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PRODUCT LIABILITY AND PRESCRIPTION DIET DRUG COCKTAIL, FEN-PHEN: A HARD COMBINATION TO SWALLOW

I. INTRODUCTION: WHAT ROLE IS PRESCRIBED TO THE HEALTH CARE INDUSTRY - REGULATOR OR BABYSITTER?

The American public places its trust in the Food and Drug Administration (FDA), pharmaceutical manufacturers, and physicians to provide safe treatment for physical and mental ailments.1 However, past and current events remind us that the health care industry is far from perfect. Although the pharmaceutical industry is developing at a rapid pace, and society is benefiting greatly from technological advances, the result of this growth is that the health care industry is vulnerable to any liability that may arise from introductory pilot drug therapies.2

One area of health care that has been particularly active for the past decade has been the diet industry. As an adjunct, or perhaps a substitute for exercise and healthful eating, appetite-suppressing drugs are relentlessly marketed.3 One of the most popular appetite suppressants marketed during the last decade was a combination of two drugs, Fenfluramine and Phentermine,4 more popularly known as Fen-phen.5 Millions

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1. See generally Product Jurisdiction, 21 C.F.R. §§ 3.1-3.10 (1997) (describing the regulatory jurisdiction the FDA has over products entered into the market for consumer use).
2. See generally Michael Lemonick, The Mood Molecule, TIME, Sept. 29, 1997, at 75 (discussing medical advances as researchers learn more about the chemicals in the brain). See also generally Frederick Golden, Who's to Blame for Redux and Fenfluramine?, TIME, Sept. 29, 1997, at 78 (naming all the possible defendants from the health care industry).
4. See Lemonick, supra note 2, at 78. Fenfluramine and Phentermine are drugs that target the brain chemical serotonin. See id. at 75. Researchers have discovered that serotonin plays a major role in the function of the human psyche including uncontrollable appetite. See id. These drugs stimulate the nerve cells into pumping out extra serotonin, which makes overeaters feel full. See id. at 78.
5. See NBC Nightly News, Profile: Morton Maxwell, co-director of UCLA
of patients, ranging from obese to slightly overweight, have haphazardly ingested this drug cocktail on the advice of physicians. Recently, this medication has fallen under attack because of its alleged connection to heart-valve abnormalities that could prove fatal.

Class action suits are being filed across the nation on behalf of patients who were prescribed Fen-phen and sustained injuries as a result of this combination drug therapy. These suits will have major ramifications for tort law in the health care industry. Liability for patients’ injuries and the legal theory for liability are important issues that must be addressed. Special considerations need to be afforded to the health care industry and to those involved in its advancement. It seems society

Obesity Center, comments on use of drugs to fight obesity (NBC television broadcast, June 5, 1996).


7. See Mayo Health O@sis, Two diet drugs pulled from market, Patients urged to taper off dosage (visited Sept. 23, 1997) <http://www.mayo.ivl.com> at 1. “Some of those identified with valvular disease associated with fen-phen have required open-heart surgery, and there have been a small number of deaths reported nationally.” Id.

8. See Golden, supra note 2, at 78.

9. See id. “Lawyers expect many thousands of lawsuits to be filed across the country. Eventually, the Fen-phen recall could be one of the largest medical liability cases in history, exceeding silicone breast implants.” Id. See Tort Binge...,, LEGAL TIMES, Oct. 20, 1997, at 3. “In Washington, two firms... have gathered more than 100 clients, mainly from the D.C. area, for product liability suits and other legal actions against the drugs' manufacturers.” Id.

10. See Golden, supra note 2, at 78.

Question: Who’s to blame for letting the public gobble up potentially deadly diet pills like so much popcorn? Choose from among the following: 1. The U.S. Food and Drug Administration, which brushed off scientists’ misgivings to approve the pills last year. 2. The drug companies that produced, tested and zealously promoted the pills. 3. The doctors and diet clinics that eagerly dispensed them, even to patients for whom they were never intended. 4. Uncritical media that ballyhooed the pills as ‘miracle’ drugs and ‘magic bullets’ in the war against fat. 5. A fanatically weight-conscious public so eager to shed pounds that it demanded the pills at any cost.

Id.

11. See W. Kip Viscusi et al., A Statistical Profile of Pharmaceutical Industry Liability, 24 SETON HALL L. REV. 1418, 1431 (1994). “It has often been hypothesized that liability awards may depress research and development because they discourage innovation of new products with unproven designs.” Id.
needs to point its finger at a member of this important industry, such as the prescribing doctors or the manufacturers in order to establish accountability for the public's safety. On the contrary, society should engage in introspection to identify who is truly supporting the use of diet prescription drugs and whether the health care industry is solely responsible for the negligent administration of diet drugs.\footnote{See Golden, supra note 2, at 78. "[There are] larger societal questions - about Americans' infatuation with quick-fix remedies for whatever ails them, real or imagined, and their doctors' willingness to cater to it." \textit{Id.}}

This Comment will provide a simple overview of state tort common law to predict the outcome of Fen-phen class action suits. While making this prediction, the analysis will remain cognizant of federal intent through FDA regulations. First, this Comment discusses the diet drug industry's development, the media's role, and its effect on weight loss patients. Second, this Comment discusses the special circumstances surrounding case law involving prescription drug liability. Third, this Comment identifies past suits in which a patient was injured by a prescribed drug, previously approved by the FDA. Included in this discussion will be descriptions of various defendants joined in the cases, the different causes of action and defenses, the successes and failures of the claims, and how the previous law will apply to the Fen-phen dispute and future diet drug cases. Finally, this Comment discusses public policy concerning the diet industry's influence on society and the possible ramifications of that influence on the law, particularly taking into account a plaintiff's case against those involved in the production and distribution of Fen-phen. This Comment concludes that because of the media, societal interaction, and the population's eagerness to be thin, liability for injuries caused by prescription diet drugs should be shared. The guilty parties include those involved in the health care industry who acted negligently, and the plaintiff who contributed to the negligence by placing their most valuable asset, themselves, at risk.

\section*{II. BACKGROUND: THE GROWTH OF THE DIET INDUSTRY - A MATTER NOT TO BE TAKEN LIGHTLY}

One woman dropped from 545 pounds to 265 pounds on the diet drug Fen-phen.\footnote{See Lemonick, supra note 2, at 75.} Some dieters claimed that this miracle drug was the only thing that has ever worked.\footnote{See \textit{id.}} But another woman who was prescribed
the same drug combination of Fenfluramine and Phentermine died of a heart attack trying to shed ten pounds.\textsuperscript{15} The dieting craze that has swept the United States, spurred by the media, may have contributed to the dangerous nature of the popular drug cocktail called Fen-phen,\textsuperscript{16} resulting in a ban on the combination use of Phentermine and Fenfluramine.\textsuperscript{17} People are left asking why the ban of such an effective product is necessary.

Cardiovascular health problems have been diagnosed in patients, particularly women, who were taking the drug to lose weight.\textsuperscript{18} This condition has been attributed to Fen-phen,\textsuperscript{19} although it has not been concluded that the drugs were causing the particular heart-valve disease diagnosed.\textsuperscript{20} The Mayo Clinic describes the condition of diagnosed patients by stating, “[t]he damaged heart valves were thickened, causing blood to flow backward through the valve[s]. The impaired valve function causes the heart to work harder and can lead to congestive heart failure.”\textsuperscript{21} Some patients identified with valvular disease associated with Fen-phen have required open-heart surgery.\textsuperscript{22} Additionally, there have been a small number of deaths reported nationally.\textsuperscript{23} There was a strong

\textsuperscript{15} See Sandra G. Boodman, Now that Two Popular Weight-Loss Drugs are off the Market, What’s Left for Dieters?, WASH. POST, Sept. 16, 1997, (Health), at 12.

\textsuperscript{16} See generally, Mayo Health O@sis, supra note 7 (stating that thirty percent of patients taking Fen-phen showed signs of heart abnormality and that these findings call for prompt action).

\textsuperscript{17} See Paul Rheingold, Fen-Phen/Redux Diet Drugs, 15 MEALEY’S LITIG. REP.: DRUGS & MED. DEVICES 22, 22 (1997).

\textsuperscript{18} See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, “Fen-phen” Update (fenfluramine, phentermine, dexfenfluramine) (visited Oct. 22, 1997) \textls[12]<http://www.fda.gov> at 1 (citing N. ENGL. J. MED., Aug. 28, 1997, 337(9), 581-88). Health care professionals presently have reported eighty-two cases of cardiac valvular disease, only two of which were men. See id.

\textsuperscript{19} See Murray M. Lumpkin, FDA Public Health Advisory, 27 FDA MED. BULLETIN No. 2, at 1 (1997). “As of July 8, 1997, there have been 33 cases reported to [the] FDA of unusual valvular morphology and regurgitation involving the mitral, aortic, and/or tricuspid valves, usually being multivalvular.” Id.

\textsuperscript{20} See Mayo Health O@sis, Heart Valve Disease and Fen-phen, An Interview with Mayo Cardiologist Heidi Connolly, M.D. (visited Sept. 23, 1997) \textls[12]<http://www.mayo.ivl.com> at 2 [hereinafter Heart Valve Disease].

\textsuperscript{21} Mayo Health O@sis, supra note 7, at 1.

\textsuperscript{22} See id.

\textsuperscript{23} See id.; see also Lumpkin, supra note 19, at 1 (“[As of July 8, 1997] surgical intervention has been required in six patients.”); Geoffrey Cowley &
enough correlation between Fen-phen therapy and the thickening of the valves\textsuperscript{24} to cause the FDA to pull Fenfluramine, commercially known as Redux\textsuperscript{©}, off the market.\textsuperscript{25} As many as thirty percent of Fen-phen patients have shown evidence of heart-valve abnormalities.\textsuperscript{26} Currently, three deaths have been reported in connection with the diet drug combination.\textsuperscript{27} The other half of Fen-phen, Phentermine, remains on the market,\textsuperscript{28} but may no longer be used in conjunction with Fenfluramine.\textsuperscript{29}

Over twenty years ago, Fenfluramine and Phentermine were approved by the FDA.\textsuperscript{30} However, the drugs were only approved for medically diagnosed obese patients to be used separately, and on a short-term basis.\textsuperscript{31} Furthermore, the FDA has neither approved nor endorsed the combination use of the drugs.\textsuperscript{32} Therefore, physicians prescribing the drugs simultaneously to patients were making an "off-label"\textsuperscript{33} use of the prescription pills; a perfectly lawful practice.\textsuperscript{34} The catalyst behind the joint

Karen Springen, \textit{After Fen-Phen}, NEWSWEEK, Sept. 29, 1997, at 47 (reporting that a waxy coating develops on the heart valves of people with this specific disease and that the coating can keep the valves from closing properly). The wax build-up disrupts the function of the heart and can lead to heart failure. See id.

\textsuperscript{24} See Heart Valve Disease, supra note 20, at 2. "We say there appears to be an association between this combination of medications and valve disease, but we can't prove it based on current information." \textit{Id.}

\textsuperscript{25} See Health Update, \textit{What's Hot! What's Not!} (visited Sept. 16, 1997) \url{<http://www.members.aol.com>} at 1. "The other half of the [fen-phen] combination, phentermine, has not been taken off the market." \textit{Id.}

\textsuperscript{26} See Lemonick, \textit{supra} note 2, at 76.


\textsuperscript{28} See Boodman, \textit{supra} note 15, at 12. It is only the combination of the drugs prescribed together that causes the abnormal waxy coating to develop on the valves of the heart. See id.

\textsuperscript{29} See Health Update, \textit{What's Hot! What's Not!}, supra note 25, at 1.

\textsuperscript{30} See Lumpkin, \textit{supra} note 19, at 1.

\textsuperscript{31} See \textit{id.}

\textsuperscript{32} See Rheingold, \textit{supra} note 17, at 22.

\textsuperscript{33} See Boodman, \textit{supra} note 15, at 13.

\[\text{While the FDA never approved the combined use of phentermine and fenfluramine - and the manufacturer warned against it - both drugs were prescribed together anyway...} \] The use of unapproved combinations of drugs, or prescribing drugs for disorders other than those for which the medicine was approved by the FDA, is called 'off-label use' and is common practice in medicine. \textit{Id.}

\textsuperscript{34} See Rheingold, \textit{supra} note 17, at 22.
drug prescription was a 1992 study which revealed that the drugs worked more effectively in treating weight-loss when ingested in combination. Still, the lead deputy FDA Commissioner said, "[t]hese are drugs that should be taken only by obese patients in conjunction with a weight loss regimen that includes a reduced-calorie diet and an exercise program, in accordance with approved labeling." The industry and patients ignored the FDA's recommendations and abused Fen-phen.

III. PRIOR LAW: FDA APPROVED DRUGS - SAFE FOR USE?

A. The Diagnosis for Liability is Found on a Case-by-Case Basis

Prior cases involving a federally approved drug which later caused patient injury, have been brought under many causes of action. Most commonly, cases have been filed under tort law theories, and have involved various defendants. The outcome of this type of litigation is difficult to predict and is often based on the unique facts and circumstances of each specific case. Based on inconsistent determinations of past cases, which were both similar and dissimilar to Fen-phen, it is clear that the law concerning tort liability for federally approved drugs is dependent on fact-specific circumstances. Prescription diet drugs

35. See Boodman, supra note 15, at 13; see also Lemonick, supra note 2, at 80. "Because fenfluramine acts on both serotonin and dopamine, it has the unfortunate side effect of putting its users to sleep. That is why doctors came up with fen/phen; the 'phen' (phentermine) is an amphetamine-like drug that wakes the patient up again and boosts metabolism to burn calories faster." Lemonick, supra note 2, at 80.


37. See discussion infra Part IV.

38. See, e.g., Espinosa v. Alford, No. 92-02936 (295th Dist. Ct., Harris County, Tex., Aug. 1995) (stating plaintiff brought negligence suit against two different doctors and the pharmacy that dispensed the drugs); Leesley v. West, 518 N.E.2d 758 (Ill. App. Ct. 1988) (stating plaintiff brought failure to warn, strict liability, negligence, and breach of implied warranty suit against physician, pharmacy, and drug manufacturer); Werner v. Upjohn Co., 628 F.2d 848 (4th Cir. 1980) (stating plaintiff brought negligence, failure to warn, breach of warranty and strict liability suit against manufacturer and doctor).

39. See Annette Marthaler, The FDA Defense: A Prescription for Easing the Pain of Punitive Damage Awards in Medical Product Liability Cases, 19
used mainly for cosmetic purposes present very special circumstances because the specific facts play such a crucial and decisive role in the outcome of pending Fen-phen litigation. A Fen-phen case will turn on who the plaintiff is, who is joined as a defendant, and how much information the plaintiff was given before starting Fen-phen therapy.

B. Jurisdiction

The jurisdiction for diversity cases with tort liability issues is currently in flux.\(^4\) Although the FDA governs practically every aspect of the distribution of prescription drugs by pharmaceutical manufacturers,\(^4\) under state law, a jury may determine the guilt of a manufacturer who has fully complied with the federal law.\(^4\) Therefore, state law will only be superseded by federal law if it is proven that Congress intended for the Food, Drug, and Cosmetic Act (FDC) to preempt state tort actions.\(^4\) This ambiguity of jurisdiction adds yet another variation to the outcome of tort liability cases in regard to prescription drugs.\(^4\) Absent federal products liability tort law,\(^4\) Fen-phen suits may be filed in either state court or, by operation of diversity jurisdiction, in federal court. The Erie Doctrine\(^4\) prevents a plaintiff from forum shopping for the jurisdiction more sympathetic to his claim. The Erie Doctrine developed from the case, *Erie Railroad Co. v. Tompkins*,\(^4\) where the court held that whether the plaintiff files in state or federal court, the court must apply the state's substantive law in which the harm occurred.\(^4\) The result is that

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41. *See id.* at 396.

42. *See id.* at 417.

43. *See id.* at 400.

44. *See generally id.*

45. *See* Jeffrey Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 197 (1987). "Although, legislation has been introduced that would establish a uniform tort law, the law of products liability is still primarily determined state by state." *Id.*

46. *See* Jeffrey Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 197 (1987). "Although, legislation has been introduced that would establish a uniform tort law, the law of products liability is still primarily determined state by state." *Id.*

47. *Id.*

48. *Id.*
factually similar Fen-phen cases may result in very dissimilar outcomes because different states are certain to have varying theories of law.

IV. ANALYSIS: LIABILITY THEORY IS A HEAVY BURDEN TO PROVE FOR PRESCRIPTION FEN-PHEN PLAINTIFFS

A. The Possible Defendants

1. The FDA and the "Discretionary Function"

Congress created the FDA to ensure that drugs would only be available to the public if they were "safe." Later, Congress required a heightened showing that the drugs were "effective" as well. Due to the FDA's mandate as a government agency, the law developed to shield the FDA from liability. In particular, the FDA benefits from a principle of law known as the "discretionary function." This special exception excuses the FDA or any federal agency from liability for a tort claim when the claim is based on the performance or failure to perform a discretionary function solely delegated to that specific government entity. For example, the FDA is charged with the responsibility of regulating warnings and labels for drugs on the market. No drug may be produced for the public unless the FDA approves the warnings disseminated with


50. See id.

51. See Jean F. Rydstrom, Annotation, Claims Based on Law Enforcement and Regulatory Activities as Within 28 U.S.C.A. § 2680(A) Excepting from Federal Tort Claims Act Claims Involving "Discretionary Function or Duty", 36 A.L.R. Fed. 240, 250 (1978). The discretionary function was intended to protect political choices from being influenced by the private sector. See id. at 252.

52. See id.

53. See id. at 250.

The 'discretionary function' exception of 28 U.S.C.A. § 2680(a) renders [a tort claim] inapplicable to any claim "based upon the exercise or performance of the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused," and was intended by Congress to apply to regulatory activities of the government. Id.

54. See Geiger & Rosen, supra note 40, at 396. The FDA also governs every aspect of testing, design, manufacture, distribution and detailing specific duties of manufacturers. See id.
the product and the label attached to the casing. The test of whether a tort claim will be dismissed, based on the exception, hinges on whether the act causing the injury was a judgment based on policy considerations.\(^{55}\) If the injury was based on policy considerations the discretionary function applies exonerating the FDA from liability. This leaves a case against the FDA rather difficult to win because almost every activity by the FDA requires a policymaking component.\(^{56}\) In fact, past cases show that very few claims against the government have been successful.\(^{57}\)

In *Gelly v. Astra Pharmaceutical Products, Inc.*,\(^{58}\) Richard Gelly brought suit against the United States claiming that employees of the FDA were negligent and strictly liable under the FDC.\(^{59}\) Richard Gelly’s wife, Carol, died allegedly due to an adverse reaction to the anesthetic, Xylocaine.\(^{60}\) The FDA had approved the drug as “safe for use” and had permitted Astra Pharmaceutical Products to manufacture and sell it.\(^{61}\) However, Carol’s cause of death was traced to an adverse reaction to the approved drug.\(^{62}\) The plaintiff alleged that under the Federal Tort Claims Act,\(^{63}\) the United States would be liable to a claimant in the same manner as a private person.\(^{64}\) The plaintiff argued that the FDA owed a duty to provide safe drugs for the market and the agency breached that duty


\(^{56}\) See id. “The effect of accepting the government’s argument would effectively immunize all governmental activity, except the most ministerial acts, from potential liability.” Id.

\(^{57}\) See id. at 467. “[O]nly a single reported case has been discovered in which federal court has considered the liability of the United States ... for damages caused by the ingestion or administration of drugs, vaccines, and the like, approved as safe for use by a government agency.” Id. at 467-68.

\(^{58}\) 466 F. Supp. 182 (D. Minn. 1979).

\(^{59}\) See id. at 182.

\(^{60}\) See id. at 184.

\(^{61}\) See id.

\(^{62}\) See Gelly, 466 F. Supp. at 184.

\(^{63}\) See BLACK’S LAW DICTIONARY 613-14. (6th ed. 1990). The government of the United States may not be sued under tort law without its consent. See id. Through the Federal Torts Claim Act consent was given making the federal government vulnerable to tort liability. See id.

\(^{64}\) See Gelly, 466 F. Supp. at 184.
by allowing Xylocaine to be prescribed.  The United States moved to dismiss on the ground that there was no actionable tort duty owed by the FDA.  The court agreed, applying the discretionary exception to “render the government immune from tort liability.” The court, interpreting the Federal Tort Claims Act, stated, “[r]egulatory activity engaged in by FDA personnel simply has no counterpart in private activity and thus cannot give rise to liability under the common law.”

Another challenge to the FDA’s immunity came in Bailey v. Eli Lilly Co.  This was a claim against the FDA for negligently performing its regulatory duties. In this case, the plaintiff’s decedent died from bladder cancer allegedly caused by taking Oraflex to treat arthritis. This drug, like Xylocaine, Fenfluramine, and Phentermine, had been previously approved as “safe for use” by the FDA. The district court determined that the acts of regulation by government agencies are encompassed within discretionary acts and as a result “the actions of the FDA were plainly of the ‘nature and quality that Congress intended to shield from tort liability.’”

These two cases illustrate the broad scope of the discretionary function as an exoneration mechanism for the FDA when approved drugs cause harm. Courts have uniformly rejected tort claims against the FDA that would otherwise provide a civil remedy to a private individual as a result of injury caused by previously approved drugs.

In the Fen-phen cases, the FDA would not only be protected by the discretionary function, but also, the facts of the case might absolve the FDA from liability. Fenfluramine and Phentermine were never approved by the FDA for use as a combination drug therapy. Rather, the

65. See id. at 185.
66. See id. at 182.
67. Id. at 185.
68. Id.
70. See id. at 661.
71. See id.
72. See id.
73. Id. at 663.
74. See supra note 51 and accompanying text.
75. See Gelly v. Astra Pharm. Prods., Inc., 466 F. Supp. 182, 186 (D. Minn. 1979); see also Rydstrom supra note 51 and accompanying text.
76. See Boodman, supra note 15, at 13.
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FDA only approved the drugs for separate use.\textsuperscript{77} Used individually, the drugs had caused no health problems.\textsuperscript{78} Fenfluramine had been used in Europe for more than twenty years with no sign of adverse health consequences.\textsuperscript{79} In addition, the drugs were only approved for short-term use.\textsuperscript{80}

In order for a tort claim to stand against the FDA, a plaintiff must prove the FDA was negligent, notwithstanding its agency role.\textsuperscript{81} Even if the FDA should have known of the heart problems associated with Fen-phen and that its warning labels were inadequate, it still would not be liable due to the "discretionary function."\textsuperscript{82} A Fen-phen claim against the FDA will be almost impossible to win.\textsuperscript{83} In fact, plaintiffs are so skeptical of success in a suit against the FDA, the suits that have been filed thus far have not named the FDA as a defendant.\textsuperscript{84}

2. Manufacturers and the "Learned Intermediary Doctrine"

Drug manufacturers are also possible defendants in cases involving drugs, previously approved by the FDA, that caused injury.\textsuperscript{85} Often the plaintiff will want to sue the manufacturer based on the "deep pockets" theory,\textsuperscript{86} a belief that a corporate entity will have greater ability to satisfy a substantial judgment, as compared to an individual.\textsuperscript{87} However, pharmaceutical manufacturers are protected, much like the FDA,

\textsuperscript{77} See id.
\textsuperscript{78} See Lemonick, supra note 2, at 82.
\textsuperscript{79} See id.
\textsuperscript{80} See Boodman, supra note 15, at 13.
\textsuperscript{81} See Schwartz, supra note 55, at 468.
\textsuperscript{82} See Rydstrom, supra note 51, at 250.
\textsuperscript{83} See Schwartz, supra note 55, at 468.
\textsuperscript{84} Interview with Rebekah Arch, Associate at Ashcraft & Gerel Law Firm, in Alexandria, Va. (Feb. 24, 1998).
\textsuperscript{85} See Barbara Pope Flannagan, Comment, Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs, 20 U. RICH. L. REV. 405, 406 (1986). Prescription drug manufacturers are encountering the same influx of products liability law suits as other types of manufacturers. See id.
\textsuperscript{86} See Neil Vidmar, Empirical Evidence on the Deep Pockets Hypothesis: Jury Awards for Pain and Suffering in Medical Malpractice Cases, 43 DUKE L.J. 217, 217-18 (1993). Many jurors believe institutions like hospitals and manufacturers have "deep pockets" to provide the compensation for a plaintiff’s serious injuries. See id.
\textsuperscript{87} See id.
through a protective doctrine called the "learned intermediary doctrine." The learned intermediary doctrine states that a drug manufacturer must warn the doctor, as a learned intermediary, of any potential risks relating to ingesting the drug. By providing adequate warning to the doctor, who is in a better position to inform patients of the risks and benefits of taking a certain drug, the manufacturer exculpates itself from liability in what otherwise would be a breach of the manufacturer's duty to warn. The majority of jurisdictions have held that the learned intermediary doctrine is proper because prescription drugs are complex medicines best understood by a doctor. Physicians have extensive education and experience, and therefore are best suited to evaluate all factors of a patient's susceptibility, including a drug's inherent dangers. A doctor who has been informed by a manufacturer can make an informed decision and advise the patient of the best means by which to treat a condition, whether it be through drug therapy or otherwise.

Furthermore, if manufacturers were responsible for issuing warnings directly to the consumer several practical problems would arise. In some circumstances, it could be difficult to make the warning comprehensible to lay persons. In others, the warning could mislead patients about the severity of the possible side effects. Finally, a direct warning

88. Flannagan, supra note 85, at 407-08.
[L]earned intermediary rule should continue to be a valid defense in the following situations: (1) where the adverse effects of an ethical drug involve medical complexities which cannot be translated into ordinary language; and (2) where warning the consumer of the drug's adverse effects would amount to a meaningless gesture on the part of the manufacturer.
Id.

89. See id. at 407.
90. See id. at 413.
91. See id. at 407.
92. See id.
93. See Flannagan, supra note 85, at 412.
94. See id.
95. See id. at 413. If patients are misled by overly cautious warning statements, or misinterpret warnings as being more severe than necessary, it could hinder the progress of medical technology and the progress of that particular patient. See id.
96. See id.
97. See id.
98. See Flannagan, supra note 85, at 413.
from the manufacturer to the consumer could be intrusive to the doctor/patient relationship.99

Because situations may differ according to the specific patient and prognosis, "[o]verall, the continued validity of the learned intermediary rule must be determined on a case-by-case basis in light of the merits of the individual claim."100 Consequently, there are certain occasions that give rise to a manufacturer's responsibility to directly warn a consumer of a given drug's side effects.101 There may be a federal labeling requirement, such as in some oral contraceptives, where the danger can be conveyed to the consumer through an inserted warning.102 In this case, a manufacturer that breaches a duty to warn incurs tort liability and fails to comply with a federal statute.103

There is a significant amount of case law that involves a claim of liability against the manufacturer of a drug.104 Alleged in these suits will be a myriad of claims including strict liability, negligence, and breach of implied warranty.105 The outcome of these cases is unpredictable and is dependent upon the facts and circumstances of each case.

In *In re Norplant Contraceptive Products Liability Litigation*,106 a class action suit involving all of the above claims mentioned, the plaintiffs asserted that the contraceptive, Norplant, caused numerous side effects, such as prolonged menstrual bleeding, headaches, mood changes, depression, weight gain, hair loss, arm pain, dizziness, and nausea.107 The plaintiffs claimed that the manufacturer failed to warn both the doctors and the consumers of these problems.108 This failure to warn gave rise to the other tort claims filed.109 The court determined that

99. *See id.*
100. *Id.* at 408.
101. *See id.* at 415-16.
102. *See id.*
103. *See Flannagan, supra* note 85, at 415-20.
105. *See In re Norplant, 955 F. Supp. at 703.*
107. *See id.* at 702.
108. *See id.*
109. *See id.* at 702-03 (stating a failure to warn can fall either under negligence theory or strict liability).
the manufacturer was relieved of liability because the doctor/patient relationship existed, creating the learned intermediary role, and therefore, placed responsibility on the doctors, rather than the manufacturer, to warn their patients. When a physician is aware of possible side effects of a prescription drug but chooses to disregard the warning, in effect, the injury is not due to the inadequacy of the manufacturer's warning. Therefore, there is no breach of the duty to warn. The court did note, "[h]owever, ... when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." 

An example of another case filed against a manufacturer is Singer v. Sterling Drug, Inc. The plaintiff, Anna Singer, took the drug, Aralen, prescribed by her physician for treatment of a facial rash. After taking the drug for seven years, she was advised by her pharmacist that the drug had serious oculatory side effects. Upon examination, it was discovered that Singer had lost a significant part of her vision due to Chloroquine Retinopathy caused by the ingestion of Aralen. It was concluded that Sterling, the manufacturer of Aralen, had failed to warn the physician prescribers of the serious side effects of the drug. The court determined that the defendant manufacturer had a duty to warn and was strictly liable because it knew the risks of Aralen and failed to warn. The court further concluded that, even in a situation where a doctor is negligent in prescribing a drug, the manufacturer’s liability will not be vitiated when it has failed to warn the “learned intermediary.”

110. See In re Norplant, 955 F. Supp. at 705-06.
111. See id. at 711.
112. Id. at 703 (citing Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 592 (Tex. 1986) (citing Bristol-Myers Co. v. Gonzales, 561 S.W.2d 801 (Tex. 1978)).
113. 461 F.2d 288 (7th Cir. 1972).
114. See id. at 289.
115. See id.
116. See id. An ophthalmologist diagnosed Singer’s visual field as constricted, and stated that her central vision was diminished and her side vision had been completely lost. See id.
117. See Singer, 461 F.2d at 289.
118. See id. at 292.
119. See id.
120. See id. Although the doctor acted negligently by prescribing Aralen for long-term use while those in the medical field were aware of its deleterious effects, the court still determined that the manufacturer would be held liable for manufacturing and marketing Aralen without adequate warning. See id.
In *McCue v. Norwich Pharmacal Co.*, the patient, Ellen McCue suffered from a chronic urinary infection. The physician directed treatment that included long-term therapy with the prescription drug, Furadantin. Norwich Pharmacal Company, the manufacturer of Furadantin, failed to warn doctors of possible side effects from continuous use of this drug. Due to McCue's uninterrupted use of Furadantin, she developed pulmonary fibrosis. At the conclusion of the presentation of evidence by all parties, the jury found that the manufacturer knew that there was a possible side effect for patients using Furadantin long-term, and that the manufacturer failed to give adequate warning to the medical profession. Subsequently, the jury found Norwich liable for damages.

The general rule is that a warning should go directly to the consumer when a manufacturer is able to convey a practicable and understandable warning, although this is unlikely in most circumstances. In the usual case, there is a duty to warn the medical profession. If the manufacturer fails in either stipulated capacity, liability may result.

The manufacturer seems to be the most popular target in the Fen-phen suits. Around the United States, a wave of litigation has developed for product liability suits and other legal actions against the drugs' manufacturers. Even with the learned intermediary doctrine, there remains some manufacturer liability in the production of prescription drugs. Presuming that the best cause of action for a plaintiff is breach of a duty to warn, the claimant may include in the suit the manufacturer's failure to warn of known dangers, unknown dangers, and those dangers that

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121. 453 F.2d 1033 (1st Cir. 1972).
122. See id. at 1034.
123. See id.
124. See id.
125. See McCue, 453 F.2d at 1033.
126. See id. at 1035.
127. See Flannagan, supra note 85, at 421-23.
128. See id.
129. See id.; see also United States v. Evers, 643 F.2d 1043, 1052 (5th Cir. 1981).

The distributor of a non-prescription drug must provide adequate information for use by a layman, for patients are allowed to administer those drugs without the advice of a physician. The distributor of a prescription drug, however, must provide adequate information to the prescribing physician in accordance with the specific conditions of the [statutes or regulations.]

*Id.*

130. See Tort Binge ..., supra note 9, at 3.
should have been discovered with reasonable care.\textsuperscript{131} The decisions of previous cases have been inconsistent leaving the outcome of Fen-phen claims difficult to predict. In \textit{McCue}, the manufacturer was found liable because it failed to warn of the possible side effects of pulmonary fibrosis caused by long-term use of the drug.\textsuperscript{132} The court found the manufacturer liable based on the fact that it \textit{knew} of the danger, but did not warn of it.\textsuperscript{133} However, in \textit{Odgers v. Ortho Pharmaceutical Corp.},\textsuperscript{134} where the plaintiff suffered partial paralysis due to blood clotting caused by an oral contraceptive, the defendant pharmaceutical company was entitled to summary judgment because the court said the doctor had been adequately warned and the warning to the doctor proved there was no causal relationship between the manufacturer’s duty to warn and the paralysis.\textsuperscript{135} \textit{Odgers} is comparable to \textit{McCue} because the manufacturer in both cases \textit{knew} of the possible side effects; however, in \textit{Odgers}, the manufacturer was absolved of liability because it satisfied its duty to warn.\textsuperscript{136}

In the Fen-phen situation, there were warnings regarding the danger of the possibility of brain damage and pulmonary hypertension.\textsuperscript{137} The heart-valve defects were only discovered shortly before the ban.\textsuperscript{138} The manufacturers followed FDA guidelines\textsuperscript{139} to warn doctors of the known

\begin{footnotes}
\item [132] See \textit{McCue} v. Norwich Pharmacal Co., 453 F.2d 1033, 1033 (1st Cir. 1972).
\item [133] See \textit{id.} at 1034.
\item [135] See \textit{id.} at 867.
\item [136] See \textit{id.}
\item [137] See \textit{Lemonick, supra} note 2, at 80.
\item [138] See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, \textit{supra} note 18, at 1. As of August 22, 1997, the FDA received 82 reports of cardio-vascular disease in Fen-phen patients. The ban on the drug cock-tail was imposed September 15, 1997. See \textit{id.}
\item [139] See 21 C.F.R. § 1.21 (1997).
\end{footnotes}
dangers, and there appears to be no evidence to show that the manufacturers of Fenfluramine and Phentermine should have known of potential heart-valve disfigurement caused by the use of the combined drugs.\textsuperscript{140} Here, it must also be noted that the drugs were not manufactured jointly, the doctor was solely responsible for prescribing their use in combination. Still, a plaintiff’s case against the manufacturer may have some merit when arguments are posed that more thorough testing should have been conducted. Possible justifications for better testing are that the manufacturer had reason to believe the diet drug would be misused, or that there was widespread use of the drug cocktail and therefore, testing the combination of the drugs was necessary. In summation, to find the manufacturer negligent due to deficient warnings, a plaintiff must prove that: (1) the manufacturer knew that the drugs were not approved for use in combination; (2) the manufacturer actively marketed the drugs in combination use for weight reduction; (3) the manufacturer profited from the drugs combined use; and (4) the manufacturer failed to adequately assure that the combined use was safe.\textsuperscript{141}

3. The Doctor

In situations where doctors prescribe drugs for patients, courts must have wide discretion in determining whether the facts truly point to a doctor’s liability through malpractice. The first factor that a court considers is the adequacy of the manufacturer’s warning to the doctor.\textsuperscript{142} The success of malpractice and negligence claims against a doctor depend upon the adequacy of the warnings.\textsuperscript{143} However, once warned by the manufacturer, the doctor has complete discretion to decide whether the particular drug is appropriate for a patient.\textsuperscript{144} This is especially true

\textsuperscript{140} Lemonick, \textit{supra} note 2, at 76. “[C]linical trials reveal only the most obvious side effects; the heart-valve changes discovered . . . do not initially cause visible symptoms in most patients.” \textit{Id}.

\textsuperscript{141} Interview with Rebekah Arch, \textit{supra} note 84.

\textsuperscript{142} See Werner v. Upjohn Co., 628 F.2d 848, 852 (4th Cir. 1980).

\textsuperscript{143} See \textit{id.} at 860. The court stated, “Dr. Carbo’s duty to his patient was so bound up in the warnings given by Upjohn, that we do not believe a judgment against him should be allowed to stand when the record contains error going to the most fundamental question in the case: the adequacy of the warning.” \textit{Id}.

when doctors prescribe an off-label combination of drugs. Because doctors keep drugs in their offices for patients’ use, they are clearly part of the distribution process and may be held liable for misbranding drugs.\textsuperscript{145}

In \textit{Leesley v. West},\textsuperscript{146} consumer Sylvia Leesley brought an action against various defendants for damages resulting from gastrointestinal bleeding caused by the prescription drug, Feldene.\textsuperscript{147} Due to the fact that the injury was not considered foreseeable by the manufacturer, the court concluded that there was no duty to warn.\textsuperscript{148} In addition, the learned intermediary doctrine applied, and the manufacturer was exculpated of any wrongdoing.\textsuperscript{149} The court then decided that the doctor was not liable because the manufacturer gave the required warnings to the physician and the drug was distributed in the usual manner.\textsuperscript{150} However, a different court may have found the doctor liable because the possibility of an injury for an individual consumer varies greatly depending on the patient’s medical history and their condition.\textsuperscript{151} Because the doctor is usually considered the learned intermediary, who possesses the knowledge required to evaluate the danger of a particular drug, the doctor is vulnerable to liability. Additionally, physicians who use their expertise to create off-label uses for drugs place themselves at an even greater risk of liability.

In \textit{Espinosa v. Alford},\textsuperscript{152} a doctor prescribed Bumex, a diuretic, and Fastin, an appetite suppressant, for a patient who asked for assistance in losing weight.\textsuperscript{153} The patient developed diabetes due to the off-label prescription of these drugs.\textsuperscript{154} In this case, the court noted the doctor’s negligence in failing to perform blood work to see if this off-label prescrip-

\textsuperscript{145} See United States v. Evers, 643 F.2d 1043, 1049 (5th Cir. 1981). Additionally, doctors prescribing off-label walk the fine line of dabbling in experimental drugs and may run the risk of lack of informed consent liability. \textit{See id.}

\textsuperscript{146} 518 N.E.2d. 758 (Ill. App. Ct. 1988).

\textsuperscript{147} \textit{See id.} at 759.

\textsuperscript{148} \textit{See id.} at 760.

\textsuperscript{149} \textit{See id.} at 762. “The fact that manufacturers of a prescription drug cannot adequately evaluate the effect of the drug on any particular patient is one of the predominant reasons that courts have adopted the learned intermediary doctrine exempting those manufacturers from the duty to directly warn consumers.” \textit{Id.}

\textsuperscript{150} See \textit{Leesley}, 518 N.E.2d at 758.

\textsuperscript{151} \textit{See id.} at 762.

\textsuperscript{152} No. 92-02936 (295th Dist. Ct., Harris County, Tex., Aug. 1995).


\textsuperscript{154} \textit{See id.}
tion was appropriate for the patient. The court was not provided the opportunity to rule on the case because the parties settled. Even though it is common practice, the doctor takes a risk when prescribing drugs off-label. However, not all courts are sympathetic to the plaintiff in off-label prescription cases. Contrary to Espinosa, the court in Werner v. Upjohn Co. decided in favor of the doctor. The plaintiff, Jack Werner, was prescribed Cleocin to relieve a chalazion on his eyelid. A known side effect of the drug was diarrhea. The plaintiff’s condition eventually resulted in the removal of part of his colon and additional operations to restore his excretory functions. Additionally, the patient continues to suffer certain effects from the ingestion of the drug. Werner brought an action to recover damages, but the court determined that the doctor’s duty to his patient was so intertwined with the manufacturer’s warnings that a judgment against the doctor would be unjust.

The success of a Fen-phen claim against the prescribing physician will depend upon the degree of information the doctor gave the patient in relation to the possible side effects and/or the dangers of the drug for that particular patient and his susceptibilities. The physician would not have been required to warn of the heart-valve problems because they were not known; however, the dangerous character of the drug, due to

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155. See id.
156. See Verdict in Suit Involving Medications Prescribed to Assist Patient in Losing Weight, supra note 153, at 367.
157. See Rheingold, supra note 17, at 22.
158. 628 F.2d 848 (4th Cir. 1980).
159. See id. at 860.
161. See Werner, 628 F.2d at 852.
162. See id.
163. See id.
164. See id.
165. See supra note 143 and accompanying text.
166. See Flannagan, supra note 85, at 412.
the known lung and brain risks, and any possible reservations about a particular patient taking the combination diet drug therapy, should have been divulged to the patient.

The FDA took steps to discourage the off-label use of Fenfluramine and Phentermine. Because of the FDA's clear suspicion of Fen-phen, it has been suggested that doctors should have done extensive testing on patients who were prescribed the drug therapy for weight-loss. The tests should have included an echocardiogram as a way to examine the valves of the heart. The facts in *Espinosa* are strikingly similar to those in the Fen-phen cases. Consequently, because the doctor in *Espinosa* was found liable, there is a strong implication that doctors who prescribed Fen-phen will be liable rather than the FDA or the manufacturers.

One item to note in the Fen-phen cases is that because dieting is so prevalent in the United States, when these seemingly miraculous drugs came on the market, weight-loss centers were established all over the country. In an interview with a doctor, who went bankrupt due to the ban, the doctor revealed that business was so intense, that authorization to use Fen-phen was given to patients over the telephone, and often clinics would forgo proper testing to quickly administer the diet drug therapy. One particular doctor blatantly stated that he disagreed with the FDA's recommendations and believed Fen-phen needed to be prescribed over the long haul in order to achieve weight-loss success. In many cases, doctors simply gave a lecture to fifty to seventy-five "patients" at a time and then prescriptions were handed out under circumstances where the physical exam consisted of only a questionnaire.

The feasibility of a negligence claim depends on each patient's experience with their own doctor. These fact-specific circumstances do not lend themselves to the class action suits that are being filed today. According to the Federal Rules of Civil Procedure, a prerequisite to a class action suit is that there are questions of law or fact common to the members of the class. In diet prescription drug cases such as Fen-

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167. See Rheingold, *supra* note 17, at 22.
168. See *id.* at 26.
169. See *id.* at 26.
171. See *id.* at A1, A14.
172. See *id.* at A1.
173. See *supra* note 84.
174. See *supra* note 9 and accompanying text.
175. FED. R. CIV. P. 23(a)(3).
phen, there are too many variables in each plaintiff’s case making it impossible for all of the members of the class action suit to have common questions.

Some of the litigation has been filed under Multi-District Litigation, which means the cases are tried jointly on causation issues only. Where factual circumstances differ greatly, this is a more reasonable route for prescription diet drug legal proceedings. The issue of causation, whether the jury finds that Fen-phen is the cause of the heart injury, will be common for all plaintiffs. Subsequently, cases may be separated depending on the specific facts and circumstances of each plaintiff.

B. The Best Common Law Claim Against Fen-phen

1. Negligence

Establishing liability in a negligence suit against a drug-related defendant will focus on the reasonableness of the defendant’s conduct. The elements are much like any other negligence claim: (1) the defendant owed the plaintiff a duty to act reasonably; (2) the defendant breached that duty; (3) the plaintiff suffered actual harm; and (4) the harm was proximately caused by the breach of duty.

Previous suits involving negligence claims and prescription drugs have been filed against the FDA, the manufacturer of the drugs, and the prescribing physician of the drug that caused the health impairment. The outcomes of the court decisions are dependent upon the plaintiffs’ ability to prove the elements of the negligence claim. In Smith v. Wyeth Laboratories, Inc., a vaccine for diphtheria, tetanus, and pertussis was manufactured and marketed by Wyeth Laboratories and administered to the plaintiff. As a result, the plaintiff suffered severe neurological damage. The court held that there was no negligence

175. Interview with Rebekah Arch, supra note 84.
176. See Gibbs & Mackler, supra note 45, at 197.
177. See id. at 197-98. “The negligence can occur at any point in the product’s life: in designing, testing, manufacturing, or labeling of the product.” Id. at 197.
178. See discussion supra Parts IV.A.1, IV.A.2, and IV.A.3.
179. See Gibbs & Mackler, supra note 45, at 197-99.
181. See id. at *1-2.
182. See id. at *1.
claim because there was no evidence that the vaccine was manufactured, stored, tested, transported or handled inadequately.\textsuperscript{183}

When considering the Fen-phen case, there are weaknesses that a potential plaintiff must overcome to sustain a negligence claim. Though it is obvious that there is a duty of care owed to patients by all possible defendants, including the FDA, the manufacturer, and the prescribing doctor, whether there was a breach of that duty depends on the circumstances of each case and each defendant. The harm is evident, judging not only from the heart problems diagnosed, but also, the surgeries and the deaths that occurred. However, whether Fen-phen proximately caused the waxy coating on the valves is yet to be determined.\textsuperscript{184} Fen-phen case decisions will depend on the physical evidence of this valve coating and will eventually turn on whether breach and causation can be proved.

In reality, most cases will join as many defendants as possible in an action for damages. For the purposes of this Comment, the FDA will not be the subject of discussion in relation to causes of action because of its built-in protection from liability under the discretionary function.\textsuperscript{185} The manufacturer also has protection under the learned intermediary doctrine,\textsuperscript{186} but liability will depend on fact-specific circumstances. Recently, much prescription drug litigation has been centered around joining the manufacturer as a defendant, and therefore much theory has been developed on manufacturer liability.\textsuperscript{187} Although the facts will play a crucial role, the prescribing doctor is left vulnerable to liability, especially in regard to off-label prescriptions.

The majority of negligence claims against a drug manufacturer allege a negligent failure to warn of the drug’s possible dangers on the label.\textsuperscript{188} The FDA imposes certain regulations concerning labeling and

\begin{\footnotesize}
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\item See id. at *10.
\item See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, \textit{supra} note 18, at 2.
\item See discussion \textit{supra} Part IV.A.1.
\item See discussion \textit{supra} Part IV.A.2.
\item See \textit{Flannagan, supra} note 85, at 406.
\item See Gibbs & Mackler, \textit{supra} note 45, at 146. "An action for negligent failure to warn offers several advantages to the plaintiff, such as a narrower set of factual issues and more favorable legal standards. The focus . . . is upon the adequacy of the warning in the labeling to the patient’s physician, the 'learned intermediary.'" \textit{id.}
\end{enumerate}
\end{\footnotesize}
The FDA, when imposing labeling precautions, balances the benefits of the drug, against the drug's risks. However, when a state tort law claim, such as failure to warn, which is often used in prescription negligence cases, is argued, it is premised on the fact that the labeling regulations imposed by the FDA are faulty. Ironically, these claims impose liability on those manufacturers that followed codified law. Notwithstanding this irony, the test imposed to determine the adequacy of the label is whether the physician, and therefore, the patient was provided with the detail needed to make an informed decision regarding the drug therapy. A plaintiff must prove three elements in a negligent breach of duty to warn claim: (1) the plaintiff must show the manufacturer knew or should have known the danger of the drug; (2) the manufacturer must not have had any reason to believe that those taking the drug would realize the drug's danger; and (3) the plaintiff must prove the manufacturer did not take reasonable steps to inform those taking the drug of its dangerous condition. If the plaintiff proves all three elements, the manufacturer may be held liable for damages.

A failure to warn will most likely be the best cause of action for a Fen-phen plaintiff to prevail against a manufacturer. This is because the

189. See Geiger & Rosen, supra note 40, at 396; see also supra note 116 and accompanying text.
190. See Geiger & Rosen, supra note 40, at 416-17.
191. See id. at 419.
192. See id.
State tort claims, on the other hand, whether premised on strict liability, negligence, or breach of warranty, are predicated on a challenge to the correctness of the FDA’s decisions and as such directly conflict with the FDA’s determination as to the optimal way to protect public health. Indeed, it is physically impossible for manufacturers to comply with both the FDC Act and state tort law when the former requires that a drug be marketed and labeled as approved by the FDA and the latter requires that it not be.

Id. at 417.

193. See Gibbs & Mackler, supra note 45, at 198.
   (a) Knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it was supplied, and (b) has no reason to believe that that [sic] for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Id.

195. See id.
manufacturer perhaps knew, or should have known, of the possible heart problems caused by Fen-phen. Manufacturers are required to continually investigate and update the information and labeling of their products on the market; this includes conducting appropriate tests as new questions arise. However, it remains difficult to determine the extent of the manufacturer's knowledge concerning the use of the drugs as a cocktail because the limited information that the manufacturer provides on the consumer warning is not representative of all that it knows. Evidence shows that the possibility of heart-valve disfigurement was never tested or conveyed to doctors or consumers. In addition, the circumstances show that Fen-phen was touted as a miracle drug by both the media and prescribing physicians, which could dilute the warnings that were included in the packaging. Manufacturers benefitted monetarily from the Fen-phen publicity that lured consumers, but did not take action or responsibility for the possible side effects of the mass consumption of the drug. Furthermore, before the ban, the FDA required manufacturers of Phentermine and Fenfluramine to revise the drugs' labels as well as the patients' package inserts to stress the potential risks associated with the drug. The FDA wanted to ensure that consumers and prescribers alike understood the potential risks involved in the long-term use of the diet products.

Although some facts may point to manufacturer liability, the doctor is also subject to liability in prescription drug cases such as Espinosa. The consumer is usually provided limited information on the label, while the physician is provided with detailed information including ex-

196. See Gibbs & Mackler, supra note 45, at 198-99.
197. See id.
198. See id. at 198.
199. See Cowley & Springen, supra note 23, at 47.
201. See Heidi M. Connolly et al., Valvular Heart Disease Associated with Fenfluramine-Phentermine (visited Oct. 22, 1997) <http://www.cnn.com/HEALTH/9707/08/fenphen.report> at 8. Fen-phen manufacturers provided inadequate warning for doctors to conduct proper testing for heart problems. See id. Consequently, no routine pretreatment echocardiographic baseline studies are available for the affected patients. See id.
202. See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, supra note 18, at 1.
203. See id. at 2.
204. See discussion supra Part IV.A.3.
tensive test data and performance characteristics. The FDA is required to provide the physician with complete data on the drug to enable the doctor to function as the "learned intermediary." In some courts, there is a presumption that a physician would not administer a drug without adequate warning, but other courts have left the burden with the plaintiff to show that the warning would have caused a different medical decision. In the Fen-phen situation, there may even be evidence to show that the patient, given adequate warning, would still have decided to take the drug, despite the drug's inherent risk in an effort to lose weight. This will play an important role in pure contributory negligence jurisdictions.

When evaluating the strength of a Fen-phen plaintiff's case, counsel should consider whether the warning could be deemed to have been diluted by over-promotion, statements by salesmen, and/or language in the warning. Attorneys will also need to review reported scientific studies, reports submitted to the FDA, and any reports submitted to the manufacturer to determine if the manufacturer should have known of the risk.

2. The Strict Liability of the Manufacturer

Strict liability provides that a manufacturer who sells a drug which is unreasonably dangerous to the consumer will be liable if the production of the drug was in its normal course of business and the drug reaches the consumer without being touched or contaminated.

205. See Gibbs & Mackler, supra note 45, at 198-99.
206. See id. at 199. "[T]he duty is a continuing one - the manufacturer must stay abreast of all new scientific developments during the life of the product that could require modification of the labeling. Warnings must be continually updated, and appropriate tests conducted when new questions arise." Id.
207. See Heafey & Kennedy, supra note 131, § 10.03 at 10-18.
208. Henry Cohen, CONG. RES. SERVS. - THE LIBRARY OF CONGRESS, American Law Div., at 5-7, (June 20, 1995). There are six remaining contributory negligence jurisdictions, Alabama, District of Columbia, Maryland, North Carolina, South Dakota and Virginia. See id.
211. RESTATEMENT (SECOND) OF TORTS § 402A (1965).
212. Gibbs & Mackler, supra note 45, at 199. If a product shows signs of tampering and is still sold, liability will attach to the seller. See id.

One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to
An action in strict liability is designed to alleviate the plaintiff's burden of proving negligence during the manufacture of the drug. Instead, the plaintiff must prove an inherent defect in the drug to prevail with a strict liability claim. Whether a drug case may be considered under strict liability is determined on a case-by-case basis. In the pharmaceutical industry, virtually all products will have an inherently unsafe aspect to them or a propensity to induce a side effect. Fen-phen was administered to patients with the understanding that it had caused brain damage in laboratory animals. Redux® had also been linked to primary pulmonary hypertension that could prove fatal. However, weakening a Fen-phen plaintiff's case is the fact that the heart-valve problem had never been identified as an issue. Furthermore, strict liability will not excuse Fen-phen plaintiffs from the burden of proving proximate cause between injury and the drug defect. As the facts stand, there is no definite causal connection between the drugs and the heart problems. Cardiovascular tests were never run for this pool of patients before treatment to determine if they had heart problems prior to drug therapy. Furthermore, when dealing with an overweight population, there is always a tendency toward heart problems due to the

liability for physical harm thereby caused to the ultimate user or consumer, or to his property if: (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Id.

213. See id.
214. See BLACK'S LAW DICTIONARY, supra note 63, at 1422 (stating to invoke the doctrine of strict liability it is essential to prove the product was defective when placed in the stream of commerce). See, e.g., Smith, No. 84-2002, 1986 U.S. Dist. LEXIS 21331, at *11-*12.
216. See Gibbs & Mackler, supra note 45, at 199-200.
217. See Today, Newscast: Florida banning phen-fen [sic] and Redux because of recent health concerns linked to individuals taking the drugs (NBC television broadcast, Sept. 9, 1997).
218. See Boodman, supra note 15, at 12. Primary pulmonary hypertension is also known as high blood pressure of the lungs. See id.
219. See Cowley & Springen, supra note 23, at 47.
220. See Gibbs & Mackler, supra note 45, at 199.
221. See Heart-valve Disease, supra note 20, at 2.
222. See Connolly et al., supra note 201, at 8.
strain on the heart caused by excess weight.223

The manufacturer of the drugs will be completely exonerated from
strict liability if the benefits of the drugs outweigh the risks caused by
possible side effects.224 This balancing test will be a strong defense in
those cases where an obese plaintiff has filed an action. The manufac-
turer may argue that the thirty percent risk of a heart-valve problem is
less risky than if the patient were to remain obese.225 Another possible
affirmative defense in cases involving an inherently unsafe product, is if
the manufacturer can prove that "the product is incapable of being made
safe given the present state of human knowledge, but that the product
possesses such a high degree of social need that its use is warranted."226
The social need for Fen-phen may be proven by the fact that in 1996,
Americans spent at least $467 million on prescription obesity drugs,227
and doctors wrote two and a half million prescriptions for Fen-phen,
exposing nearly sixty million people to the drugs worldwide by June
1997.228

Historically, courts have avoided deciding cases on strict liability the-
ory.229 In light of the fact that diet products are put on the market for the
purpose of alleviating a health problem, there is a general belief that
manufacturers should not be held strictly liable if the risk is
reasonable.230 In addition, there is no flexibility for fact-specific circum-
stances under strict liability. The resultant risk of a lawsuit poses a seri-
ous threat that could deter health research.231

223. See Lemonick, supra note 2, at 76. "[M]orbid obesity carries signifi-
cant risks of its own: heart disease, diabetes, high blood pressure and stroke." Id.
224. See Gibbs & Mackler, supra note 45, at 200.
226. See 63-AM. JUR. 2D Products Liability, supra note 215, § 591.
227. See Prouix, supra note 6, at 13.
228. See Golden, supra note 2, at 79.
229. See, e.g., McLeod v. W.S. Merrell Co., 174 So. 2d 736 (Fla. 1965)
(holding plaintiff had no strict liability claim for harmful side effects of an unadul-
terated drug when the prescription was properly filled).
230. See 63 AM. JUR. 2D Products Liability, supra note 215, § 591.
Provided that such products are properly prepared and marketed,
and proper warning is given a seller is not to be held to strict li-
ability for unfortunate consequences attending their use, merely
because he has undertaken to supply the public with an apparently
useful and desirable product, attended with a known but appar-
ently reasonable risk.

Id.
231. See supra note 9 and accompanying text.
a. Doctors, Risk/Benefit Analysis, and Comment k of Restatement (Second) Section 402(A)

Both the FDA, when approving an unavoidably dangerous drug, and the physician, when prescribing an unavoidably dangerous drug must consider risk/benefit analysis. In considering the risks and benefits, the doctor needs to take into account the benefit of the drugs, the patient’s health, and any alternatives such as surgery or therapy that may be available in a particular situation. Clearly, where the plaintiff is only ten to twenty pounds over the recommended weight, and the physician has prescribed Fen-phen as a first line of defense to the weight problem, it is unlikely that this situation will allow the doctor to say there was no better alternative.

However, risk/benefit analysis lends itself to a common defense for prescription drug handlers in strict liability suits. The reasoning behind the risk/benefit analysis is “[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended ordinary use.” The risk/benefit analysis allows a defense called the Comment k defense and it states that the product was unavoidably unsafe but still provided enough benefit that it should be prescribed. Comment k defenses can be defeated by proving either the risk was avoidable through more thorough testing, or the benefit did not outweigh the danger. Therefore, the claim becomes a negligence claim.

In Fen-phen litigation, strict liability claims are likely to fail because the FDA approved the individual drugs through the normal process, and therefore thought the drugs important enough to be marketed. The successful strict liability claim occurs where the physician has prescribed the Fen-phen drugs together for off-label use. In the Fen-phen

232. See Gibbs & Mackler, supra note 45, at 200.
233. See id. (stating that the risk is warranted regarding the side effects of chemotherapy when cancer is otherwise untreatable, but the same effects are not acceptable for one suffering from the flu).
234. Id.
235. See id. at 201 (citing RESTATEMENT (SECOND) § 402A cmt. k (1965)).
236. See id.
238. See 63A AM. JUR. 2D Products Liability § 1133 (1996) “[I]n the
situation, although the doctors were justified in relying on the materials from the manufacturer which promoted the combined use of Fenfluramine and Phentermine, they should have demanded more thorough testing based on the risk data regarding the lung and brain problems, and the vast number of patients receiving the drugs. The tests may have revealed that the benefits of the drugs no longer outweighed the dangers.\textsuperscript{239}

A plaintiff can defeat a Comment k defense with a public policy argument that the potential harm outweighs the public benefit.\textsuperscript{240} An obese patient may not succeed with this argument because there is a significant public benefit to helping severely overweight people lower their weight, therefore, possibly saving lives.\textsuperscript{241} In the case of slightly overweight individuals, this claim is also difficult to accept because the plaintiffs themselves were intrigued enough to take the drug. As a factual matter, the statistics and media coverage prove a significant public interest in prescription diet drugs.

\textit{b. Duty to Warn Under Strict Liability}

Much like the duty to warn under negligence theory, a manufacturer may escape strict liability if it has adequately warned the doctor and/or the patient of the risk.\textsuperscript{242} Because it is difficult to show that Comment k does not apply to a specific prescription, a plaintiff usually bases a strict liability claim on the inadequacy of product labeling.\textsuperscript{243} Comment j to section 402A of the Restatement\textsuperscript{244} explains this duty as a requirement of the manufacturer to warn or give directions to prevent the drug from being unreasonably dangerous.\textsuperscript{245} The manufacturer need not warn of the absence of any duty upon a seller to test an unavoidably unsafe drug for side effects, there is no duty on such seller to warn of side effects of which he has no knowledge.” \textit{Id.}

\textsuperscript{239} See Heafey & Kennedy, \textit{supra} note 131, § 10.03[2] at 10-22. “A manufacturer may also be liable for failing to warn of known or foreseeable misuses of its product.” \textit{Id.}

\textsuperscript{240} See Gibbs & Mackler, \textit{supra} note 45, at 201.

\textsuperscript{241} See Lemonick, \textit{supra} note 2, at 76 (stating morbid obesity carries significant risks including heart disease, diabetes, high blood pressure and stroke).

\textsuperscript{242} See 63A AM. JUR. 2D Products Liability, \textit{supra} note 238, §§ 1114, 1129.

\textsuperscript{243} See Gibbs & Mackler, \textit{supra} note 45, at 201.

\textsuperscript{244} See RESTATEMENT (SECOND) OF TORTS, \textit{supra} note 211, § 402A cmt. j.

\textsuperscript{245} See id.
dangers related to excessive or negligent use. The test for strict liability for duty to warn, much like the test for negligent duty to warn, is whether the doctor was properly apprized of all the information concerning the drug. Courts generally treat both duties to warn as having the same elements.

In Wyeth Laboratories, where the plaintiff suffered neurological damage because of a vaccine, and was denied a negligent duty to warn claim, the court also denied a strict liability duty to warn claim. The drug had a potential danger even when it was administered precisely as planned, and the manufacturers rigidly followed FDA procedures for manufacturing, testing, and labeling. Fen-phen suits are distinguishable from Wyeth Laboratories in that the two drugs used in the cocktail were prescribed off-label and, therefore, the FDA had no regulations for the drugs as a combined cocktail.

In general, the FDA does not want to interfere with the doctor/patient relationship. The question presented is whether the manufacturer had a duty to test the combination, when the drugs were not originally approved for the intermingled use the doctors were prescribing. As mentioned above, the manufacturer only would have a duty to test if it was aware of the danger. Whether the manufacturer was aware of the prevalent off-label use of Fenfluramine and Phentermine, and whether it had come to its attention that the drug cocktail posed a risk to consumers.

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Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use ... But a seller is not required to warn with respect to products ... which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized ... The seller may reasonably assume [the warning] will be read and heeded.

Id.

247. See Gibbs & Mackler, supra note 45, at 201.

248. See id. at 201-02.


250. See id. at *10-11.

251. See Health Advisory on Fenfluramine/Phentermine for Obesity, supra note 36, at 1.

252. See Heafey & Kennedy, supra note 131, § 10.03[1]. For example, there is concern that mandating direct patient warnings on prescription products would interfere with the doctor/patient relationship. See id.

253. See id. § 10.03[4].
ers’ health, will be matters for the fact finder to determine. In addition, when scrutinizing the language of Comment j, the law does not impose a duty to warn in situations where danger is generally known.\textsuperscript{254} When applied to Fen-phen, this proposition is not beneficial to a plaintiff’s case because the public had knowledge through label warnings, of the risk of brain and lung damage caused by Fen-phen and the general knowledge that these diet drugs were only to be ingested short term as mandated by the FDA.\textsuperscript{255}

3. Breach of Implied Warranty or Contract

The allegations of breach of implied contract to a prescription drug case are as follows: "(1) breach of the warranty of merchantability, (2) breach of an implied warranty, or (3) breach of an express warranty."\textsuperscript{256} The Uniform Commercial Code assumes all goods in commerce are merchantable through an implied warranty.\textsuperscript{257} However, a manufacturer cannot be responsible under any implied warranty to insure against a particular patient’s susceptibility\textsuperscript{258} because "a prescription drug with a legally adequate warning does not breach the implied warranty of merchantability even if it causes adverse side effects in some users."\textsuperscript{259}

It may be difficult for Fen-phen users to allege a breach of an implied warranty because presently, not all users have shown signs of heart-valve regurgitation.\textsuperscript{260} In fact, some patients and care givers who have met with great success via the drugs are quite unhappy with the manu-

\textsuperscript{254} See supra note 246 and accompanying text.
\textsuperscript{255} See Health Update, What’s Hot! What’s Not!, supra note 25, at 1.
\textsuperscript{256} Gibbs & Mackler, supra note 45, at 202.
\textsuperscript{257} See id.
\textsuperscript{259} Id. at *19 (citing Fellows v. USV Pharm. Corp., 502 F. Supp. 297 (D. Md. 1980)) (emphasis added).
\textsuperscript{260} See Lumpkin, supra note 19, at 1.

As of July 8, 1997, there have been 33 cases reported to FDA of unusual valvular morphology and regurgitation involving the mitral, aortic, and/or tricuspid valves, usually being multivalvular. About half of the women were reported to have pulmonary hypertension with their valvular disease. All 33 patients were American women with a mean age of 43.3 years (range: 35-72), all of whom had received combined fenfluramine an phentermine therapy for between 1 and >16 months (mean 10) before presentation of their valvular disease.
manufacturers' recall. The success of the breach of warranty claim lies within both, an implied warranty, which may be difficult to prove, and the breach of merchantability, which is unlikely to succeed, because of prior FDA approval.

Much like a claim for breach of implied warranty, a breach of an implied contract has logistical problems. The manufacturer never claimed that Fen-phen did not cause heart problems, it only claimed patients would lose weight, which occurred in most instances.

C. Defenses

1. Primary Assumption of the Risk

Under the affirmative defense of primary assumption of the risk doctrine, the defendant has not breached a duty of care to the plaintiff and, therefore, there is a complete bar to recovery. This would apply in situations where the FDA, the manufacturer, and the doctor have all followed guidelines as accurately as possible and warned of all known risks that are applicable to the prescription drug. In the Fen-phen claims, this defense is feasible because the heart-valve coating was not a known danger, nor should it have been known. Thus, there was no breach of a duty when the industry only warned of the brain and lung risks.

The data of these specific risks that were involved with Fen-phen were disclosed to the patients in some cases and, therefore, for those patients, the duty of care was satisfied. The patients, especially those who were only using the drugs for cosmetic purposes, assumed the risk by utilizing this weight-loss method with the knowledge of its dangers. A comparison can be drawn to consumers of oral contraceptives, be-

261. See Cowley & Springen, supra note 23, at 47 (stating that the ban could set back obesity treatment for many years).
262. See Stecklow & Johannes, supra note 169, at A14. Dr. Bowen’s Centers for Medical Weight Loss issued a brochure boasting an “astounding 93% success rate.” Id.
263. See 57A AM. JUR. 2D Negligence § 810 (1989).
264. See Cowley & Springen, supra note 23, at 47; see also Lemonick, supra note 2, at 80.
265. See 57A AM. JUR. 2D Negligence, supra note 263, § 810.

Whereas a patient’s involvement in decision making concerning use of a prescription drug necessary to treat a malady is typically
cause, in both situations, the patient was actively involved in choosing their own method and the prescribing physician was relegated to a passive role. Even though the Fen-phen patients may not have predicted heart problems, it is likely they were aware that there were safer ways to shed pounds. Therefore, injured patients assumed the risk of their injury or of the possibility of injury.

2. Secondary Assumption of the Risk and Contributory Negligence

Generally, assumption of risk operates on two grounds. First, the plaintiff implicitly accepts the known risks of taking Fen-phen. Second, it would be unfair to impose liability on a defendant for the plaintiff's own negligence. Fen-phen was put on the market with the understanding that it caused brain damage in laboratory animals, and was linked to primary pulmonary hypertension. The small-print information sheets that are included in the packaging of the pills acknowledged these risks.

Additionally, secondary assumption of risk is similar to contributory negligence in that it relies on the reasonable person standard to determine the possibility of shared liability for the plaintiff. This affirmative defense is jurisdiction-specific, and for some defendants it may
mitigate damages. The cases encompassed by this doctrine involve defendants who have breached a duty owed to a plaintiff who has knowingly encountered an injury caused by that breach. In *Singer*, the court held Sterling, the manufacturer, strictly liable unless Singer, the patient, "did affirmatively assume the risk" in taking Aralen for a rash. This could be determined by any misuse or misconduct by the plaintiff. Secondary assumption of the risk may be a defense for those manufacturers who breached their duty to warn. However, in light of other warnings, these manufacturers can claim that the plaintiffs took a drug known to be harmful. Some evidence for the defense of secondary assumption of risk rests in the simple fact that professionals in the diet field have commented that there was curiously little in the way of national outrage.

V. COMMENT: A FAT RESPONSIBILITY TO ONESELF

The "discretionary rule" and the "learned intermediary doctrine" are illustrative of the methods the law has developed to protect health care industry professionals from frivolous claims. The FDA, drug manufacturers, and physicians play important roles in our society and deference is paid to their good faith judgments.

A successful claim in a Fen-phen case will depend largely on subjective circumstances unique to the case, including who is the complainant. Examples of issues that will have a bearing on the success of a case are: whether the plaintiff followed a doctor's instructions, whether the instructions were adequate, and whether the plaintiff read, and understood the warnings, if there were any.

Another factor in Fen-phen cases is the role of society and the media. There is a societal pressure to be thin, and women are increasingly turning to prescription drugs to solve their weight problems. The me-synonymous with contributory negligence." *Id.* See also *supra* text accompanying note 208.

278. *See id.*
279. *See* Johnson, *supra* note 237, at 490. "'I'm still waiting for some reaction,' says Joe Risser, M.D., the director of Clinical Research at the Lindora Medical Clinics, a group of weight-loss centers located in Southern California . . . ." *Id.*
280. *See* discussion *supra*, Parts IV.A.1, IV.A.2.
dia’s impact on the desire to stay thin is significant. Its effect is evidenced by courts stating that if a manufacturer advertises a drug to the consuming public, the manufacturer has an automatic duty to warn patients, not the doctor, thus constituting an exception to the learned intermediary rule. \textsuperscript{282} NBC Nightly News commented in 1996, “[t]he sales of these drugs have increased 5,000 percent in the last year.” \textsuperscript{283} The media binge included numerous web-sites that are now posted with “TEMPORARILY CLOSED FOR REMODELING” messages, \textsuperscript{284} and the best-selling diet book, THE REDUX REVOLUTION. \textsuperscript{285} By saturating the market with information of miracle diet drugs many inappropriate candidates sought prescriptions. The media’s role supports a plaintiff’s case to some extent in the fact that the advertising could be considered misleading. However, the media’s part in the Fen-phen tragedy may also be supportive of a defendant’s case because the media is representative of society’s, and therefore individuals’, overzealous attitude about weight loss.

The media is not likely to be joined as a defendant in diet prescription drug suits, especially given the First Amendment protections for commercial speech. Therefore, it is unfortunate and unfair that the health care industry finds itself submerged in voluminous liability as a result of over-publicity.

\textit{A. The Obese}

As compared to individuals desiring to shed a few pounds, obesity is an illness that is more appropriately treated with diet prescription drugs such as Fen-phen. \textsuperscript{286} For those who fight a desperate struggle with their weight just to be healthy, Fen-phen was an answer. \textsuperscript{287} Medical professionals still endorse the use of prescription diet drugs to treat the obese. \textsuperscript{288}

\textsuperscript{282} See Heafey & Kennedy, supra note 131, § 10.03[1][a] at 10-21.
\textsuperscript{283} See NBC Nightly News, supra note 5.
\textsuperscript{284} See Johnson, supra note 237, at 490.
\textsuperscript{285} See id. (emphasis added).
\textsuperscript{286} See NBC Nightly News, supra note 5 (stating that obesity will be treated much like high blood pressure or diabetes because, when obese patients stopped taking the drugs, they immediately began to regain weight).
\textsuperscript{287} See John Schwartz, supra note 27, at A6. “The diet drugs in conjunction with exercise and diet programs, have ‘given patients a lot of hope, a sense of optimism about finally getting control’ over their weight.” Id.
\textsuperscript{288} See Boodman, supra note 15, at 13. “Big, fat people are different.
An interview conducted with Marge Friel, a five-foot seven-inch, forty-eight year old secretary weighing 230 pounds, revealed the positive results of Fen-phen in weight loss therapy. Friel claimed that drug therapy was the only thing to work and that as soon as she was taken off the drug she gained fifteen pounds in nine weeks. Friel says, “It’s a tradeoff. I may be safer taking those drugs than I am being really, really heavy.”

In another success story, Beth Herwig says that after twenty-nine years of dieting she finally dropped from 545 pounds to 265 pounds on her five foot four inch frame. Though these women tout Fen-phen as a miracle drug, it is conceded that the weight loss from taking Fen-phen will not last unless some behavior modifications are made, such as exercise and proper diet.

B. The Chubby

Drug regulators have indicated their desire to keep diet drugs available simply for those who are seriously obese while preventing their abuse by people who just want them for cosmetic reasons. Since the Fen-phen ban, the FDA requires strict wording on diet drug labels, stating that these products should only be used by the severely obese.

One of the most famous Fen-phen cases to attract attention was the fatal heart attack of the wife of the Mayor of North Miami Beach. Patricia Ann Mishcon had been taking Fen-phen for six months to shed about ten pounds. She received her prescription from an ophthalmologist running a weight-loss clinic. In fact, many doctors freely pre-

They’re sick and they have a biochemical defect’ that is amenable to drug therapy.”

Id.

290. See id.
291. Id. at 46-47. “It’s a fiasco for patients who have lost weight and improved their health.” Id. at 47.
292. See Lemonick, supra note 2, at 75. Herwig states, “It’s not that I don’t want that Twinkie still . . . [B]ut before, I would see it, and there was almost nothing that could stop me.” Id.
293. See Hayes, supra note 273, at 15.
294. See Today, supra note 217.
295. See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, supra note 18, at 1.
296. See Boodman, supra note 15, at 12.
297. See id.
298. See id.
scribed the diet drugs without the proper screening. One sympathetic doctor prescribed Fen-phen as a solution for a woman who had gained twenty pounds during pregnancy and wanted to shed the weight quickly. She developed pulmonary hypertension and will struggle to breathe for the rest of her life. Even though the drugs were approved only for the morbidly obese, it seems that many who do not fit this category are being lured by the "drug solution" to lose a couple of pounds, despite the warnings accompanying these drugs.

VI. CONCLUSION: SOCIETY EATS WHAT IT IS FED

In reality, most plaintiffs will plead all claims that remotely apply and join all possible defendants in a suit, but very rarely, will the entire suit be successful. This discussion reveals that class action suits against the manufacturer, though usually the most monetarily rewarding, may not be as legally sound as other suits. The prescribing doctors who took the off-label risks may be the true Fen-phen defendants. But where the doctor has acted with the best medical knowledge known at the time, the patient will need to take responsibility for his own actions.

The purpose of this Comment is to reveal both the strong and weak arguments against potential defendants in litigation resulting from heart defects allegedly caused by Fen-phen. Perhaps more importantly, this Comment seeks to raise an awareness of the roles society and individuals play in exposing victims to the dangers of these so-called miracle weight loss drugs to take the place of exercise and a healthy diet.

In the end, diet and exercise still are effective measures for weight loss, but ""[o]f course, it is not magic. People have to work at it, and we're a pill-popping society' looking for an easy quick fix."

Physician, David Satcher, now Surgeon General, still promotes, ""[t]he best approach to combating obesity is through physical activity."
cans continue to idolize the thin; despite this, over a third of the population is overweight and will “swallow any cure that comes along,” including potentially fatal diet pills.\(^{305}\)

The diet drug industry will continue to grow and develop in order to help those who truly need assistance for weight loss, and in order for the industry to financially profit. The replacement for Fen-phen is rumored to be Phen-pro, a combination of Phentermine and Prozac.\(^{306}\) Others say, the new diet drug will be Meridia.\(^{307}\) Generically known as Sibutramine, Meridia ironically has the same precautionary warning that it should only be taken by the obese.\(^{308}\) Commentators state, “[Y]ou’d think that drug makers would have learned their lesson. But scientists (and the public) will probably never let go of the idea that some day a magic pill will make people thin.”\(^{309}\) Patients need to abandon their search for the easiest way to lose weight, and determine what is the most practical and safest way for them to lose weight.

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\(^{305}\) See Hayes, _supra_ note 273, at 15.

\(^{306}\) See Boodman, _supra_ note 15, at 12-13. “[Since the Fen-phen ban] diet clinics, commercial weight-loss programs including Nutri/System and obesity doctors have been scrambling to come up with alternatives . . . .” _Id._ See also Lemonick, _supra_ note 2, at 82 (“[I]n the wake of the Redux-fenfluramine debacle, it could be many years before the FDA is ready to approve the new drugs.”).


\(^{308}\) See _id._

\(^{309}\) See _id._