

January 2004

How the Rise of Federal Bureaucratic Powers Challenges the Role of Courts in Adjudicating Claims of Injury Inflicted by Prescription Drugs

Denise K. Top

Follow this and additional works at: <http://digitalcommons.law.ggu.edu/ggulrev>

 Part of the [Consumer Protection Law Commons](#), and the [Health Law and Policy Commons](#)

Recommended Citation

Denise K. Top, *How the Rise of Federal Bureaucratic Powers Challenges the Role of Courts in Adjudicating Claims of Injury Inflicted by Prescription Drugs*, 34 Golden Gate U. L. Rev. (2004).
<http://digitalcommons.law.ggu.edu/ggulrev/vol34/iss2/6>

This Comment is brought to you for free and open access by the Academic Journals at GGU Law Digital Commons. It has been accepted for inclusion in Golden Gate University Law Review by an authorized administrator of GGU Law Digital Commons. For more information, please contact jfischer@ggu.edu.

COMMENT

HOW THE RISE OF FEDERAL BUREAUCRATIC POWERS CHALLENGES THE ROLE OF COURTS IN ADJUDICATING CLAIMS OF INJURY INFLICTED BY PRESCRIPTION DRUGS

INTRODUCTION

Chris Magnotta was one of the few people working in the World Trade Center buildings who survived the terrorist attack on September 11, 2001.¹ The aftermath of the traumatic event left him with nightmares, disrupted sleep, and anxiety attacks—none of which he had experienced before the attack.² Chris's doctor diagnosed him with post-traumatic stress disorder and prescribed Paxil.³ After six months, Chris was feeling better and consequently decided to stop taking the drug.⁴ Within 48 hours, he began to experience symptoms such as nausea, severe fatigue, and the sensation of electric “zaps” shooting through his body.⁵ These debilitating symptoms

¹ *A Big Letdown?*, PEOPLE MAGAZINE, May 12, 2003, at 191-92.

² *Id.*

³ DSM-IV-TR 463 (4th ed, 2000). Posttraumatic stress disorder is when a person re-experiences an extremely traumatic event accompanied by symptoms that cause a significant impairment in social, occupational, or other important areas of functioning *Id.*; *supra* note 1.

⁴ *Id.*

⁵ THOMAS C. TIMMRECK, PH.D., HEALTH SERVICES CYCLOPEDIA A COMPENDIUM OF HEALTH-CARE AND PUBLIC HEALTH TERMINOLOGY 522 (Jones and Bartlett Publishers 1997) (1982). The sensation of “electric zaps” or strange sensations felt on the skin (e.g., burning, tickling, and tingling) is medically termed paresthesia. *Id.*

forced him back onto Paxil.⁶ With the help of his doctor, he weaned himself off the drug completely within four months.⁷ Chris was never warned of the potential adverse withdrawal reactions that can occur when the drug is stopped abruptly.⁸ He explained, "I want a clear warning of the side effects. . . [n]obody should have to go through this."⁹

Katherine Keith was prescribed Paxil for menopausal symptoms in 1997.¹⁰ After experiencing relief from her symptoms, she stopped taking the drug.¹¹ Within 24 hours, Keith started experiencing nonstop vomiting and diarrhea, and intolerable brain "zaps" that caused uncontrollable crying.¹² Keith claims that the symptoms were intolerable to such a degree that on two separate occasions she stuck a pistol in her mouth and had to convince herself not to pull the trigger.¹³ Like Chris Magnotta, she was forced back onto Paxil and with her doctor's help was able to wean herself completely off the drug.¹⁴

Magnotta and Keith are just two of tens of millions of Americans, one out of every ten, that have taken a Selective Serotonin Reuptake Inhibitor (hereinafter "SSRI") antidepressant.¹⁵ Prozac, Zoloft, Paxil, Luvox, and Celexa are drugs included in this newer class of antidepressant medications.¹⁶ As a class, the SSRIs are easy to use--they usually just require one pill per day and have fewer, less complicated side effects than

⁶ *Supra* note 1.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See JOSEPH GLENMULLEN, M.D., PROZAC BACKLASH 15 (Simon & Schuster 2000); There are many stories like the ones detailed above. *Id.* Tanya, a Paxil patient, went swimming at her health club. *Id.* at 64. On her second lap she felt like she was stuck by a bolt of lightning. *Id.* She was terrified and began flailing in the water. *Id.* Eventually another swimmer pulled her out of the water. *Id.* Immediately she asked her rescuer if he had experienced any sensation of electrical shocks in the water. *Id.* He had not. *Id.* The electric shocks continued as she sat poolside. *Id.* at 64-65. Starting from her brain she felt the shocks travel down her arms; her vision was jumping back and forth; she felt nausea and dizziness accompanied by a buzzing in her ears. *Id.* at 65. She thought she was experiencing a panic attack. *Id.* Her doctor explained that she was probably experiencing withdrawal symptoms. *Id.* Tanya had stopped taking Paxil two days earlier. *Id.*

¹⁶ WILLIAM S. APPLETON, M.D., PROZAC AND THE NEW ANTIDEPRESSANTS 50 (Deborah Brody ed., Penguin Books 2000) (1997).

older antidepressants.¹⁷ There is also extensive scientific documentation that patients may experience withdrawal when they discontinue use of SSRIs.¹⁸

In August 2001, thirty-five Californians who allegedly suffered severe withdrawal reactions from taking Paxil filed a class action against the manufacturer, GlaxoSmithKline Corporation (hereinafter “GSK”), in California Superior Court.¹⁹ The action sought to hold GSK liable for suppressing information about the drug’s withdrawal effects. The plaintiffs asserted that GSK knew but failed to warn about Paxil’s addictive traits.²⁰

The plaintiff class sought a preliminary injunction to enjoin GSK from publicizing the statement, “Paxil is non habit-

¹⁷ *Id* at 57. Older antidepressants meaning the tricyclics which include trofanil, elavil, norpramin to name a few. *Id*.

¹⁸ Michelle Fitzgerald, B.Sc (Pharm), *SSRI Discontinuation Syndrome*, 4 ATLANTIC PSYCHOPHARMACOLOGY QUARTERLY 3 (Issue 2, 2001). Reports indicate that 30% of patients will experience some withdrawal type symptom upon reduction of dosage or discontinuation of use. *Id*. The symptoms may include dizziness, light-headedness, vertigo or feeling faint; shock-like sensations (called paresthesia); anxiety; diarrhea; fatigue; gait instability; headache; insomnia; nausea; tremor; and visual disturbances. *Id*. Symptoms may develop within one to seven days of discontinuation or reduction in dosage, after at least one month’s use of an SSRI. *Id*. See also Robert N. Golden, Ph.D, *Selective Serotonin Reuptake Inhibitor Elimination Half-Lives: The Long and the Short of It*, 44 BIOLOGICAL PSYCHIATRY 75-6 (Issue 2, 1998) (finding that, “[t]his reported relationship between SSRI elimination half-life and risk of withdrawal syndrome is reminiscent of what we learned some time ago about benzodiazepines and their addictive derivatives.”); see APPLETON, at 73, *supra* note 16.

¹⁹ *Paxil Users File Class Suit Over Withdrawal Reaction*, 5 NO. ANDREWS DRUG RECALL LITIG, REP. 9 (November 2001) (reporting that *Keith v. GloxoSmithKline Corp.* was filed in Cal. Superior Court, Los Angeles County on August 23, 2001); *California Court to Consider Renewed Paxil Class Suit*, 19 NO. ANDREWS PHARMACEUTICAL LITIG, REP. 10 (July 2003). In January 2003, a federal judge refused to certify a nationwide class stating the proposal would create a trial plan too complicated for a jury to follow. *Id*. The judge denied the class certification with leave to amend. *Id*. The plaintiffs refiled their suit to form two classes, an injunction class and a general damages class, limited to representing all Californians who were prescribed and consumed Paxil. *Id*.

²⁰ See generally Notice of Motion and Motion for Preliminary Injunction; Memorandum of Points and Authorities in Support Thereof, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed July 1, 2002) (asking that GSK be prohibited from making claims that Paxil is non habit-forming; stopped from downplaying the side effects as mild and temporary; and prohibited from claiming that the drug has been studied in short and long-term use and is not associated with dependence or addiction). Telephone interview with Cindy Hall, Paralegal, Baum, Hedlund, Aristei, Guilford & Shiavo (Oct. 3, 2003). Also, the plaintiffs seek to stop GSK from using the term “discontinuation syndrome” because they allege the term has no purported medical meaning. *Id*.

forming,” in national television commercials.²¹ The plaintiffs claimed that because patients suffered from severe withdrawal reactions after attempting to discontinue Paxil, the use of the phrase was false and misleading.²² The court found the plaintiffs had demonstrated that severe withdrawal reactions do in fact occur in at least some patients.²³ The court reasoned that the phrase hindered the efforts of patients to seek and receive proper treatment for withdrawal symptoms.²⁴ As a result, the motion for a preliminary injunction was granted.²⁵

In response to the order, GSK filed a motion to suspend the preliminary injunction, as well as a motion for reconsideration.²⁶ In addition, the Food and Drug Administration (hereinafter “FDA”) filed a brief supporting GSK’s position that the advertisements were not misleading.²⁷ The court reversed itself and denied the injunction based specifically on evidence presented by the FDA regarding the internal review process involved in the advertisements in question.²⁸ Incidentally, certification of the proposed class was rejected in June of 2003.²⁹ The litigation, however, is continuing in the form of a mass joinder.³⁰

Although Paxil is the SSRI most likely to cause severe withdrawal effects, the drug manufacturer and the FDA insist that Paxil is not habit-forming.³¹ The FDA has complicated this legal battle by alleging that courts lack jurisdiction over

²¹ Memorandum of Decision re: Preliminary Injunction at 2, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed August 16, 2002)

²² *Id.* at 1.

²³ *Id.* at 2

²⁴ *Id.* at 10.

²⁵ *Id.*

²⁶ Memorandum of Decision re: Motion for Reconsideration of Order Granting Preliminary Injunction at 10, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed October 21, 2002).

²⁷ *Id.* at 1-2.

²⁸ *Id.* at 4.

²⁹ Telephone interview with Donald Farber, Law Office of Donald J. Farber (Oct. 3, 2003). The certification of the state-wide proposed class was rejected in June 2003, but the litigation is continuing in the form of a national mass joinder. *Id.* There are fifteen cases across the country filed in both state and federal court. *Id.* The plaintiffs are hoping for a consolidation of all fifteen cases in Los Angeles, California for discovery purposes. *Id.*

³⁰ *Id.*

³¹ See Brief of the United States at 3-4, *In re Paxil Litigation*, No. CV-01-07937 (CWx), (C.D. Cal. filed Sept. 4, 2002).

the issue of whether Paxil is habit-forming.³² The FDA contends that the determination of whether a drug is habit-forming falls within the exclusive power of the agency.³³

The recent litigation surrounding Paxil illustrates the obstacles injured plaintiffs face in recovering for harms suffered from side effects associated with prescription drugs. This Comment uses the recent Paxil litigation as an example of how the rise of federal bureaucratic powers, specifically those exercised by the FDA to administer the Food Drug and Cosmetic Act (hereinafter “FDCA”), increasingly challenge the role of courts in adjudicating tort claims of injury inflicted by prescription drugs. Part I explains the current labeling requirements for prescription drugs.³⁴ Part II describes product liability law regarding claims involving prescription drugs.³⁵ Part III analyzes the drug manufacturers’ and FDA’s defenses to state tort claims, specifically preemption and primary jurisdiction.³⁶ Part IV discusses the current law as it applies to the recent Paxil litigation.³⁷ Part V analyzes alternative interpretations that would achieve fairer results.³⁸ Finally, Part VI of this Comment concludes that FDA prescription drug labeling requirements should be viewed as minimal guidelines subject to enhancement by state court jury verdicts.³⁹

I. CURRENT REGULATIONS FOR PRESCRIPTION DRUGS

Congress delegates authority to agencies to carry out their missions through the use of enabling statutes.⁴⁰ One example of an enabling statute is the Federal Food, Drug and Cosmetic Act (hereinafter “FDCA”).⁴¹ The FDCA assigns responsibility to the FDA to ensure that drugs marketed in the United States

³² See discussion in Part III, *infra*.

³³ Brief of the United States at 9, *In re Paxil Litigation*, No. CV-01-07937 (CWx), (C.D. Cal. filed Sept. 4, 2002).

³⁴ See *infra* notes 40-71 and accompanying text.

³⁵ See *infra* notes 72-96 and accompanying text.

³⁶ See *infra* notes 97-162 and accompanying text.

³⁷ See *infra* notes 163-206 and accompanying text.

³⁸ See *infra* notes 207-251 and accompanying text.

³⁹ See *infra* notes 252 and accompanying text.

⁴⁰ ELIZABETH C. RICHARDSON, J.D., *ADMINISTRATIVE LAW AND PROCEDURE* 48 (Delmar Publishers 1996).

⁴¹ 21 U.S.C. § 301 *et seq.* (2000).

are safe and effective.⁴² The regulation of drugs marketed in the United States includes a process for approval, promotion, and labeling of new drugs.⁴³ The FDA has designed a regulatory labeling scheme to ensure that necessary information is given to physicians so that they can prescribe the safe and effective use of drugs.⁴⁴

A. LABELING REQUIREMENTS FOR PRESCRIPTION DRUGS

Prescription medications are drugs that are approved by the FDA and available to the public only when dispensed by licensed physicians and pharmacists.⁴⁵ The availability of prescription medications is limited because they are considered unsafe if used without the supervision of a physician.⁴⁶ A licensed medical practitioner balances the benefits of using a particular prescription drug against the accompanying risks on a patient-by-patient basis.⁴⁷ To assist medical practitioners in balancing important risk information, the FDA provides strict labeling requirements for prescription drugs.⁴⁸

A drug cannot be legally introduced into the market unless it is approved by the FDA.⁴⁹ The approval process begins by the submission of a New Drug Application (hereinafter "NDA").⁵⁰

⁴² 21 U.S.C. § 335 (2000); 21 C.F.R. § 5.10(a)(1) (2003) (The United States Secretary of Health and Human Services delegated authority to the FDA).

⁴³ See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2000).

⁴⁴ See *infra* Part II for further discussion about the duty to warn and the learned intermediary doctrine.

⁴⁵ TIMMRECK, at 572 *supra* note 5 (providing the medical definition of prescription drugs); see 21 U.S.C. § 393 (2000) (granting the FDA the authority to ensure that drugs are safe and effective).

⁴⁶ 21 U.S.C. § 353(b)(1) (2000).

⁴⁷ See *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); see also *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir. 1974).

⁴⁸ 21 U.S.C. §393 (2000). The FDA's mission is to promote public health by reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner. *Id.* The FDA is the agency that ensures that human and veterinary drugs are safe and effective. *Id.*; see *United States v. Sullivan*, 332 U.S. 689, 696 (1948) (stating that the FDA was created to "protect consumers from dangerous products.").

⁴⁹ 21 U.S.C. § 355(a) (2000); *Edison Pharm. Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed., and Welfare*, 600 F.2d 831 (D.C. Cir. 1979). (finding that new drug application could not be approved "[w]here drug manufacturer failed to comply with this chapter and regulations governing the manufacturing, sampling and labeling of proposed new drug...").

⁵⁰ 21 U.S.C. § 355 (b) (1)(F) (2000); 21 C.F.R. § 201.100(c)(2) (2003); See 21 C.F.R. § 314.50 (2003) (detailing the contents of the NDA).

When filing an NDA, a drug manufacturer is required to submit all proposed labeling, which includes the information of risks associated with the drug.⁵¹ FDA drug labeling regulations categorize risk information according to the severity of the risk and the degree to which the risk has been scientifically validated.⁵² The label hierarchy for disclosing risk information spans from the most severe situations, called contraindications, to the least serious side effects, known as adverse reactions.⁵³ As side effects increase in intensity and severity, the manufacturer's warning with respect to the drug's potential for harm ascends to a higher label heading.⁵⁴ In the NDA labeling, a manufacturer must establish that a drug is safe and effective for its specified uses.⁵⁵

⁵¹ 21 U.S.C. § 355 (b) (1) (F) (2000); 21 C.F.R. §§ 314.50 (c)(2)(i) (2003), 314.110 (2003) (detailing the approval letter after NDA application meets requirements).

⁵² See generally 21 C.F.R. § 201.57 (a)-(m) (2003). See also Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" From the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 327 (1994).

⁵³ 21 C.F.R. § 201.57 (a)-(m) (2003) (specifying the topic headings and mandated order for prescription drug labeling as: Description, Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Drug Abuse and Dependence, Overdosage, Dosage and Administration, How Supplied, Animal Pharmacology and/or Animal Toxicology, and "Clinical Studies" and "References."). See *McFadden v. Haritatos*, 448 N.Y.S.2d 79, 81 (N.Y. App. Div. 1982) (stating it was obvious the labeling sections were set forth in the C.F.R. in descending order of importance.); 21 C.F.R. § 201.57 (d) (2003) (Contraindications "shall describe those situations in which the drug should not be used because the risk of the use clearly outweighs any possible benefit...[k]nown hazards and not theoretical possibilities shall be listed."). Cf. 21 C.F.R. § 201.57 (g) (2003) (describing an adverse reaction as an "undesirable effect" reasonably associated with the drug). The drug manufacturer must list the approximate frequency of each adverse reaction in rough estimates or orders of magnitude. *Id.* For example, "[t]he most frequent adverse reactions(s) to (name of drug) is (are)(list reactions). This (these) occur(s) in about (e.g., on-third of patients; one in 30 patients; less than one-tenth of patients). Less frequent adverse reactions are (list reactions), which occur in approximately (e.g., one in 100 patients). Other adverse reactions, which occur rarely, in approximately (e.g., one in 1,000 patients), are (list reactions)." *Id.* Percent figures are only permitted if they are well documented by controlled studies, they reflect general experience, and they do not imply a greater degree of accuracy than what exists.). *Id.*

⁵⁴ *Id.*

⁵⁵ 21 U.S.C. § 355 (b), (d) (2000). See also Declaration of Thomas Scarlett at 3, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal filed July 19, 2002). Thomas Scarlett is a partner in Hyman, Phelps, & McNamara, a law firm that specializes in matters concerning the FDA. *Id.* at 2.

B. FDA PROCESS FOR DRUG APPROVAL

The FDA determines safety and effectiveness by reviewing the conditions of use that are specified in the labeling contained in the NDA.⁵⁶ The drug manufacturer and the FDA attempt to reconcile any differences on what content should appear in the labeling.⁵⁷ Ultimately, the FDA reserves the right to condition the final approval of a new drug based on label revisions suggested by the agency.⁵⁸ The labeling is commonly referred to as the “package insert” or “prescribing information” and is considered the official labeling for a drug.⁵⁹ Once approved, the labeling may not be changed without FDA approval, except for minor changes.⁶⁰ The labeling is intended to summarize all information a physician requires to prescribe the drug in a safe and effective manner.⁶¹

After receiving all contents of the NDA, the FDA conducts a comprehensive safety review of the clinical data contained in the application.⁶² The safety review is designed to identify potential safety risks, to assess whether the drug is sufficiently safe for public use and whether certain risks should be disclosed in the drug labeling.⁶³ During its review, the FDA performs a drug abuse liability assessment.⁶⁴ Abuse liability is

⁵⁶ *Id.* at 3.

⁵⁷ *Id.*

⁵⁸ See 21 U.S.C. § 355 (b) (1) (F) (2000); 21 C.F.R. §§ 314.50 (c) (2) (i) (2003), 314.110 (2003).

⁵⁹ SCARLETT at 3, *supra* note 55.

⁶⁰ *Id.*; 21 C.F.R. §§ 201.100(c)(2) (2003); 314.70 (2003); see notes 154-155, *infra*. (citing state court holdings in which the drug manufacturer was responsible for providing more information than required by FDA regulations).

⁶¹ *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 658 n.11 (1st Cir. 1981); SCARLETT at 3, *supra* note 55.

⁶² Declaration of Thomas Kline at 4, *In re Paxil Litigation*, No. CV-01-07937 (CWx), (C.D. Cal. filed July 19, 2002). Thomas Kline is the Director of U.S. Regulatory Affairs at GSK. *Id.* As a director he is required to act as a liaison between GSK and the FDA regarding marketed and investigational drug products. *Id.* at 2.

⁶³ *Id.* at 4.

⁶⁴ See 21 U.S.C. § 811 (2000); 21 U.S.C. § 301 (2000); Draft Guidelines for Abuse Liability Assessment at 1, Drug Abuse Advisory Committee, FDA (July 1990), *In re Paxil Litigation*, No. CV-01-07937 (CWx), Exhibit 2. The FDA created the Drug Abuse Advisory Committee (hereinafter “DAAC”) to prepare the guidelines for abuse liability assessments. *Id.* In drafting the guidelines the DDAC considered (1) the promotion of public health by encouraging the development of safe and effective drugs; and (2) the protection of the public health by insuring that new products are introduced with an adequate degree of scientific knowledge and, where indicated, and appropriate degree of regulatory control related to their abuse liability. *Id.*

“the likelihood that a drug with psychoactive or central nervous system effects will sustain patterns of non-medical self-administration that result in disruptive or undesired consequences.”⁶⁵ Although the FDA does not prescribe an exact standard for testing, it does place the responsibility on the manufacturer to test for abuse liability in animals and humans.⁶⁶ All NDAs include a section addressing possible issues concerning abuse liability.⁶⁷ The drug manufacturer is required to submit its testing information in this section in the NDA.⁶⁸

If the FDA determines the drug does have abuse potential, it notifies the Drug Enforcement Agency (hereinafter “DEA”), who may consider scheduling the drug as a controlled substance under the Controlled Substances Act.⁶⁹ If the FDA decides the drug does not have abuse potential, it does not notify the DEA.⁷⁰ After a new drug is approved and introduced to the public, the FDA continues to monitor the frequency and severity of adverse drug experiences to assess whether labeling changes are necessary.⁷¹

II. PRODUCT LIABILITY LAW AND PRESCRIPTION DRUGS

Typically, under product liability law, an injured plaintiff can bring an action to recover against a manufacturer based on strict liability theory.⁷² Section 402A of the Restatement (Sec-

⁶⁵ *Id.* at 2.

⁶⁶ *Id.*

⁶⁷ *Id.* at 3.

⁶⁸ *Id.*

⁶⁹ See 21 U.S.C. §§ 811(c), (f) (2000); 21 C.F.R. § 314.104 (2003).

⁷⁰ SCARLETT at 10-11, *supra* note 55; see generally DRAFT GUIDELINES at 1, *supra* note 64.

⁷¹ 21 C.F.R. §§ 310.303(a) (2003), 310.305 (b) (2003), 314.80(a) (2003). The manufacturer has a duty to advise the FDA of any reports of “adverse experiences” with the drug, often referred to as postmarketing reports. 21 C.F.R. § 314.80(a) (2003). An adverse drug experience is any adverse event occurring in the course of the use of a drug product in professional practice; from drug overdose, whether accidental or intentional; from drug abuse; from drug withdrawal; and any failure of expected pharmacological action. *Id.* The “adverse experience” must be reported whether it is reasonably associated with the drug or not. *Id.* For the purpose of this Comment, the terms “risks,” “dangers,” and “(adverse) side effects” will be used interchangeably even though there may be subtle differences distinguishing the terms.

⁷² See RESTATEMENT (SECOND) OF TORTS § 402A (1965). For the origin of the strict liability doctrine, see *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436 (Cal. Dist. Ct. App. 1944) (Traynor, J., concurring) (formulating the strict liability doctrine which holds a manufacturer absolutely liable if when it placed a product on the market, it

ond) of Torts suggests a manufacturer of a product is strictly liable for injuries to consumers, or their property, caused by defects in the design of the product.⁷³ Products deemed “unavoidably unsafe” are an exception to the general strict liability rule.⁷⁴ An injured plaintiff, however, can bring an action for an unavoidably unsafe product if the manufacturer has not provided adequate warnings on the product.⁷⁵

A. PRESCRIPTION DRUGS ARE UNAVOIDABLY UNSAFE PRODUCTS

Under products liability law, prescription drugs are presumed to be unavoidably unsafe.⁷⁶ Unavoidably unsafe products create risks to the user even when used as intended.⁷⁷ Comment k to Restatement Section 402A acknowledges that there exist products that, in the present state of human knowledge, are incapable of being made safe for their intended use.⁷⁸

knew the product was to be used without inspection, and the product proved to have a defect that caused injury).

⁷³ RESTATEMENT (SECOND) OF TORTS § 402A (1965). This section suggests that manufacturers are strictly liable for injuries to the consumer or his/her property if the court deems a “defective condition unreasonably dangerous.” *Id.* See 63 AM. JUR. 2D *Products Liability* § 545 (1997). This is true even if the manufacturer shows that the product was faultlessly designed and manufactured, but dangerous or likely to cause harm if not properly used. *Id.*; see also *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 923 (Kan. 1990) (identifying the three main types of product defects: manufacturing flaws, design defects, and inadequate warnings with regard to use); PROSSER & KEETON, *THE LAW OF TORTS* § 99, at 695-98 (5th ed. 1984).

⁷⁴ See *Grunberg v. The Upjohn Co.*, 813 P.2d 89 (Utah 1991) (analyzing the application of comment k).

⁷⁵ See generally, RESTATEMENT (SECOND) OF TORTS § 402A (1965).

⁷⁶ See e.g., *Grunberg*, 813 P.2d at 92 (finding that UTAH CODE ANN. § 78-18-2(1) (Supp. 1990) presents a rebuttable presumption that FDA-approved drugs are unavoidably unsafe). Cf. *Kearl v. Lederle Laboratories*, 172 Cal.App.3d 812 (1985) (stating that California was the first state to utilize a risk/benefit analysis to determine which drugs fell within the protective scope of comment k). But see *Brown v. Superior Court*, 751 P.2d 470, 483 (Cal. 1988) (overturning *Kearl* and establishing the rule in California, that all prescription drugs are entitled as a matter of law to an exemption from strict liability claims based upon design defects). Some courts have applied comment k on a case-by-case basis to determine if a drug is “unavoidably unsafe.” See *Toner v. Lederle Lab.*, 732 P.2d 297 (Idaho 1987; *Savina*, 795 P.2d at 915; see also *Feldman v. Lederle Lab.*, 479 A.2d 374, 382-83 (N.J. 1984) (dealing with allegations of failure to warn, but asserting, “Whether a drug is unavoidably unsafe should be decided on a case-by-case basis....”).

⁷⁷ See RESTATEMENT (SECOND) OF TORTS § 402A cmt k (1965). There are some products that are incapable of being made safe for their intended and ordinary use. *Id.* These are especially common in the field of drugs. *Id.*

⁷⁸ *Id.*

Accordingly, products that fall within this category are protected against strict liability claims.⁷⁹ Therefore, manufacturers of unavoidably unsafe products are not held strictly liable for injuries so long as their products are accompanied by proper warnings.⁸⁰ In the absence of a strict liability claim, a manufacturer may nevertheless be held liable for injuries to a consumer if the plaintiff can show the manufacturer failed to adequately warn of the product's risks.⁸¹

B. DUTY TO WARN: THE LEARNED INTERMEDIARY DOCTRINE

Generally, the manufacturer of an unavoidably unsafe product has a duty to warn the product's intended and foreseeable users of the product's dangers.⁸² Prescription drug manufacturers constitute an exception to the general rule.⁸³ A prescription drug manufacturer's duty to warn is satisfied when a warning of the risks associated with a drug is given directly to the physician.⁸⁴ The physician acts as the "learned intermediary" between the drug manufacturer and the patient.⁸⁵ The

⁷⁹ *Id.*

⁸⁰ *Id.* See *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981); *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 128-9 (9th Cir. 1968); *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 163 (D.S.D.1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969); *Brown*, 751 P.2d at 481; *Toner*, 732 P.2d at 305; *Savina*, 795 P.2d at 924; *Feldman*, 479 A.2d at 374; *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 780 (R.I. 1988); Theresa Schwartz, *Product Liability Law and Pharmaceuticals: New Developments and Divergent Trends*, 43 FOOD DRUG COSM. L.J. 33 (1988) (giving an explanation of the widespread court-acceptance of comment k's applicability to prescription drug manufacturers).

⁸¹ *Grundberg*, 813 P.2d at 92, *citing Toner*, 732 P.2d at 305 ("The purpose of comment k is to protect from strict liability products that cannot be designed more safely. If however, such products are mismanufactured or unaccompanied by adequate warnings, the seller may be liable even if the plaintiff cannot establish the seller's negligence....This limitation on the scope of comment k immunity is universally recognized.").

⁸² RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965) (mandates that manufacturers provide warnings). PROSSER & KEETON ON THE LAW OF TORTS, 698 (5th ed. 1984). (Warnings should be directed at the intended users as well as at reasonably foreseeable users.).

⁸³ *Lindsay*, 637 F.2d at 91 (holding that "the manufacturer's duty is to warn the doctor, not the patient. The doctor acts as an 'informed intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use.")

⁸⁴ *Id.* See *e.g.*, *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992); *Sterling Drug*, 408 F.2d at 992 (8th Cir. 1969); *Wyeth Lab., Inc. v. Fortenberry*, 530 So. 2d 688, 691-92 (Miss. 1988).

⁸⁵ See *Lindsay*, 637 F.2d at 91; *Reyes*, 498 F.2d at 1276 (summarizing the underlying principle behind the learned intermediary doctrine).

“learned intermediary” rule exists because it is the physician who evaluates the risks and benefits of prescription treatments when selecting drugs for the patient.⁸⁶ Furthermore, it is the physician who has a duty to communicate the risks associated with drug treatment directly to the patient.⁸⁷ For that reason, it is the physician, rather than the patient, who requires the warning from the manufacturer.⁸⁸

If the manufacturer does not adequately warn the physician, the patient could file a lawsuit claiming that the manufacturer breached its duty to provide adequate warnings.⁸⁹ Most commonly, the manufacturer has provided a warning that the plaintiff alleges is inadequate.⁹⁰ A patient may, for instance, experience a side effect that was not included in the label.⁹¹ When the label clearly warns of the plaintiff’s injury, a court will grant summary judgment in favor of the manufacturer.⁹² Courts must assess on a case-by-case basis whether a particular risk warning is adequate.⁹³

Courts generally find warnings to be adequate if they convey a fair message of the necessary level of caution required to avoid the potential dangers.⁹⁴ For instance, warning labels have been considered inadequate because of diluted language

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Reyes*, 498 F.2d at 1276 (finding that the choice the physician makes is “an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative,” but that there are situations where the manufacturer must warn the patient directly because doses are standardized). *See, e.g., Id.* (extending duty to vaccine manufacturers because doses are standardized); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass.1985)(extending duty to birth control pill manufacturers because birth control is taken by healthy women, who should be made aware of the high incidence of serious risks associated with their use, and recognizing that some courts have gone so far as to impose a duty on the manufacturer to warn the patient in a different language from that which the FDA sets forth in its labeling restrictions). *See also* *In re Certified Question from The United States Dist. Court for the E. Dist. of Mich.*, 358 N.W. 2d 873 (Mich.1984).

⁸⁹ *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965); PROSSER & KEETON, THE LAW OF TORTS § 99, at 695-98 (5th ed. 1984);

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *E.g., Brick v. Barnes-Hines Pharm. Co.*, 428 F. Supp. 496, 498 (D.D.C. 1997); *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 105 (Fla. 1989); *Johnson v. Am. Cyanamid Co.*, 774 F.2d 830, 834-35 (7th Cir. 1985).

⁹³ *See Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975); *Tampa Drug Co. v. Wait*, 103 So. 2d 603, 609 (Fla. 1958); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 837 (Ohio 1981).

⁹⁴ *Id.*

or improper tone.⁹⁵ Therefore, drug manufacturers who are acting in compliance with FDA labeling regulations may nevertheless be held liable in state courts for inadequate warnings.⁹⁶ The next section discusses common defenses a drug manufacturer may employ in response to failure-to-warn claims based on inadequate prescription drug labeling.

III. DEFENSES TO STATE TORT CLAIMS: FEDERAL PREEMPTION AND PRIMARY JURISDICTION

Drug manufacturers are required to follow the drug application and labeling guidelines set forth by the FDA.⁹⁷ The FDA's labeling guidelines strike the balance between providing enough risk information to provide adequate warning information without over-warning.⁹⁸ The policy behind this balance is that providing too many warnings could intimidate consumers or lessen the importance of the warning system in general.⁹⁹

A successful state tort claim against a drug manufacturer for failure to provide adequate warnings may create a perverse result.¹⁰⁰ This is because the drug manufacturer has complied with FDA regulations but is nevertheless being punished for a violation of state law.¹⁰¹ To avoid this result, drug manufacturers have asserted defenses of federal preemption and primary jurisdiction.¹⁰² Both of these defenses are grounded in the notion that the power found, either explicitly or implicitly, within an agency's enabling statute divests the state courts of their

⁹⁵ *Sterling*, 408 F.2d at 994; *See e.g., McFadden*, 448 N.Y.S.2d at 81 (commenting that when label stated that the drug side effects were reversible the court commented that "tends to qualify and dilute the whole of the [adverse reactions] section's admonition."); *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 451 (S.D.N.Y. 1968) (finding that a warning was "water[ed] down" with "shrewd use of descriptive adjectives").

⁹⁶ *See, e.g., Needham v. White Lab.*, 639 F.2d 394, 396 (7th Cir. 1981); *Davis*, 399 F.2d at 122.

⁹⁷ *See supra* Part I for discussion of the labeling requirements for prescription drugs.

⁹⁸ *See supra* Part I for discussion of the FDA process for drug approval.

⁹⁹ *See* NOAH at 374, *supra* note 52. The fourth section contains an in-depth discussion on the hazards and causes of excessive warnings. *Id.*

¹⁰⁰ *See Needham*, 639 F.2d at 396.

¹⁰¹ *Id.*

¹⁰² *E.g.*, Memorandum of Decision re: Motion for Reconsideration of Order Granting Preliminary Injunction at 2-3, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Oct. 22, 2002).

jurisdictional power.¹⁰³ The two doctrines are easily confused, which can lead to misapplication.¹⁰⁴ An understanding of the doctrines is necessary to grasp how each is applied to litigation concerning prescription drugs.

A. FEDERAL PREEMPTION

Federal preemption is derived from the Supremacy Clause of the United States Constitution.¹⁰⁵ It is the principle that federal law can supersede any incongruent state law or regulation.¹⁰⁶ The doctrine is fundamental because it allocates power between the federal and state governments.¹⁰⁷

For preemption purposes, courts have broadly defined federal and state law.¹⁰⁸ Federal law is defined to include the United States Constitution, federal statutes, and federal regulations promulgated by agencies.¹⁰⁹ State law encompasses common-law tort actions, state statutes, and state regulations.¹¹⁰ Hence, state court tort actions that are inconsistent with federal regulations violate the Supremacy Clause.¹¹¹

Congress may supersede state law either by express or implied preemption.¹¹² Express preemption occurs when Congress explicitly states that federal law preempts contrary state law.¹¹³

¹⁰³ See *infra* note 106 and accompanying text.

¹⁰⁴ See *infra* Part IV for discussion of the controversy over the application of the preemption doctrine as an affirmative defense.

¹⁰⁵ See U.S. CONST. art. VI, cl. 2; *Gibbons v. Ogden* 22 U.S. 1, 3 (1824).

¹⁰⁶ See U.S. CONST. art. VI, cl. 2; BLACKS LAW DICTIONARY, 545, (2d ed. 2001) (defining preemption, derived from the Supremacy Clause, as a principle that a federal law can supersede any incongruent state law or regulation); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984) (finding that under the Supremacy Clause a state regulation may be pre-empted by federal law first, when Congress has expressed a clear intent to pre-empt state law through statute; second, when it is expressly stated or implied that Congress intended to leave no room for the States to supplement federal law; and third, when compliance with both state and federal law is impossible (*citations omitted*)).

¹⁰⁷ *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984); see generally Foote, *Administrative Preemption: An Experiment in Regulatory Federalism*, 70 VA. L. REV. 1429 (1984).

¹⁰⁸ See *infra* notes 109-111.

¹⁰⁹ See *Hillsborough County v. Automated Med. Lab.*, 471 U.S. 707, 713 (1985); *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982).

¹¹⁰ See *Sperry v. Florida*, 373 U.S. 379, 403 (1963).

¹¹¹ See note 97, *supra*.

¹¹² *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

¹¹³ See *e.g.*, 15 U.S.C. § 1334 (1988) (expressing preemption regarding cigarettes); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 515 (1992) (holding federal Cigarette

Preemption is usually viewed as implied when Congress intends that federal law occupy a given field.¹¹⁴ Under this form of implied preemption, courts will find that the federal regulatory scheme is sufficiently comprehensive that there is no room for additional state law.¹¹⁵ Finally, even if Congress has not intended that federal law occupy a field, state law may nevertheless be preempted if it actually conflicts with federal law, such that compliance with both state and federal law is impossible.¹¹⁶

Congress has not enacted an express preemption provision covering prescription drugs.¹¹⁷ As a result, common-law failure-to-warn claims have been brought against drug manufacturers notwithstanding the detailed federal labeling requirements.¹¹⁸ Several courts have held that the FDCA does not impliedly preempt state law.¹¹⁹ In the absence of any Supreme Court interpretation, however, the debate continues over whether FDA labeling regulations preempt state tort law.¹²⁰

Labeling and Advertising Act preempted State laws regulating and prohibiting advertising based on smoking and health.)

¹¹⁴ *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

¹¹⁵ *Id.* at 232 (finding that “[a]ll the Federal Act requires is that warehousemen receive products for storage without making discriminations between persons,” and that “[w]hat the Illinois Commission promulgates or requires...might indeed strengthen and bolster the federal regulatory scheme and in no way dilute, impair, or oppose it.”).

¹¹⁶ *California v. ARC Am. Corp.* 490 U.S. 93 (1989).

¹¹⁷ *See, e.g., Hillsborough County*, 471 U.S. at 714-23; *Pharm. Soc’y of the State of N.Y. v. Lefkowitz*, 586 F.2d 953, 958 & n.6 (2d Cir. 1978) (holding that a state regulation mandating that drug manufacturer be identified on the label was not preempted).

¹¹⁸ NOAH at 356, *supra* note 52; *see John F. Del Giorno, Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL L. REV. 629 (1989) (applying four basic tests, from varied case law, to determine implied preemptive intent and concluding that Congress implied that FDA regulations preempt state law).

¹¹⁹ *See, e.g., Knoll Pharm. Co. v. Sherman*, 57 F. Supp. 2d 615, 625 (N.D. Ill. 1999) (considering Knoll’s assertion that the FDA’s detailed federal regulations covering advertisement of prescription drugs preempted Illinois’ attempt to restrict advertisement by regulating the content of broadcast television a “frivolous argument.”); *Ohler v. Purdue Pharma. L.P.*, 2002 WL 88945, at *9 (E.D. La. 2002) (arguing that “the evidence presented does not clearly demonstrate either that Congress or the FDA intended to preempt the field by implementing regulations pursuant to statutory mandate in the field of prescription drugs labeling, and thereby completely displacing State laws and regulations which may have the affect of elevating the standards and duties owed by manufacturers with respect to warnings and labeling of prescription drugs.”)

¹²⁰ *E.g., Brief of the United States of America, In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Sept. 5, 2002); *Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court’s Order Denying Partial Summary Judgment to Defendant-Appellee*

B. PRIMARY JURISDICTION

If a court does not find that federal law preempts a state tort claim, the FDA may still claim to have exclusive authority to make the final determinations.¹²¹ Over time, some governmental agencies have developed into adjudicative bodies and have consequently started to decide issues that were traditionally brought before courts.¹²² Primary jurisdiction is a judicially-made doctrine used to clarify powers allocated between the agencies and the courts.¹²³ The doctrine of primary jurisdiction allows a district court to refer a matter within its original jurisdiction if doing so will “promot[e] proper relationships between the courts and administrative agencies charged with particular regulatory duties.”¹²⁴

Primary jurisdiction applies when hearing a dispute involves the resolution of issues that, “under a regulatory scheme, have been placed in special competence of an administrative body.”¹²⁵ There is no set formula that a court uses to determine if primary jurisdiction is applicable.¹²⁶ Instead, case-by-case analysis is performed to determine if the rationale underlying the doctrine is present and whether the purposes of the doctrine will be accomplished, if applied.¹²⁷ There are factors, however, for a court to consider when determining

and cross-Appellant, *Motus v. Pfizer, Inc.*, Nos. 02-55372, 02-55498, (9th Cir. filed Sept. 2, 2002).

¹²¹ See *infra* notes 125-148 and accompanying text.

¹²² See 2 KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 14.1 (3rd ed. 1994); Fred Huntsman, Comment, *Who Makes the Call? The Primary Jurisdiction Doctrine in Texas after Cash America International Inc., v. Bennett, Subaru of America, Inc. v. McDavid Nissan, Inc. and Butnaru v. Ford Motor Co.*, 54 BAYLOR L. REV. 897, 901-06 (2002).

¹²³ *Id.*

¹²⁴ *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 303 (1976); *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645, at *2 (S.D.N.Y. 2000) (explaining that “[t]he doctrine...allows a federal court to refer a matter extending beyond the ‘conventional experiences of judged’ or ‘falling within the realm of administrative discretion’ to an administrative agency with more specialized experience, expertise, and insight.”).

¹²⁵ *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956); *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1363 (9th Cir. 1987) (holding that “[t]he particular agency deferred to must be one that Congress has vested with the authority to regulate an industry or activity such that it would be inconsistent with the statutory scheme to deny the agency’s power to resolve the issues in question.”).

¹²⁶ *W. Pac. R.R. Co.*, 352 U.S. at 64; KENNETH DAVIS, at 275-76, *supra* note 122 (explaining how this decision established the test for applying the primary jurisdiction doctrine).

¹²⁷ *W. Pac. R.R. Co.*, 352 U.S. at 64.

whether to invoke the doctrine: first, the need for uniformity and consistency in the regulation of industry delegated to an agency; second, the need for agency expertise in disputes involving complicated issues of fact that is outside the general experience of the judiciary; and lastly, the extent that referral to an agency will add expense and delay.¹²⁸ It is important to note that these factors should be examined in light of the circumstances of each case.¹²⁹

Courts refer to the agency's enabling statute to evaluate the three factors listed above, to decide if invocation of primary jurisdiction is appropriate.¹³⁰ Statutory interpretation has led many courts to misapply and misuse the doctrine.¹³¹ Added to the seeming confusion is the fact that the doctrine of primary jurisdiction covers two distinct situations.¹³²

The first situation arises when an issue falls within an agency's exclusive statutory jurisdiction.¹³³ If the statute provides that the disputed issue falls within the exclusive original jurisdiction of the regulatory agency, the court is ousted of its jurisdiction.¹³⁴ Nonetheless, the agency's resolution of the issue will be subject to judicial review.¹³⁵ If the agency's resolution of the issue does not resolve the entire case, then the case continues along whatever path the statute prescribes.¹³⁶

The second situation permits a court to refer an issue to an agency that possesses more information about the issue than

¹²⁸ See *Weinberger v. Bentex Pharm., Inc.* 412 U.S. 645, 654 (1973); *Far E. Conference v. United States*, 342 U.S. 570 (1952); *Nader*, 426 U.S. at 303; *Bernhardt*, 2000 WL 1738645, at *2 (balancing the "advantages of applying the...doctrine against any potential costs and delays resulting from the referral of the matter...."); see KENNETH DAVIS, *ADMINISTRATIVE LAW*, at 272-80, *supra* note 122.

¹²⁹ *W. Pac. R.R. Co.*, 352 U.S. at 64.

¹³⁰ See *Primary Jurisdiction—Effect of Administrative Remedies on the Jurisdiction of Courts*, 51 HARV. L. REV. 1251, 1252 (1937-38).

¹³¹ *E.g.*, *Farmers Ins. Exch. v. Superior Court*, 6 Cal Rptr. 2d 487, 499 n.15 (1992) (reasoning thus: "[a]s have other state and federal courts in other contexts, we referred to "exhaustion" of administrative remedies in this portion of *Rojo* although we were in fact considering a question of prior resort to administrative procedures under the primary jurisdiction doctrine.").

¹³² See Memorandum of Decision re: Preliminary Injunction at 5, *In re Paxil Litigation*, No. CV 01-07937 MRP (CWx), (C.D. Cal. Issued Aug., 16, 2002) (citing *Arsberry v. State of Ill.*, 244 F.3d 558, 563 (7th Cir. 2001); see also KENNETH CULP DAVIS, at 272-280, *supra* note 122.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

the court.¹³⁷ Applicability of the doctrine of primary jurisdiction in this situation is based on the application of a practical test that balances the advantages and disadvantages of allowing the agency to resolve the issue.¹³⁸ In this situation, a court can consult an agency even if the agency does not have exclusive jurisdiction.¹³⁹ The doctrine of primary jurisdiction in this kind of situation is usually invoked when regulations involve arcane issues, when a court requests an amicus curiae brief from an agency, or when the court has appointed an agency to be a special master.¹⁴⁰ Either the court and the agency share concurrent jurisdiction or the court holds jurisdiction alone and solicits the advice of the agency.¹⁴¹ In sum, one situation under the primary jurisdiction analysis requires judicial deferral on a disputed issue to the appropriate agency.¹⁴² The other situation provides the court discretion in seeking out agency assistance.¹⁴³

When a legal issue overlaps with factual determinations that fall within an agency's expertise, the courts must apply the doctrine of primary jurisdiction to clarify how the courts and agency need to interface to solve the legal matter.¹⁴⁴ In order to do this, the court must determine "the character of the controverted question and the nature of the enquiry necessary for its solution."¹⁴⁵ That is to say, exclusive jurisdiction over an issue is vested in an agency when it is the regulation itself that is being attacked or disputed.¹⁴⁶ When a suit is brought for either a discriminatory application or violation of the regulation (i.e., the regulation itself is not being attacked), the question of fact does not call for agency discretion and courts may hear the

¹³⁷ *Id.*

¹³⁸ *Arsberry*, 244 F.3d at 563.

¹³⁹ *Id.*

¹⁴⁰ See Memorandum of Decision re: Preliminary Injunction at 5-6, *In re Paxil Litigation*, No. CV 01-07937 MRP (CWx), (C.D. Cal. Issued Aug., 16, 2002)(citing *Arsberry*, 244 F.3d at 563; see also KENNETH CULP DAVIS, at 272-280, *supra* note 122.

¹⁴¹ *Id.*

¹⁴² See *id.*

¹⁴³ See *id.*

¹⁴⁴ *Bernhardt*, 2000 WL 1738645, at *2 (applying primary jurisdiction specifically "to cases involving technical and intricate questions of fact and policy that Congress has assigned to a specific agency.").

¹⁴⁵ PRIMARY JURISDICTION at 1254, *supra* note 130 (quoting Brandeis, J., in *Great N. Ry. v. Merchants Elevator Co.*, 259 U.S. 285, 291 (1922)).

¹⁴⁶ *Arsberry*, 244 F.3d at 563; see PRIMARY JURISDICTION at 1256, *supra* note 130; see also KENNETH CULP DAVIS at 305-09, *supra* note 122.

dispute.¹⁴⁷ Thus, questions of law can be decided by courts exclusively, as long as the questions do not depend on technical knowledge or administrative discretion.¹⁴⁸

Even though a court may have jurisdiction over a suit, it may still decline to review an agency action if it is not final or if the petitioner did not exhaust all the administrative remedies available.¹⁴⁹ Courts generally require the exhaustion of administrative remedies prior to judicial review.¹⁵⁰ A petitioner must first take a dispute through the agency's administrative process prescribed in the statute before bringing a dispute to the courts.¹⁵¹ Most cases use "finality" and "exhaustion" interchangeably, because if a petitioner has not exhausted an administrative remedy the agency action is not final.¹⁵²

The policy behind requiring exhaustion is that if an administrative remedy is unexhausted, the suit is premature; judicial resources should not be wasted until all possible avenues of administrative relief have been explored.¹⁵³ If, however, "considerations of individual justice, efficiency, or wise judicial administration support the need for judicial review," exhaustion may not be required.¹⁵⁴ Exhaustion is also usually not required when it would be futile, for instance, when the agency has already stated that it would deny relief.¹⁵⁵

¹⁴⁷ *Id.*

¹⁴⁸ See e.g. PRIMARY JURISDICTION at 1256, *supra* note 130 (arguing that "[i]f the interpretation of a tariff turns on the peculiar technical meaning of words, as distinguished from their ordinary meaning, or on the existence of incidents of service alleged to be attached by usage to the transaction, the question is within the primary jurisdiction of the agency).

¹⁴⁹ PRIMARY JURISDICTION at 1261, *supra* note 130; KENNETH CULP DAVIS at 305-09, *supra* note 122.

¹⁵⁰ *Id.*

¹⁵¹ KENNETH CULP DAVIS at 305-09, *supra* note 122.

¹⁵² *Id.*

¹⁵³ See PRIMARY JURISDICTION at 1261, *supra* note 130; see also KENNETH CULP DAVIS at 309, *supra* note 121 (listing five reasons for the exhaustion requirement).

¹⁵⁴ KENNETH CULP DAVIS at 307, *supra* note 122 (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1938) "[It is] the long settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted").

¹⁵⁵ PRIMARY JURISDICTION at 1264, *supra* note 130.

C. CONTROVERSY OVER APPLICATION OF PREEMPTION DOCTRINE AS AN AFFIRMATIVE DEFENSE

Proponents of FDA preemption insist that it was Congress's intent to give the FDA complete authority, utilizing scientific opinion to determine what prescription drug information should be made available to the public.¹⁵⁶ The reasoning is that if courts of various jurisdictions are allowed to decide what constitutes adequate warnings for safe and effective use, the public will receive inconsistent labeling information from jurisdiction to jurisdiction.¹⁵⁷ Ultimately, this would frustrate the FDA's efforts to promote uniformity and consistency in the regulation of prescription drug labeling.¹⁵⁸

Opponents of FDA preemption contend that the FDA's drug labeling requirements are minimum standards subject to supplementation by a jury's verdict.¹⁵⁹ They believe that it is up to a lay jury to determine, based on the facts of each case, if a drug manufacturer has met its common-law duty to warn.¹⁶⁰ Courts have supported this view by verifying that additional warnings may be added to labeling without advance FDA ap-

¹⁵⁶ 21 U.S.C. § 393(b)(4)(2000) (explaining the FDA's mission as one "in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products"); see John F. Del Giorgio, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing On State Court Jury Decision in Products Liability Cases*, 22 J. MARSHALL L. REV. 629, 644-656 (1989) (giving a detailed analysis establishing that FDA labeling regulations meet all four of the tests for implied preemption and, thus, preempt state law); see also Brief of the United States of America at 4-6, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Sept. 5, 2002).

¹⁵⁷ See *Bernhardt*, 2000 WL 1738645, at *3 (directing Pfizer to issue the notices that would not preclude the FDA from issuing a second notice or requiring Pfizer to do so, thus creating "the potential for inconsistent directions concerning a serious medical ailment and how it is best treated").

¹⁵⁸ See 21 U.S.C. § 355 (2000); see also 21 U.S.C. § 301(2000); *Weinberger*, 412 U.S. at 654; Brief of the United States of America at 5, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Sept. 5, 2002).

¹⁵⁹ RESTATEMENT (SECOND) OF TORTS § 288C (1965) (instructing that "[c]ompliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.").

¹⁶⁰ *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (finding that "[a]n FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes."); *Savina*, 795 P.2d at 931; *Feldman*, 479 A.2d at 391.

proval.¹⁶¹ In fact, the FDA itself has recognized that manufacturers may add warnings without advance FDA approval.¹⁶² This supports the argument that federal prescription labeling regulations do not preempt state tort law.

IV. APPLICATION OF AGENCY PROCEDURES AND LEGAL DOCTRINES TO PAXIL AND PAXIL LITIGATION

In GSK's motion for reconsideration of the preliminary injunctive order, the drug manufacturer asserted several defenses.¹⁶³ GSK's defense was that the court did not have jurisdiction to make a ruling on prescription drug advertising.¹⁶⁴ GSK and the FDA argued that Congress intended the FDA's drug approval guidelines to preempt state law.¹⁶⁵ Consequently, argued GSK and the FDA, the control and regulation of the Paxil television advertisements were within the FDA's exclusive jurisdictional power.¹⁶⁶

If the court did not find that the FDA had exclusive jurisdiction, GSK and the FDA alternatively argued that the FDA had primary jurisdiction over the issues of drug effectiveness and drug side effects.¹⁶⁷ According to this argument, since court lacks the scientific sophistication required to make scientific determinations, it would be an improper allocation of power to allow the court to have jurisdiction over issues that require scientific expertise.¹⁶⁸ Under this theory, GSK and the FDA ar-

¹⁶¹ *E.g.*, *Feldman*, 479 A.2d at 390; *In re Tetracycline Cases*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989).

¹⁶² Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (Food and Drug Admin. June 26, 1979) (stating "[t]he addition to labeling and advertising of additional warnings, as well as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters directed to health care professionals is not prohibited by these regulations.").

¹⁶³ See Memorandum of Decision re: Motion for Reconsideration of Order Granting Preliminary Injunction at 2-3, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed October 21, 2002).

¹⁶⁴ *Id.* at 2.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 3.

¹⁶⁸ *Id.*

gued that the court would be acting outside of its core competencies.¹⁶⁹

The court first addressed GSK's and the FDA's position that the FDCA preempted state law.¹⁷⁰ The court found that there was no evidence that Congress intended, either expressly or impliedly, for the FDCA to preempt state law.¹⁷¹ By suggesting that the FDA preempted state law, GSK and the FDA were in effect arguing that Congress opted not to provide for a private cause of action while simultaneously doing away with state common-law claims.¹⁷² In fact, the court found, GSK's and the FDA's preemption position actually diminished, rather than advanced, the FDCA's purpose to protect the public.¹⁷³

The court next addressed the deference of issues to the FDA under the doctrine of primary jurisdiction.¹⁷⁴ In its opinion, the court emphasized that it was not called on to resolve the question of whether Paxil is habit-forming.¹⁷⁵ It was concerned only with whether the phrase could be misleading to consumers.¹⁷⁶ Accordingly, the court held that it was not necessary to explore issues such as drug effectiveness or drug side effects, which are areas undisputedly within the FDA's expertise.¹⁷⁷

In contrast, the court explained that in the case of the "non habit-forming" phrase used in commercials, the question of whether members of the general public are likely to "[misinterpret] a statement is within one of the courts' core competencies."¹⁷⁸ The court stated that it was unwilling to accept the FDA's determination, though it had given consideration to the extensive research done by the FDA with regard to Paxil and

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 2.

¹⁷¹ *Id.* at 2. The court said that GSK and the FDA arguments run contrary to other decisions. *Id.*, citing *Knoll*, 57 F. Supp. 2d at 615; *Ohler*, 2002 WL 88945, at *7,8.

¹⁷² *Id.* at 3.

¹⁷³ *Id.* (arguing that FDA and GSK's position on Congressional intent when enacting the FDCA "contravenes common sense" and declining the parties' invitation to find that Congress declined to provide for a private cause of action and to eliminate availability of common law state claims).

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 4.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 3.

¹⁷⁸ *Id.*

its approval of Paxil's advertisements."¹⁷⁹ Ultimately, the court denied the preliminary injunction because the FDA's evidence was persuasive to the extent that it changed the court's evaluation of the plaintiffs' likelihood of success on the merits.¹⁸⁰

While the court denied the injunction, it succinctly analyzed the doctrines of preemption and primary jurisdiction within the context of the Paxil commercials.¹⁸¹ Although the same court also denied the certification of a state-wide class, plaintiffs are continuing to bring state actions against GSK, asserting, among other things, failure-to-warn claims.¹⁸² The next section sets out the current warning label found on Paxil, discusses the FDA's process of determining whether a drug is habit-forming, and illustrates the potential roadblocks plaintiffs may face.

A. PAXIL WARNING LABELS

The safety review of Paxil was conducted one year prior to its approval.¹⁸³ Under the heading "Abuse," the FDA's safety review states:

Incidents of tolerance, dependence and drug seeking were not observed in patients in the [Paxil] clinical trials. The absence of such incidents precluded the need for systematic study of this issue. [Prozac], a widely prescribed and pharmacologi-

¹⁷⁹ *Id.* at 4. It should be noted that despite the court's reversal, GSK stopped using the phrase "Paxil is non habit-forming" at the end of television commercials. Zoloft, a different SSRI antidepressant, is currently running a television commercial which ends with the phrase "Zoloft is non habit-forming."

¹⁸⁰ Memorandum of Decision re: Preliminary Injunction at 7, *In re Paxil Litigation*, No. CV 01-07937 MRP, (C.D. Cal. filed Aug. 16, 2002) (citing *Am. Motorcyclist Assoc. v. Watt*, 714 F.2d 962 (9th Cir. 1983)). In order for the court to grant a preliminary injunction, the plaintiffs must establish four elements. *Id.* First plaintiffs must show a likelihood of success on the merits. *Id.* Second, plaintiffs must show a significant threat of irreparable injury. *Id.* Third, they must at least tip the scales of justice in the balance of hardships in favor of the plaintiff. *Id.* Finally, plaintiffs must prove a furtherance of public interest. *Id.*

¹⁸¹ Memorandum of Decision re: Motion for Reconsideration of Order Granting Preliminary Injunction at 4 (C.D. Cal. filed October 21, 2002).

¹⁸² Interview with Donald Farber, Plaintiff Attorney, Law Offices of Donald J. Farber, in San Rafael, Cal. (Oct. 31, 2003)

¹⁸³ *KLINE* at 4, *supra* note 62.

cally similar compound, has not been abused since its introduction into the market.¹⁸⁴

Based on the safety review, the agency decided that it did not consider Paxil to be a habit-forming drug.¹⁸⁵ The FDA considers the term “habit-forming” to fall within the general category of “drug abuse and dependence.”¹⁸⁶

The FDA evaluated Paxil and its product labeling each time it has been approved for treatment of an additional condition.¹⁸⁷ In addition, Paxil’s labeling has been reviewed as a result of post-marketing reports of adverse events.¹⁸⁸ For instance, in April 2001, Paxil was approved for treatment of generalized anxiety disorder.¹⁸⁹ Included with the approval letter was a package label insert for the Adverse Reactions indicating potential side effects associated with discontinuation of its use.¹⁹⁰ Eight months later, in December 2001, Paxil was approved for treatment of post-traumatic stress disorder.¹⁹¹ The package insert attached to that approval letter was revised due to additional reports of side effects associated with discontinuation.¹⁹² The label change moved the description of the discontinuation side effects up from the Adverse Reactions section to the more significant Precautions section.¹⁹³

¹⁸⁴ *Id.*; Martin Brecher, M.D., D.M.Sc., *Review and Evaluation of Clinical Data, Safety Review* at 32, Original NDA 20-031, Paroxetine, (June 19, 1991), *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), Exhibit 1.

¹⁸⁵ SCARLETT at 13, *supra* note 55.

¹⁸⁶ *Id.* at 11.

¹⁸⁷ See Declaration of Robert J. Temple, M.D. at 2, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Sept. 5, 2002). In September of 2002, Dr. Temple was the Director of the Office of Medial Policy and the Acting Director of the Office of Drug Evaluation. *Id.* at 1-2. Both offices are within the FDA’s Center for Drug Evaluation and Research Department. *Id.* The Office of Drug Evaluation decides whether to approve NDA’s for neuropharmacologic/psychopharmacologic drug products. *Id.* He personally reviewed and approved the drug Paxil and its product labeling. *Id.*

¹⁸⁸ *Id.* at 2.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* Though the FDA doesn’t consider SSRIs to be habit-forming, it does recognize that SSRIs have been known to cause withdrawal symptoms known as “discontinuation syndrome.” *Id.* at 4-5. The FDA believes that there is a critical distinction between the phenomenon of “discontinuation syndrome” and the drug-seeking behavior associated with habit-forming drugs. *Id.*

¹⁹¹ *Id.* at 2.

¹⁹² *Id.*

¹⁹³ *Id.*

Ultimately, the FDA has backed GSK's position claiming that there is no evidence that Paxil is habit-forming.¹⁹⁴ Because the FDA does not associate the drug with addiction, it only required that GSK add a precaution to the labeling of Paxil to warn of potential side effects that may occur upon discontinuation.¹⁹⁵ The Precautions category falls third in the descending hierarchy of label sections.¹⁹⁶ Precautions contain special care information for the practitioner, to ensure safe and effective use of the drug.¹⁹⁷ The package insert for Paxil carries the following precaution:

. . . [T]he following adverse events were reported at an incidence of 2% or greater for *Paxil* and were at least twice that reported for placebo: abnormal dreams (2.3% vs 0.5%), paresthesia (2.0% vs 0.4%), dizziness (7.1% vs 1.5%). In the majority of patients, these events were mild to moderate and were self-limiting and did not require medical intervention.

During *Paxil* marketing, there have been spontaneous reports of similar adverse events, which may have no causal relationship to the drug, upon the discontinuation of *Paxil* (particularly when abrupt), including the following: dizziness, sensory disturbances, (e.g., paresthesias such as electric shock sensations), agitation, anxiety, nausea, and sweating. These events are generally self-limiting. Similar events have been reported for other selective serotonin reuptake inhibitors.

Patients should be monitored for these symptoms when discontinuing treatment, regardless of the indication for which *Paxil* is being prescribed. A gradual reduction in the dose rather than abrupt cessation is recommended whenever pos-

¹⁹⁴ *Id.* at 4.

¹⁹⁵ <http://www.fda.gov/medwatch/SAFETY/2001/dec01.htm> (last visited 9/3/03); *Federal Judge Reverses Order Barring Paxil TV Ads*, 18 NO. 8 ANDREWS PHARMACEUTICAL LITIG. REP. 14 (Nov. 2002); Telephone interview with Cindy Hall, Paralegal, Baum, Hedlund, Aristei, Guilford & Shivo (Oct. 2, 2003). Karen Barth of Baum, Hedlund, Aristei, Guilford & Shivo, the firm representing the plaintiff's case, has commented that it took the FDA over a decade to classify Valium, an anti-anxiety drug, as habit-forming. *Id.*

¹⁹⁶ NOAH at 327, *supra* note 52 (explaining that the second most important labeling category, called Warnings, is designated for serious adverse reaction risks, but the risks are not so serious as to clearly outweigh any possible benefit of the drug).

¹⁹⁷ 21 C.F.R. § 201.57 (f) (1), (2) (2003). There is a subsection under the Precautions label designated for information to be given to patients to ensure safe and effective use of the drug. *Id.* This is generally where one would find precautionary information, for example, not to drive while using the drug. *See id.*

sible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing dose but at a more gradual rate (see DOSAGE and ADMINISTRATION)¹⁹⁸

The label change reads that the symptoms “may have no causal relationship to the drug.” Neither does it mention the terms “withdrawal” or “addictive.”¹⁹⁹ Because of this, the plaintiffs contend the label changes are too vaguely worded, even for physicians; hence they do not provide an adequate warning.²⁰⁰ The FDA maintains that during its review of the NDA for Paxil, medical reviewers and scientists determined that there was no clinical evidence of drug-seeking behavior associated with its use.²⁰¹ Since the FDA determined Paxil to be non habit-forming, it considered patients to be adequately warned.²⁰²

B. APPLICATION OF CURRENT LABELING REGULATIONS MAY PRODUCE UNJUST RESULTS

Although drug manufacturers may theoretically change a label at any time to enhance drug safety, the reality is that manufacturers cannot change a label without FDA approval.²⁰³ The FDA reinforces its control over label revisions by requiring manufacturers to report all adverse experiences with a drug after it has been introduced to the general public.²⁰⁴ It is the FDA that makes the final determination whether reports of

¹⁹⁸ <http://www.fda.gov/medwatch/SAFETY/2001/dec01.htm> (last visited 10/15/03). TEMPLE at 2, *supra* note 187 (disclosing that the final printed label was released in January 2002).

¹⁹⁹ <http://www.fda.gov/medwatch/SAFETY/2001/dec01.htm> (last visited 10/15/03). See paragraph two of label text. *Id.*

²⁰⁰ PEOPLE, *supra* note 1.

²⁰¹ TEMPLE at 4, *supra* note 187; SCARLETT at 4, *supra* note 55; KLINE at 4, *supra* note 62.

²⁰² TEMPLE at 4, *supra* note 187.

²⁰³ 21 C.F.R. § 314.70(c)(2)(i)-(iv) (2003) (permitting label changes to enhance safety). *Cf.* Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 236 (1986) (explaining that both the FDA and manufacturers do not foresee that labels may be changed without prior approval).

²⁰⁴ 21 C.F.R. §§ 310.303(a) (2003), 310.305(b) (2003), 314.80(a) (2003).

adverse experiences warrant a label revision.²⁰⁵ Therefore, under current law, even if courts continue to hold that manufacturers can add more information to warning labels, the FDA's regulations could make it difficult for manufacturers to make label revisions.²⁰⁶

V. ALTERNATIVE INTERPRETATIONS THAT WOULD ACHIEVE FAIRER RESULTS

Plaintiffs in the recent Paxil litigation are claiming that the drug manufacturer failed to give adequate warnings that the drug produced withdrawal side effects commonly associated with habit-forming drugs.²⁰⁷ Whether the Paxil plaintiffs can successfully litigate claims against GSK could turn on how the court interprets "habit-forming." If a court applying state law decides that the question of whether Paxil is "habit-forming" is an essential part of the claim, the question should be deferred to the FDA for a factual determination.²⁰⁸ In contrast, if a court decides that whether Paxil is habit-forming is not essential to adjudicate the claim, a drug manufacturer could be held accountable to supplement labeling in accordance with factual determinations made by the jury.²⁰⁹

A. IF A COURT VIEWS "HABIT-FORMING" AS AN ESSENTIAL PART OF A PLAINTIFF'S CLAIM

1. *Strict Judicial Review*

The legal system must enforce a strict judicial review of the FDA's factual determinations before sending the determination back into the deferring court.²¹⁰ If a court determines

²⁰⁵ *Id.*

²⁰⁶ Interview with Donald Farber, San Rafael, Ca (11/26/03). It should be noted that since the FDA does not possess any powers beyond those conferred on the federal government by the Constitution, prohibiting manufacturers from strengthening label warnings is a violation of the First Amendment. *Id.* Therefore, manufacturers have all the power they need to supply more information to the consumer. *Id.*

²⁰⁷ See *supra* notes 19-20 and accompanying text.

²⁰⁸ See *supra* Part III for explanation of primary jurisdiction.

²⁰⁹ *Id.*

²¹⁰ KENNETH CULP DAVIS at 272-280, *supra* note 122; ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW § 13.1 (2d ed. 2001); PRIMARY JURISDICTION at 1252, *supra* note 130.

that deciding the question of whether Paxil is habit-forming is an essential part of a claim, deferral to the FDA is appropriate.²¹¹ If the issue is deferred to the FDA, the agency would need to assess Paxil for abuse potential.²¹² Next, the FDA's determination on the question would undergo judicial review.²¹³ If the FDA's action passes judicial review, the resolved issue would be returned to the deferring court.²¹⁴ That court would then apply the law to the FDA's factual determination.²¹⁵

According to the FDA, Paxil is not habit-forming.²¹⁶ If this determination passes judicial review, then there is no duty to warn the plaintiffs and, therefore, no breach.²¹⁷ The result: the suit would be dismissed on summary judgment grounds.²¹⁸ The effect: plaintiffs who suffered from severe withdrawal symptoms have no place to go to seek legal redress.²¹⁹ This would suggest that Congress barred relief for persons injured by prescription drugs as a result of a determination made by the very agency it empowered to provide for the safe and effective use of prescription drugs.²²⁰

2. *Adoption of an Accepted Scientific Method*

If the FDA has exclusive jurisdiction over the issue of "habit-forming," it is necessary for the FDA to adopt an accepted scientific method for determining the abuse potential of a drug. Abuse liability is complex and has many dimensions.²²¹

²¹¹ *See id.*

²¹² *See id.*

²¹³ *See* 5 U.S.C. § 706 (2000) (defining the scope of judicial review and giving courts the power to set aside an agency action).

²¹⁴ *Id.*; *see supra* note 135 and accompanying text.

²¹⁵ *Id.*

²¹⁶ Brief of the United States at 2, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx) (C.D. Cal filed Sept. 4, 2002); TEMPLE at 4, *supra* note 187.

²¹⁷ *See id.*

²¹⁸ *See id.*

²¹⁹ *See supra* notes 170-173 and accompanying text.

²²⁰ Declaration of Erwin Chemerinsky at 3, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx) (C.D. Cal. filed Sept. 12, 2002) (*citing* *Medtronic v. Lohr*, 518 U.S. 470, 486-87 (1996)). Erwin Chemerinsky is a law professor at the University of Southern California. *Id.* at 2. He has written four books, over 100 law review articles, and two treatises all relating to constitutional law and federal court jurisdiction. *Id.*

²²¹ DRAFT GUIDELINES at 2, *supra* note 64. (stating that "there is no single test or assessment procedure that, in itself, is likely to provide a full and complete characterization. Rather the assessment of abuse liability must be based upon review of all available data. . .and summary risks intended to the public health following introduction of the substance to the general population").

Currently the FDA's approach to determining abuse potential is outlined in the Draft Guidelines for Abuse Liability Assessment (hereinafter "guidelines").²²² Due to the many different assessment procedures and the continually evolving nature of science in the area of substance abuse, the FDA's guidelines decline to adopt a "cookbook" of specific tests.²²³ Rather, the guidelines encourage a "considerable degree of scientific flexibility with respect to precise methods."²²⁴

According to the guidelines, not all drugs are assessed to the same degree for abuse potential.²²⁵ The FDA characterizes the substance in relation to its chemical structure and class.²²⁶ The guidelines point out that "some" assessment should be performed for any new drug that is being developed for an indication that has previously been treated with habit-forming drugs.²²⁷ Determinations of whether more specific testing is needed are based on the substance's categorical class.²²⁸ If the substance is from a new class of drugs, then the guidelines suggest that it "may" be better to select a comparison class to act as a reference against which the new substance can be compared.²²⁹

Paxil is an SSRI antidepressant.²³⁰ According to FDA scientists, SSRIs as a class are not habit-forming.²³¹ As a result, during Paxil's safety review, the FDA examined only those clinical studies provided by the drug manufacturer.²³² The FDA felt that no further independent testing was necessary.²³³ The FDA affirmed their conclusion by comparing Paxil with Prozac, another SSRI.²³⁴

²²² *Id.* Note that the guidelines are in draft form; this author was not able to find them submitted in the federal register, or codified in the Code of Federal Regulation.

²²³ *Id.*

²²⁴ *See id.* (The emphasis of the guidelines is on the types of issues to be addressed rather than specific methodology).

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *See* JOHN H. GREIST, M.D. AND JAMES W. JEFFERSON, M.D., DEPRESSION AND ITS TREATMENT 51 (American Psychiatric Press 1992) (explaining that people suffering from depression may abuse alcohol or other drugs in attempts to self-medicate).

²²⁸ DRAFT GUIDELINES at 2, *supra* note 64.

²²⁹ *Id.* at 5.

²³⁰ *See supra* notes 15-18 and accompanying text.

²³¹ *See supra* note 31 and accompanying text.

²³² *See* BRECHER at 32, *supra* note 184; KLINE at 4, *supra* note 62.

²³³ *Id.*

²³⁴ *Id.*

The safety review noted that there have been no reports of “habit-forming” traits since Prozac’s introduction to the market.²³⁵ The FDA, however, has not independently assessed Paxil’s abuse potential.²³⁶ It has, instead, reached its determination solely from information provided by the drug manufacturer.²³⁷

If the FDA is granted exclusive jurisdiction over the factual determination of whether Paxil is habit-forming, the FDA needs to conduct independent studies on Paxil’s abuse potential.²³⁸ It would be highly likely that a judicial review of the FDA’s factual determinations regarding abuse potential would disclose when a drug, such as Paxil, has not been independently tested.²³⁹ Judicial review would therefore be an effective way to ensure that the FDA performs independent studies on a drug rather than simply relying on information provided by the drug manufacturer.

B. A COURT MAY NOT NEED TO KNOW IF PAXIL IS “HABIT-FORMING” IN ORDER TO RESOLVE A CLAIM

A court may decide that it is not necessary to resolve the technical issue of “whether Paxil is habit-forming” to resolve the plaintiffs’ failure-to-warn claim.²⁴⁰ The court could then compare Paxil’s label warnings with the plaintiffs’ alleged experiences to determine if the manufacturer’s warnings were

²³⁵ *Id.*

²³⁶ *Id.*; see *supra* notes 221-229 and accompanying text.

²³⁷ See *supra* note 18 for discussion about Paxil’s short half-life and the relationship between habit-forming traits and the half life of a drug.

²³⁸ Interview with Donald Farber, Law Offices of Donald J. Farber, San Rafael, Cal. (Nov. 26, 2003).

²³⁹ *Id.*

²⁴⁰ Plaintiff’s Reply to Defendant’s Opposition to Plaintiff’s Motion for Preliminary Injunction at 19, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Aug., 12, 2002), (quoting *In re Methyl Tertiary Butyl Ether Products Liability Litigation*, 175 F. Supp.2d 593, 617 (S.D.N.Y. 2001) (“[T]he issues raised by these claims may require some technical analysis, questions of whether a product is in fact defective, whether defendants breached any duties owed to plaintiffs by marketing such a product or failing to give adequate warnings, whether a defendant has conspired to mislead the public regarding the hazards of a product, and whether a plaintiff’s injuries were caused by a defendant’s conduct, are legal questions that fall within the conventional experience of judges, not administrative agencies.”).

adequate.²⁴¹ In the Paxil litigation, plaintiffs would be able to litigate claims and possibly obtain relief for damages.²⁴²

1. *Labeling Requirements Should Be Minimal Standards*

The FDA should not be granted exclusive jurisdiction over the term “habit-forming” for several reasons. First, the term has no accepted medical meaning and should not fall within the FDA’s expertise.²⁴³ “Habit-forming” is a lay term and should be defined from a societal perspective.²⁴⁴ As such, in a failure-to-warn situation, the issues should be resolved by the jury.²⁴⁵

Second, the effect of allowing the FDA to determine what “habit-forming” means to the general population is that important risk information would be diluted or kept from drug labeling. Under the learned intermediary doctrine, if the information is not included in the drug label, physicians do not have access to it.²⁴⁶ If a physician is not aware of a drug’s potential risk, he or she cannot properly balance the information or pass important information on to patients.

Third, the issue is not whether Paxil is habit-forming. Rather, the issue is whether physicians and patients are adequately warned of the potential withdrawal side effects associated with discontinuation of Paxil. When a patient experiences severe side effects from a drug without proper warning (as alleged by the plaintiffs in the Paxil litigation) it is a factual determination within the jurisdiction of the courts.²⁴⁷

²⁴¹ See *supra* Part I for current labeling requirements and Part IV for withdrawal symptoms associated with Paxil.

²⁴² See *supra* notes 82-96 and accompanying text.

²⁴³ Interview with Donald Farber, San Rafael, Cal. (Nov. 26, 2003).

²⁴⁴ TEMPLE at 4, *supra* note 187 (declaring that “[the FDA thinks that habit-forming] generally implies that patients will seek out the drug and continue to take it in the absence of a medical need.”); *But cf.* Declaration of Kellyanne Conway at 2-5, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Sept., 12, 2002) (Explaining results of opinion poll which asked the average American to define “habit-forming” in their own words). To define “habit-forming” more than 25% used the terms “addiction” or “becoming addicted.” *Id.* Almost 20% responded that it was “something you do over and over,” “all the time,” or “a lot.” *Id.* Close to 15% said it was “something you can’t stop.” *Id.*

²⁴⁵ *Id.*

²⁴⁶ See *supra* notes 82-96 and accompanying text.

²⁴⁷ See Chemerinsky at 4, *supra* note 220.

2. *Exhaustion of Administrative Remedies*

Finally, the administrative process prescribed in the FDCA requires an aggrieved person to petition the FDA by filing a citizen petition.²⁴⁸ The FDA must consider the petition and issue a decision to the citizen within 180 days.²⁴⁹ The FDA has already stated that it does not view Paxil as “habit-forming.”²⁵⁰ As such, the filing of a citizen petition would be a futile effort increasing delay.²⁵¹ Therefore, a court should not require the exhaustion of this administrative remedy before reviewing the FDA’s determination.

VI. CONCLUSION

Even though the FDA has concluded that Paxil is non habit-forming, it is unlikely that the litigation surrounding Paxil will disappear. The fact that the FDA has moved the description of withdrawal effects into the Precautions label heading is not enough to ensure that physicians are being adequately educated about potential severe withdrawal effects associated with Paxil and SSRIs. The reality is that when some patients try to stop using Paxil they experience withdrawal effects that are so debilitating that they are forced back onto the drug. They feel violated because they were not warned.²⁵²

In light of the flood of recent litigation, it is important for courts to understand how preemption and primary jurisdiction arguments fit into products liability law. Courts need to establish an appropriate working relationship with the FDA regarding claims that arguably fall within the FDA’s regulatory scheme. The FDA needs to adopt an accepted scientific method to assess the abuse potential of new drugs. Strict judicial review is essential to examine the breadth of the FDA’s regulatory power, to ensure that the agency is promoting public health through the safe and effective use of prescription drugs. Otherwise, primary jurisdiction becomes a judicially-made doctrine employed by agencies to avoid liability for injuries to

²⁴⁸ 21 C.F.R. § 10.30 (2003).

²⁴⁹ *Id.*

²⁵⁰ Plaintiff’s Response to Brief of the United States at 9, *In re Paxil Litigation*, No. CV-01-07937 MRP (CWx), (C.D. Cal. filed Sept. 23, 2002).

²⁵¹ *Id.*

²⁵² See *supra* notes 1-22 and accompanying text.

plaintiffs. This result would grant the FDA a plenary power that conflicts with the very purpose of our court system.

DENISE K. TOP*

* Denise K. Top, J.D. Candidate, 2005, Golden Gate University School of Law. I would like to thank my editor Efi Rubinstein for her rigorous review. I would also like to show gratitude to Professor Leslie Rose for her organizational genius; Maryanne Gerber, J.D., for her commitment to legal research; and Teresa Wall for her positive attitude and encouragement. Finally, I would like to express my appreciation to Donald Farber, J.D., for sharing his knowledge, copy machine, and time.