IN THE COURT OF COMMON PLEAS
FRANKLIN COUNTY, OHIO

STATE OF OHIO ex rel. ATTORNEY GENERAL MICHAEL DEWINE 30 E. Broad Street, 14th Floor Columbus, Ohio 43215 Plaintiff, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. 900 Ridgebury Road Ridgefield, Connecticut 06877 Defendant.	)	CASE NO.: JUDGE **Complaint and Request for Declaratory Judgment, Injunctive Relief, Civil Penalties, Consumer Damages, and Other Appropriate Relief**

JURISDICTION

1. Plaintiff, State of Ohio, through counsel Attorney General Michael DeWine, having reasonable cause to believe that violations of Ohio's consumer protection laws have occurred, brings this action against Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., in the public interest and on behalf of the State of Ohio under the authority vested in the Attorney General by R.C. 1345.07.
2. The actions of Defendant have occurred in the State of Ohio, including in Franklin County, and, as set forth below, are in violation of the Consumer Sales Practices Act ("CSPA"), R.C. 1345.01 et seq.
3. Jurisdiction over the subject matter of this action lies with this Court pursuant to R.C. 1345.04 of the CSPA.
4. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(B)(3), in that Franklin County is where Defendant conducted some of the transactions complained of herein.

DEFENDANT

5. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

6. Defendant was, at all times relevant to this action, engaged in the business of marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent to consumers in Franklin County and other Ohio Counties.

7. Defendant is a "supplier" as that term is defined in R.C. 1345.01(C) as Defendant was, at all times relevant herein, engaged in the business of effecting or soliciting consumer transactions by offering for sale and selling prescription drugs to individuals for purposes that were primarily personal, family, or household within the meaning specified in R.C. 1345.01(A) and (D).

STATEMENT OF FACTS

Aggrenox

8. 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.

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

10. 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).

11. BIPI represented that Aggrenox was superior to Plavix and Plavix/aspirin combinations,

when in fact, BIPI did not have the requisite evidence to substantiate those claims.

12. 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 the requisite evidence to substantiate those claims.

Micardis

13. 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).
14. The FDA approved Micardis in 1998 as the fourth ARB on the market.
15. At that time, the hypertension market was already dominated by Diovan, Cozaar, and Avapro.
16. 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.
17. Both Cozaar and Avapro received additional indications for treatment of renal nephropathy among diabetics, which distinguished them from other hypertension drugs, including Micardis.
18. Similarly, there was data suggesting that Cozaar was effective in the prevention of secondary myocardial infarction.
19. To increase sales, BIPI created marketing messages that lacked substantiation in an effort to distinguish Micardis from the competition.
20. 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 the requisite evidence to substantiate that claim.

21. 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 the requisite evidence to substantiate those claims.

Atrovent and Combivent

22. 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.

23. 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.

24. 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 the requisite evidence to support that claim.

25. 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 the requisite evidence to support that claim.

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

CAUSE OF ACTION

Violations of the CSPA

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

28. Defendant, in the course of marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, engaged in unfair or deceptive acts or practices in violation of R.C. 1345.02 of the CSPA by making omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

29. Defendant, in the course of marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, engaged in unfair or deceptive acts or practices in violation of R.C. 1345.02 of the CSPA 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, respectfully requests that this Court grant the following relief:

A. ISSUE A PERMANENT INJUNCTION, pursuant to R.C. 1345.07(A)(2), enjoining Defendant, doing business under its own name or any other name, 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 the CSPA in the marketing, promotion, and sale of the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

B. ISSUE A DECLARATORY JUDGMENT, pursuant to R.C. 1345.07(A)(1), declaring that each act or practice complained of herein violates the CSPA in the manner set forth in this Complaint.

C. ORDER Defendant, pursuant to R.C. 1345.07(B), to pay damages, including non-economic damages, to all consumers injured by the conduct of the Defendant as set forth in this Complaint.

D. ASSESS, FINE, AND IMPOSE upon Defendant a civil penalty of $25,000 for each separate and appropriate violation described herein pursuant to R.C. 1345.07(D).

E. ORDER Defendant to pay all court costs.

F. GRANT Plaintiff its costs in bringing this action

G. GRANT all such other relief as this Court deems to be just, equitable, and appropriate.

Respectfully submitted,

MICHAEL DEWINE
Ohio Attorney General

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