

**MARKETING PHARMACEUTICAL PRODUCTS IN THE
TWENTY-FIRST CENTURY: AN ANALYSIS OF THE
CONTINUED VIABILITY OF TRADITIONAL
PRINCIPLES OF LAW IN THE AGE OF DIRECT-TO-
CONSUMER ADVERTISING**

VICTOR E. SCHWARTZ,* CARY SILVERMAN,**
MICHAEL J. HULKA*** & CHRISTOPHER E. APPEL****

INTRODUCTION335

I. MARKETING AND REGULATION OF
PHARMACEUTICALS FROM PAST TO PRESENT336

 A. Concepts of Product Mislabeling and
 Pre-Market Regulation336

 B. Establishment of the Modern Regulatory
 Regime for Approval and Marketing of
 Prescription Drugs340

 C. DTC Advertising and Its
 Regulation Today344

 D. The Relevance of History to DTC
 Advertising Today349

II. THE POTENTIAL BENEFITS AND PITFALLS
OF DTC ADVERTISING.....350

* Chairman, Public Policy Group, Shook, Hardy & Bacon L.L.P. (Washington, D.C.); Co-Author, PROSSER, WADE AND SCHWARTZ'S TORTS (11th ed. 2005); Member, Advisory Committees of the American Law Institute's Restatement of the Law (Third) Torts: Products Liability, Apportionment of Liability, General Principles, Liability for Physical and Emotional Harm projects; J.D., Columbia University (magna cum laude); B.A., Boston University (summa cum laude).

** Of Counsel, Shook, Hardy & Bacon L.L.P. (Washington, D.C.); J.D., M.P.A., The George Washington University Law School (2000) (with honors); B.S., Management Science, State University of New York College at Geneseo (1997).

*** Counsel, Eli Lilly and Company; Law Clerk, Judge Michael S. Kanne, U.S. Court of Appeals for the Seventh Circuit; J.D., Indiana University Bloomington School of Law (magna cum laude); Editor-in-Chief, Indiana Law Journal. The views expressed herein do not necessarily represent the position of Eli Lilly and Company.

**** Attorney, Public Policy Group, Shook, Hardy & Bacon L.L.P. (Washington, D.C.); J.D., Wake Forest University School of Law; B.S., University of Virginia.

III. TRADITIONAL RULES OF LAW REMAIN VIABLE, SOUND PUBLIC POLICY TODAY	354
A. Ask Your Doctor: The Learned Intermediary Doctrine	355
1. Learned Intermediary Fundamentals.....	355
2. Traditional Limited Exceptions to the Rule	357
3. A Few Recent Decisions Chip Away at the Learned Intermediary Rule	361
4. Exceptions for DTC Marketing Represent Unsound Policy	364
B. Effect of Compliance with FDA Requirements on Liability	369
1. Common Law Principles	369
2. Statutory Consideration of the Effect of Regulatory Compliance on Liability	371
a. Presumption of Nondefectiveness ...	372
b. Preclusion of Punitive Damages for FDA-Approved Pharmaceuticals.....	373
c. Placing Regulated Conduct Beyond the Scope of Consumer Protection Laws.....	375
C. Conflicts with Federal Authority: Preemption.....	377
1. Methods of Preemption	378
2. The FDA's Changing Priorities in a DTC Environment	379
3. Public Policy Supports Expanding Scope of Preemption.....	384
CONCLUSION.....	386

INTRODUCTION

According to a recent article in the *New England Journal of Medicine*, total pharmaceutical industry spending on direct-to-consumer (DTC) advertising of prescription drugs rose from \$985 million in 1996 to \$4.2 billion in 2005—an increase of 330%.¹ As a result, advertisements for prescription drugs are pervasive and consumers regularly view them in magazines and online, watch them on television, and listen to them on the radio.

This figure, however, must be put in perspective. Research also shows that during the same period, spending on pharmaceutical marketing increased not only for DTC advertising, but also across the board, from about \$11.4 billion to \$29.9 billion.² In fact, although DTC advertising has increased steadily both in absolute terms and as a percentage of pharmaceutical sales, promotion of drug treatments directly to physicians and other health care professionals still far outweighs DTC advertising.³ In 2005, \$7.2 billion was spent on promotion to physicians alone.⁴ Relatively speaking, DTC advertising is concentrated on a small number of brands.⁵ Its reach, however, is considerable, and DTC advertising is the subject of significant debate among courts and commentators.⁶

In light of these changes in the marketing environment, this Article examines whether traditional legal principles governing the duty to warn of the risks of pharmaceutical products remain sound public policy. First, the Article considers the early history of the sale and marketing of pharmaceutical products,

1. Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 *NEW ENG. J. MED.* 673, 673, 676 (2007).

2. *Id.*

3. *See id.* at 675–77 (finding that only 14% of total industry expenditures on pharmaceutical promotion were devoted to DTC advertising in 2005).

4. U.S. GEN. ACCOUNTING OFFICE, GAO-07-54, *PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING* 13 (2006) [hereinafter 2006 GAO REPORT]. Manufacturer spending on DTC advertising also pales in comparison to industry spending on research and development, with \$31.4 billion spent in 2005. *Id.*

5. Donohue, *supra* note 1, at 676 (finding that the twenty drugs with the highest DTC spending made up 54.4% of total industry spending on DTC advertising).

6. *See, e.g., infra* Part III.C (discussing the preemption debate for DTC-advertised drugs).

discussing the initial tragic absence of regulation, followed by the establishment of the FDA and the pre-market approval process. It then examines the modern age of pharmaceutical advertising, including the FDA's relatively recent guidance on DTC broadcast advertising and the extent of its regulation. Finally, the Article examines rules of law that establish the legal landscape for warnings and advertising in the pharmaceutical context. This includes the learned intermediary doctrine, the effect of regulatory compliance on product liability and consumer protection claims, and the application of conflict preemption principles to tort law claims involving FDA-approved products.

The Article finds that the two foundational tenets underlying these doctrines have not changed. First, on a societal level, the FDA continues to regulate the pharmaceutical industry closely, both in approving pharmaceutical products as safe and effective for certain classes of patients and in mandating disclosure of risks so that physicians can accurately counsel their patients. Second, physicians remain individually responsible for diagnosing each patient regardless of advertising and for helping each patient make an educated treatment decision in light of the risks and benefits of a drug. Because of their authority to write prescriptions, physicians have ultimate responsibility for deciding whether a given drug is appropriate and beneficial for the patient. Prescription drug manufacturers, therefore, have obligations to report all material information to the FDA, both before and after approval, so that the FDA can make a fully informed decision about what products should be available to the market and can convey adequate information to physicians for patient counseling purposes.

The Article concludes that, irrespective of the rise of DTC advertising, traditional principles of law fully retain their viability in the post-DTC world both as a matter of jurisprudence and sound public policy.

I. MARKETING AND REGULATION OF PHARMACEUTICALS FROM PAST TO PRESENT

A. *Concepts of Product Mislabeling and Pre-Market Regulation*

Before examining modern regulation of pharmaceutical products and their advertising, placing the current system in historical context is useful. Companies that sell medications

have advertised their products directly to consumers since the beginning of medicine. The increasing regulatory scrutiny regarding approval, marketing, and sale of prescription drugs, however, is a relatively recent development. The new oversight is meant to ensure that drugs are safe and effective and that drug advertising does not mislead the public.

During much of the eighteenth and nineteenth centuries, companies regularly advertised patent medicines, which were available without a prescription, directly to consumers in American newspapers. Indeed, during the 1800s, patent medicine advertisers spent more on newspaper advertisements than any other group.⁷ At the time, no regulatory structure existed to provide for pre-market review of these medicines to ensure their safety or efficacy or to substantiate the claims their producers made in these advertisements. The grifting snake oil salesman, a character that still pervades the mythology of the American West, dates to this unregulated period.

In 1906, Upton Sinclair published his novel, *The Jungle*, with its detailed account of the unsanitary conditions of the Chicago stockyards.⁸ Prompted by the resulting public outcry from the book and public reaction to similar disclosures in the nation's newspapers about poisonous preservatives and dyes in foods and cure-all patent medicines, Congress passed the original Pure Food and Drugs Act.⁹

But if the 1906 Act was meant to curb the deceptive practices of snake oil salesmen, it was poorly equipped for the task. First, the 1906 Act did not prevent manufacturers from placing worthless medicines on the market because proof of safety or efficacy was not required. Second, the Act was directed only at product labels,

7. See Michael S. Wilkes et al., *Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, and Implications*, 19 HEALTH AFF. 110, 112 (2000).

8. See UPTON SINCLAIR, *THE JUNGLE* (1906).

9. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, *repealed by* the Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-399 (2000)); *see also* U.S. Food & Drug Admin., *Milestones in U.S. Food and Drug Law History*, FDA BACKGROUNDER, May 3, 1999, <http://www.fda.gov/opacom/backgrounders/miles.html> (citing, in addition to reaction to *The Jungle*, public unrest over "the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines" as the "major problems leading to the enactment of" the 1906 Act and the Meat Inspection Act).

not extra-label advertising.¹⁰ It defined a drug as “misbranded” only if the stated claims on the label regarding its curative or therapeutic qualities were proven false or fraudulent.¹¹

These inadequacies became tragically apparent some three decades later. In June 1937, a salesman for the S.E. Massengill Co. reported that his customers sought a liquid version of the drug sulfanilamide, which had been used to treat streptococcal infections and had been proven to have dramatic curative effects in tablet or powder form.¹² Responding to the market need, a chemist and pharmacist for the company experimented with sulfanilamide’s solubility and found that it would dissolve in diethylene glycol.¹³ Although the company tested the product for flavor, appearance, and fragrance, it did not test the product’s toxicity.¹⁴ In sufficient doses, diethylene glycol is toxic to humans and animals, causing renal failure, encephalopathy, and death.¹⁵ A scientific literature review or a few simple animal tests would have revealed its lethal properties.¹⁶ S.E. Massengill, however, shipped the product without taking these precautions. Between September and October 1937, more than one hundred people across the country obtained the product from their doctors or bought it from a pharmacy and died after consuming it.¹⁷

After news of the strange deaths began surfacing, the FDA investigated and intervened, seizing shipments from pharmacies and doctor’s offices across the country. But the FDA’s sole authority for these seizures was not—as one might expect—that the drug was manufactured and sold without any pre-market toxicity review. Ironically, the FDA only had authority

10. See Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 424–25 & n.12 (2002) (noting the portion of the 1906 Act stating that a drug would be deemed misbranded if “its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article . . . which is false or fraudulent” (quoting the Pure Food and Drugs Act § 8, 34 Stat. at 770)).

11. See *id.* at 425 & n.12.

12. See Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER, June 1981, available at <http://www.fda.gov/oc/history/elixir.html>.

13. See *id.*

14. See *id.*

15. See, e.g., Pankaj Hari et al., *Fatal Encephalopathy and Renal Failure Caused by Diethylene Glycol Poisoning*, 56 J. TROPICAL PEDIATRICS 442 (2006).

16. See Ballentine, *supra* note 12.

17. See *id.*

to intervene through the 1906 Act's prohibition against label misbranding.¹⁸ The term "elixir" on the product's label implied that the product was an alcohol solution when, in fact, it contained no alcohol.¹⁹ Had the product instead been labeled a "solution," the FDA would have had no authority under the 1906 Act to intervene.²⁰

In response to the crisis, Congress repealed the 1906 Act and replaced it with the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).²¹ The increased protections of the new act included an FDA pre-market notification (but not approval) requirement for all "new drugs."²² In order to market a new drug, a manufacturer would submit a New Drug Application (NDA) to the FDA. If the FDA did not affirmatively deny the application within sixty days, then the manufacturer could market the drug immediately.²³ Unsurprisingly, given the Elixir Sulfanilamide incident, this pre-market notification system focused solely on proof of the new product's safety, not its efficacy.²⁴ Thus, the FDA retained jurisdiction over the product label and it obtained authority under the 1938 Act to conduct a pre-market safety review.

In the same year Congress expressly vested jurisdiction over all drug advertisements with the Federal Trade Commission (FTC).²⁵ Congress had created the FTC in 1914 with the passage of the Federal Trade Commission Act.²⁶ Under that Act, Congress authorized the FTC to regulate advertising generally, though the Supreme Court's interpretation of the statute lim-

18. See David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 20 (1939), reprinted in PETER BARTON HUTT ET AL., FOOD AND DRUG LAW, CASES AND MATERIALS 577, 577-78 (3d ed. 2007).

19. See Ballentine, *supra* note 12.

20. See *id.*

21. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-399 (2000)).

22. HUTT ET AL., *supra* note 18, at 577.

23. See *id.*

24. See *id.* at 578.

25. See Palumbo & Mullins, *supra* note 10, at 426.

26. Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41-58 (2000)) (establishing the FTC).

ited the FTC's purview to deceptive advertising that harmed a competitor company.²⁷

Earlier proposals to amend the 1906 Act had sought to regulate DTC advertising of drugs. The legislative history of those attempts reveals the nature and extent of DTC advertising at the time. Legislation introduced in 1933 named some thirty-six particular disease states or conditions for which any advertising would be necessarily deemed false, including measles, mumps, scarlet fever, sexual impotence, tuberculosis, and venereal diseases.²⁸ The bill included an exception, however, if the advertisement was "disseminated to members of the medical and pharmacological professions only or [if the advertisement] appears in scientific periodicals."²⁹ The list of diseases and the need for a direct-to-physician exception suggest that DTC advertising was pervasive in the early 1930s and provide clues as to the conditions these products were marketed to address.

*B. Establishment of the Modern Regulatory Regime
for Approval and Marketing of Prescription Drugs*

Before 1951, there was no recognized category under federal law for prescription drugs. That year, Congress enacted the Durham-Humphrey Amendments to the FDCA, which required licensed pharmacists to dispense drugs that cannot be safely used without medical supervision.³⁰ It is uncertain whether the prescription requirement put an immediate halt to DTC advertising. If we assume that the history of the 1933 legislation is indicative of the nature and extent of DTC advertising at the time of that bill's consideration, then we can extrapolate on the legislative history of the next major alteration to the FDCA, the 1962 Kefauver-Harris Drug Amendments. That legislative history suggests that implementation of a prescription-drug regulatory scheme in 1951 curbed DTC advertising for prescription drugs and shifted the industry's marketing focus to physicians and health care professionals.

27. See Palumbo & Mullins, *supra* note 10, at 425 & n.14 (citing *FTC v. Raladam Co.*, 283 U.S. 643 (1931)).

28. See *id.* at 425 n.18 (quoting S. 1944, 73d Cong. § 9(c) (1933)).

29. *Id.*

30. See *id.* at 426.

In 1962, the Kefauver-Harris Drug Amendments authorized the FDA to regulate the marketing of prescription drugs.³¹ By this time, Congress was drawing a distinction between the advertising of over-the-counter (OTC) medicines, which are directed at consumers, and the marketing of prescription drugs, the bulk of which, in Congress's estimation, was already directed at the medical community.³² A memorandum of understanding between the two agencies governs this allocation of responsibilities in which the FTC continues to regulate OTC advertising, whereas the FDA regulates the marketing of prescription drugs.³³

The 1962 Amendments and their implementing regulations set two major requirements for all prescription drug advertising.³⁴ First, advertisements must contain a "summary" that provides a description of the drug's side effects, contraindications, warnings, and precautions, as well as its directions for use.³⁵ Second, the advertisement, when viewed in its entirety, must present a "fair bal-

31. 1962 Kefauver-Harris Drug Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 352(n) (2000)); *see also* 15 U.S.C. §§ 45, 52 (2000); 21 U.S.C. § 352(n) (2000) (removing any "advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs," from the purview of the provisions of 15 U.S.C. §§ 52-57); 21 U.S.C. § 393(b)(1) (2000) ("The [FDA] shall . . . promote the public health by . . . taking appropriate action on the marketing of regulated products in a timely manner.").

32. *See* Palumbo & Mullins, *supra* note 10, at 427 n.29 ("There is a marked difference in the advertising and promotion of proprietary and ethical drugs. Proprietary drugs—those sold over the drugstore counter—are like most other products in that sales pressures are exerted upon the final consumer who is subjected to an intensive barrage of advertisements for brand name products in newspapers, magazines, radio, and television. In the case of ethical drugs—those sold under prescription—the brunt of promotion effort is directed to the prescribing physician. Since his prescription dictates the particular drug to be used, usually the brand name, the physician is the focal center of advertising and promotional pressures." (citing S. Rep. No. 87-448, at 115 et seq. (1961))).

33. *See* Memorandum of Understanding Between FTC and the FDA, 36 Fed. Reg. 18,539 (Sept. 15, 1971) (providing most recent agreement).

34. The FDCA's treatment of prescription drug advertising is quite brief. It requires only that the advertisement include the drug's name and formula, and a brief summary describing the drug's effectiveness and its safety risks. *See* Palumbo & Mullins, *supra* note 10, at 428 (citing 21 U.S.C. § 352(n) (2002)). Shortly after the 1962 Drug Amendments' passage, the FDA implemented its original drug-advertising regulations. *See* HUTT ET AL., *supra* note 18, at 535 (citing 28 Fed. Reg. 1448 (Feb. 14, 1963), 28 Fed. Reg. 6375 (June 20, 1963), 28 Fed. Reg. 9837 (Sept. 10, 1963), 28 Fed. Reg. 10993 (Oct. 15, 1963), 29 Fed. Reg. 257 (Jan. 10, 1964)). The FDA further revised those regulations later that same decade. *See id.*

35. 21 C.F.R. § 202.1(e) (1979).

ance" between the information relating to the drug's efficacy and information relating to its safety and risk profile.³⁶

The 1962 Amendments also strengthened the FDA's pre-market review process, implementing the procedure that remains largely in effect today. Once again, the prompt for regulation arose out of a public health crisis. Thalidomide, a drug approved for marketing in various European countries, was discovered to be a teratogen, an agent that can cause malformations of an embryo or fetus.³⁷ A manufacturer had submitted an NDA to market the drug for use in the United States, which was pending at the time of this discovery. Congress responded by amending the FDCA to require affirmative approval by the FDA for NDAs, replacing the notification and automatic-approval system put in place by the 1938 Act.³⁸ In addition, Congress required manufacturers submitting NDAs to prove not only that a drug was safe,³⁹ but also that the product was effective.⁴⁰ For its part, the FDA now had to reach an affirmative conclusion that the drug was both safe and effective before the drug could be marketed.⁴¹ The standards for approval have remained relatively

36. 21 C.F.R. § 202.1(e)(5)(ii) (1979).

37. See HUTT ET AL., *supra* note 18, at 578.

38. See *id.* at 579.

39. Section 505(d) of the FDCA requires "the FDA to withhold approval unless the sponsor's NDA shows the drug to be safe 'by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions of use prescribed, recommended, or suggested' in the proposed labeling." *Id.* at 685.

40. Section 505(d) of the FDCA requires the FDA to withhold approval unless the sponsor's NDA provides "'substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.'" *Id.* at 579. Section 505(e) requires the FDA to "withdraw approval of any drug after notice and opportunity for hearing if he finds that 'on the basis of new information before him' substantial evidence of efficacy is lacking." *Id.*

41. See 21 U.S.C. § 355(d)-(e) (2000). Specifically, an NDA must summarize the general understanding of the application, the drug type, and the rationale for approval, as well as a description of the drug's chemistry, its manufacturing practices, and its quality controls. See 21 C.F.R. § 314.50(c)-(d) (2000). It must contain pre-clinical data (that is, the results of animal and *in vitro* studies) regarding the product's pharmacology and toxicology, and that data must be accompanied by a statement of compliance with good laboratory practices. See *id.* The NDA must describe the drug's pharmacokinetics and bioavailability (that is, how the drug is expected to react in the human system). See *id.* It must contain a wealth of clinical data from Phase I, II, and III clinical trials on humans. That data must also be accompanied by an integrated summary of the product's effectiveness and safety profile, along with full disclosure of the study results. Finally, the NDA must include both a sample of the product and the product's labeling. See 21 C.F.R. § 314.50(e) (2000).

unchanged in the decades following their implementation and continue to guide both the industry and the FDA in their daily decisions to the present.⁴²

Procedurally, the FDA's Center for Drug Evaluation and Research (CDER) reviews and approves NDAs,⁴³ and then evaluates the drug's proposed labeling.⁴⁴ The FDA must find that the results and data submitted in the NDA justify each statement proposed for drug labeling.⁴⁵ Federal regulations require dividing the label's content into sections, including a list of the drug's approved indications and usage,⁴⁶ contraindications,⁴⁷ warnings,⁴⁸ precautions,⁴⁹ and adverse reactions.⁵⁰ The FDA must ap-

42. See HUTT ET AL., *supra* note 18, at 688. The process from the discovery of a molecule's treatment potential to its submission in an NDA is laborious, long, and expensive. On average, for 10,000 drugs identified as having treatment potential and therefore submitted to laboratory and animal testing, only one might make it through Phase I, II, and III clinical testing on humans and become the subject of an NDA. See PhRMA, Innovation (2008), <http://www.phrma.org/innovation>. The Tufts Center for the Study of Drug Development, for example, calculated that the average cost of bringing a new drug to market in 2001 was \$802,000,000. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (presenting study by Tufts Center for the Study of Drug Development). In a 2006 study, the Center for the Study of Drug Development pegged the average cost of developing a new biotechnology drug at \$1,200,000,000. See TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, OUTLOOK 2008, at 2 (2008), available at <http://csdd.tufts.edu/InfoServices/OutlookReports.asp>.

43. 21 U.S.C. § 355(b) (2000). CDER examines six components of the NDA: medical, biopharmaceutical, pharmacological, statistical, chemical, and microbiological. Medical reviewers are responsible for evaluating the clinical sections of submissions and therefore take the lead role in NDA review. See CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., CDER HANDBOOK 15–19 (1998), available at <http://www.fda.gov/cder/handbook/index.htm> [hereinafter CDER HANDBOOK]. CDER may also host Advisory Committee meetings at this stage to obtain outside advice and opinions from experts. See *id.* at 11.

44. See 21 U.S.C. § 352 (2000); 21 C.F.R. § 201.56 (2008) (general requirements for prescription drug labeling).

45. See 21 C.F.R. § 201.56 (2008).

46. See 21 C.F.R. § 201.57(a)(6)–(8), (c)(4) (2008).

47. See 21 C.F.R. § 201.57(a)(9), (c)(5) (2008) (requiring a description of situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit).

48. See 21 C.F.R. § 201.57(a)(10), (c)(6) (2008) (requiring a description of any serious adverse reactions and potential safety hazards, subsequent limitation in use, and steps that should be taken if they occur).

49. See 21 C.F.R. § 201.57(a)(10), (c)(6), (c)(8) (2008) (requiring a description of any special care to be exercised for the safe and effective use of the drug, including general precautions and information for patients on drug interactions).

50. See 21 C.F.R. § 201.57(a)(11), (c)(7) (2008) (requiring a description of any undesirable effects reasonably associated with the proper use of the drug).

prove the label's content *before* it accepts the NDA and the company begins marketing the drug.

C. DTC Advertising and Its Regulation Today

The Division of Drug Marketing, Advertising, and Communications (DDMAC), a separate component of CDER, reviews pharmaceutical marketing practices. There are no formal regulations that distinguish DTC advertising from direct-to-physician advertising.⁵¹ Rather, the FDA recognizes three distinct types of advertising, based on the advertisements' content. First, "reminder" advertisements are promotional pieces that call attention to a product or brand name, but contain no reference to the purpose of the drug, its benefits, or risks.⁵² Reminder advertisements are exempt from the brief-summary requirement.⁵³ Second, "help-seeking" advertisements describe a disease or condition and direct the consumer to see his doctor, but do not mention the drug's name.⁵⁴ Finally, product-claim advertisements reveal both the product's name and its contraindications.⁵⁵ These product-claim advertisements must satisfy the "brief summary" and "fair balance" requirements.⁵⁶

In the twenty years following enactment of the 1962 Amendments, pharmaceutical manufacturers directed advertisements and promotional practices almost exclusively toward physicians.⁵⁷ It was not until the early 1980s that manufacturers began to place advertisements for prescription medicines in main-

51. See Palumbo & Mullins, *supra* note 10, at 429.

52. 21 C.F.R. § 202.1(e)(2)(i) (2008). PhRMA's Guiding Principles urge its members not to engage in this practice. See PHRMA, PHRMA GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES 4 (2005), <http://www.phrma.org/files/DTCGuidingprinciples.pdf> (Principle 10: "DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.").

53. See 21 C.F.R. § 202.1(e)(2) (2008).

54. Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,581, 42,582 (Aug. 16, 1995).

55. See 21 C.F.R. § 202.1(e)(1) (2008).

56. See 21 C.F.R. § 202.1(e)(5)-(6) (2008) (listing ways in which drug advertisements fail to satisfy fair balance requirements).

57. See KIM SHEEHAN, CONTROVERSIES IN CONTEMPORARY ADVERTISING 209 (2004).

stream print media.⁵⁸ Soon after these advertisements began to run, the FDA asked for a voluntary moratorium of the practice.⁵⁹

In 1985, the FDA decided to permit DTC advertising so long as the manufacturer complied with the “brief summary” and “fair balance” requirements applicable to physician-directed advertising.⁶⁰ Historically, in print media, the product’s approved physician labeling was reprinted in the advertisement to satisfy the “brief summary” requirement. This practice, however, presented challenges for broadcast advertising. A thirty-second TV spot was both too expensive and too short for a manufacturer to read the brief summary or scroll through the product’s package insert.⁶¹

In response to industry inquiry, the FDA held public hearings on DTC broadcast advertising in 1995. The agency issued a Draft Guidance document in 1997, which became its final position in 1999.⁶² The Guidance document removed barriers to broadcast advertising largely by transforming the “brief summary” requirement for print advertising into what is now known as the “major statement” requirement for broadcast advertising.⁶³ Under that requirement, the advertisement need not repeat all potential side effects, contraindications, warnings, and precautions associated with the product, but it must, in consumer-friendly language, disclose the drug’s major risks in either the audio or visual component.⁶⁴ Further, to make “adequate provision” of the approved product labeling, the Guidance document makes clear that the advertisement must publicize a toll-free telephone number through which the patient can obtain a copy of the product’s label, refer the patient to a print advertisement or other non-web-based resource for additional information, include a web address providing access to the product’s labeling,

58. See *id.* at 210; Palumbo & Mullins, *supra* note 10, at 424.

59. See SHEEHAN, *supra* note 57, at 210.

60. Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677 (Sept. 9, 1985).

61. See SHEEHAN, *supra* note 57, at 210–11.

62. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (August 1999) [hereinafter GUIDANCE], available at <http://www.fda.gov/cder/guidance/index.htm>.

63. *Id.* at 1; SHEEHAN, *supra* note 57, at 211.

64. See 21 C.F.R. § 202.1(e)(1) (2008). On September 27, 2007, the President signed the Food and Drug Administration Amendment Acts of 2007, imposing a requirement that the major statement be presented in a “clear, conspicuous and neutral manner.” FDA Amendment Act of 2007, Pub. L. No. 110-85, § 503(B), 121 Stat. 823, 940 (to be codified at 21 U.S.C. § 353(b)).

and refer the patient to his doctor or pharmacist.⁶⁵ Although the Guidance document does not have binding legal effect, the FDA essentially placed manufacturers on notice that it would not take regulatory action when a broadcast advertisement complies with the Guidance document's terms.⁶⁶

Additionally, as with all advertisements, the broadcast messaging must not be false or misleading in any respect. Beyond assessing the pure content, DDMAC may also consider the form of the audio and video production and presentation (for example, the graphics and superimposition of text, the pacing and clarity of voiceovers, the visual editing, and sound effects or music) to ensure that the advertisement is "fairly balanced" and that risk information is adequately communicated.⁶⁷

Should DDMAC determine that an advertisement or promotional piece in distribution violates the law or FDA guidelines, it sends one of two types of letters to the offender.⁶⁸ Minor violations are noted in a Notice of Violation (NOV) letter.⁶⁹ A recipient of an NOV letter typically discontinues the offending marketing practice and responds to DDMAC in writing within ten days, informing it of the discontinuation.⁷⁰ For more serious violations, DDMAC sends a warning letter.⁷¹ These letters put the recipient on notice of the FDA's intent to initiate further

65. GUIDANCE, *supra* note 62, at 2–3.

66. See Palumbo & Mullins, *supra* note 10, at 430.

67. On May 8, 2008, Ruth S. Day, Ph.D, testified before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, on the field of "cognitive accessibility," which is the study of what people understand and remember after viewing DTC advertising. Dr. Day recommended that the FDA adopt a formal "evidence-based approach" for analyzing the cognitive accessibility of broadcast DTC advertising. See *Direct-to-Consumer Drug Ads: What do People Understand and Remember: Hearing Before Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 110th Cong.* (2008) (testimony of Ruth S. Day), available at <http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/Testimony/OI/110-oi-hrg.050808.Day-testimony.pdf>.

68. See 21 C.F.R. § 312.84(c) (2008) (FDA not approvable for marketing letter); see also Palumbo & Mullins, *supra* note 10, at 429.

69. See Palumbo & Mullins, *supra* note 10, at 429.

70. See 21 C.F.R. § 314.120(a) (FDA "not approvable letter").

71. See Palumbo & Mullins, *supra* note 10, at 429. A study by the General Accounting Office (GAO) found that, in a five-year period between August 1997 and August 2002, the FDA issued eighty-eight NOV and warning letters for violative DTC advertising. See U.S. GEN. ACCOUNTING OFFICE, GAO-03-177, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 18 (2002) [hereinafter 2002 GAO REPORT].

regulatory action against the recipient if it refuses to rectify the offending practice promptly. Manufacturers have consistently taken the appropriate corrective action indicated in such letters, without the need for further action from the FDA.⁷² In addition, the Food and Drug Administration Amendments Act of 2007 (FDAAA) gave the FDA the authority to impose civil penalties directly for false or misleading advertisements.⁷³

Federal law does not currently mandate pre-market review of DTC advertising. Rather, unless the FDA provides otherwise,⁷⁴ manufacturers are required to submit their marketing materials to the agency at the time of the product's distribution in the marketplace.⁷⁵ Many manufacturers, however, routinely submit proposed advertisements before dissemination on a voluntary basis. This provides the FDA with an opportunity to review advertisements before they are released publicly and to suggest improvements.⁷⁶ For example, between 2000 and 2006, the FDA received an average of approximately 150 television advertisements each year for advisory review.⁷⁷ In fact, the Pharmaceutical Research and Manufacturers of America (PhRMA), the leading industry group of drug manufacturers, encourages its members to submit all television advertising to the FDA for review before airing.⁷⁸ Manufacturers have widely adopted the PhRMA code and continue the longstanding practice of submitting DTC advertisements to the FDA before dissemination.⁷⁹

72. See 2002 GAO REPORT, *supra* note 71, at 21.

73. FDA Amendments Act of 2007, Pub. L. No. 110-85, § 901, 121 Stat. 823, 939-42 (to be codified at 21 U.S.C. § 353b).

74. The FDAAA provides the FDA with authority to mandate submission of television advertisements not later than forty-five days prior to broadcast. *Id.* at 939-43.

75. See 21 C.F.R. § 202.1(j) (2008).

76. See 21 C.F.R. § 202.1(j)(4) (2008).

77. User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Request for Notification of Participation and Number of Advertisements for Review, 72 Fed. Reg. 60,677, 60,678 (Oct. 25, 2007) [hereinafter User Fee Notice].

78. PhRMA, PHRMA GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES 5 (2005), available at <http://www.phrma.org/files/DTCGuidingprinciples.pdf> (Principle 8).

79. See, e.g., ELI LILLY & CO., PROVIDING VALUE TO PATIENTS AND SOCIETY: LILLY CORPORATE CITIZENSHIP REPORT 2006-07, at 28-29, available at http://www.lilly.com/pdf/citizenship_report_0607.pdf; GLAXOSMITHKLINE, ANSWERING THE QUESTIONS THAT MATTER: CORPORATE RESPONSIBILITY REPORT 2007, at 64, available at <http://www.gsk.com/responsibility/cr-review-2007/downloads/CR-Report-2007.pdf>; MERCK, MERCK'S ALIGNMENT WITH THE "PHRMA GUIDING PRINCIPLES-DIRECT TO

Some critics, including the General Accounting Office (GAO), have highlighted shortcomings in the regulatory process overseeing pharmaceutical marketing and have suggested that DDMAC needs additional resources. In 2002, a GAO study examined two deficiencies in the regulation of DTC advertising: the FDA's inability to be certain that manufacturers submit their advertisements to the agency and the lengthy period before the FDA reviews advertisements and issues warning letters for misleading information.⁸⁰ When the GAO revisited the issue four years later, it found that this lag time had worsened considerably, leading to a situation where, more often than not, the publication or broadcast of the misleading advertisement had already concluded before the FDA issued its violation letter.⁸¹ It also noted that the FDA had the capacity to review only a small portion of the increasingly large amount of the DTC materials submitted. Therefore, the FDA closely examined only advertisements for those drugs with the greatest potential to impact the public health.⁸² As the FDA recently noted, "[t]he lack of timely, predictable FDA review times for DTC television advertisements has hindered companies' ability to accurately set timeframes for their marketing campaigns and has discouraged companies from taking advantage of the DTC advisory review process."⁸³

Congress attempted to address the inability of the FDA to keep pace with the increasing number of DTC advertisements submitted for its review when it enacted FDAAA, which included a new user's fee program to provide the agency with resources to hire additional staff for its voluntary review program.⁸⁴ The program would have required any company that intended to submit DTC television advertisements for voluntary FDA review to pay an annual fee to help maintain the program.⁸⁵ The Act provided, however, that this new program would not go into effect unless the FDA received \$11,250,000 in

CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINE" 3, available at http://www.merck.com/about/public_policy/docs/mercks_alignment_with_pharma_guiding_principles_final.pdf.

80. See 2002 GAO REPORT, *supra* note 71, at 21–23.

81. See 2006 GAO REPORT, *supra* note 4, at 21–27.

82. See *id.* at 17–19.

83. User Fee Notice, *supra* note 77, at 60,678.

84. See FDA Amendments Act of 2007, Pub. L. No. 110-85, §§ 101–109, 121 Stat. 823, 825–42.

85. See *id.*

fees within 120 days of enactment (that is, by January 25, 2008).⁸⁶ In January 2008, the FDA announced that because a subsequent appropriation bill did not include a corresponding authorization for the FDA to collect and spend user fees for the purposes of the program, and because the FDA had not collected the mandated minimum level of funds, it would not implement the new program.⁸⁷ Therefore, the FDA continues to review advertisements voluntarily submitted for review “in as timely a manner as resources permit.”⁸⁸

D. The Relevance of History to DTC Advertising Today

The previously discussed history and development of pharmaceutical regulation reveals some interesting insights. First, DTC advertising is not a new phenomenon; in fact, it predates regulation of pharmaceuticals.⁸⁹ Second, the major developments in early pharmaceutical regulation, the 1906 Pure Food and Drugs Act and the Federal Food, Drug, and Cosmetic Act of 1938, were born out of responses to public health crises resulting from inadequate testing, not deficiencies specific to DTC advertising.⁹⁰ Third, regulation discouraging DTC advertising (by deeming it false) was initially proposed and rejected by Congress in an age when the advertisements were likely to have been in printed materials.⁹¹ This history implies that Congress did not find DTC advertising a significant threat to consumer safety, given the need for a prescribing physician.⁹²

86. *See id.* § 104, 121 Stat. at 837–38.

87. User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drugs and Biological Products; Program Will Not Be Implemented, 73 Fed. Reg. 2924 (Jan. 16, 2008).

88. *Id.* The FDA responded in May 2008 to a GAO recommendation and developed criteria to prioritize its review of promotional material for those products that have the greatest potential to negatively affect the public health. But a GAO representative testified before a congressional subcommittee that the FDA still needed to document its application of that criteria and systematically track its review of voluntarily submitted materials in order to improve oversight. U.S. GEN. ACCOUNTING OFFICE, GAO-08-758T, PRESCRIPTION DRUGS: TRENDS IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 3 (2008).

89. *See supra* Part I.A.

90. *See supra* Part I.A.

91. Palumbo & Mullins, *supra* note 10, at 425 n.18 (quoting S. 1944, 73d Cong. § 9(c) (1933)).

92. *See id.* at 425–26.

Modern regulation of pharmaceuticals follows such sentiment. In developing comprehensive regulation regarding the safety, efficacy, and marketing of a drug, the FDA has refrained from regulation specific to DTC advertising and has instead approached this form of marketing under the same analysis as direct-to-physician advertising.⁹³ As DTC advertising resurfaced from dormancy and became more mainstream in the early 1980s, the FDA instituted a voluntary moratorium to examine again whether DTC advertising posed a legitimate concern to consumers and found none.⁹⁴ Over the past two decades the FDA has clearly recognized, through its Guidance document and other agency statements, that DTC marketing does not pose a heightened risk to consumers, and may actually prove beneficial.⁹⁵

There is, however, a recognized need to provide the FDA with additional staffing so that it may more promptly review advertisements and suggest improvements. Such action can only come from Congress. Despite that particular criticism regarding the regulatory review of DTC advertisements, repeated examination of DTC advertising over the past century has not found that it interferes with the doctor-patient relationship or diminishes the role of the FDA in closely regulating the safety and efficacy of the drug. Because DTC marketing of prescription drugs has not fundamentally altered the playing field, traditional rules of law should remain fully viable.

II. THE POTENTIAL BENEFITS AND PITFALLS OF DTC ADVERTISING

Reaction to the resurgence of DTC advertising within the modern regulated pharmaceutical environment is mixed. Critics argue that DTC advertising overemphasizes benefits and downplays risks, which might cause patients to believe that a particular medicine works better or more safely than it actually does.⁹⁶ Some critics express concern that the presence of DTC

93. See Palumbo & Mullins, *supra* note 10, at 429.

94. See SHEEHAN, *supra* note 57, at 210.

95. See *id.* at 216.

96. A 2007 study in the *Journal of Health Communication* took issue with the FDA's effectiveness in policing the "fair balance" requirement, finding that the average sixty-second commercial contained less than eight seconds of side-effect information. See Wendy Macias et al., *A Wonderful Life or Diarrhea and Dry Mouth?*

campaigns negatively affect the doctor-patient relationship, prompting patients to pressure their physicians to prescribe unneeded medications or to demand a brand name pharmaceutical over cheaper or safer generic alternatives.⁹⁷ Beyond issues with the message itself, critics cite the rapid increase in industry spending on DTC advertising—a 330% rise from \$985 million in 1996 to \$4.2 billion in 2005—as contributing to a contemporaneous rise in drug spending.⁹⁸ Critics also perceive an inverse relationship between this increased spending and decreasing regulatory action documenting noncompliance, such as NOV or warning letters, as evidence of an overworked and inefficient FDA.⁹⁹

Proponents counter that DTC advertising fosters healthy physician-patient relationships by providing information to patients that prompts discussion with their physicians. When first surveyed in the 1980s about whether they would value DTC advertising, patients responded that they believed DTC advertising would be useful, but they would still prefer that physicians control prescribing decisions.¹⁰⁰ Twenty years later,

Policy Issues of Direct-to-Consumer Drug Advertising on Television, 22 HEALTH COMM. 241, 247 (2007).

97. See *Public Views of Direct-to-Consumer Prescription Drug Advertising: Hearing Before the H. Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce*, 110th Cong. 1–7 (2008) (statement of Mollyann Brodie, Vice President and Director, Public Opinion and Media Research, Henry J. Kaiser Family Foundation), available at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.050808.DTC.shtml.

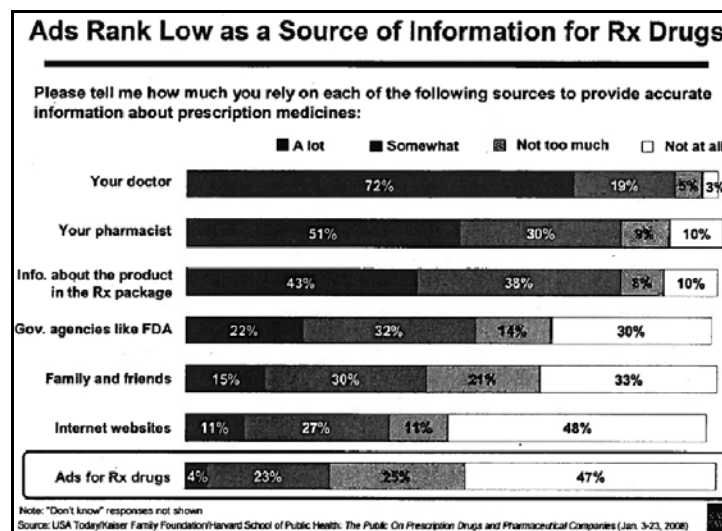
98. See Donohue, *supra* note 1, at 676.

99. See, e.g., *id.* at 676, 679–80 (noting that violation letters sent by the FDA to manufacturers had fallen from 142 in 1997 to only 21 in 2006, and attributing the decrease to policies and understaffing at the FDA that have weakened the FDA's capacity to enforce these regulations); 2006 GAO REPORT, *supra* note 4, at 21–27. Reconciling the debate is beyond the scope of this Article, but it deserves mention that such a theory presupposes that transgressions of advertising regulations remain constant in proportion to spending (that is, violations are occurring at the same rate, but are going undetected), which rejects the notion of applied learning from previous experience or the use of DDMAC's voluntary pre-market advertising review. It should be noted that, after an initial uptick in 1999 in companies seeking FDA input through launch-campaign advisory letters pursuant to the FDA's pre-market voluntary submission process, FDA advisory letters have remained relatively stable from 2000 to 2005. This fact suggests that the industry continues to seek out the FDA's insight and approval before releasing campaigns to the public. See, e.g., U.S. FOOD & DRUG ADMIN., CDER 2005 REPORT TO THE NATION: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 45 (2005).

100. See SHEEHAN, *supra* note 57, at 210; see also Louis A. Morris et al., *The Attitudes of Consumers toward Direct Advertising of Prescription Drugs*, 101 PUB. HEALTH REP. 82, 87 (1986), cited in Palumbo & Mullins, *supra* note 10, at 424.

in response to one study on consumer perceptions, the majority of patients reported that DTC advertising had allowed them to take a more active role in their own health care and encouraged them to seek medical care from their physicians.¹⁰¹ Nevertheless, DTC advertising ranked dead last in a recent poll of which sources consumers report relying upon to provide accurate information about prescription medications. Internet websites, family and friends, the FDA, the package label, and pharmacists all ranked progressively higher on the list. In fact, “Your doctor” topped the list overwhelmingly.¹⁰²

Figure 1



Doctors, for their part, greeted DTC advertising with skepticism, but by the early 1990s, the American Academy of Family Physicians expressed an opinion that DTC advertising encourages patients to seek needed medical care.¹⁰³ Later, the American Medical Association reversed its blanket policy against DTC advertising in favor of a case-by-case approach.¹⁰⁴ By

101. See SHEEHAN, *supra* note 57, at 215.

102. *Public Views of Direct-to-Consumer Advertising of Prescription Drugs*, *supra* note 97, at 5, 12 fig.7.

103. See SHEEHAN, *supra* note 57, at 210.

104. See *id.* Although it continues to support a case-by-case approach, the AMA remains generally skeptical of DTC advertising. In testimony before Congress in May 2008, it recommended additional research into the effect, if any, of DTC ad-

2002, one report showed that the "overwhelming" majority of physicians polled believed that DTC advertising has had a beneficial effect on the doctor-patient relationship.¹⁰⁵

In 2003, the FDA published results from what is perhaps the most comprehensive survey to date of physician attitudes toward DTC advertising.¹⁰⁶ The data set included 250 general practitioners and 250 specialists in the fields of dermatology, allergy, endocrinology, and psychiatry.¹⁰⁷ Most doctors polled believed that DTC advertising led patients to ask more thoughtful questions, made patients more aware of possible treatments, made patients more concerned about their health care, prompted better discussions between patients and physicians about health, and thus helped educate patients about their health problems.¹⁰⁸ The survey also found that doctors believe patients understand that they need to consult a healthcare professional about appropriate treatment.¹⁰⁹

This Article does not attempt to resolve this debate or answer whether DTC advertising is good or bad for the industry, patients, or physicians. But however valid the arguments are on both sides, neither the available data nor current medical practice supports the notion that DTC advertising alters a physician's control of, or ethical and legal responsibility for, the ultimate decision to prescribe medicines to a patient. For

vertising on the doctor-patient relationship. *Direct-to-Consumer Advertising: Marketing, Education or Deception?: Hearing Before the H. Subcomm. on Oversight & Investigation of the H. Comm. on Energy & Commerce, 110th Cong. 12 (2008)* (statement of Nancy H. Nielson, President Elect, American Medical Association), available at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.050808.Nielson-Testimony.pdf. The AMA additionally recommended a set of guidelines for DTC advertising, including a moratorium on DTC advertising of all newly approved drugs until physicians "have been appropriately educated about the drug." *Id.* at 6–7. The AMA recommends that the length of the moratorium be determined by the FDA in consultation with the manufacturer and be dependent upon numerous factors, including the innovative nature of the drug, the severity of the disease the drug is intended to treat, the availability of alternative therapies, and the intensity and the timeliness of education about the drug for physicians who are likely to prescribe it. *See id.*

105. SHEEHAN, *supra* note 57, at 216.

106. KATHRYN J. AIKIN, DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: PHYSICIAN SURVEY PRELIMINARY RESULTS (2003), <http://www.fda.gov/cder/ddmac/globalsummit2003>.

107. *Id.* at 3.

108. *See id.* at 32, 38.

109. *See id.* at 34.

example, the FDA responded to concerns of undue influence in prescribing decisions by asking doctors in its 2003 survey whether a patient's having seen a product advertisement created any problems for the doctor when interacting with that patient. Overwhelmingly, those polled responded that it did not.¹¹⁰ Of the 18% who did believe that problems arose, most reported that the problem either stemmed from additional time spent with the patient correcting misperceptions about the product or confirming that the patient did not have the condition the drug was designed to treat.¹¹¹ When asked whether the patient tried "to influence the course of treatment in a way that would have been harmful to him or her," 91% of doctors polled said no.¹¹² Furthermore, although some doctors reported moderate to heavy pressure to prescribe medications to their patients, the majority of doctors polled reported that they felt "not at all pressured" to do so.¹¹³ In any event, even those reporting some level of pressure to prescribe still ultimately had to make the decision whether to prescribe individually. Thus, the results of the survey demonstrate that prescribing decisions still rest firmly with the physician and that the patient relies necessarily upon his physician's medical judgment.

III. TRADITIONAL RULES OF LAW REMAIN VIABLE, SOUND PUBLIC POLICY TODAY

Three traditional rules—the learned intermediary doctrine, regulatory compliance exemptions to consumer protection statutes, and federal preemption—are particularly relevant in evaluating liability related to drug warnings. The learned intermediary doctrine is a judicial doctrine, regulatory compliance is a statutory policy rooted in common law, and federal preemption is a constitutional principle deriving from the Supremacy Clause of the Constitution. Although each originates from a different source, they share a common underlying policy. That policy recognizes that close regulation by the FDA and oversight by individual doctors appropriately preclude holding

110. *See id.* at 12.

111. *Id.* at 12–13.

112. *Id.* at 21.

113. *Id.* at 22.

pharmaceutical manufacturers liable for alleged flaws in communicating information to individual patients.

A. *Ask Your Doctor: The Learned Intermediary Doctrine*

1. *Learned Intermediary Fundamentals*

The learned intermediary doctrine provides that manufacturers or suppliers of prescription drugs fulfill their duty to warn consumers of the dangerous propensities of their products by conveying accurate warning information to prescribing physicians.¹¹⁴ It is the physician's duty to evaluate the benefits and risks of the medication as they apply to the individual patient.¹¹⁵ The rule establishes a manufacturer's legal duty to warn physicians, rather than individual consumers directly.¹¹⁶

Several commonsense rationales support the learned intermediary doctrine. First, training and experience place physicians in a better position than the manufacturer to convey complex medical information and terminology to patients.¹¹⁷ Second, the physician has a relationship with the individual patient, making it possible to evaluate the patient's treatment needs and provide an assessment of the potential benefits and

114. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998) [hereinafter RESTATEMENT (THIRD)].

115. See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative."); see also *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 266 (E.D.N.Y. 2007) (stating that "[w]hether the physician in fact reads [the drug manufacturer's] warning or passes its contents along to the recipient of the drug is irrelevant" for purposes of the learned intermediary doctrine (quoting *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997))); *West v. Searle & Co.*, 806 S.W.2d 608, 613-14 (Ark. 1991) (stating that physicians must make independent judgments as to whether drugs are beneficial for their patients).

116. See Diane Schmauder Kane, Annotation, *Construction and Application of the Learned-Intermediary Doctrine*, 57 A.L.R.5th 1 (1998).

117. See RESTATEMENT (THIRD), *supra* note 114, § 6 cmt. b ("[O]nly-health care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."); see also Barbara Pope Flannagan, *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, 412 (1986).

likely risks specific to the patient's medical and family history.¹¹⁸ Third, it is more effective and efficient for manufacturers to provide a common set of warnings to an intermediary with more definable knowledge and skill characteristics than to a broad spectrum of consumers. In fact, it is difficult, if not impossible, to convey comprehensive drug warnings to consumers because of the highly technical nature of the information and the various needs of individual patients.¹¹⁹ The learned intermediary doctrine was established, therefore, in recognition of these significant challenges and the physician's superior position and ability to communicate warnings.¹²⁰

Almost all jurisdictions follow the learned intermediary doctrine with regard to claims involving prescription drugs.¹²¹ The modern doctrine was first expressed by the Eighth Circuit, which recognized that pharmaceutical companies have a duty to warn physicians directly about potential risks of their products,

118. See *Vitanza v. Upjohn Co.*, 778 A.2d 829, 846 (Conn. 2001) (acknowledging that a physician "is in the best position to convey adequate warnings based upon the highly personal doctor-patient relationship"); see also *West*, 806 S.W.2d at 613 (listing common rationales supporting the doctrine); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) ("The reasons for this rule should be obvious."); David P. Graham & Jeremy C. Vest, *Doctors, Drugs, and Duties to Warn*, 72 DEF. COUNS. J. 380, 381 (2005) ("The assumptions that underlie the doctrine are that patients rely upon the advice of their physicians, and physicians, in light of their experience and expertise, are in a better position than their patients to evaluate and communicate the manufacturers' warnings directly to the patients.").

119. See Monica Renee Matter, *Emerging DTC Advertising of Prescription Drugs and the Learned Intermediary Doctrine*, 69 DEF. COUNS. J. 79, 81 (2002) (discussing common rationales favoring the rule).

120. See, e.g., *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. 1973) ("The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people.").

121. See *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806-09 (E.D. Tex. 2002) (concluding that forty-eight states, the District of Columbia, and Puerto Rico have either applied or recognized the learned intermediary doctrine, and providing chart reflecting the same); *Vitanza*, 778 A.2d at 838 n.11 (finding that forty-four other jurisdictions have adopted the learned intermediary doctrine, including lower state courts and federal courts applying state law); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 767 & n.3 (Ky. 2004) (observing that thirty-four states have specifically adopted the learned intermediary doctrine). West Virginia appears to be the only state expressly declining to adopt the learned intermediary doctrine. See *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 914 (W. Va. 2007). New Jersey does not apply the learned intermediary doctrine where the prescription drug manufacturer attempts to advertise directly to consumers and the consumer relies on that advertisement. See *Perez v. Wyeth Labs.*, 734 A.2d 1245, 1257-58 (N.J. 1999); see also *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69 (Mass. 1985) (recognizing an exception to the general application of the learned intermediary doctrine for oral contraceptives).

whereas physicians must serve as “learned intermediaries” who interpret this information and advise patients appropriately.¹²² It was embraced quickly by other jurisdictions.¹²³ The doctrine has also come to include prescription medical devices under the same rationale.¹²⁴ Although the doctrine finds support in the *Restatement (Second) of Torts* § 388,¹²⁵ *Restatement (Third) of Torts: Products Liability* § 6 sets forth its underpinnings more completely.¹²⁶ The *Restatement (Third)* specifically addresses liability for sellers of prescription drugs and medical devices, deals with the application of the learned intermediary rule, and sets forth narrow exceptions to the doctrine’s application.¹²⁷ It presents the rule as adopted by the majority of jurisdictions, either through judicial pronouncement or statutory enactment.¹²⁸

2. Traditional Limited Exceptions to the Rule

The *Restatement (Third)* recognizes a limited set of circumstances in which applying the learned intermediary doctrine may be inappropriate.¹²⁹ This may occur when a prescription drug is administered “without the personal intervention or evaluation of a health-care provider.”¹³⁰ In such situations, manufacturers are directly responsible for providing patients with warnings and instructions.

Vaccines and other immunizations administered en masse or to the general public present the most common example of this

122. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966); *see also Hruska v. Parke, Davis & Co.*, 6 F.2d 536, 538 (8th Cir. 1925) (acknowledging public is “not on an equal footing” with prescription drug manufacturers in terms of knowledge); *Marcus v. Specific Pharms.*, 77 N.Y.S.2d 508, 508–10 (Sup. Ct. 1948) (first holding that a manufacturer’s duty to warn was fulfilled by informing the physician).

123. *See Kane, supra* note 116.

124. *See, e.g., Beyette v. Ortho Pharm. Corp.*, 823 F.2d 990, 992 (6th Cir. 1987); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1227–28 (Kan. 1987); *Terhune v. A. H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978).

125. *See* RESTATEMENT (SECOND) OF TORTS § 388 cmt. n (1965) (“Modern life would be intolerable unless one were permitted to rely to a certain extent on others’ doing what they normally do, particularly if it is their duty to do so.”).

126. *See* RESTATEMENT (THIRD), *supra* note 114, § 6 (1998).

127. *Id.* § 6 cmt. e.

128. *See, e.g.,* MISS. CODE § 11-1-63(c) (2008); N.C. GEN. STAT. § 99B-5(c) (2007); N.J. STAT. § 2A:58C-4 (2008); OHIO REV. CODE § 2307.76 (2008) (codifying the learned intermediary doctrine).

129. *See* RESTATEMENT (THIRD), *supra* note 114, § 6 cmt. e.

130. *Id.*

exception to the learned intermediary rule.¹³¹ Health care providers typically dispense these treatments in an expedited manner without establishing a doctor-patient relationship or evaluating risks given the patient's medical history. In some instances, the role of the physician may be reduced to that of a delivery mechanism, leaving the position of learned intermediary vacant. Thus, in such rare instances, the manufacturer may reemerge as the entity best suited to warn consumers directly of the risks associated with its vaccine.¹³²

Courts deciding whether to apply the exception to the learned intermediary doctrine for mass immunizations have tread carefully, resisting hard-line rules or blanket policy exemptions.¹³³ For example, a federal court applying Georgia law held that manufacturers of a measles, mumps, and rubella vaccine were not required to warn the vaccine recipients directly where the vaccine was not administered as part of a massive, nationwide immunization program.¹³⁴ In that case, the court found that a vaccination program aimed only at select students throughout a county was enough to retain application of the learned intermediary defense.¹³⁵ Similarly, a federal court in Oklahoma avoided adopting an over-expansive exception to the rule after a child developed permanent neurological damage after receiving a diphtheria vaccine.¹³⁶ Because the child's

131. See, e.g., *Mazur v. Merck & Co.*, 964 F.2d 1348, 1355 (3d Cir. 1992) (applying the "mass immunization exception" to the learned intermediary doctrine in an action brought against the manufacturer of a measles, mumps, and rubella vaccine (MMR II) by the parents of a child who developed a serious neurological disorder after being inoculated); *Brazzell v. United States*, 788 F.2d 1352, 1357-58 (8th Cir. 1986) (swine flu vaccine); *Petty v. United States*, 740 F.2d 1428, 1438-39 (8th Cir. 1984) (same). The most common example of the mass immunization exception has occurred with polio vaccines. See, e.g., *Plummer v. Lederle Labs.*, 819 F.2d 349, 356 (2d Cir. 1987); *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Davis v. Wyeth Labs.*, 399 F.2d 121, 131 (9th Cir. 1968); see also *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1380 (Okla. 1974).

132. See *Brooks v. Medtronic*, 750 F.2d 1227, 1232 (4th Cir. 1984) ("[T]he exception established for the [vaccine] cases is quite narrow and highly fact specific." (quoting *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 647 (4th Cir. 1981))).

133. See, e.g., *Mazur*, 964 F.2d at 1363 (stating that it is not the size of the immunization program that matters but whether the vaccine is administered "without an individualized medical balancing of the risks and benefits of inoculation").

134. *Walker v. Merck & Co.*, 648 F. Supp. 931, 934-35 (M.D. Ga. 1986), *aff'd*, 831 F.2d 1069 (11th Cir. 1987).

135. See *id.* at 932.

136. *Percival v. Cyanamid Co.*, 689 F. Supp. 1060, 1061-63 (W.D. Okla. 1987).

personal physician administered the vaccine at her office, it was impermissible to apply the exception.¹³⁷ Moreover, as these cases illustrate, courts have shown great reluctance to define exceptions to the learned intermediary doctrine broadly, and apply this exception only where immunizations are conducted in an “assembly-line” or “clinic-like” fashion where no individualized medical judgment is rendered.¹³⁸ An additional consideration arises because, as a matter of public policy, placing special liability on manufacturers who develop vaccines might have adverse consequences for public health.¹³⁹

A minority of courts have adopted an even narrower exception to the learned intermediary doctrine with regard to oral contraceptives.¹⁴⁰ These courts have permitted an exception for birth control pills because they believe that a unique set of circumstances separates oral contraceptives from other prescription drugs.¹⁴¹ For instance, the Massachusetts Supreme Judicial Court reasoned that:

Whereas a patient’s involvement in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use “the pill,” as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.¹⁴²

The court went on to conclude that oral contraceptives “stand[] apart” from ordinary prescription drugs, permitting liability

137. *See id.* at 1062.

138. *See, e.g., Mazur*, 964 F.2d at 1363.

139. *See* Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 394 (1987) (discussing the availability of vaccines as one of the public policy reasons underlying Congress’s enactment of a no-fault system for compensation of childhood vaccine-related injuries).

140. *See, e.g., Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 873–75 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380–81 (E.D. Mich. 1985); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964–65 (E.D. Wis. 1981), *amended on other grounds*, 532 F. Supp. 211 (E.D. Wis. 1981); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69–70 (Mass. 1985). *But see* *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991) (holding the learned intermediary doctrine applicable in cases involving oral contraceptives because oral contraceptives do not significantly differ from other prescription drugs).

141. *See, e.g., MacDonald*, 475 N.E.2d at 69.

142. *Id.*

when a manufacturer fails to convey an adequate warning directly to consumers.¹⁴³

There is considerable judicial disagreement over the merits of allowing an exception for oral contraceptives.¹⁴⁴ This debate has also spread to contraceptive intrauterine devices (IUDs), which a few jurisdictions have exempted from the doctrine by applying a similar rationale as that used to exclude drug contraceptives.¹⁴⁵ Courts opposed to this minority approach have generally acknowledged the more "elective" nature of treatment for contraceptives, yet strongly relied on the principle that "[i]n the final analysis it is the physician who ultimately prescribes the drug or device."¹⁴⁶ For this reason, courts have rejected further exceptions to the learned intermediary rule for other prescription treatments with characteristics arguably similar to prescription contraceptives,¹⁴⁷ while declining to apply the learned intermediary rule to nonprescription contraceptives.¹⁴⁸

143. *Id.* at 70.

144. *See* *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 357 (Ill. 1996) (concluding that the learned intermediary doctrine relieved manufacturer of duty to warn consumers that its contraceptives could cause physical deformities in children whose mothers ingested it during pregnancy); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974) (finding the same for contraceptive warnings related to circulatory and visual damage); *see also In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) (applying Texas law); *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 425–26 (D.D.C. 1991) (applying District of Columbia law); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1514–15 (S.D. Fla. 1990) (applying Florida law); *Goodson v. Searle Labs.*, 471 F. Supp. 546, 549 (D. Conn. 1978) (applying Connecticut law); *Chambers v. G.D. Searle*, 441 F. Supp. 377, 381 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977).

145. *See, e.g., Hill v. Searle Labs., Inc.*, 884 F.2d 1064, 1070 (8th Cir. 1989) ("[W]e believe that IUDs, like other forms of birth control, are atypical from most prescription drug products because the treating physician generally does not make an intervening, individualized medical judgment in the birth control decision.").

146. *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989) (applying the learned intermediary doctrine to IUD manufacturer where patient was required to undergo surgical removal of her ovaries and fallopian tubes after the IUD perforated her uterus).

147. *See Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 273 (D. Me. 2004) (rejecting application of learned intermediary exception for oral contraceptives to failure-to-warn claim brought by patient against manufacturer of prescription drug developed for treatment of obsessive-compulsive disorder (OCD)).

148. *See Mitchell v. VLI Corp.*, 786 F. Supp. 966, 970 (M.D. Fla. 1992) (concluding that the learned intermediary doctrine did not apply in products liability action brought by user of a nonprescription contraceptive sponge); *cf. Prager v. Allergan, Inc.*, No. 89-C-6721, 1990 WL 70875, at *4 (N.D. Ill. May 2, 1990) (holding that doctrine did not apply to manufacturer of a nonprescription contact lens solution that allegedly caused plaintiff permanent eye damage).

3. *A Few Recent Decisions Chip Away at the Learned Intermediary Rule*

Jurisprudence keeping exceptions to the learned intermediary doctrine very limited has remained remarkably consistent since the rule's inception. The debate over the scope of the traditional exceptions is more a product of reasonable disagreement over the physician's role in issuing one unique type of prescription than any challenge to the basic functioning of the doctrine.¹⁴⁹ In fact, the debate regarding courts' aversion to expanding exceptions for mass immunizations not conducted in "clinic like" conditions and contraceptives illustrates just how solidified the doctrine has become. In the past decade, however, Oklahoma has recognized a narrow exception to the doctrine and state supreme courts in New Jersey and West Virginia have made a sudden, radical departure from this long-established judicial rule.

In 1997, Oklahoma recognized a very limited exception to the learned intermediary doctrine in a failure-to-warn claim involving a prescription nicotine patch. In *Edwards v. Basel Pharmaceuticals*, the Oklahoma Supreme Court held that an exception to the rule applied where the FDA mandated that manufacturers, through labeling their products, directly communicate warnings to patients.¹⁵⁰ In such situations, the court ruled, "an exception to the 'learned intermediary doctrine' has occurred and the manufacturer is not automatically shielded from any liability by properly warning the prescribing physician."¹⁵¹ Rather, the court declared that when the FDA requires manufacturers to provide DTC information, the warning must adequately explain to the user the possible danger associated with the product.¹⁵² The Oklahoma Supreme Court's decision does not abrogate the learned intermediary doctrine on the basis of DTC advertising, but only in those rare instances in which the FDA *mandates* communication of warnings directly from manufacturer to patient.

149. See *supra* notes 140–48 and accompanying text.

150. *Edwards v. Basel Pharms.*, 933 P.2d 298, 301 (Okla. 1997).

151. *Id.* at 303.

152. See *id.*

The first true schism occurred in 1999 with the New Jersey Supreme Court's decision in *Perez v. Wyeth Labs., Inc.*¹⁵³ *Perez* involved a prescription contraceptive called Norplant, a "hybrid" medical device consisting of a drug capsule that is surgically implanted in the patient.¹⁵⁴ The plaintiffs alleged inadequate DTC warnings concerning the possibility of pain and other side effects.¹⁵⁵ In reversing an intermediate appellate court ruling, the New Jersey Supreme Court went beyond adopting the minority approach of exempting contraceptives, and created a broader exception to the learned intermediary doctrine for prescription drugs or devices marketed through DTC advertising.¹⁵⁶ This about-face was largely premised on the court's belief that "[o]ur medical-legal jurisprudence is based on images of health care that no longer exist."¹⁵⁷ DTC marketing, the court explained, fundamentally changed the medical landscape through radio, television, internet, and print advertisements such that it was no longer justified for consumers to rely exclusively on their physicians for risk information concerning a prescription drug or device.¹⁵⁸ As a result, the court held that the doctrine no longer provided full protection for pharmaceutical manufacturers that provided accurate information to physicians on the benefits and risks of a drug.

For almost a decade, Oklahoma and New Jersey stood alone in permitting a DTC-marketing exception to the learned intermediary doctrine.¹⁵⁹ Courts applying the doctrine during this

153. 734 A.2d 1245 (N.J. 1999). Until 2007, the closest resemblance to the *Perez* ruling came in an Oklahoma Supreme Court ruling more than a decade earlier which recognized a narrow exception to the learned intermediary doctrine where the FDA mandated communication of a particular warning directly to the patient as well as to the physician. See *McKee v. Moore*, 648 P.2d 21, 25 (Okla. 1982); see also *Edwards*, 933 P.2d at 303 (FDA compliance does not necessarily satisfy state requirements which may or may not conform to the learned intermediary rule); *Tansy v. Dacommed Corp.*, 890 P.2d 881, 886 (Okla. 1994) (applying the exception to a medical device). This exception for FDA-required patient warnings is not based on an impression of an altered medical landscape, nor does it apply to all prescription drugs. Rather, it is tied to compliance with existing laws applicable to a limited subset of prescription drugs. See *Edwards*, 933 P.2d at 301.

154. *Perez*, 734 A.2d at 1251.

155. See *id.* at 1248.

156. See *id.* at 1247.

157. *Id.* at 1246.

158. See *id.* at 1247.

159. See *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) ("In the intervening period [after *Perez*], no other state has followed

period repeatedly rejected attempts to create such an exception.¹⁶⁰ Then, in 2007, another crack appeared in the dam. In *State ex rel. Johnson & Johnson Corp. v. Karl*, the West Virginia Supreme Court of Appeals arrived at the same result as the New Jersey Supreme Court with regard to DTC marketing, but followed a different approach, wholly rejecting the learned intermediary doctrine.¹⁶¹

Before 2007, the West Virginia high court had not considered application of the doctrine. Deciding the case as one of first impression, the court found the “justifications for the learned intermediary doctrine to be largely outdated and unpersuasive.”¹⁶² Specifically, the court named DTC marketing as the impetus for its holding, stating that the “Norman Rockwell image of the family doctor no longer exists”¹⁶³ and that the doctor-patient relationship has been transformed such that “all of the [doctrine’s] premises are absent.”¹⁶⁴ Although the court acknowledged that four state supreme courts had adopted the now “widely accepted” doctrine during the very same decade in which DTC advertising proliferated, it determined that these decisions did not adequately consider changes occurring in the pharmaceutical industry.¹⁶⁵

In addition, the West Virginia court found traditional exceptions to the learned intermediary doctrine to be unwieldy, stating, “Given the plethora of exceptions to the learned interme-

New Jersey’s lead.”); see also Corey Schaecher, Comment, “Ask Your Doctor if This Product is Right for You”: *Perez v. Wyeth Laboratories, Inc., Direct-to-Consumer Advertising and the Future of the Learned Intermediary Doctrine in the Face of the Flood of Vioxx® Claims*, 26 ST. LOUIS U. PUB. L. REV. 421, 443 (2007) (stating that post-*Perez* courts have been “reluctant, at best, . . . to delineate an exception”).

160. See, e.g., *In re Meridia*, 328 F. Supp. 2d at 812 n.19 (“The Court thus could not apply *Perez*’s logic even if it desired to do so.”); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, at 827 (E.D. Tex. 2002) (“This argument . . . lacks merit in all jurisdictions, except New Jersey. . . . [A]part from New Jersey, direct-to-consumer advertising does not negate the applicability of the learned intermediary doctrine.”); *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001); *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594 (Ga. 2003); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

161. *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007).

162. *Id.* at 906.

163. *Id.* at 910 (quoting Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 160–61 n.78 (1997)).

164. *Id.* at 911.

165. See *id.* at 908–09.

diary doctrine, we ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.”¹⁶⁶ Based on these rationales, the court concluded that, under West Virginia law, the learned intermediary doctrine did not apply to warnings relating to pharmaceutical products. West Virginia law provides, therefore, that manufacturers are directly liable for conveying warnings and may not rely on physicians to transmit correct drug information to patients.

The court clearly was incorrect, however, when it spoke of a “plethora” of exceptions to the rule. Courts have recognized only three: mass immunizations, prescription contraceptives—followed by only a minority of courts—and the uncommon situation where the FDA explicitly requires a DTC warning. The absolute rule drastically expands the analysis of *Perez* by making West Virginia the only state expressly to reject the learned intermediary doctrine.

4. *Exceptions for DTC Marketing Represent Unsound Policy*

Perez and *Karl* each dramatically depart from the traditional rule of law relating to prescription drug warnings. These departures are unsupported by precedent, practice, or sound public policy. Established exceptions to the learned intermediary doctrine remain few and narrowly designed. *Perez*, however, creates a gaping exception for DTC marketing. The primary justification for this exception is that increasingly common DTC advertisements fundamentally change the physician-patient relationship.¹⁶⁷ Yet the ethical and legal obligations of the medical community with regard to communicating drug warnings are unchanged and show no indication of abrogation. As the dissent in *Karl* further explained: “[B]y attaching undue importance to the effects of direct marketing, the majority downplays the continuing and vital role that a physician plays in the decision as to which prescription drugs are appropriate for a given patient based upon that particular individual’s specific medical needs.”¹⁶⁸

166. *Id.* at 913.

167. See *supra* notes 153–58 and accompanying text.

168. *Karl*, 647 S.E.2d at 917 (Albright, J., dissenting).

Comparatively, a DTC marketing exception does not comport with the traditional learned intermediary doctrine exceptions. A DTC marketing exception is open-ended, theoretically encompassing all drugs. The three established exceptions represent a small fraction of prescription drugs where it is apparent the physician does not provide an individualized medical assessment. This is simply not the case with all DTC-marketed prescription drugs. Physicians have a legal and ethical duty to provide an individualized medical assessment before prescribing a drug regardless of how often it is advertised on television, radio, or any other media.¹⁶⁹ Suggesting that the playing field has changed to the extent physicians can no longer be fully relied upon to discuss with their patients the benefits and risks of a drug presents an untenable and illogical assertion when juxtaposed with the fact that no court has made any attempt to modify this basic duty of physicians.

The relatively recent development of the *Restatement (Third) of Torts: Products Liability*, § 6, and subsequent case law further demonstrate the continued viability of the learned intermediary doctrine's application to DTC-marketed prescription drugs. An early draft of the *Restatement (Third)* section relating to pharmaceutical manufacturer liability included an exception to the doctrine where "the manufacturer advertised or otherwise promoted the drug or medical device directly to users and consumers."¹⁷⁰ This black letter exception in Council Draft 1 was promptly deleted a few months later by the Reporters in Council Draft 1A.¹⁷¹ The Reporters explained that the change was a

169. See Am. Med. Ass'n, Council on Ethical & Judicial Affairs, Code of Medical Ethics, Direct-to-Consumer Advertising of Prescription Drugs, Op. 5-015, at 126 (2006–2007) ("Physicians must maintain professional standards of informed consent when prescribing. When a patient comes to a physician with a request for a drug he or she has seen advertised, the physician and the patient should engage in a dialogue that would assess and enhance the patient's understanding of the treatment. Although physicians should not be biased against drugs that are advertised, physicians should resist commercially induced pressure to prescribe drugs that may not be indicated. Physicians should deny requests for inappropriate prescriptions and educate patients as to why certain advertised drugs may not be suitable treatment options, providing, when available, information on the cost effectiveness of different options.").

170. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 103 (Council Draft No. 1, 1993); see also Noah, *supra* note 163, at 162–63 (detailing the Restatement Reporters' changes regarding DTC advertising).

171. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b)(3) (Council Draft No. 1A, 1994).

result of Council discussions that “demonstrated concern about creating a wholly new common law duty to warn when there was no case law to support it.”¹⁷²

Comment e accompanying the amended draft explained that the DTC marketing exception merged into the draft’s learned intermediary exception for FDA-required warnings.¹⁷³ Practically speaking, however, the deletion marked a clear retreat from acknowledging the third exception to the rule. By the time the Council issued Tentative Draft No. 1 later that year—four years before the final *Restatement* draft was published—both the DTC-marketing exception and the doctrine’s inapplicability where the FDA has required direct-to-patient warnings were completely eliminated.¹⁷⁴ Only the exception for mass immunizations withstood the scrutiny of the Council. There was also no revival by the Reporters of the *Restatement*, the Advisory Committee, or the articulate plaintiffs’ and defense counsel membership at the ALI of the express DTC marketing exception in any of the subsequent *Restatement* drafts.¹⁷⁵ Instead, the final version of comment e inserts a catch-all that “leaves to developing case law” the determination of whether any other exceptions to the learned intermediary doctrine exist.¹⁷⁶

In the decade following the issuance of the *Restatement (Third)*, it is notable that no state court except the New Jersey Supreme Court in *Perez* created an express DTC marketing exception to its learned intermediary rule. On the contrary, over the same period, four state supreme courts joined the growing list of high courts to adopt expressly the *Restatement* version of

172. *Id.*, Memorandum at 2.

173. *See id.* (“We have removed from the black letter a special exception to the learned intermediary rule for direct advertising to patients. Instead we have amended comment e to indicate that, where government agencies mandate that advertisements carry warnings to patients, the learned intermediary rule does not apply.”).

174. The learned intermediary exception relevant to advertisements was amended such that liability could exist if “[r]easonable instructions or warnings regarding foreseeable risks of harm posed by the drug or medical device were not provided directly to the patient when the manufacturer knew or had reason to know that no medical provider would be in the position” to reduce the risks of harm through appropriate warnings or instructions.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b)(3) (Tentative Draft No. 1, 1994).

175. *See Noah, supra* note 163, at 166.

176. RESTATEMENT (THIRD), *supra* note 114, at § 6 cmt. e.

the rule.¹⁷⁷ Further, sound public policy supporting the doctrine has led to its significant expansion in other ways. For example, some courts have extended the doctrine beyond the doctor-patient relationship to the role of a nurse¹⁷⁸ or applied it to veterinarians.¹⁷⁹ The doctrine has also expanded outside the medical community and into the workplace where courts routinely analyze the rule in conjunction with the bulk-supplier and sophisticated-user defenses. These defenses incorporate similar rationales to relieve industrial manufacturers and intermediaries of a duty to warn directly end-user workers and to impart that duty on the most knowledgeable party. That party is usually the purchaser or employer who knows the use for the materials and the associated risks and can best communicate the warning and provide protective equipment.¹⁸⁰

Such extensions of the principles underlying the learned intermediary doctrine, in addition to courts' general repudiation of additional exceptions when left to "developing case law," clearly

177. See *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001); *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594 (Ga. 2003); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

178. See *Rohrbough by Rohrbough v. Wyeth Labs.*, 719 F. Supp. 470, 478 (N.D. Va. 1989) (finding that a registered nurse who administered a Diphtheria and Tetanus Toxoids and Pertussis Vaccine (DTP) in a public health clinic qualified as a learned intermediary), *aff'd on other grounds* 916 F.2d 970 (4th Cir. 1990); *Walker v. Merck & Co.*, 648 F. Supp. 931, 934 (M.D. Ga. 1986); *Singleton v. Airco, Inc.*, 314 S.E.2d 680, 682 (Ga. Ct. App. 1984) (implying a nurse anesthetist qualified as a learned intermediary).

179. See *Haste v. Am. Home Prods. Corp.*, 577 F.2d 1122, 1124 (10th Cir. 1978), *cert. denied* 439 U.S. 955 (1978) (suggesting a veterinarian could be a learned intermediary in product liability action brought against the manufacturer of an animal vaccine).

180. See, e.g., *Smith v. Walter C. Best, Inc.*, 927 F.2d 736, 739 (3d Cir. 1990) (using the term "knowledgeable purchaser"); *Higgins v. E.I. DuPont de Nemours & Co.*, 671 F. Supp. 1055, 1061 (D. Md. 1987) (referring to a "knowledgeable industrial purchaser"); *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874, 883 (Pa. Super. Ct. 1993) (using the term "knowledgeable employer"); see also Keith Laughery, *Warnings in the Workplace: Expanding the Learned Intermediary Rule to Include Employers in the Context of Product Manufacture/Employer/Employee Relationship*, 46 S. TEX. L. REV. 627 (2005) (advocating expansion of the doctrine in certain manufacturing relationships); Victor E. Schwartz & Christopher E. Appel, *Effective Communication of Warnings in the Workplace: Avoiding Injuries in Working with Industrial Materials*, 73 MO. L. REV. 1 (2008) (discussing the parallels and doctrinal interplay of the learned intermediary rule with the sophisticated user doctrine in the case of industrial materials); Carole A. Cheney, Comment, *Not Just For Doctors: Applying the Learned Intermediary Doctrine to the Relationship Between Chemical Manufacturers, Industrial Employers, and Employees*, 85 NW. U. L. REV. 562, 575 (1991) (discussing the mixed results of the learned intermediary doctrine outside of the prescription drug context).

support the continued viability of the rule. Courts and commentators have long recognized that physicians are in the best position to determine the appropriateness, effectiveness, and risks of a drug based on a patient's medical and family history.¹⁸¹ Physicians' legal and ethical duty to warn patients adequately about any treatment, including prescription drugs, extends from this relationship. DTC advertising does not change the calculus. To find otherwise would presume that the physician's legal and ethical duties to warn either no longer exist or are so altered that a physician need not exercise any individualized medical judgment when determining a treatment course.¹⁸² This proposition would turn the law, and medical practice, on its head. It would require redefining the physician's duty to warn and effectively lessen the duty requirements and ethical obligations of doctors in the name of strengthening patient care. Not surprisingly, no case law appears to advocate lessening the duty of physicians to warn; if anything, the physician's duty to warn has become more comprehensive.¹⁸³

In addition to placing the responsibility of translating drug warnings on the more able physician, the learned intermediary doctrine achieves other important practical policy objectives. The broad range and complexities of potential prescription drug users make it ill-advised, and perhaps impossible, to tailor comprehensive warnings to consumers. Differences in patients' medical histories, ages, education levels, and drug interactions with current treatments are only a few of the multitude of barriers that a pharmaceutical manufacturer would have to overcome if directly liable for warnings both to doctors and to consumers. Liability for two types of warnings could serve to eliminate DTC marketing because no prescription drug company could warn effectively. The result would impede the at-

181. See *supra* notes 117–120 and accompanying text.

182. See *State ex rel. Johnson & Johnson Co. v. Karl*, 647 S.E.2d 899, 917 (W. Va. 2007) (Albright, J., dissenting) (“But to presume, as the majority appears to, that the mere presence of pharmaceutical advertising in our society relegates the role of the physician to a mere dispensary of prescriptions is simply not true.”).

183. The Massachusetts Supreme Judicial Court, for example, recently held that a physician could be liable to third parties injured as a result of the failure to warn a patient. See *Coombes v. Florio*, 877 N.E.2d 567, 571–72 (Mass. 2007) (holding that a doctor may be liable when his patient, who alleged he was not adequately warned that the medication he was on could cause drowsiness or fainting, injured the plaintiff in an automobile accident).

tempts of many consumers to take a more active role in their personal health. The extended liability would also likely increase drug prices, hampering the accessibility of the drugs.¹⁸⁴ Worse, if a majority of courts held drug manufacturers liable for DTC advertisements, it could create a self-fulfilling prophecy whereby consumers, aware of this obligation, begin to rely solely on the less comprehensive DTC warnings and physicians take fewer steps to evaluate treatments individually because there is shared liability with manufacturers.

As the saying goes, “A little knowledge can be a dangerous thing.” With prescription drugs, it can turn into a deadly thing. For that reason, liability for prescription drug warnings to consumers is entrusted to physicians and not to less comprehensive DTC advertisements. Rather, DTC advertisements caution to “see your doctor” or “consult a physician” so that the patient can take on a more active role while the doctor calculates the array of treatment risks. Because the learned intermediary doctrine establishes liability rules to facilitate this practice and improve health care, it is as viable in today’s world of DTC marketing as it ever was.

B. Effect of Compliance with FDA Requirements on Liability

Whereas the learned intermediary doctrine places the duty to warn patients of the risks of drugs on physicians, other common law and statutory enactments consider the deference warnings should receive when they are reviewed and approved by government regulators.

1. Common Law Principles

In the absence of a statute instructing courts how to weigh compliance with a government safety standard or government approval of a product or service, states vary on how they consider such evidence. Most courts find that compliance with government standards is one of many factors to be considered by the jury in determining whether or not a prod-

184. See *Brown v. Superior Court*, 751 P.2d 470, 478–79 (Cal. 1988) (expressing concern that increased liability would drive prices of drugs too high and make them less available).

uct is unreasonably dangerous.¹⁸⁵ These courts reason that government regulations provide only “minimum standards,” and, therefore, are not dispositive on the issue of liability for design or failure to warn.¹⁸⁶ Although most jurisdictions consider a violation of a safety regulation as evidence that a product is defective as a matter of law, they do not accord evidence of compliance with government regulations similarly deferential treatment.¹⁸⁷

In 1991, the American Law Institute (ALI) published a Reporter’s study recommending that compliance with regulatory requirements imposed by a government agency preclude tort liability in certain situations. Under the Reporter’s study recommendations, tort liability would be precluded when: (1) a legislature has placed the risk at issue under the authority of a specialized administrative agency; (2) that agency has established and periodically revises regulatory safety controls; (3) the manufacturer or other entity complied with the relevant regulatory standards; and (4) the manufacturer or other entity disclosed to the agency any material information in its possession, or of which it has reason to be aware, concerning the products’ risks and means of controlling them.¹⁸⁸

The *Restatement (Third)* incorporates a similar approach. It suggests that a product should not be considered defective as a matter of law in the following circumstances:

[W]hen the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.¹⁸⁹

185. See Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1241 (1996).

186. See *id.* at 1241–47 (1996) (providing examples of cases in which courts gave little weight to federal safety regulations spanning a variety of areas, such as flammability standards for clothing, pesticide warnings, automobile design, prescription drug warnings, aircraft design, and workplace safety standards).

187. See *id.*

188. See 2 AM. LAW INST., REPORTER’S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 95–97 (1991); see also Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2168–70 (2000).

189. RESTATEMENT (THIRD), *supra* note 114, at § 4 cmt. e.

The *Restatement (Third)* also acknowledges that this liability protection would not apply “when the deliberative process that led to the safety standard . . . was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product.”¹⁹⁰

The *Restatement (Third)* recognizes that courts frequently cite compliance with safety regulations as a factor used to justify a directed verdict for a defendant.¹⁹¹ In some cases, courts have accorded weight to government safety standards and approvals, even if they find compliance is not conclusive of liability.¹⁹² Courts occasionally find that meeting a safety standard set by government regulations precludes tort liability.¹⁹³ For example, the Maryland Court of Appeals has recognized that “where no special circumstances require extra caution, a court may find that conformity to the statutory standard amounts to due care as a matter of law.”¹⁹⁴

2. *Statutory Consideration of the Effect of Regulatory Compliance on Liability*

Aside from these common law principles, three types of state statutes impact liability related to the marketing of pharmaceutical products. The first comes into play in product liability cases and provides a presumption that a product approved by a government agency is not defective. The second type of these laws, also applicable in product liability actions, precludes an award of punitive damages with respect to injuries from FDA-approved drugs, with limited exceptions. The third includes provisions which place conduct that is closely regulated or ap-

190. *Id.*

191. *See id.* § 4 Reporters’ Note cmt. d (citing as an example *Hawkins v. Evans Cooperage Co.*, 766 F.2d 904, 909 (5th Cir. 1985)).

192. *See, e.g., Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 565 (Tex. App. 1995) (“Compliance with government regulations is strong evidence, although not conclusive, that a machine was not defectively designed.”).

193. *See, e.g., Lorenz v. Celotex Corp.*, 896 F.2d 148, 152 (5th Cir. 1990) (compliance with safety regulation is strong and substantial evidence of lack of defect); *Dentson v. Eddins & Lee Bus Sales, Inc.*, 491 So. 2d 942, 944 (Ala. 1986) (ruling that a school bus that is not equipped with seatbelts is not defective when the legislature has not required seatbelts); *Ramirez v. Plough, Inc.*, 863 P.2d 167, 176 (Cal. 1993) (concluding that “the prudent course is to adopt for tort purposes the existing legislative and administrative standard of care”).

194. *Beatty v. Trailmaster Prods., Inc.*, 625 A.2d 1005, 1014 (Md. 1993).

proved by government agencies beyond the scope of more general state statutes prohibiting deceptive advertising.

a. Presumption of Nondefectiveness

Seven states provide that compliance with federal or state government safety regulations creates a rebuttable presumption that a product is not defective.¹⁹⁵ The relevant statutes respect the decision making of federal and state regulatory agencies charged with protecting public safety in tort lawsuits. Such laws are broadly applicable to any product governed by government safety regulations and have been invoked in cases involving a wide range of products including ladders,¹⁹⁶ nail guns,¹⁹⁷ cleaning products,¹⁹⁸ clothing,¹⁹⁹ airplanes,²⁰⁰ and automobiles.²⁰¹ The statutes generally provide a presumption that a product is not unreasonably dangerous if it meets safety re-

195. See *infra* note 203 and accompanying text.

196. See *States v. R.D. Werner Co.*, 799 P.2d 427, 430 (Colo. Ct. App. 1990) (ruling that the trial court did not err by admitting expert testimony on a ladder's compliance with federal regulations).

197. See *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 321 (Utah 1999) (ruling that federal OSHA standards regulating the design of a pneumatic nailer were admissible as government standards and established a rebuttable presumption of nondefectiveness as they provided "a legitimate source for determining the standard of reasonable care").

198. See *Uptain v. Huntington Lab, Inc.*, 685 P.2d 218, 222 (Colo. Ct. App. 1984) (finding that manufacturer of a cleaning compound was entitled to presumption of nondefectiveness where an expert testified that the product label's warnings complied with federal and local laws and was approved by the Environmental Protection Agency).

199. See *Alvarado v. J.C. Penney Co.*, 735 F. Supp. 371, 372-74 (D. Kan. 1990). In a case involving a nightgown and robe that were ignited by an open-flame gas heater, the court held that the regulatory compliance provision of the Kansas Products Liability Act did not create a conclusive presumption and thus a constitutional challenge by plaintiffs was moot. See *id.*

200. See *Champlain Enters., Inc. v. United States*, 957 F. Supp. 26, 28 (N.D.N.Y. 1997) (ruling that the regulatory compliance provision of the Kansas Products Liability Act would provide an airplane manufacturer with a defense against liability if it established that the aircraft complied with government safety standards, unless the plaintiff can show that "a reasonable prudent product seller could and would have taken additional precautions").

201. See *Brand v. Mazda Motor Corp.*, 978 F. Supp. 1382, 1387-88, 1391-93 (D. Kan. 1997) (ruling that automobile manufacturer's compliance with federal regulatory standards was not dispositive of liability or punitive damages absent clear and convincing evidence that the manufacturer acted with reckless indifference to consumer safety).

quirements, thus reducing the potential for a finding of liability. For example, since 1977 Colorado law has provided:

In any product liability action, it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product . . . [c]omplied with, at the time of sale by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States or by this state.²⁰²

Kansas, Kentucky, Michigan, Tennessee, Texas, and Utah have chosen similar routes.²⁰³ These laws assure that courts allow juries to hear and appropriately consider a product's compliance with government standards when they consider whether the product is defective.

Such laws appear to include claims challenging the sufficiency of a pharmaceutical product's labeling and warnings, including failure-to-warn claims associated with DTC marketing. Curiously, there is very little case law applying the statutory presumptions of nondefectiveness to FDA-approved warnings.²⁰⁴

b. Preclusion of Punitive Damages for FDA-Approved Pharmaceuticals

Special considerations come into play when lawsuits charge that a prescription drug manufacturer acted with such malice in offering a product to patients that it should be subject to punitive damages even though the FDA approval process includes a rigorous review that can span thousands of hours over more than a decade.²⁰⁵

202. COLO. REV. STAT. § 13-21-403(1) (2008).

203. See KAN. STAT. § 60-3304(a) (2007); KY. REV. STAT. § 411.310(2) (2008); MICH. COMP. LAWS § 600.2946(4) (2000); TENN. CODE § 29-28-104 (2008); TEX. CIV. PRAC. & REM. CODE § 82.008 (2008); UTAH CODE § 78B-6-703 (2008).

204. See, e.g., *Kernke v. The Menninger Clinic, Inc.*, 173 F. Supp. 2d 1117, 1121–22 (D. Kan. 2001) (finding insufficient evidence to overcome Kansas's presumption of nondefectiveness and raise a jury question with respect to an FDA-approved clinical trial of an experimental treatment for schizophrenia). At least two additional states, Arkansas and Washington, specifically provide by statute that parties may introduce evidence of regulatory compliance to show that a product is not defective or that its warnings are not inadequate. See ARK. CODE § 16-116-105(a) (2007); WASH. REV. CODE § 7.72.050(1) (2008). These statutes do not assign any particular evidentiary weight to compliance with safety standards.

205. See Henry I. Miller, *Failed FDA Reform*, 21 REGULATION 24, 24 (1998) (attributing an increase in cost for new drug development and approval from \$359 mil-

For this reason, five states have enacted statutes that preclude punitive damage liability when the manufacturer received FDA approval for the product at issue. New Jersey, Oregon, and Ohio were the first states to adopt such laws.²⁰⁶ Arizona and Utah followed when they passed laws addressing punitive damages in cases involving FDA-approved or licensed products.²⁰⁷ Additionally, Michigan, a state that does not recognize punitive damages, limits manufacturer liability for compensatory damages in product liability actions involving FDA-approved drugs. Michigan law defers to the federal agency's comprehensive regulatory process by providing a rebuttable presumption that a drug, including its labeling and packaging, is not defective or unreasonably dangerous if the drug is approved for safety and efficacy by the FDA.²⁰⁸

There are variations as to the scope of these laws, such as whether the limitation on liability applies solely to prescription drugs or to other FDA-approved products as well. Generally, each law includes exceptions permitting full liability in three circumstances: (1) if the drug was sold after an FDA product recall or withdrawal of approval; (2) if the defendant knowingly withheld material information from or misrepresented material information to the FDA; or (3) if the defendant bribed a public official. Ohio law further permits punitive damages upon a finding that the manufacturer acted in "flagrant disregard of the safety of persons who might be harmed by the product" and provides that the court is to decide the amount of punitive damages upon a jury verdict finding punitive dam-

lion to \$500 million—in pretax 1990 dollars—between 1990 and 1993, and an increase in the time for approval from 8.1 years to 15.2 years since the 1960s, to the "FDA's regulatory zeal").

206. See N.J. STAT. § 2A:58C-5c (2008); OHIO REV. CODE § 2307.80(C) (2008); OR. REV. STAT. § 30.927 (2007). In 2005, the Ohio legislature expanded coverage of the statute to include medical devices and over-the-counter drugs in addition to prescription drugs. OHIO LAWS FILE 144 (Am. Sub. S.B. 80) (amending OHIO REV. CODE § 2307.80) (effective Apr. 7, 2005).

207. See ARIZ. REV. STAT. § 12-701(A) (2009); UTAH CODE § 78B-8-203(1) (2008).

208. See MICH. COMP. LAWS § 600.2946(5) (2000). The Supreme Court of the United States recently found that an exception in the Michigan law which preserves liability if the drug company withheld or misrepresented information that would have altered the FDA's decision to approve the drug product (i.e., "fraud-on-the-FDA") was valid and not preempted. *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008).

ages appropriate.²⁰⁹ The laws also differ on the burden of proof required to overcome the limitation on liability.²¹⁰

It is inaccurate, however, to call this an “FDA-approval” defense. The defense neither completely eliminates liability (except in Michigan, with limited exceptions), nor results in the elimination of punitive damages simply based on FDA approval. FDA approval of a prescription drug is insufficient to merit such treatment unless the manufacturer follows FDA rules and submits the extensive test results required by FDA regulations. In addition, FDA regulations require submission of certain information after approval of the drug, such as adverse reaction reports and new developments in scientific knowledge on the drug, which allows the agency to determine whether it should withdraw its approval and require the manufacturer to withdraw the product.²¹¹

Protection from punitive damages would only apply when the manufacturer has met all of these requirements. Thus, these laws encourage pharmaceutical companies to disclose fully all pre- and post-marketing data and to meet or exceed the agency’s requirements in order to qualify for protection from extensive punitive damages should it later be found that the manufacturer failed to warn of known risk.

c. Placing Regulated Conduct Beyond the Scope of Consumer Protection Laws

Product liability claims against pharmaceutical manufacturers are generally brought on behalf of plaintiffs who have experienced physical injuries. Increasingly, lawyers are alleging claims under state consumer protection laws.²¹² Although these types of claims appear to be increasing across the board, pharmaceutical manufacturers are a principal target.²¹³

209. See OHIO REV. CODE § 2307.80(B)–(C) (2008).

210. Compare OR. REV. STAT. § 30.927 (2007) (requiring “clear and convincing” evidence of the misconduct), with OHIO REV. CODE § 2307.80(C) (2008) (providing a preponderance of the evidence standard).

211. See 21 C.F.R. § 314.80(b)–(c) (2008).

212. See generally James P. Muehlberger & Cary Silverman, *Lawsuits Without Injury: The Rise of Consumer Protection Claims*, LITIG. WATCH, Oct. 2006, at 4.

213. See *id.*

Typically, lawyers bring Consumer Protection Act (CPA) claims involving prescription drugs as class actions on behalf of a group of individuals who purchased the drug but did not suffer any ill effects. These lawsuits usually allege that the company promoted a drug as safe and effective, when in fact either the product was not as effective as consumers believed or the advertising failed to disclose a known risk associated with the drug. Claims may allege that the company's aggressive advertising of the drug resulted in artificial inflation of the product's price beyond its actual value. Damages sought are usually either a complete refund of the purchase price (on behalf of thousands of consumers) or the difference between the sale price and the hypothetical actual value. In recent years, such claims have been made involving Claritin,²¹⁴ OxyContin,²¹⁵ Prempro,²¹⁶ Rezulin,²¹⁷ and Vioxx,²¹⁸ among other products.

State consumer protection laws were once primarily used by government regulators to attack truly deceptive practices and by consumers to bring small claims to get reimbursement for being duped at the cash register, but now they are routinely tacked on to substantial lawsuits.²¹⁹ These laws are particularly attractive for private claims because they often provide for

214. See *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003) (holding plaintiffs who claimed allergy medication was not as effective as advertised failed to establish a causal nexus between representations and any loss suffered under the New Jersey Consumer Fraud Act).

215. See *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 177–78 (dismissing District of Columbia's Consumer Protection Procedures Act claim that the manufacturer over-promoted the drug as providing "smooth and sustained" pain relief for twelve hours with little chance of addiction, which allowed the manufacturer artificially to inflate its prices).

216. See *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 566–68 (E.D. Ark. 2005) (denying certification of a consumer-protection class due to material variations in the consumer laws of the twenty-nine states at issue and the need to show individual plaintiffs relied on the allegedly deceptive advertisement and were injured as a result).

217. See *In re W. Va. Rezulin Litig.*, 585 S.E.2d 52, 62–65 (W. Va. 2003) (ruling that the statutory requirement that a plaintiff show an "ascertainable loss" under West Virginia Consumer Credit and Protection Act did not require a showing of actual damages and finding that plaintiffs needed only to allege that they received a product that was different or inferior to that which they believed they purchased).

218. See *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007).

219. See Victor E. Schwartz & Cary Silverman, *Common-Sense Construction of Consumer Protection Acts*, 54 KAN. L. REV. 1, 32–33 (2005).

minimum awards set by statute in absence of proof of injury, treble damages, and attorneys' fees.²²⁰

Some have argued that the scope of CPAs was never meant to include FDA-approved drugs.²²¹ That is why approximately two-thirds of CPAs exclude from their scope conduct regulated by state or federal government agencies.²²² The clear public policy behind these provisions is that CPAs were meant to fill a "legal gap" by protecting consumers where product safety was not already closely monitored and regulated by the government.²²³ These provisions are only infrequently applied in cases involving pharmaceutical marketing. Instead, courts appear more frequently to apply principles of conflict preemption in claims challenging drug warnings.²²⁴

C. Conflicts with Federal Authority: Preemption

The constitutional principle of preemption provides a final safeguard in the development and communication of drug warnings. Under the Supremacy Clause of the United States Constitution, state law must yield to federal law when the two conflict.²²⁵ Acts of Congress or agencies empowered to act on Congress's behalf override any state law that is inconsistent with the exercise of federal power.²²⁶ In the prescription drug context, the FDA acting pursuant to the FDCA is such an agency, able to exercise federal power.²²⁷ In some instances,

220. *See id.* at 22–27.

221. *See, e.g.,* Victor E. Schwartz, Cary Silverman & Christopher E. Appel, "That's Unfair!" Says Who—The Government or Litigant? *Consumer Protection Claims Involving Regulated Conduct*, 47 WASHBURN L.J. 93, 119 (2007).

222. *See id.* at 102. Regulatory-compliance exemptions to state consumer laws vary from state to state but generally fit within three categories: (1) rules of construction suggesting or requiring that courts interpret the state consumer law consistently with the interpretations and policy of the FTC; (2) exemptions for authorized or permitted conduct; (3) exemptions applicable to specific regulated industries or conduct. *See id.* at 102–17.

223. *Id.* at 106 (quoting *Taylor v. Bear Stearns & Co.*, 572 F. Supp. 667 (N.D. Ga. 1983)).

224. *See id.* at 119–22; *see also* Muehlberger & Silverman, *supra* note 212, at 5–6.

225. U.S. CONST. art. VI, cl. 2.

226. *See* *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 369 (1986) ("Pre-emption may result not only from action taken by Congress itself; a federal agency action within the scope of its congressionally delegated authority may pre-empt state regulation.").

227. *See* 21 U.S.C. § 393(b) (2006) (charging the FDA with ensuring that drugs are safe and effective).

preemption establishes an affirmative defense for drug manufacturers, in effect barring state tort actions that rely on court decisions contrary to FDA decisions.

1. *Methods of Preemption*

There are several types of preemption. The most straightforward, known as “express preemption,” occurs where a federal law preempts state statutes and common law within the text of the statute. For example, the Medical Device Amendments to the FDCA contain an express preemption provision barring certain state actions where the device complies with FDA regulations.²²⁸ This practice has the benefit of reducing uncertainty over Congressional intent; it may still, however, leave questions over the scope of the preemption.²²⁹

In other cases, preemption can be implied through the purpose or structure of the federal law.²³⁰ Such “implied preemption” occurs in three situations: (1) “field preemption,” in which Congress intends to occupy an entire regulatory field, leaving no room for state lawmaking;²³¹ (2) “conflict preemption,” in which “compliance with both federal and state regulations is a physical impossibility”;²³² and (3) “obstacle preemption,” in which state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”²³³ In practice, only the latter two forms apply to prescription drugs as no court

228. See 21 U.S.C. § 360k(a) (2006) (providing that a state shall not “establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under [federal law] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under” relevant federal law).

229. See, e.g., *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006–08 (2008) (discussing the scope of the MDA’s express preemption provision regarding medical device compliance with FDA pre-market approval process); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67–68 (2002) (analyzing the confines of an express preemption provision in the Federal Boat Safety Act).

230. See *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (“Even without an express provision for preemption, we have found that state law must yield to a congressional Act . . .”).

231. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230–31 (1947).

232. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963); see also *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985).

233. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869–74 (2000); see also *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

has yet found implied field preemption for the FDA's regulation of drugs and medical devices.²³⁴ These two forms are generally joined together by courts and commentators under the term "conflict preemption" despite distinct inquiries of analysis.²³⁵ Because express preemption is relatively clear cut in most instances and field preemption is not yet recognized for the FDA's regulatory coverage, implied conflict preemption principles represent the common method for recognizing preemption in pharmaceutical regulations.

2. *The FDA's Changing Priorities in a DTC Environment*

In recent years, the FDA has increasingly recognized implied conflict preemption of state tort claims as a result of its regulations and decision making.²³⁶ Since 2000, the agency has filed a number of amicus curiae briefs arguing that its regulatory interpretations support a finding of preemption.²³⁷ As amicus, the FDA takes the clear position that, under the agency's comprehensive regulatory scheme, a drug manufacturer cannot unilaterally strengthen a drug warning without FDA approval.²³⁸ This view represents the agency's "authority to implement the statute," its "thorough understanding of its own regulation,"

234. See James O'Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 291 (arguing that it is unlikely that an implied field preemption claim could prevail in the prescription drug field).

235. See, e.g., *Crosby*, 530 U.S. at 372; see also Christine H. Kim, *The Case for Preemption of Prescription Drug Failure-to-Warn Claims*, 62 FOOD & DRUG L.J. 399, 402 (2007) (separating the three distinct forms of implied preemption).

236. See Kim, *supra* note 235, at 400–01 (discussing the FDA's increased amicus curiae filings in federal preemption cases); Mark C. Levy & Gregory J. Wartman, *Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA's Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 FOOD & DRUG L.J. 495, 497–99 (2005); Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013, 1032–34 (2007).

237. See, e.g., Corrected Amicus Brief for the United States, *Kallas v. Pfizer, Inc.*, No. 04-00998 (D. Utah Sept. 29, 2005); see also Sharkey, *supra* note 236, at 1038 (estimating that the FDA is directly involved in one quarter of federal court drug preemption cases since 2000).

238. See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 528 (E.D. Pa. 2006) (citing 21 C.F.R. § 314.150).

and its “uniquely qualified” position to “comprehend the likely impact of state requirements.”²³⁹

In 2006, the FDA issued a Preamble to a rule updating and strengthening prescription drug labeling requirements, which expressed its view that several types of product liability claims were preempted by federal regulation.²⁴⁰ The agency explained that these claims either stood as an obstacle to carrying out its mission or conflicted with the FDA’s decision-making authority. Specifically, the Preamble states that “FDA approval of labeling [under the new guidelines] . . . preempts conflicting or contrary State law, regulations, or decisions of a court of law for purposes of product liability litigation.”²⁴¹ The Preamble emphasizes the agency’s “statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs,”²⁴² and cautions that state tort actions can “encourage, and in fact require, lay judges and juries to second guess the assessment of benefits versus risks of a specific drug” and create “pressure on manufacturers to attempt to add warnings . . . [and] to propose ‘defensive labeling’ . . . which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.”²⁴³ The Preamble cites six instances where preemption should be implied.²⁴⁴ Hence, although still acknowledging that “FDA labeling requirements represent a minimum safety standard,” the FDA interpreted its comprehensive regulatory procedures as creating “both a ‘floor’ and a ‘ceiling’” for the imposition of liability.²⁴⁵

The Preamble sparked debate over the FDA’s role in regulating drugs²⁴⁶ and the relative deference a court should afford an

239. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 863 (2000) (internal quotation marks omitted).

240. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933–34 (Jan. 24, 2006) (effective date June 30, 2006) [hereinafter “FDA Preamble”].

241. *Id.*

242. *Id.* at 3935.

243. *Id.*

244. *Id.* at 3935–36.

245. *Id.* at 3935.

246. See, e.g., W. Wylie Blair, *Implied Preemption of State Tort Law Claims Against Prescription Drug Manufacturers Based on FDA Approval*, 27 J. LEGAL MED. 289, 301 (2006) (proposing amendment of the Food, Drug, and Cosmetic Act, enactment of state statutes, or the use of judicial intervention to adopt the FDA’s interpretation of the scope of implied preemption); Teresa Curtin & Ellen Relkin, *Preamble Pre-*

agency's interpretation of the scope of preemption as expressed in a preamble.²⁴⁷ Courts have varied in the deference given to the FDA's view.²⁴⁸ In past decisions, the Supreme Court has expressed the view that agency statements warrant some degree of deference. For example, in *Medtronic, Inc. v. Lohr*, a medical device case, Justice Breyer's concurrence noted, "in the absence of a clear congressional command as to preemption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect."²⁴⁹ Likewise, in *Hillsborough County v. Automated Medical Laboratories, Inc.*, the Court recognized that "because agencies normally address problems in a detailed manner and can speak

emption and the Challenged Role of Failure to Warn and Defective Design Pharmaceutical Cases in Revealing Scientific Fraud, Marketing Mischief, and Conflicts of Interest, 35 HOFSTRA L. REV. 1773, 1778 (2007) (juxtaposing the FDA's preemption position with deficiencies in the agency's post-market regulatory scheme and suggesting a possible retreat from the FDA's strong stance on implied preemption); Margaret Gilhooley, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347, 388 (2008) (recommending the FDA change its policy and require that drug sponsors petition the agency for a statement of preemptive effect on the need for a warning).

247. Compare Howard L. Dorfman et al., *Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate*, 61 FOOD & DRUG L.J. 585, 610–11 (2006) (advocating substantial, or *Chevron* level, deference to the Preamble), with Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 FOOD & DRUG L.J. 227, 247 (2007) (concluding that the Preamble warrants low level or *Skidmore* deference). See also Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 243–45 (2007) (examining increased use of preemption by federal agencies and corresponding judicial deference to agency determinations).

248. Compare *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05-1699, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (same *Celebrex*), *Conte v. Wyeth, Inc.*, No. 04-437382, 2006 WL 2692469 (Cal. App. Dep't Super. Ct. Sept. 14, 2006) (same *metoclopramide*), and *Abramowitz v. Cephalon, Inc.*, No. BER-L-617-04, 2006 WL 560639 (N.J. Super. Ct. Law Div. Mar. 3, 2006) (finding implied preemption for FDA's approval of risks associated with pain-management drug *Actiq*), with *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd sub. nom.*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666 (E.D. Ky. 2006), *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964 (D. Neb. 2006), and *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (2008).

249. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505 (1996) (Breyer, J., concurring); see also *Chevron v. Nat'l Res. Def. Council*, 467 U.S. 837, 863–64 (1984) ("The fact that the agency has from time to time changed its interpretation . . . does not . . . lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency interpretation is not instantly carved in stone.").

through a variety of means, including regulations, preambles, interpretative statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive."²⁵⁰

Although the Court has not yet directly addressed the preemptive effect of the FDA's regulation of prescription drugs or the level of deference to be accorded to the FDA's view, the Court's consideration of *Levine v. Wyeth* is likely to shine significant light on these issues as well as the modern role of the FDA.²⁵¹ In *Levine*, the plaintiff went to the hospital for treatment of a serious migraine headache and, after injection with the drug Phenergan, was left with injuries that led to the amputation of her arm.²⁵² The injury occurred as a result of direct intravenous (IV) injection, a risk the FDA had closely considered when deeming the anti-nausea medication safe for use.²⁵³ The agency approved a warning cautioning against inadvertent injection and providing instructions to minimize the risk but chose not to prohibit IV push as a means of administration.²⁵⁴ In fact, Wyeth asked the FDA in 2000 to alter the warning to place greater emphasis on the risk at issue, but the FDA indicated the warning should remain unaltered.²⁵⁵ Wyeth acquiesced and the warning was unchanged leading up to the state lawsuit.

The Vermont Supreme Court found that FDA compliance is only a minimum standard and referred to FDA approval as simply a "first step" in pharmaceutical labeling.²⁵⁶ The court rejected both conflict and obstacle preemption, concluding that the manufacturer was "free" to supplement or strengthen

250. *Hillsborough County*, 471 U.S. 707, 718 (1985); see also *Dowhal v. Smith-Kline Beecham Consumer*, 88 P.3d 1, 5–6, 9–10 (Cal. 2004) (accorded deference to FDA position expressed in letters issued in response to a manufacturer inquiry and citizen petition stating that California law was preempted to the extent it required warnings on nicotine replacement devices that conflicted with the FDA's determination that a manufacturer could include only approved warnings).

251. *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (2008) (No. 06-1249). The Court also decided two other cases this term considering preemption in the FDA context. See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008).

252. See *Levine*, 944 A.2d at 182.

253. See *id.* at 183.

254. See *id.* at 189.

255. See *id.* at 188.

256. *Id.*

warnings at any time.²⁵⁷ The court also acknowledged the FDA Preamble, yet held that “irrespective of the level of deference [it] might apply, the statement would not affect the outcome of [the] appeal,” and further stated that the agency’s interpretation was undeserving of any deference.²⁵⁸

The Solicitor General, in a brief as amicus curiae filed at the invitation of the U.S. Supreme Court, disagreed with the Vermont ruling.²⁵⁹ The Solicitor recognized that labeling is an inextricable component of the approval process, noting that the FDA may convey to physicians and their patients the conditions under which the potential benefits of the product exceed its risks, while not unnecessarily deterring beneficial uses.²⁶⁰ “If manufacturers were free to make unilateral changes to labeling the day after FDA’s approval, based on information that was previously available to FDA, the approval process would be greatly undermined and the agency’s careful balancing of risks and benefits thwarted.”²⁶¹ Having granted certiorari, the Court will decide whether FDA-approved warnings are merely a floor, as suggested by the Vermont Supreme Court, or both floor and ceiling, as argued by the Solicitor General.²⁶²

Other courts have found that state tort law claims challenging conduct in compliance with FDA requirements are preempted. For instance, a federal district court in Pennsylvania considered state claims for failure to warn relating to an anti-depression and anti-anxiety drug’s (Paxil) risk of suicide, and found them to be preempted.²⁶³ The case, which also involved the drug’s generic versions, examined the FDA’s position on preemption, holding that it is “abundantly clear” that such evidence of intent is entitled to “significant deference.”²⁶⁴ Similarly, a federal district court in California reached a similar de-

257. *Id.* at 194.

258. *Id.* at 192.

259. See Brief for the United States as Amicus Curiae Supporting Petitioner, *Wyeth v. Levine*, No. 06-1249 (U.S. filed Dec. 2007), available at <http://www.usdoj.gov/osg/briefs/2007/3mer/1ami/2006-1249.mer.ami.pdf>.

260. *Id.* at 9–11.

261. *Id.* at 9.

262. See *id.* at 11.

263. See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006).

264. *Id.* at 529; see also *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 308–10 (E.D. Pa. 2007) (preempting state tort actions against pediatric vaccine manufacturers under the National Childhood Vaccine Injury Compensation Act).

termination and preempted state claims for failure to warn of the drug Celebrex's cardiovascular risks.²⁶⁵

Armed with evidence of the FDA's understanding of the scope of preemption, a growing number of courts acknowledge implied conflict preemption in drug warnings. Although this development is gradual and uneven, it signals a renewed viability of implied preemption as a final, constitutional check on the sufficiency of drug warnings.

Federal law may not only preclude state product liability claims, but it may also preempt CPA claims. For example, in *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*, the plaintiffs claimed that the manufacturer of Nexium violated the Delaware Consumer Fraud Act by advertising that Nexium was superior to Prilosec.²⁶⁶ Both drugs treat acid reflux disease and frequent heartburn. Delaware's consumer protection law exempts advertising or mechanizing practices that comply with the rules and regulations of the FTC, but does not contain a general regulatory compliance exemption for conduct in compliance with the rules of other government agencies.²⁶⁷ The Third Circuit, although noting that the FTC and FDA initially had concurrent jurisdiction over prescription drug advertising, declined to extend the clear statutory language to conduct that now falls exclusively within the FDA's jurisdiction.²⁶⁸ The court found, however, that the purpose of the Food, Drug, and Cosmetic Act "would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA."²⁶⁹ Thus, the court found claims under Delaware's consumer protection law challenging labeling or advertising of FDA-approved prescription drugs implicitly preempted.²⁷⁰

3. Public Policy Supports Expanding Scope of Preemption

The FDA's interpretation of the scope of implied preemption appears cognizant of the bigger picture unfolding within the

265. See *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, MDL No. 1699, 2006 WL 2374742, at *9 (N.D. Cal. Aug. 16, 2006).

266. 499 F.3d 239, 241 (3d Cir. 2007).

267. See DEL. CODE tit. 6 § 2513(b) (2009).

268. See *Pennsylvania Employees*, 499 F.3d at 243.

269. *Id.* at 251.

270. See *id.* at 252.

pharmaceutical industry: As the scale and complexity of pharmaceutical production reaches new heights, the need for comprehensive federal regulation becomes increasingly imperative.²⁷¹ Greater recognition of federal preemption helps to achieve the objectives of such regulation by assuring definitive and uniform application. Further, preemption serves public policy goals of predictability and fundamental fairness by informing pharmaceutical participants of their complete set of legal obligations rather than simply setting a floor and forcing manufacturers to abide by fifty different state law interpretations.²⁷²

From a practical standpoint, the FDA's interpretation is a logical, perhaps inevitable, step toward meeting its congressional mandate as the federal agency responsible for regulating drugs.²⁷³ The FDCA, originally enacted in 1938, does not contain express preemption language with regard to drug regulation.²⁷⁴ Hence, implied conflict preemption is necessary for the FDA to assert its regulatory authority, provide definitive standards, and safeguard drug manufacturers when they comply with existing regulations.

In comparison, the MDA, enacted over a half century after the FDCA, does contain an express preemption provision for medical devices.²⁷⁵ Given the similarities established in other contexts, such as application of the learned intermediary rule, between prescription drugs and prescription medical devices,²⁷⁶ there appears to be little justification for such a discrepancy if the FDA was not supposed to preempt implicitly state laws regarding drug warnings. Rather, the FDA's stronger endorsement of implied preemption seems to align

271. See Richard Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. 1, 1 (2006) ("[F]ederal preemption of state tort actions for pharmaceuticals is long overdue, both under current law and as a matter of sound legal policy.").

272. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA . . .").

273. See FDA Preamble, *supra* note 240, at 3934 ("In order to more fully address the comments expressing concern about the product liability implications of revising the labeling for prescription drugs, we believe it would be useful to set forth in some detail the arguments made in those amicus briefs.").

274. See 21 U.S.C. § 301 (2006).

275. See 21 U.S.C. § 360k(a) (2006).

276. See *supra* Part III.A.

preemption principles between these Acts, promoting the policy goal of consistency among laws.

Growth in DTC marketing plays an important part in the changing landscape of drug regulation and the modern role of the FDA. Although the dynamics of the physician-patient relationship remain unaffected by DTC marketing, the scale of the marketing efforts is national and warrants comprehensive federal regulation. Many states have long recognized the policy benefits of a uniform federal system of regulation and apply state law regulatory compliance exceptions to further this result.²⁷⁷ Where the scope of these regulatory exemptions is limited, constitutional principles of preemption should apply to preclude most state tort claims based on design, failure to warn, and consumer protection acts if the drug manufacturer strictly complies with federal law.

CONCLUSION

The debate on whether DTC advertising encourages individuals to seek effective treatment for health conditions or pushes them to pressure their doctors for unnecessary designer medications is likely to rage on far into the future. The answer to that question is beyond the scope of this Article. What is clear, however, is that despite increasing DTC advertising, the basic relationship between pharmaceutical manufacturers and the medical community with regard to drug warnings remains virtually unchanged. After the FDA approves a prescription drug as safe and effective, patients must still consult with a physician before obtaining the medication. Physicians, based on the specific medical history and individual characteristics of each patient, must adequately inform their patients of potential side effects and evaluate other relevant risks before pursuing a treatment course. The role, and indeed the objective, of DTC advertising in this doctor-patient relationship is to prompt the patient to question his doctor about potential drug treatments. Even though all

277. See *supra* Part III.B; see also Dorfman et al., *supra* note 247, at 622 (“[T]he public policy balance weighs in favor of a uniform federal scheme to provide for the introduction of urgently needed medical therapies without compromising FDA’s role of ensuring that prescription drug labels are accurate, contain appropriate and scientifically sound precautionary language with regard to adverse events, and allow for clear understanding by the recipients.”).

advertisements direct patients to, “ask [their] doctor about” the drug in question, it remains the physician’s ultimate responsibility to evaluate whether that drug is the most effective, or even a beneficial, treatment. DTC advertising can never replace or undermine the personal relationship between a physician and a patient and the communication of the risks and benefits of a drug discussed in the doctor’s office. That many patients are able to become more informed about possible treatments through DTC advertising and take a more active role in improving their health should be viewed as a considerable benefit to the healthcare system—one that in no way undercuts the traditional rules of law related to drug warnings.²⁷⁸

All this is not to say, however, that the regulation of DTC advertising is without any gaps or weaknesses. Regulation could potentially be improved if the FDA considered making pre-dissemination submission of DTC advertisements for the agency’s review mandatory, rather than voluntary, and requiring affirmative FDA approval before permitting advertisements to air. The practicality, effectiveness, and fairness of such a requirement, however, would largely depend on whether Congress provided the FDA with sufficient resources to review promptly a surge in submissions, because, according to the GAO, the process at present already takes too long.

Despite the potential benefit of the aforementioned changes, this Article has shown that the learned intermediary doctrine retains its viability in our current post-DTC world. Most state courts continue to apply the doctrine fully, despite aberrations such as the recent West Virginia Supreme Court of Appeals decision or more limited exclusions for common oral contraceptives. Moreover, this Article has also shown that extensive federal regulation of pharmaceutical products, including DTC advertising, should preclude state product liability and consumer protection claims, whether on the basis of common-law compliance with standards defenses, statutory exemption, or

278. See, e.g., Jennifer Girod, *The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present*, 40 IND. L. REV. 397, 398, 416 (2007) (discussing the potential benefits of DTC advertising); Jack B. Harrison & Mina J. Jerrerson, “Some Accurate Information is Better Than No Information at All”: Arguments Against An Exception to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising, 78 OR. L. REV. 605, 606 (1999) (“DTC advertising increases consumer awareness of illnesses and their symptoms, empowers consumers to take charge of their healthcare decisions, and enhances the quality of the dialogue between physicians and patients.”).

federal preemption. These measures are all supported by sound public policy, particularly where there is tension between the FDA's reasoned decision making and the theory of the lawsuit.