. Leibe. Esq.
Daniel C. Sale, Esq.
King & Spalding LLP

Counsel for Boehringer Ingelheim Pharmaceuticals, Inc.

FOR BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

By: _____ Date: 12/12/17

Christian Orth
Senior Vice President and Chief Financial Officer
Boehringer Ingelheim Pharmaceuticals, Inc.

STATE OF MAINE
KENNEBEC, ss.

SUPERIOR COURT
CIVIL ACTION
Docket No. CV-17-

STATE OF MAINE,	)	
	)	
Plaintiff	)	
	)	
v.	)	**COMPLAINT**
	)	**(Injunctive Relief Requested)**
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	)	
	)	
Defendant	)	

INTRODUCTION

1. Plaintiff State of Maine brings this action, by and through its Attorney General, against Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., for violating 5 M.R.S. § 207 of the Maine Unfair Trade Practices Act (the "UTPA," 5 M.R.S. §§ 205-A – 214).

PARTIES

2. Plaintiff, State of Maine, brings this action by and through its Attorney General, Janet T. Mills, in the public interest, pursuant to authority granted her by 5 M.R.S. § 209.

3. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a Delaware corporation with its principal place of business at 900 Ridgebury Road, in Ridgefield, Connecticut 06877. At all relevant times, BIPI engaged in trade or commerce in the State of Maine by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 4 M.R.S. § 105 and 5 M.R.S. § 209. This Court has jurisdiction over BIPI pursuant to 14 M.R.S. § 704-A(2) because

BIPA has transacted business within the State of Maine at all times relevant to this Complaint.

5. Venue for this action is properly laid in Kennebec County, pursuant to 5 M.R.S. § 209.

ALLEGATIONS

Aggrenox

6. Aggrenox (a combination of aspirin and dipyridamole) is an antiplatelet drug that was approved by the U.S. Food and Drug Administration ("FDA") in 1999 to reduce the risk of secondary stroke in patients who have had a transient ischemic attack ("TIA"), which is sometimes referred to as a "mini stroke," or stroke due to a blood clot.

7. Aggrenox's main competitor was Plavix, which the FDA approved in 1997.

8. Plavix had an indication to reduce the risk of secondary stroke following a TIA or stroke due to a blood clot; however, it also had indications to treat a broader range of secondary clot-related events, including myocardial infarction and peripheral artery disease ("PAD"), which is also referred to as peripheral vascular disease ("PVD").

9. BIPI represented that Aggrenox was superior to Plavix and Plavix/aspirin combinations when, in fact, BIPI lacked competent and reliable scientific evidence to substantiate its claims.

10. BIPI also represented that Aggrenox was effective "below the neck" to treat myocardial infarction (heart attack), congestive heart failure, and PAD/PVD when, in fact, BIPI lacked competent and reliable scientific evidence to substantiate its claims.

Micardis

11. Micardis (telmisartan) belongs to a class of drugs called angiotensin receptor blockers ("ARBs") and is indicated to treat hypertension (high blood pressure) and to reduce cardiovascular risk in patients unable to take angiotensin-converting-enzyme ("ACE") inhibitors.

12. The FDA approved Micardis in 1998 as the fourth ARB on the market.

13. At that time, the hypertension market was already dominated by Diovan, Cozaar, and Avapro.

14. Initial sales for Micardis were poor, in part, because BIPI had no comparative data proving Micardis was superior to any of the existing hypertension drugs.

15. Both Cozaar and Avapro received additional indications for treatment of renal nephropathy among diabetics, which distinguished them from other hypertension drugs, including Micardis.

16. Similarly, there was data suggesting that Cozaar was effective in the prevention of secondary myocardial infarction.

17. To increase sales, BIPI created marketing messages that lacked substantiation in an effort to distinguish Micardis from the competition.

18. BIPI represented that Micardis best protects consumers from the "early morning risk" of strokes or cardiac events due to rising blood pressure for patients at the end of a dosing interval for hypertension drugs when, in fact, BIPI lacked competent and reliable scientific evidence to substantiate its claim.

19. BIPI also represented that Micardis could treat the constellation of symptoms popularly known as "Metabolic Syndrome," protected the kidneys, and prevented heart attacks

and strokes when, in fact, BIPI lacked competent and reliable scientific evidence to substantiate its claims.

Atrovent and Combivent

20. Both Atrovent (ipratropium bromide) and Combivent (ipratropium bromide and albuterol) are bronchodilators indicated to treat bronchospasms (airway narrowing) associated with chronic obstructive pulmonary disease ("COPD") and contain albuterol plus a drug belonging to a class called anticholinergics.

21. Atrovent is approved as a first line treatment; however, Combivent is only approved for use when a person continues to have evidence of bronchospasm when using a regular aerosol bronchodilator.

22. BIPI represented Combivent could be used as a first line treatment for bronchospasms associated with COPD when, in fact, Combivent is not indicated as a first line treatment and BIPI lacked competent and reliable scientific evidence to substantiate its claim.

23. BIPI also represented that both Atrovent and Combivent could be used at doses that exceed the maximum dosage recommendation in the product labeling when, in fact, BIPI lacked competent and reliable scientific evidence to substantiate its claim.

24. BIPI further represented that anticholinergics were essential for treatment of COPD when, in fact, BIPI lacked competent and reliable scientific evidence to substantiate its claim.

VIOLATIONS OF MAINE UNFAIR TRADE PRACTICES ACT
5 M.R.S. § 207

25. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 24 of this Complaint.

26. BIPI, in the course of marketing, promoting, and selling the prescription drugs

Micardis, Aggrenox, Atrovent, and Combivent, has engaged in unfair and deceptive practices through its omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, in violation of 5 M.R.S. § 207.

27. BIPI, in the course of marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, has engaged in unfair and deceptive practices through its representations that the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent 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. Declare that BIPI has violated 5 M.R.S. § 207 through its omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent and Combivent, and through its representations that these drugs have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have;

B. Pursuant to 5 M.R.S. § 209, permanently enjoin and restrain BIPI, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in any unfair and deceptive act or practice that violates 5 M.R.S. § 207 in the marketing, promotion, and sale of the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent;

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

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

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

Dated: December 20, 2017

Respectfully submitted,

JANET T. MILLS
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