

DISTRICT COURT, DENVER CITY AND COUNTY, COLORADO 1437 Bannock Street Denver, Colorado 80202	
STATE OF COLORADO, ex rel. JOHN W. SUTHERS, ATTORNEY GENERAL,  Plaintiff,  v.  Pfizer Inc,  Defendant.	
Attorneys for Plaintiff: JOHN W. SUTHERS Attorney General MARK T. BAILEY, *36861 Assistant Attorney General JAY B. SIMONSON, 24077* First Assistant Attorney General 1525 Sherman Street, 5 <sup>th</sup> Floor Denver, CO 80203 (303) 866-5079 (303) 866-4916 Fax *Counsel of Record	▲ COURT USE ONLY ▲  Case No.:
<b>COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF</b>	

**INTRODUCTION**

1. This is an action brought by the State of Colorado pursuant to the Colorado Consumer Protection Act, §§ 6-1-101 *et. seq.*, C.R.S. (2012) (“CCPA”), to enjoin and restrain Defendants from engaging in certain unlawful deceptive trade practices, for statutorily mandated civil penalties, for disgorgement, restitution, and other relief as provided in the CCPA.

**PARTIES**

2. John W. Suthers is the duly appointed Attorney General of the State of Colorado and is authorized under C.R.S. § 6-1-103 to enforce the provisions of the CCPA.

3. Defendant is Pfizer Inc, a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY 10017. At all relevant times, Pfizer did business in Colorado selling and promoting prescription drugs, including Zyvox® and Lyrica®. Pfizer may be served with process by serving its registered agent, the Corporation Company, at 1675 Broadway Ste. Denver, CO 80202.

### **JURISDICTION AND VENUE**

4. Pursuant to C.R.S. §§ 6-1-103 and 6-1-110, this Court has jurisdiction to enforce the CCPA and enter appropriate orders prior to and following an ultimate determination of liability.

5. The violations alleged herein occurred, in part, in Denver County. Therefore, venue is proper in Denver County, Colorado, pursuant to C.R.S. § 6-1-103 and Colo. R. Civ. P. 98 (2012).

### **COMMERCE AND APPLICABLE LAW**

6. Under the CCPA, C.R.S. § 6-1-105(e),

A person engages in a deceptive trade practice when, in the course of such person's business, vocation, or occupation, such person . . . [k]nowingly makes a false representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith.

Under C.R.S. § 6-1-105(u),

“A person engages in a deceptive trade practice when, in the course of such person's business, vocation, or occupation, such person . . . [f]ails to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction.”

7. Defendant was at all times relative hereto, engaged in trade or commerce in the State of Colorado by selling, promoting and distributing the prescription drugs Zyvox® or Lyrica®.

## **BACKGROUND**

8. The Food and Drug Administration (“FDA”) approved Pfizer’s Zyvox® as an antibacterial agent to treat certain types of infections, including among other approved indications, nosocomial pneumonia caused by methicillin-resistant *Staphylococcus aureus* (“MRSA”) and complicated skin and skin structure infections due to MRSA.

9. Pfizer marketed Zyvox® as superior to vancomycin, an antibiotic that has been on the market for nearly fifty years and used in the treatment of infections caused by MRSA, although Zyvox® has not been demonstrated by substantial evidence to be superior to vancomycin for certain uses as Pfizer marketed.

10. Additionally, on July 20, 2005, the FDA sent a Warning Letter to Pfizer concerning a journal advertisement for Zyvox®. The FDA claimed that Pfizer’s advertisement misbranded Zyvox® by making misleading and unsubstantiated implied superiority claims that broadened the indications for Zyvox®.

11. Despite notifying its sales force to cease using the promotional material identified in the FDA Warning Letter, Pfizer did not provide adequate guidance to its sales force regarding what statements were permissible concerning data from head-to-head trials and retrospective analyses and what promotional statements were not permitted.<sup>1</sup> As a result, Pfizer’s sales personnel continued to make superiority claims that were inconsistent with the FDA’s Warning Letter and the FDA approved label for Zyvox.®

12. Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox® was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised.

13. In addition to Zyvox®, Pfizer marketed another of its drugs, Lyrica® for off-label uses. Lyrica® was approved by the FDA for the treatment of diabetic peripheral neuropathy (DPN), post-herpetic peripheral neuropathy (PHN) and for the adjunct treatment of partial seizures in December, 2004. Contrary to the approved intended uses, Pfizer marketed Lyrica® for the treatment of chronic pain, neuropathic pain (other than DPN and PHN), perioperative pain, and migraine. Subsequently, the FDA did approved Lyrica® for the treatment of fibromyalgia in June 22, 2007.

14. Pfizer also encouraged its sales force to promote Lyrica® as superior to another Pfizer drug, Neurontin, and its generic equivalent, gabapentin. Moreover Pfizer

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<sup>1</sup> At the FDA’s request, Pfizer agreed to publish a corrective advertisement in February 2006, which was entitled “IMPORTANT CORRECTION OF DRUG INFORMATION ZYVOX.” In this corrective advertisement, Pfizer noted that the FDA had objected to the presentation, in its previous advertisement, of clinical data that showed a more favorable comparison of Zyvox to vancomycin than was shown in the data included in the Zyvox label.

encouraged its sales force to encourage physicians to convert their patients from Neurontin to Lyrica® and motivated their sales force by sales incentive plans.

**VIOLATIONS OF THE CCPA – COUNT I**

15. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 14.

16. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drugs Zyvox® and Lyrica® has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under C.R.S. § 6-1-105(1)(e) by promoting Zyvox®, despite assuring FDA in response to its Warning Letter that it discontinued such promotion, and Lyrica® by claiming superiority of these drugs over other drugs without substantial evidence.

**VIOLATIONS OF THE CCPA – COUNT II**

17. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 16.

18. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drugs Zyvox® and Lyrica® has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under C.R.S. § 6-1-105(1)(e) by promoting these drugs for uses that have not been shown to be safe or effective, thereby representing that these drugs have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

**VIOLATIONS OF THE CCPA – COUNT III**

19. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 18.

20. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drugs Zyvox® and Lyrica® has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under C.R.S. § 6-1-105(1)(u) by failing to disclose material information relating to its claims of superiority, safety, and effectiveness of Zyvox® and Lyrica®. Such material information was known at the time of the advertisement or sale of Zyvox® and Lyrica® and the failure to disclose such information was intended to induce consumers to enter into transactions.

**PRAYER FOR RELIEF**

WHEREFORE, the Plaintiff respectfully requests that:

A. Pursuant to Colorado Consumer Protection Act, § 6-1-105 (1)(e), C.R.S. (2012) the Court permanently enjoin and restrain Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with it from engaging in deceptive practices in the promotion and marketing of pharmaceutical products.

B. An Order pursuant to C.R.S. § 6-1-112(1)(a) for civil penalties payable to the general fund of this state of not more than two thousand dollars for each such violation of any provision of the CCPA with respect to each consumer or transaction involved not to exceed five hundred thousand dollars for any related series of violations.

B. Pursuant to C.R.S. § 6-1-113(4), Defendant be ordered to pay costs and reasonable attorneys' fees incurred by the State in connection with the investigation and litigation of this matter;

C. An order pursuant to C.R.S. § 6-1-112(1)(c) for civil penalties payable to the general fund of this state of not more than ten thousand dollars for each violation of any provision of the of the CCPA with respect to each elderly person.

D. That the Court grant such further relief as the Court deems necessary to remedy the effects of Defendant's unlawful trade practices.

DATED: December 12, 2012

Respectfully submitted,

JOHN W. SUTHERS  
Attorney General

/s/ Mark T. Bailey  
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**Plaintiff's Address**

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