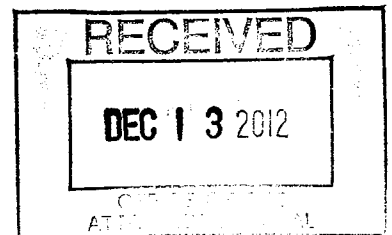
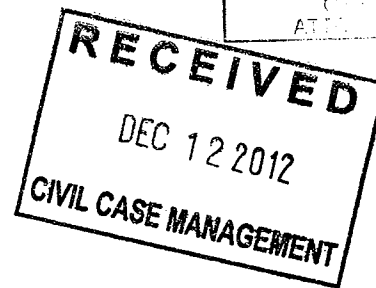


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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION,
MERCER COUNTY
DOCKET NO. _____

JEFFREY S. CHIESA, Attorney General of the
State of New Jersey, and ERIC T. KANEFSKY,
Acting Director of the New Jersey Division of
Consumer Affairs,

Plaintiffs,

v.

PFIZER INC,

Defendant.

Civil Action

COMPLAINT

1. Plaintiffs, Jeffrey S. Chiesa, Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Eric T. Kanefsky, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs") bring this action against Pfizer Inc. ("Defendant" or "Pfizer") for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA"), by among other things: (1) advertising, selling and/or offering for sale the prescription drug Zyvox® as superior to vancomycin, an antibiotic that has been on the market for nearly fifty years, for the treatment

of certain infections, without substantial evidence; and (2) advertising, selling and/or offering for sale the prescription drug Lyrica® for off-label uses for which there was no substantiated efficacy.

2. This Complaint is being filed concurrently with a Final Consent Judgment.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action and over the Defendant pursuant to the CFA, N.J.S.A. 56:8-1 et seq. Venue is proper pursuant to R. 4:3-2 because Mercer County is a county in which the Defendant has advertised and/or conducted business.

PARTIES

4. The Attorney General is charged with enforcing the CFA. The Director is charged with administering the CFA on behalf of the Attorney General. By this action, the Attorney General and the Director seek injunctive and other relief for violations of the CFA, pursuant to N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19, against Defendant for engaging in unconscionable commercial practices, deception and misrepresentations in connection with the advertising, offer for sale and/or sale of its prescription drugs Zyvox® and Lyrica®.

5. The Defendant is incorporated in Delaware, with its principal place of business at 235 East 42nd Street, New York, New York, 10017. The Defendant has marketed, distributed, offered for sale and sold Zyvox® and Lyrica® to consumers throughout the United States, including New Jersey.

GENERAL ALLEGATIONS

6. 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.

7. 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.

8. 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®.

9. 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.¹ 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®.

10. 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.

¹ 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.

11. 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 approve Lyrica® for the treatment of fibromyalgia on June 22, 2007.

12. Pfizer also encouraged its sales force to promote Lyrica® as superior to another Pfizer drug, Neurontin, and its generic equivalent, gabapentin. Moreover, Pfizer encouraged its sales force to encourage physicians to convert their patients from Neurontin to Lyrica® and motivated their sales force by sales incentive plans.

COUNT I

VIOLATION OF THE CFA BY DEFENDANT (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)

13. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 12 as if more fully set forth herein.

14. The CFA, N.J.S.A. 56:8-2, prohibits:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or knowing[] concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . .

15. Defendants, in the course of marketing, distributing, offering for sale and selling Zyvox® and Lyrica® as alleged herein, have engaged in unconscionable commercial practices and deception in violation of the CFA, namely Defendants violated the CFA in the advertising,

selling and/or offering for sale of the prescription drugs Zyvox® and Lyrica® by promoting Zyvox®, despite assuring the 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.

COUNT II

VIOLATION OF THE CFA BY DEFENDANT (MISREPRESENTATIONS)

16. Plaintiffs reallege and incorporate by reference herein each and every allegation contained in the preceding paragraphs 1 through 15.

17. The acts and practices engaged in and employed by Defendant as alleged herein, are misrepresentations in violation of the CFA, namely that Defendant violated the CFA by promoting Zyvox® and Lyrica® 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.

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

- (a) Finding that the acts of Defendant constitute unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;
- (b) Permanently enjoining Defendant and its owners, officers, directors, shareholders, members, founders, managers, agents, servants, employees, representatives, corporations, independent contractors, subsidiaries, affiliates, successors, assigns and all other entities or persons directly under its control, to cease and desist from engaging in continuing to engage in, or doing any acts or practices in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in the Complaint;

- (c) Directing the assessment of restitution amounts against Defendants to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any practice alleged herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;
- (d) Assessing the maximum statutory civil penalties against Defendant for each and every violation of the CFA, in accordance with the CFA, N.J.S.A. 56:8-13;
- (e) Directing the assessment of costs and fees, including attorneys' fees, against Defendant for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and
- (f) Granting such other relief as the interest of justice may require.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: December 11, 2012
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in controversy in this action involving the aforementioned violations of the CFA, is not the subject of any other action pending in any other court of this State. I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General

Dated: December 11, 2012
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General

Dated: December 11, 2012
Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorneys General Patricia Schiripo and Cathleen O'Donnell are hereby designated as trial counsel for the Plaintiffs in this action.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General

Dated: December 11, 2012
Newark, New Jersey