



Defendant's acts and practices that violate these statutes occurred in Dallas County, Texas.

**PUBLIC INTEREST**

4. Because Plaintiff STATE OF TEXAS has reason to believe that Defendant has engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendant has caused and will cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

**ACTS OF AGENTS**

5. Whenever in this petition it is alleged Defendant did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by agents or employees of Defendant and in each instance, the agents or employees of Defendant were then authorized to and did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of Defendant.

**NOTICE BEFORE SUIT**

6. Plaintiff informed Defendant herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

**PARTIES**

7. Plaintiff, State of Texas, by Attorney General Ken Paxton through his Consumer Protection Division, is charged with enforcing the DTPA, which prohibits deceptive acts or practices affecting the conduct of any trade or commerce.

8. 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 Texas by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

### **TRADE AND COMMERCE**

9. BIPI was, at all times relative hereto, engaged in trade or commerce in the State of Texas as defined in § 17.45(6) of the DTPA by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

### **ALLEGATIONS**

#### Aggrenox

10. 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.

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

12. 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).

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

14. 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

15. 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).
16. The FDA approved Micardis in 1998 as the fourth ARB on the market.
17. At that time, the hypertension market was already dominated by Diovan, Cozaar, and Avapro.
18. 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.
19. Both D and Avapro received additional indications for treatment of renal nephropathy among diabetics, which distinguished them from other hypertension drugs, including Micardis.
20. Similarly, there was data suggesting that Cozaar was effective in the prevention of secondary myocardial infarction.
21. To increase sales, BIPI created marketing messages that lacked substantiation in an effort to distinguish Micardis from the competition.
22. 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.
23. 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

24. 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.

25. 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.

26. 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.

27. 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.

28. 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 DTPA**

29. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 28.

30. 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 false, misleading or deceptive practices, and is therefore unlawful under the DTPA by making omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

31. 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 false, deceptive, or misleading practices, and is therefore unlawful under the DTPA, 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**

32. WHEREFORE, Plaintiff, State of Texas 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 false, misleading, or deceptive or conduct, acts, or practices which violate the DTPA in the marketing, promotion, and sale of the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, pursuant to the DTPA.

- A. Pursuant to the DTPA, Defendant be order to pay civil penalties of up to \$20,000 per violation, as provided in § 17.47(c)(1) of the DTPA;
- B. Pursuant to the DTPA, Defendant be ordered to pay costs and reasonable attorneys' fees pursuant to the laws of the State of Texas including Tex. Gov't Code Ann. § 402.006(c) in connection with the investigation and litigation of this matter; and
- C. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of Defendant's unlawful trade practices.

Respectfully submitted,

**Plaintiff State of Texas**

KEN PAXTON  
Attorney General of Texas

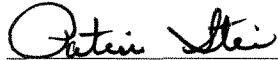
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