IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, INC.
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20854
(301) 827-2410

Defendant.

C.A. No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Public Citizen brings this action pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 and 706, to compel the United States Food and Drug Administration (FDA) to act on Public Citizen's petition seeking a phased withdrawal of the painkiller propoxyphene (Darvon) and all propoxyphene-containing products such as Darvocet. On February 28, 2006, pursuant to 21 C.F.R. § 10.30, Public Citizen petitioned the FDA to begin immediately a phased withdrawal from the market of propoxyphene and all propoxyphene-containing products, citing the drug's considerable human toxicity, addiction potential, susceptibility to abuse, and very limited therapeutic usefulness. Although more than two years have passed since Public Citizen filed its petition, the FDA has

neither granted nor denied the petition, and has taken no action to remove propoxyphene from the market. Therefore, to protect public safety and prevent needless death and injury, Public Citizen seeks a declaration that the FDA has acted unlawfully by withholding action on Public Citizen's petition and an order requiring the FDA to act thereon.

PARTIES

2. Plaintiff Public Citizen is a national non-profit, public interest organization headquartered in Washington, D.C., with approximately 80,000 members. Since its founding in 1971, Public Citizen has worked before Congress, regulatory agencies, and in the courts to advance the interests of its members on a wide range of consumer protection issues. In particular, Public Citizen's Health Research Group (HRG) promotes research-based, system-wide changes in health care policy and provides oversight concerning drugs, medical devices, doctors, hospitals, and occupational health. HRG works to ban or relabel unsafe or ineffective drugs and publishes "Worst Pills, Best Pills News," a consumer guide to avoiding drug-induced death or illness. "Worst Pills, Best Pills News" has about 170,000 subscribers. Public Citizen and its members have been, and continue to be, injured by the FDA's failure to act on Public Citizen's petition and its failure to initiate a phased withdrawal of propoxyphene and propoxyphene-containing products from the market. As long as propoxyphene remains on the market, Public Citizen's members are at risk of suffering adverse effects of this drug, including addiction and death.

3. The Department of Health and Human Services (HHS) is an agency of the federal government, and the FDA is an agency within HHS. The FDA is responsible for administration of the FDCA. In particular, the FDA is responsible for withdrawing approval of unsafe drugs. *See* 21 U.S.C. § 355(e). As set forth in more detail below, the FDA has violated the law by failing to act on Public Citizen's petition seeking the phased withdrawal of marketing approval of all propoxyphene-containing products.

JURISDICTION

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

5. Propoxyphene is a widely prescribed narcotic painkiller sold by several companies as a generic drug and also sold as Darvon (propoxyphene) and Darvocet (propoxyphene and acetaminophen) by AAIPharma.

6. Propoxyphene is a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and is a new drug within the meaning of 21 U.S.C. § 321(p).

7. The FDCA prohibits the introduction into interstate commerce of any new drug without FDA approval. 21 U.S.C. § 355.

8. The FDCA requires the FDA to withdraw approval of unsafe drugs. 21 U.S.C. § 355(e).

9. Propoxyphene is a widely prescribed painkiller, with 22 million prescriptions filled in retail pharmacies in 2007.

10. The Drug Abuse Warning Network (DAWN), which provides autopsy information from medical examiners nationwide, reported 5,462 propoxyphene-

related deaths, including 2,110 accidental deaths, between 1981 and 1999. Because DAWN only collects data from selected counties that together contain one-third of the U.S. population, the true number of propoxyphene-related deaths is likely about three times greater.

11. Propoxyphene has also been used in suicides. According to DAWN data for 1995-1999, one-third of deaths involving propoxyphene were suicides. Banning propoxyphene would likely result in a significant reduction in the total number of drug-related suicides. Experience with the restriction of barbiturates, another drug used in suicides, shows that restricting a drug can decrease the number of total drug suicides. *See* Inst. of Medicine, *Sleeping Pills, Insomnia, and Medical Practice: Report of a Study* 66 (1979). Further, removing propoxyphene from the market will make it less likely that attention-seeking suicide attempts do not unintentionally result in death due to the unusually high toxicity of propoxyphene.

12. Medical experts have deemed propoxyphene inappropriate for prescription to the elderly. Nevertheless, doctors have prescribed this drug to the elderly at alarming rates, with propoxyphene having been prescribed 3.3 million times to elderly patients during emergency room visits from 1992 to 2000 and with 15.5 percent of institutionalized elderly Medicare beneficiaries using the drug.

13. Propoxyphene can produce physical addiction manifested by withdrawal symptoms, strong psychological dependence, and diminution in response to the drug after prolonged use. Research suggests that addiction can occur at less than the recommended daily dose and unequivocally confirms that addiction occurs at just twice the recommended daily dose.

14. Propoxyphene is a relatively ineffective painkiller. A recent comprehensive review of randomized clinical trials found that, for most kinds of pain, ibuprofen is more effective than propoxyphene-acetaminophen. Another study showed that propoxyphene-acetaminophen is no more effective for post-operative pain than acetaminophen (the ingredient in Tylenol) alone. Propoxyphene alone has been shown to be no more effective than two aspirin for relief of most kinds of pain.

15. In 1978, HRG proposed banning propoxyphene or tightening restrictions on use of the drug by placing it in Schedule II of the Controlled Substances Act, the category for drugs with high potential for abuse. The Department of Health, Education, and Welfare rejected these proposals, in large part because of the manufacturer's commitment to a program designed to educate prescribers and patients about the hazards of propoxyphene. This educational program, however, did not have "an important impact into physician decision-making," according to an FDA memorandum. Memorandum from Dr. Louis Morris to the Director of the Division of Drug Experience, Memorandum on the Lilly Quarterly Report on Darvon (Feb. 5, 1980).

16. Even though propoxyphene was eventually placed in Schedule IV of the Controlled Substances Act, a category including drugs with a limited potential for dependence, the drug remains among the top-selling drugs on the market.

17. In 2005, the British government, on the advice of the United Kingdom Committee on Safety of Medicines (CSM), ordered a phased withdrawal of Darvocet (propoxyphene and acetaminophen) from the market. CSM could not "identify any patient group in whom the risk-benefit [ratio] may be positive" and noted that

the effectiveness of the drug was poorly established, while the "risk of toxicity in overdose, both accidental and deliberate, is unacceptable." Letter from Professor Gordon Duff, Chairman, Committee on Safety of Medicines, to health care professionals, Withdrawal of Co-Proxamol Products and Interim Updated Prescribing Information 1 (Jan. 31, 2005), *available at* www.info.doh.gov.uk/doh/embroadcast.nsf/.

18. On February 28, 2006, pursuant to 21 C.F.R. § 10.30, Public Citizen filed a petition with the FDA, docket no. 2006P-0090, urging the FDA immediately to begin the phased removal from the market of propoxyphene and all propoxyphene-containing products.

19. In support of its petition, Public Citizen cited numerous medical studies evidencing the dangers and limited efficacy of propoxyphene and the actions of the British government to withdraw approval of the drug.

20. On August 22, 2006, the FDA responded to Public Citizen's petition, indicating that the FDA had not yet reached a decision because the petition "raises complex issues requiring extensive review and analysis by Agency officials."

21. Public Citizen's petition provides sufficient grounds for the FDA to begin a phased withdrawal from the market of propoxyphene and propoxyphene-containing products pursuant to 21 U.S.C. § 355(e).

22. To date, the FDA has not issued a decision on Public Citizen's petition, nor has it taken action to begin withdrawing propoxyphene and propoxyphene-containing products from the market. The FDA has failed to act despite the significant rates

of accidental and suicidal deaths and addiction and the availability of equally effective, safer alternatives.

23. The considerable danger to public health caused by the FDA's failure to begin withdrawing propoxyphene and propoxyphene-containing products from the market counsels in favor of expeditious action on Public Citizen's petition. The pace of the FDA's decisional process is lagging unreasonably in light of the nature and extent of the public health interests harmed by the FDA's delay. Without FDA action on Public Citizen's petition to begin a phased withdrawal of propoxyphene and propoxyphene-containing products from the market, Public Citizen's members will continue to suffer injury or the threat of injury because they are at risk of being prescribed propoxyphene and suffering injury as a result.

CLAIMS FOR RELIEF

24. The FDA's failure to act on Public Citizen's petition constitutes agency action unlawfully withheld or unreasonably delayed and violates the Administrative Procedure Act, 5 U.S.C. § 706(1).

25. The FDA's failure to act on Public Citizen's petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

WHEREFORE, Plaintiff requests that this Court

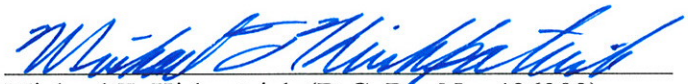
A. Declare unlawful the FDA's failure to act on Public Citizen's petition;

B. Order the FDA to issue a decision on Public Citizen's petition within 30 days of declaring the FDA's failure to act unlawful;

C. Award Public Citizen its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,



Michael T. Kirkpatrick (D.C. Bar No. 486293)
Brian Wolfman (D.C. Bar No. 427491)
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
202-588-1000
202-588-7795 (fax)

Attorney for Plaintiff Public Citizen

Dated: June 19, 2008