



Jeff Landry  
Attorney General

**State of Louisiana**

DEPARTMENT OF JUSTICE  
PUBLIC PROTECTION DIVISION  
P.O. BOX 94005  
BATON ROUGE  
70804-9005

December 20, 2017

Honorable Doug Wellborn  
East Baton Rouge Parish Clerk of Court  
300 North Boulevard  
Baton Rouge, LA 70801

STATE  
DEC 20 2017  
BY \_\_\_\_\_  
DEPUTY CLERK OF COURT

**Re: State of Louisiana, by and through Attorney General, Jeff Landry v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Docket No. \_\_\_\_\_, Section No. \_\_\_\_\_, 19<sup>th</sup> Judicial District Court, Parish of East Baton Rouge, State of Louisiana**

Dear Sir,

Enclosed please find the original and two copies of both the Petition and Consent Judgment in the above named matter.

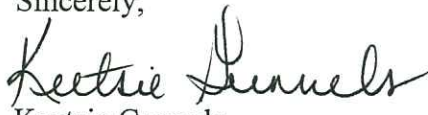
Please file the original pleadings and return a file stamped copy of each to our representative. Our office will hand deliver a stamped copy to the assigned Judge for his or her signature.

Please be advised that pursuant to La. R. S 13:4521, the State of Louisiana is not required to pay court costs at the time of filing.

Please do not hesitate to contact me at 225-326-6449 with any questions regarding this matter.

Thank you for your assistance.

Sincerely,

  
Keetsie Gunnels  
Assistant Attorney General

19<sup>th</sup> JUDICIAL DISTRICT COURT, PARISH OF EAST BATON ROUGE  
STATE OF LOUISIANA

STATE OF LOUISIANA, )

By and Through )  
ATTORNEY GENERAL, JEFF LANDRY, )

Plaintiff, )

versus )

BOEHRINGER INGELHEIM )  
PHARMACEUTICALS, INC. )

Defendant )

Case No. 664562

**SEC. 24**  
Section No. 4

**PETITION FOR PERMANENT INJUNCTION AND OTHER RELIEF**

Plaintiff, State of Louisiana, in its sovereign capacity, by and through Jeff Landry, Attorney General of the State of Louisiana, ("Attorney General" or "State") brings this action against Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., for violating La. R.S. 51:1401 et seq., the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA).

1.

The Attorney General brings this action pursuant to the La. R.S. 51:1401 et seq., the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA), in the public interest, to protect the public's health, safety and welfare and pursuant to his constitutional and general statutory authority, powers and duties. La. Const. art. 4, Sec. 8, La. R.S. 13:5036, 51:1404, 51:1405, 51:1414 and related statutes and Louisiana law. The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the La. R.S. 51:1401 et seq., the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA). The Attorney General also has reason to believe that this action is in the public interest.

2.

Upon interest and belief, the State of Louisiana alleges as follows:

**JURISDICTION AND VENUE**

3.

This Court has jurisdiction over Boehringer Ingelheim Pharmaceuticals, Inc. pursuant to La. C.C. P. Art. 6, La. R.S. 13:3201, 51: 1407(A), 51:1418 and related statutes because Boehringer Ingelheim Pharmaceuticals, Inc. has transacted business within the State of Louisiana at all times relevant to this Petition.

FILED  
EAST BATON ROUGE PARISH, LA.

CC 17 DEC 20 PM 2:49

CLERK OF COURT

4.

Venue for this action properly lies in East Baton Rouge Parish, 19<sup>th</sup> Judicial District Court, pursuant to La. C.C.P. Art. 42, 51:1407 and related statutes because defendant Boehringer Ingelheim Pharmaceuticals, Inc. transacts business in East Baton Rouge Parish, and/or some of the transactions out of which this action arose occurred in East Baton Rouge Parish.

**PARTIES**

5.

Plaintiff, State of Louisiana, ex rel. Jeff Landry, Attorney General, is charged with enforcing La. R.S. 51:1401 et seq., the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA), which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA) the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA) and to secure such equitable and other relief as may be appropriate in each case.

6.

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

**COMMERCE**

7.

La. R.S. 51:1402 (10) provides, "Trade" or "commerce" means the advertising, offering for sale, sale, or distribution of any services and any property, corporeal or incorporeal, immovable or movable, and any other article, commodity, or thing of value wherever situated, and includes any trade or commerce directly or indirectly affecting the people of the state.

8.

BIPI was, at all times relative hereto, engaged in trade or commerce in the State of Louisiana by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

## ALLEGATIONS

### Aggrenox

9.

Aggrenox (a combination of aspirin and dipyridamole) is an antiplatelet drug and 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.

10.

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

11.

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).

12.

BIPI represented that Aggrenox was superior to Plavix and Plavix/aspirin combinations, when in fact, BIPI did not have evidence to substantiate those claims.

13.

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 did not have evidence to substantiate those claims.

### Micardis

14.

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 inhibitors (ACE inhibitors).

15.

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

16.

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

17.

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.

18.

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

19.

Similarly, there was data suggesting that Cozaar was effective against prevention of secondary myocardial infarction.

20.

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

21.

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 did not have evidence to substantiate that claim.

22.

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 did not have evidence to substantiate those claims.

#### Atrovent and Combivent

23.

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.

24.

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.

25.

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 did not have evidence to support that claim.

26.

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 did not have evidence to support that claim.

27.

BIPI further represented that anticholinergics were essential for treatment of COPD, when in fact, BIPI did not have evidence to support that claim.

**VIOLATIONS OF LAW:**  
**LOUISIANA UNFAIR TRADE PRACTICES AND**  
**CONSUMER PROTECTION LAW**

28.

Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 27.

29.

BIPI, in the course of engaging in the marketing, promotion, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, has engaged in a course of trade or commerce that constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the LUTPA statute by making omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

30.

BIPI, in the course of marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, has engaged in a course of trade or commerce that constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under LUTPA, by representing that the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

**PRAYER FOR RELIEF**

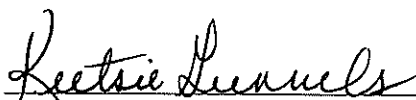
**WHEREFORE**, Plaintiff, State of Louisiana, respectfully requests that this Court:

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 unfair, deceptive or misleading conduct, acts, or practices which violate the La. R.S. 51:1401 et seq., the Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA).

- A. In the marketing, promotion, and sale of the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, pursuant to (LUTPA).
- B. Order BIPI to pay civil penalties of up to \$5,000 for each and every violation of the La. R.S. 51:1407;
- C. Order BIPI to pay all costs for the prosecution and investigation of this action, pursuant to La. R.S. 51:1408; and
- D. Grant Plaintiff such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

**JEFF LANDRY**  
**ATTORNEY GENERAL FOR THE**  
**STATE OF LOUISIANA**



---

Jeff Landry (No. 29942)  
Stacie deBlieux (No. 29142)  
Keetsie T. Gunnels (No. 12952)  
Office of the Attorney General  
State of Louisiana  
1995 North 3<sup>rd</sup> Street  
Baton Rouge, LA 70802  
Tel: (225) 326-6449  
Fax (225) 326-6499

**19<sup>th</sup> JUDICIAL DISTRICT COURT, PARISH OF EAST BATON ROUGE  
STATE OF LOUISIANA**

STATE OF LOUISIANA,	)	
	)	
By and Through	)	
ATTORNEY GENERAL, JEFF LANDRY,	)	
	)	
Plaintiff,	)	
	)	
versus	)	Case No. _____
	)	
BOEHRINGER INGELHEIM	)	
PHARMACEUTICALS, INC.	)	
	)	
Defendant	)	Section No. _____

---

**FINAL JUDGMENT AND CONSENT DECREE**

Plaintiff has filed a Complaint for a permanent injunction and other relief in this matter pursuant to Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA) La. R.S. 51:1401 *et seq.* and plaintiff, by its counsel, and Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), by its counsel, have agreed to the entry of this Final Judgment and Consent Decree (“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.

**IT IS HEREBY ORDERED THAT:**

**1. PARTIES**

1.1 Plaintiff, STATE OF LOUISIANA, By and Through ATTORNEY GENERAL, JEFF LANDRY is charged with the enforcement of Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA) La. R.S. 51:1401 *et seq.*

1.2 Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., 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 Louisiana by marketing, selling, and Promoting the drugs Aggrenox, Atrovent, Combivent, and Micardis (hereinafter the “Covered Products”).

**2. PREAMBLE**

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

2.2 BIPI further represents 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 Final Judgment and Consent Decree shall be governed by the laws of the State of Louisiana

3.3 Entry of this Final Judgment and Consent Decree 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 Final Judgment and Consent Decree

3.5 BIPI is willing to enter into this Final Judgment and Consent Decree 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 Final Judgment and Consent Decree and thereby avoid significant expense, inconvenience, and uncertainty.

3.6 BIPI is entering into this Final Judgment and Consent Decree 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 Final Judgment and Consent Decree. No part of this Final Judgment and Consent Decree, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by BIPI.

3.7 This Final Judgment and Consent Decree 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 Final Judgment and Consent Decree. 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/Commonwealth is not releasing hereunder. This Final

Judgment and Consent Decree 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 Final Judgment and Consent Decree. Unless otherwise provided under state law, no part of this Final Judgment and Consent Decree 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 Final Judgment and Consent Decree. Notwithstanding the foregoing, Final Judgment and Consent Decree, Louisiana may file an action to enforce the terms of this Final Judgment and Consent Decree.

3.8 This Final Judgment and Consent Decree (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 (“FDCA”), 21 U.S.C. § 301 *et seq.*, U.S. Food and Drug Administration (“FDA”) regulations, or FDA Guidances for Industry, currently issued or as revised. Further, the Final Judgment and Consent Decree 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 Final Judgment and Consent Decree shall require BIPI to:

- (a) 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
- (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 Final Judgment and Consent Decree:

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 Final Judgment and Consent Decree.

4.7 “Covered Product” shall mean BIPI 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 Final Judgment and Consent Decree, duly executed by BIPI and by the Signatory Attorney General, is approved by, and becomes a Final Judgment and Consent Decree 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<sup>1</sup>, 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<sup>2</sup>, 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.

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.

---

<sup>1</sup> 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.

<sup>2</sup> 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.

4.19 “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 Louisiana or his authorized designee, who has agreed to this Final Judgment and Consent Decree.

4.21 “State Consumer Protection Laws” shall mean Louisiana Unfair Trade Practices and Consumer Protection Law (LUTPA) La. R.S. 51:1401 *et seq.*

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 Final Judgment and Consent Decree:

### **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 Final Judgment and Consent Decree.

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 Final Judgment and Consent Decree 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 Paragraph 5.22 (a) and Paragraph 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 Final Judgment and Consent Decree, 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 Final Judgment and Consent Decree, the State of Louisiana 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 Louisiana 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 Final Judgment and Consent Decree, 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 Louisiana.
- (b) any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Louisiana 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 [Insert State] arising from the purchase of a Covered Product, except for the release of civil penalties under the [Insert State consumer protection law].
- (c) any claims individual consumers have or may have under the State of Louisiana'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 Final Judgment and Consent Decree, 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 Final Judgment and Consent Decree 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 Final Judgment and Consent Decree 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 Final Judgment and Consent Decree, 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 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

Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

9.5 This Final Judgment and Consent Decree 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 Final Judgment and Consent Decree 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 Final Judgment and Consent Decree.

9.7 The parties agree that neither of them shall be deemed the drafter of this Final Judgment and Consent Decree and that, in construing this Final Judgment and Consent Decree, 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 Final Judgment and Consent Decree shall be provided to the following via email and Overnight Mail:

For the State of Louisiana:

Keetsie Gunnels, Assistant Attorney General  
Louisiana Dept. of Justice  
Public Protection Division  
Post Office Box 94005, 4th Floor  
Baton Rouge, LA 70804-9005

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.**

---

**Date**

---

**Presiding Judge**


JOINTLY APPROVED AND  
SUBMITTED FOR ENTRY

**FOR PLAINTIFF, STATE OF LOUISIANA**

By: Ketzie Guenels


Date: 12/20/2017

**FOR BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**

By:  Date: 12/13/17  
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.