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MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

STATE OF MONTANA,)	
)	
Plaintiff,)	Cause No. <u>DDU</u> 2017-1008
)	
v.)	COMPLAINT
)	
BOEHRINGER INGELHEIM)	
PHARMACEUTICALS, INC.)	
Defendants.)	

1. Plaintiff, State of Montana, in its sovereign capacity, by and through Tim Fox, Attorney General of the State of Montana, (“Attorney General” or “State”) brings this action against Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., for violating the Montana Unfair Trade Practices and Consumer Protection Act (Consumer Protection Act), Mont. Code Ann. § 30-14-101 *et seq.*

2. The Attorney General brings this action pursuant to the Consumer Protection Act in the public interest, to protect the public’s health, safety and welfare and pursuant to his general statutory and common law authority powers and duties. The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the

Consumer Protection Act. The Attorney General also has reason to believe that this action is in the public interest.

3. Upon interest and belief, the State of Montana alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over Boehringer Ingelheim Pharmaceuticals, Inc. pursuant to Mont. Code Ann. § 3-5-302 because Boehringer Ingelheim Pharmaceuticals, Inc. has transacted business within the State of Montana at all times relevant to this Complaint.

2. Venue for this action properly lies in Lewis and Clark County, Montana, pursuant to Mont. Code Ann. § 30-14-111(3) because Boehringer Ingelheim Pharmaceuticals, Inc. transacts business in Lewis and Clark County, Montana and/or some of the transactions out of which this action arose occurred in Lewis and Clark County, Montana.

PARTIES

3. Plaintiff, State of Montana, through Attorney General Tim Fox, is charged with enforcing the Consumer Protection Act, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to Mont. Code Ann. § 30-14-111(1), the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Consumer Protection Act and to secure such equitable and other relief as may be appropriate in each case.

4. 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 Montana by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

COMMERCE

5. The Consumer Protection Act defines “trade” and “commerce” as the “advertising, offering for sale, sale, or distribution of any services, any property, tangible or intangible, real, personal, or mixed, or any other article, commodity, or thing of value, wherever located, and includes any trade or commerce directly or indirectly affecting the people of this state. Mont. Code Ann. § 30-14-102(8).

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

ALLEGATIONS

Aggrenox

7. 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.

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

9. 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).

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

11. 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 competent and reliable scientific evidence to substantiate those claims.

Micardis

12. 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).

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

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

15. 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.

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

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

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

19. 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.

20. 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 competent and reliable scientific evidence to substantiate those claims.

Atrovent and Combivent

21. 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.

22. 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.

23. 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 competent and reliable scientific evidence to support that claim.

24. 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 competent and reliable scientific evidence to support that claim.

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

**VIOLATIONS OF LAW: MONTANA UNFAIR TRADE PRACTICES
AND CONSUMER PROTECTION ACT**

26. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 25.

27. 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 Consumer Protection Act by making omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

28. 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 the Consumer Protection Act, 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 Montana, respectfully requests that this Court:

- A. Find that BIPI violated the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. § 30-14-103.
- B. 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 Consumer Protection Act in the marketing, promotion, and sale of the prescription drugs

Micardis, Aggrenox, Atrovent, and Combivent, pursuant to Mont. Code Ann. § 30-14-111(4);

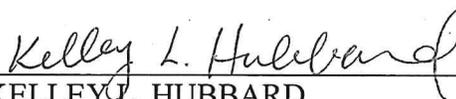
C. Order BIPI to pay civil penalties of up to \$10,000 for each and every violation of the Consumer Protection Act, pursuant to Mont. Code Ann. § 30-14-142;

D. Order BIPI to pay all costs for the prosecution and investigation of this action, pursuant to Mont. Code Ann. § 30-14-131; and

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

Respectfully submitted this 20th day of December, 2017.

FOR THE STATE OF MONTANA



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