

Negligence in the Manufacturing and Marketing of Pondimin and Redux by the American Home Products Corporation

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Introduction

The Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 allots to the Food and Drug Administration (FDA) and to drug manufacturers the responsibility to ensure the safety of pharmaceutical products and the effectiveness of claimed outcomes. Yet, it has become apparent that pharmaceutical companies sometimes disregard their social and legal duties in order to maximize their economic ventures even when their unethical business strategies harm the safety of their consumers. The class action lawsuit against the American Home Products Corporation (AHP), now known as Wyeth, for its breach of duty in manufacturing and marketing the drugs fenfluramine (Pondimin) and dexfenfluramine (Redux), despite the company's awareness of the potential medical risks to consumers, illustrates the extent to which businesses are willing to go in order to seek profit. Indeed, AHP's records show that, long before the FDA's decision to withdraw both Pondimin and Redux from the market in 1997, the firm received considerable information from various sources that both drugs could potentially lead to valvular heart disease (VHD) and pulmonary hypertension (PH), but AHP ignored the evidence and failed to put health warnings on these drugs' labels. This exemplary tort case leads critics to raise concern about the fact that FDA-approved drugs, which have been on the market for over twenty years, are being withdrawn. Additionally, this case of corporate negligence sheds light on a growing phenomenon of companies' refusal to make the sensible decision of ensuring the safety and effectiveness of their products in order to indulge their thirst for short-term profit.

I. AHP's exclusive responsibility for manufacturing, marketing, and labeling of Pondimin (fenfluramine) and Redux (dexfenfluramine)

Until 1989, A.H. Robins was the sole company in the United States responsible for the manufacturing and marketing of fenfluramine, a drug approved for weight loss

purposes by the FDA in 1973. When AHP acquired A.H. Robins in 1989, the company also acquired the exclusive right to manufacture and market fenfluramine in America, but under the brand name Pondimin. Starting from 1992, the popular social trend of mixing Pondimin (fenfluramine) with the drug phentermine, known as Fen-Phen, for rapid weight loss helped boost AHP's sales of Pondimin. The large momentum in the sales of Pondimin led AHP in 1994 to acquire the Lederle Division of American Cyanamid, the only company responsible for the development and promotion of Redux (dexfenfluramine).¹ Critics think that AHP's decision to purchase American Cyanamid might have been strategic based on two main reasons:

- By the time AHP acquired American Cyanamid, the company was already dealing with a number of reports of Pondimin-related pulmonary hypertension (PH), and thus was probably trying to replace fenfluramine with its isomer,² dexfenfluramine, before the company was exposed.
- Dexfenfluramine was believed to lead to faster weight loss than fenfluramine when mixed with phentermine.

In addition, AHP knew that one guaranteed advantage was that the isomer of an already approved product (fenfluramine) can be patented anew and marketed as if it were a breakthrough product.³ AHP also knew that the approval process of an isomer drug would be significantly shorter. In fact, "the longest study done on dexfenfluramine was for one year"⁴ until it was finally approved by the FDA on April 29, 1996.

The quick approval and the sudden withdrawal of Redux led the Federal Bureau of Investigation (FBI) to question the legality of the methods used by AHP to have Redux approved by the FDA. FBI investigators held interviews with the purpose of finding out "whether AHP and other companies involved told the FDA all they knew about adverse reactions to the diet pills ... [and looking] into the deliberations of an

¹ Sheila Brown, et al., v. American Home Products Corporation, Order No. 1415, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000), 1.

² Isomers are compounds that possess the same chemical formula as another chemical species but have different structures. In other words, isomers contain the same number of atoms as another chemical, but these atoms are differently arranged.

Dexfenfluramine, also called dexfenfluramine hydrochloride, is an isomer or mirror image of fenfluramine. Both dexfenfluramine and fenfluramine are "cogeners of amphetamines" and are classified as serotonin releasing agents as they significantly elevate the concentration of serotonin in the brain. The rapid release of serotonin fools the individual's brain into thinking that the stomach is full, thus causing the loss of appetite.

³ Jerry Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*, 1st Ed. (New York: Alfred A. Knopf, 2004), 75.

⁴ Camille N. Tragos, "Fen-Phen Litigation Against American Home Products Corporation: The Widespread Use of Fenfluramine (Pondimin) and Dexfenfluramine (Redux) for Weight Loss, the Health Problems Associated with Those Drugs, the Resulting Litigation Against American Home Prod.," Digital Collection, Harvard Law School (Cambridge, MA, Harvard University, 2000), 55, http://dash.harvard.edu/bitstream/handle/1/8965626/Tragos,_Camille.html?sequence=2 (accessed March 1, 2014).

FDA advisory committee that recommended approval of Redux.”⁵ The FDA officials confessed that the approval of Redux was not easy and that the advisory committee had initially rejected the drug in September 1995 by a vote of 5-3 due to safety concerns. However, later that year the panel reversed itself by a vote of 6-5, deciding that the benefits for the clinically obese outweighed the risks.⁶

While many consumers found in the fen-phen mix a remedy for obesity, the health consequences were soon to be fatal. The fen-phen phenomenon has spawned thousands of lawsuits, later consolidated in the federal District Court for the Eastern District of Pennsylvania, and a multitude of scientific studies concerning VHD and PH.

A. Background information on fenfluramine (Pondimin) and dexfenfluramine (Redux)

Fenfluramine and its derivatives are amphetamine anti-obesity drugs, appetite suppressants that act through serotonergic mechanisms such as smell receptors to send messages to the brain to inhibit appetite, thus generating weight loss.⁷ In the process of fooling the brain, these drugs have drastic toxic effects on the central nervous system, leading to a high risk of dependency and rapid deterioration of organs. Records show that from the 1970s until 1992, fenfluramine was a modestly selling drug due to its inefficacy, an inefficacy that had led the FDA to approve it only for short-term weight loss.⁸ However, starting in 1992, the drug’s stature was transformed when Dr. Michael Weintraub, a clinical pharmacologist who directed one of the FDA’s divisions of new drug approval,⁹ published a series of articles in the *Journal of Clinical Pharmacology and Therapy* arguing that the synergic interaction of fenfluramine with phentermine would lead to quicker and greater weight loss results.

Fenfluramine’s limits as a weight loss drug hurt the sales of Pondimin until Dr. Weintraub’s advocacy of the drug combination that would soon be known as fen-phen. Nevertheless, one can argue that even though Dr. Weintraub is responsible for planting the seed of the fen-phen craze, his suggestions about the off-label¹⁰ use of the drugs

⁵ David S. Cloud and Richard B. Schmitt, “FBI Looks into the Approval of American Home’s Redux,” *The Wall Street Journal*, September 9, 1999, <http://online.wsj.com/news/articles/SB936834524950994967>, (accessed March 5, 2014).

⁶ Ibid.

⁷ Toxicology Data Network (Toxnet), National Institutes of Health, “Hazardous Substances Data Bank: Fenfluramine,” <http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+458-24-2> (accessed February 23, 2014).

⁸ Avorn, *Powerful Medicines*, 73-74.

⁹ Gina Kolata, “How Fen-Phen, a Diet ‘Miracle,’ Rose and Fell,” *New York Times*, September 23, 1997, <http://www.nytimes.com/1997/09/23/science/how-fen-phen-a-diet-miracle-rose-and-fell.html> (accessed February 20, 2014).

¹⁰ Off-label use of a drug occurs when a practitioner prescribes a drug for a use, or in a manner, not authorized by the Food and Drug Administration. The off-label use of drugs is not considered illegal practice as long as these drugs are FDA-approved. Nevertheless, the FDA requires that physicians encouraging off-label use of a drug be well-informed about the potential risks and benefits of the drug, maintain safe dosage, and keep scrupulous records of the product’s use and effects.

would have been unsuccessful without the contribution of prescribing physicians. In addition to the worsening obesity epidemic in the United States, which brought a wave of various unconventional and unsafe weight loss methods, the physicians' role in advocating and prescribing fen-phen popularized the regimen amongst millions of Americans. In fact, AHP's revenues from the sales of Pondimin are recorded as follows: \$3.7 million in 1993, \$8.5 million in 1994, \$48.7 million in 1995, and \$150.1 million in 1996.¹¹ As this frenzy grew, more people were willing to try the drug combination. From January 1995 to mid-September 1997, the number of Pondimin consumers in the United States was evaluated at 4,000,000 persons.

B. Off-label use and side effects of fen-phen

It is reported that "just three months after the introduction of Redux, doctors [were] writing 85,000 prescriptions a week,"¹² which can be extrapolated to 4 to 5 million prescriptions a year. And while most fen-phen users saw the combination as an antidote to obesity, the drug use quickly took a deadly turn. In fact, in March 1997, "researchers at the Mayo Clinic in Rochester, Minnesota who conducted a research with 24 women using fen-phen began observing an association between the cocktail and a particular type of valvular heart disease."¹³ The two deadly risks created by the use of fenfluramine and dexfenfluramine are valvular heart disease (VHD) and pulmonary hypertension (PH). VHD is characterized as a defect in one of the four heart valves that interferes with the normal flow of blood in the heart and causes the heart to function poorly. This abnormal flow of blood then increases the pressure in the pulmonary arteries, which are responsible for carrying blood from the heart to the lungs, thus causing PH. The damage to the pulmonary arteries affects the transport of oxygen through the body, quickly leads to severe breathing difficulty and heart failure, and eventually may cause death. In fact, fen-phen was so dangerous that a 29-year-old woman, previously diagnosed as healthy, took the cocktail for a 23-day period and succumbed eight months later from severe PH due to the combination.¹⁴

The publication of these findings in the *New England Journal of Medicine* on August 28, 1997, raised public awareness and led the FDA to withdraw fenfluramine from the U.S. market that same year. Phentermine was not implicated in the fen-phen litigation and remained on the market since it was not found to have caused the health problems associated with the fen-phen combination.¹⁵ On the other hand, fenfluramine was withdrawn because it depresses rather than stimulates the central nervous system

¹¹ Avorn, *Powerful Medicines*, 76.

¹² Michael D. Lemonick, "The New Miracle Drug?" *Time Magazine*, September 23, 1996. <http://content.time.com/time/magazine/article/0,9171,985187,00.html> (accessed February 20, 2014).

¹³ Sheila Brown, et al., v. American Home Products Corporation, Order No. 1415, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000), 2.

¹⁴ Eugene J. Mark et al., "Fatal Pulmonary Hypertension Associated with Short-Term Use of Fenfluramine and Phentermine," *The New England Journal of Medicine* 337, no. 9 (August 28, 1997): 602, <http://www.nejm.org/doi/pdf/10.1056/NEJM199708283370904> (accessed February 23, 2014).

¹⁵ Tragos, "Fen-Phen Litigation Against American Home Products Corporation," 4.

and affects the cellular processing of serotonin.¹⁶ The problem was that “since fenfluramine and dexfenfluramine cause an increase in the amount of serotonin released by the body and a decrease in the amount the body reabsorbs, when phentermine interferes with the pulmonary clearance of that serotonin, it magnifies the serotonin related effects of the fenfluramines in the lungs,”¹⁷ thus promoting valvular heart disease and PH.

The off-label use of fen-phen weighed on the physicians and pharmacists who encouraged its use. Doctors like Israel Levavi admit having prescribed and encouraged obese patients to take fen-phen; even Dr. Weintraub, who is responsible for launching the fen-phen trend, confesses, after medical studies showed the danger of taking fen-phen, that he had figured these drugs were safe since they had been on the market for over ten years.¹⁸ However, even though fenfluramine and dexfenfluramine were respectively approved by the FDA in 1973 and 1996, they were never approved to be taken in combination with other drugs like phentermine.

II. Class action lawsuit against AHP for the manufacturing and selling of Pondimin and Redux

The withdrawal of Pondimin and Redux from the U.S. market in 1997 was followed by a wave of litigation involving approximately 18,000 individuals, filing lawsuits against either AHP, pharmacies that distributed these drugs, or physicians who prescribed them.¹⁹ Additionally, more than a hundred plaintiffs brought lawsuits, mainly seeking three remedies from AHP:

- (1) to create an equitable fund providing medical screening services to patients who had used Pondimin and/or Redux ... to determine if they had asymptomatic valvular heart disease; and/or
- (2) to recover the amounts expended by consumers to purchase Pondimin and/or Redux or to obtain echocardiograms as a consequence of exposure to these drugs; and/or
- (3) to recover personal injury damages on behalf of classes of persons who took Pondimin and/or Redux.²⁰

The class actions were filed in the federal courts and consolidated as *Sheila Brown, et al., v. American Home Products Corporation* in the United States District Court for the Eastern District of Pennsylvania. The court created a Plaintiffs' Management Committee (PMC) to act for plaintiffs in pretrial proceedings and conduct discovery.²¹

¹⁶ Mark et al., “Fatal Pulmonary Hypertension,” 605.

¹⁷ Tragos, “Fen-Phen Litigation,” 13.

¹⁸ Kolata, “How Fen-Phen.”

¹⁹ Sheila Brown, et al., v. American Home Products Corporation, Order No. 1415, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000), 3.

²⁰ Ibid..

²¹ Sheila Brown, et al., v. American Home Products Corporation, 2002 WL 32154197 (E.D.Pa. Oct. 3, 2002), 2.

In 1999, AHP and plaintiffs' attorneys representing the PMC and plaintiffs in state class actions certified in seven states agreed to a comprehensive settlement.²² The settlement was approved by the federal Court of Appeals for the Third Circuit on January 3, 2002.²³

Under the Settlement Agreement, AHP agreed to provide the following:

- Reimbursement of purchase cost of drugs
- Compensation of medical diagnostics for those who took or had been exposed to fen-phen
- More substantial compensation for those who had been diagnosed with injuries as a result of taking fen-phen²⁴

The amount compensated depended on the plaintiff's age and the level of severity of his/her injuries. Ultimately, AHP was obligated for a total of approximately \$3.8 billion.²⁵

III. Who has liability for the damages of fen-phen?

A. AHP's egregious negligence and breach of duty

The fen-phen case provides reason to worry about diet pills and drug manufacturers' negligence to test and inform consumers of the risk they run by taking these drugs. For the benefit of the consumers, the FDA requires that all companies include on their drug labels facts about the drugs and evidence of efficacy, as well as potential risks, so that consumers can make informed choices about whether to use a given product.²⁶ Yet, despite AHP's awareness of the health complications caused by its drugs, it did not fully report the risks of taking the fenfluramines with phentermine or even put a warning on its labels. Records show that by 1994 AHP had been informed of about forty-one Pondimin-related VHD and PH cases but informed the FDA of only four cases to be inserted on Pondimin's label. During the early stages of the litigation in 1997, a Texas law firm representing plaintiffs posted on the internet a number of corporate memos in which AHP officials discuss their concerns regarding the serious risks of the fenfluramines.²⁷ Indeed, around mid-1994 Fred Wilson, a company official,

²² Sheila Brown, et al., v. American Home Products Corporation, 2002 WL 32154197 (E.D.Pa. Oct. 3, 2002), 4.

²³ Ibid.

²⁴ "Welcome to the Diet Drugs Claims Administration Web Site," *AHP Diet Drug Settlement*, n.d., <http://www.settlementdietdrugs.com/> (accessed February 12, 2014).

²⁵ "Fen-phen Class Action Settlement Information," Petroff & Associates Attorneys at Law, n.d., <http://www.petroffassociates.com/fen-phen-settlement.cfm> (accessed February 12, 2014); Sheila Brown, et al., v. American Home Products Corporation, 2002 WL 32154197 (E.D.Pa. Oct. 3, 2002), 6;

"Summary of Available Settlement Benefits and Registration Requirement," *AHP Diet Drug Settlement*, n.d., <http://www.settlementdietdrugs.com/> (accessed February 12, 2014).

²⁶ Avorn, *Powerful Medicines*, 74.

²⁷ Ibid.

wrote to a colleague: “I have been concerned that our approved labeling contains only four such cases when in fact, we have 37 reports in addition to those mentioned in the labeling.”²⁸ Wilson initially proposed to fully disclose the information about Pondimin to the FDA and the public, but it took over two years, until about 1997, for the company to inform the FDA.²⁹

The federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938³⁰ allots to the Food and Drug Administration (FDA) and drug manufacturers the responsibility to ensure the safety of the products and the effectiveness of the claimed outcomes. Thus, AHP breached a duty of care through its negligence to inform its consumers about the risks of Pondimin and Redux, which caused severe injuries and deaths. By marketing a defective product, AHP ran afoul of the law on strict liability. Critics attest that had American Home Products supplied an adequate warning about fenfluramine and dexfenfluramine, AHP could have been exempt from strictly liability for adverse effects resulting from ingestion of these drugs.³¹ Adopted in 1997, the Restatement Third of Torts³² concerning products liability

provides [clear] answers to the question of whether a product is defective by formulating three distinct categories of product defect:

- Manufacturing defects
- Design defects
- Warning defects

and the legal standards appropriate to each.³³

In this case, AHP was liable due to both the design and warning defects of Pondimin and Redux. The design defects of Pondimin and Redux came from the drugs’ dangerous side effects while the warning defects came from the fact that AHP did not inform the FDA or the public of the dangers of its drugs. The fact is that the dangers of Pondimin and Redux could have been avoided had AHP ensured the drugs’ safety before selling them. AHP’s decision to disregard its social and legal duty mentioned in the FD&C Act of 1938 also illustrates the popular tendency for companies to prioritize their own profit even if the consumers’ lives are on the line.

AHP’s unethical strategic decisions vis-à-vis the dangers of fen-phen frame the growing tendency for businesses to choose compromising routes in order to maximize their profits, and lead one to ask why businesses follow unscrupulous paths that can

²⁸ Ibid, 75.

²⁹ Ibid.

³⁰ The FD&C Act of 1938 refers to a set of laws passed by the Congress in 1938 with the objectives of expanding the FDA’s role in regulating foods, drugs, and cosmetic products and of enhancing businesses’ manufacturing and marketing standards.

³¹ Tragos, “Fen-phen Litigation Against American Home Products Corporation,” 63.

³² Restatement (Third) of Torts, which replaces Restatement (Second) of Torts, is a treatise issued by the American Law Institute which elaborates on a wide range of legal matters such as companies’ strict liability for manufacturing and marketing defective products. The purpose of the Restatement is to establish a basis for the interpretation of the common law.

³³ “Restatement of the Law Third, Torts: Products Liability,” The American Law Institute, 1997, http://www.ali.org/ali_old/promo6081.htm (accessed March 23, 2014).

only lead to short-term profit instead of pursuing an honest route that leads to the company's long-term profitability. While AHP's cupidity greatly benefited the firm from 1992 until 1994, the \$3.8 billion settlement fund reduced AHP to ashes and led the company to change its name to Wyeth on March 11, 2002.

B. Physicians' promotion of off-label use of drugs

Despite the fact that AHP was the principal party held liable in the fen-phen litigation, one can argue that the physicians who prescribed the mix share liability since they prescribed the cocktail without having any evidence about the efficacy and safety of these drugs. Even though off-label use of drugs is not considered a crime in the U.S., the FDA requires that physicians be well informed about the product, to base their use on firm scientific rationale and on sound medical evidence.³⁴ The dilemma here is that AHP did not inform the public about the potential danger of the drugs, but the firm did not promote the off-label use of fen-phen either: the practitioners are the ones who, based on their reading of the articles of Dr. Weintraub, advocated the use of fen-phen to their patients for longer periods than originally approved by the FDA. "Every drug has at least two effects: the one intended and the one unintended,"³⁵ and Dr. Weintraub's fault in the matter is that when he put his hypothesis to the test using 121 obese patients, he merely focused on the weight loss aspect and failed to observe the circulatory symptoms developed by the participants.³⁶ This case shows how the off-label uses recommended by medical textbooks and scientific articles have become a ubiquitous part of mainstream medical practice. In order to prevent unfortunate patients from paying the price for their physicians' careless decisions, the doctors should be held liable for the damages caused by the dangerous drugs that they prescribe.

Practitioners who prescribe unapproved dosages and/or combinations of drugs from which the patients develop diseases have committed a tort by not having the diligence to gather proper information about the potential side effects arising from the drug use. As a result, they should be charged with medical malpractice and held liable for the damages caused. In fact, in a Philadelphia fen-phen trial, the prescribing doctor was held liable for a \$4 million verdict after having prescribed the cocktail to his patient for two years, a period significantly beyond the two weeks recommended by the manufacturer.³⁷ Nevertheless, in order to legally hold physicians liable for their wrong, President Clinton's Modernization Act of 1997,³⁸ "which changed the law on off-label

³⁴ "Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices," FDA, last modified August 10, 2011, <http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm> (accessed February 12, 2014).

³⁵ Avorn, *Powerful Medicines*, 72.

³⁶ Kolata, "How Fen-Phen?"

³⁷ Tragos, "Fen-Phen Litigation Against American Home Products Corporation," 60.

³⁸ The Food and Drug Administration Modernization Act, which amended the federal Food, Drug, and Cosmetic Act and the Public Health Service Act, was enacted on November 21, 1997, under Bill Clinton's presidency. One of the most important changes brought by the Modernization Act relates to off-label promotion. Indeed, before November 1997, the marketing by manufacturers or physicians of drugs for uses unapproved by the FDA was an illegal practice.

promotion and made it a circumstantially permissible practice,”³⁹ needs to be amended so that the FDA can extend its power on drug regulation. Critics believe that had it not been for the off-label promotion of fen-phen by physicians and publications in peer-reviewed journals, the fen-phen craze would undoubtedly not have taken such an unsavory turn.⁴⁰ Yet, the disadvantage of having the FDA oversee all uses of drugs is that the additional regulation would be costly and time-consuming.

C. The FDA’s role in approving fenfluramine and dexfenfluramine

The FDA’s responsibility is to “protect the public health by assuring the safety, efficacy and security of human and veterinary drugs.”⁴¹ How then is it possible that drugs that are FDA-approved are being withdrawn after being on the market for over twenty years? Like Pondimin and Redux, since 1990 a large number of drugs have been withdrawn for substantial unexpected safety problems due to insufficient premarketing studies to detect rare side effects.⁴² In fact, the premarketing study done on dexfenfluramine lasted only one year. The ease of the approval process for drugs has proven to be a profitable advantage to greedy and dishonest manufacturers, but has been fatal to the consumers. While critics admit that requiring that all drugs on the market be completely safe is an impossible matter, the FDA must promote higher and stricter standards. The agency should impose longer periods of preapproval trials that can provide information that is not just “good enough” but that covers the most foreseeable scenarios.

The common perception that the FDA conducts studies on drugs before they are marketed is false. In reality, this agency does not study any drugs prior to approval but mainly relies on the manufacturer to generate that information in studies conducted or commissioned by the company.⁴³ Nevertheless, with the new powers granted to the FDA through the Food and Drug Administration Amendments Act (FDAAA) of 2007, the agency is now able to require a Risk Evaluation and Mitigation Strategy from manufacturers of approved drugs. The FDAAA, signed by George W. Bush, could prove to be the beginning of a new era of diligence from the FDA and drug manufacturers.

Conclusion

Every business has the duty to satisfy the needs of its customers either through the effective services provided or through the safe and high quality products manufactured. When a company breaches the duty of care, it is liable for the damages resulting from its negligence. The fen-phen case is a buoy that signals the danger of off-

However, with the Modernization Act, firms and physicians were no longer constrained and could encourage consumers and patients to choose off-label use of drugs.

³⁹ Tragos, “Fen-Phen Litigation Against American Home Products Corporation,” 56.

⁴⁰ Ibid, 56.

⁴¹“About FDA,” FDA, last modified September 19, 2013, <http://www.fda.gov/aboutfda/whatwedo/> (accessed February 12, 2014).

⁴²Avorn, *Powerful Medicines*, 85.

⁴³Ibid., 71.

label use and the growing tendency for corporate negligence. Because of AHP's negligence to report the dangers of taking the fenfluramine drugs, the company breached its duty and thus needs to be held strictly liable for the damages caused by the drugs. The lack of information and the poor judgment of the medical practitioners have also harmed patients. While the physicians' unawareness of the risks of the fenfluramines can be blamed on AHP, they are still at fault for their decision to write prescriptions for a drug mix based on inadequate medical studies and for a period beyond that recommended. Additionally, the FDA must impose higher standards when overseeing drug pretrial studies and must regulate the off-label use of drugs. With all the power held by the FDA, the agency should have been able to prevent the occurrence of such an avoidable drug plague as the fen-phen epidemic. Compensation for damages is necessary, but is not the best way of punishing companies for their dangerous negligence. If drug manufacturers know that in addition to providing compensation they might be subjected to more severe sanctions, such as incarceration of top employees, they will become more diligent and minimize the risks of dangerous products.