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IS PREEMPTION RIGHT FOR YOU? THE THIRD CIRCUIT APPLIES PREEMPTION TO A MISLEADING DRUG ADVERTISEMENT CLAIM IN PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND v. ZENECA, INC.

I. DISCLAIMER: PRESCRIPTION DRUG ADVERTISEMENTS MAY CAUSE DEBATE

The daily flood of mass drug advertisements that appears across a wide variety of media outlets makes it difficult to imagine a time when commercials for Nexium, Lunesta and Viagra were not commonplace. In reality, it was only a decade ago that the Federal Drug Administration (FDA) relaxed advertisement requirements, thus enabling direct-to-consumer (DTC) advertisements to become widespread. Today, information


<table>
<thead>
<tr>
<th>Year</th>
<th>DTC Spending</th>
</tr>
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<tbody>
<tr>
<td>1989</td>
<td>$12 million</td>
</tr>
<tr>
<td>1992</td>
<td>$156 million</td>
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<tr>
<td>1995</td>
<td>$313 million</td>
</tr>
<tr>
<td>1998</td>
<td>$1.17 billion</td>
</tr>
<tr>
<td>2001</td>
<td>$2.38 billion</td>
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Id. (stating DTC spending amounts between 1989 to 2001). Nexium, Lunesta and Viagra are among the ten most visible DTC brands, with combined DTC ad spending in television, magazines, newspapers, internet, radio and outdoor advertising ranging from $411.5 million to $1.08 billion between 2002 and 2006. See Matthew Arnold, DTC: The First 10 Years, Med. Marketing & Market, Apr. 2007, at 37 (listing top ten most visible DTC brands).

2. See generally Palumbo & Mullins, supra note 1, at 423-27 (providing historical overview of DTC prescription drug advertising). DTC advertising has technically been legal for years. See id. at 424 (discussing how first DTC prescription drug advertisements appeared in 1981). In 1997, however, the FDA issued new guidelines that relaxed content requirements and facilitated the increase in DTC advertisements. See Meredith B. Rosenthal et al., Promotion of Prescription Drugs to Consumers, 346 New Eng. J. Med. 498, 498 (2002) (explaining FDA’s role in increase of DTC advertising). Prior to 1997, broadcast DTC advertisements had to provide all of the risk information associated with the prescription drug. See U.S. Gen. Accounting Office, Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations 7-8 (Oct. 2002), available at http://www.gao.gov/new.items/d03177.pdf [hereinafter PRESCRIPTION DRUGS I] (explaining previous broadcasting requirements). This requirement caused broadcasting to be unfeasible because it greatly increased the length of the broadcast. See id. at 8 (acknowledging impracticability of pre-1997 advertisement requirements). After 1997, however, the FDA presented pharmaceutical companies with alternatives for fulfilling the regulatory requirements. See id. (describing methods of meeting regulatory requirements). For example, pharmaceutical companies could meet the
is readily available at the click of a mouse or the flip of a channel, creating great concern for the potential for dissemination of false or misleading advertisements. Indeed, despite the FDA’s heavy regulation of drug advertisements, that concern has generated litigation under state consumer protection acts (CPAs) for misleading or deceptive advertisements.

Recently, a debate has emerged over whether the states or the federal government should be responsible for determining whether such drug advertisements are false or misleading. Specifically, courts are divided as to risk requirement by "presenting the major side effects, either in audio or in audio and visual form, and by telling consumers where to find additional information, including how or where to obtain the approved product labeling." Id. (detailing method of meeting regulation requirements).


Supporters of DTC advertising maintain that it educates consumers about medical conditions and care options and that the increased use of prescription drugs that DTC advertising encourages has improved the public health. Critics of DTC advertising contend that it is sometimes misleading, leads consumers to seek prescription drugs when other treatments may be more appropriate, and causes some patients to ask their physician to prescribe new drugs that are more expensive but may not be more effective than older drugs. Critics also argue that pharmaceutical companies spend too much money on drug promotion rather than on research and development initiatives.

Id.


5. See generally John Shaeffer, Prescription Drug Advertising—Should States Regulate What is False and Misleading?, 58 FOOD & DRUG L.J. 629, 630 (2003) (arguing that "FDA is the best judge of the veracity of prescription drug advertising"); Linda A. Willett, Litigation as an Alternative to Regulation: Problems Created By Follow-on Lawsuits with Multiple Outcomes, 18 GEO. J. LEGAL ETHICS 1477 (2005) (encouraging state courts to give deference to FDA’s role as regulator of prescription drugs). In
whether FDA regulations preempt state claims that are based upon both "misleading" prescription drug advertisements and drug labeling accompanied by inadequate warnings. The recent proliferation of litigation over the preemption of tort and fraud claims filed against drug manufacturers derives from the FDA changing its position on preemption.

Historically, federal safety regulations and common law tort principles were thought to operate concurrently with one another; however, this notion changed in 2002. For the first time in its 100-year history, the FDA

addition, scholars have advocated other ways to decrease the dissemination of false or misleading advertisements. See generally Marshall H. Chin, The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids, 5 YALE J. HEALTH POL'Y, L. & ETHICS 771 (2005) (promoting patient's active involvement in regulating prescription drug advertisements); Winkler, supra note 3, at 331 (arguing that DTC advertising should include disclaimer of superiority to lessen misleading advertisements); see also Erin J. Asher, Comment, Lesson Learned from New Zealand: Pro-Active Industry Shift Towards Self Regulation of Direct to Consumer Advertising Will Improve Compliance with the FDA, 16 ALB. L.J. SCI. & TECH. 599 (2006) (recommending regulation of misleading advertisements by self-regulatory private sector).


took the position that its approval of prescription drug labeling and advertisements preempted common law claims. In addition, on January 18, 2006, the FDA asserted in its preamble to the prescription drug labeling rule that "FDA approval of labeling under the act . . . preempts conflicting or contrary State law." Since the FDA issued this Final Rule, courts have struggled to determine whether to grant deference to the FDA's preemption position articulated in the preamble. Consequently, there has arisen in federal courts a strong debate on both the proper role of federal regulation in effectuating product safety and the application of implied conflict preemption to conflicting state claims.

law and the administrative state in the twenty-first century is likely to be far less congenial than it was for much of the twentieth. . . . [This is because] developments in both areas increasingly cast the two less as complimentary [sic] regimes than as institutional rivals.

Shaeffer, supra note 5, at 629 ("Courts have long recognized that FDA and the States share responsibility for drug safety, and Congress has not expressly preempted state action with respect to prescription drug safety packaging, labeling, promotion, or advertising."); Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 587-90 (2005) (examining relationship between tort system and FDA).

9. See Harrison & Horwitz, supra note 8, at 55 (summarizing position of FDA and Daniel Troy, then-Chief Counsel for FDA, regarding preemption). In 2002, FDA Chief Counsel Daniel Troy announced that permitting state judges and juries to create additional burdens on manufacturers of medical drugs and devices conflicted with the FDA's role in determining product safety. See id. (explaining Troy's rationale for preemption). In addition, the FDA promoted this position by submitting amicus briefs in state law tort claims filed against drug or medical device manufacturers. See id. (citing Daniel E. Troy, FDA Involvement in Product Liability Lawsuits, FDLI UPDATE 4, 7 (Jan./Feb. 2003)) (explaining FDA's involvement in products liability lawsuits). For a detailed discussion of the amicus briefs filed by the FDA, see 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, 591-92 (2006).

10. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). In the preamble, the FDA explained its reasoning for adopting this position:

FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in [drug] labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.

Id. at 3938.


12. See, e.g., Sykes, 484 F. Supp. 2d at 318 (determining that FDCA preempted failure-to-warn claim); Prohias v. Pfizer, Inc., 490 F. Supp. 2d 1228, 1233 (S.D. Fla. 2007) (finding no conflict at motion to dismiss stage because "FDA recognizes that FDA's regulation of drug labeling will not preempt all State law actions"); Zyprexa, 489 F. Supp. 2d at 277 (refusing to limit ability of courts in redressing injuries);
The United States Court of Appeals for the Third Circuit recently addressed the preemption issue when it considered whether FDA regulations preempted a consumer fraud claim in Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.\textsuperscript{13} The Zeneca court held that implied conflict preemption existed because state consumer fraud laws posed an "obstacle to the FDA's congressionally-mandated regulation of prescription drug advertising."\textsuperscript{14} In Zeneca, the Third Circuit became the first federal circuit court to apply the FDA's preemption position to prescription drug advertising.\textsuperscript{15}

This Casebrief explains the Third Circuit's recent determination that FDA regulations preempt plaintiffs' state consumer fraud claims in prescription drug cases.\textsuperscript{16} First, Part II explains the historical relationship between federal and state regulation of prescription drug advertisements leading up to the preemption debate.\textsuperscript{17} In addition, Part II discusses the Supreme Court's current approach in applying the preemption doctrine.\textsuperscript{18} Part III summarizes the facts and holding of Zeneca, and explains the Third Circuit's reasoning for applying the FDA's preemption position to prescription drug advertising.\textsuperscript{19} Part IV provides a guide for practitioners, by analyzing how Zeneca will impact pharmaceutical litigation in the Third Circuit.\textsuperscript{20} Finally, Part V concludes by explaining that the Third Circuit correctly determined that federal regulations preempt advertising-based state consumer protection claims in order to further the FDA's purpose of protecting the health and safety of consumers.\textsuperscript{21}

\begin{footnotesize}
\begin{enumerate}
\item Vioxx, 501 F. Supp. 2d at 781-82 (detailing role of federal government in regulating prescription drugs).
\item 499 F.3d 239, 247 (3d Cir. 2007) (stating issue of case).
\item Id. at 247, 253. For a discussion of the holding and rationale of Zeneca, see infra notes 104-13 and accompanying text.
\item For a discussion of the Third Circuit's application of the FDA's preemption position to a consumer fraud claim, see infra notes 104-13 and accompanying text.
\item For a discussion of the historical and modern relationship between federal and state regulation of prescription drugs, see infra notes 28-63 and accompanying text.
\item For a discussion of modern Supreme Court jurisprudence, see infra notes 64-98 and accompanying text.
\item For a discussion of the facts and holding of Zeneca, see infra notes 99-113 and accompanying text.
\item For a discussion of how litigators in the Third Circuit should address preemption in light of Zeneca, see infra notes 122-44 and accompanying text.
\item For a discussion of why the Third Circuit was correct in holding FDA regulations preempt consumer fraud claims, see infra notes 149-53 and accompanying text.
\end{enumerate}
\end{footnotesize}
II. FOR YOUR INFORMATION: BALANCING FEDERAL AND STATE REGULATIONS OF PRESCRIPTION DRUGS

The Supremacy Clause of the United States Constitution proclaims that the laws of the United States are "the supreme Law of the land; ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." In theory, the Supremacy Clause invalidates all state laws that conflict or interfere with an act of Congress. Nevertheless, federal courts—in recognition of the states' historic police powers in regulating health and safety—apply a presumption against the preemptive effect of federal statutes and regulations. Therefore, in order to find preemption, a court must find a congressional intent to preempt, called the "ultimate touchstone" of the preemption analysis. Congress can either expressly or impliedly demonstrate its intent to preempt. The Food,

23. See id. (establishing that Constitution, federal statutes and U.S. treaties are "the supreme Law of the Land"); Cipollone v. Liggett Group, Inc., 505 U.S. 505, 516 (1992) ("Consideration of issues arising under the Supremacy Clause starts with the assumption that the historic police powers of the States are not to be superseded by Federal Act unless that is the clear and manifest purpose of Congress.") (internal citations omitted).
24. See Cipollone, 505 U.S. at 518 (explaining how express preemption statements must be construed "in light of the presumption against the pre-emption of state police power regulations"); see also Davis, supra note 7, at 1132-33, explaining: The presumption against preemption maintains vitality particularly in cases involving traditional areas of historic state power. The presumption is especially forceful in implied conflict preemption doctrine because a determination of actual conflict is intended to be a substitute for congressional intent, and, because it is a weak substitute, the Court has been careful to require strong, clear evidence of such conflicts.
26. See Christine H. Kim, The Case for Preemption of Prescription Drug Failure-to-Warn Claims, 62 Food & Drug L.J. 399 (2007) (discussing law of preemption). First, Congress can explicitly state and define the extent to which it intends to preempt state law in the statute or regulation. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 484 (1996) (stating that preemptive language found in statute requires courts only to identify "the domain expressly pre-empted" and not to determine whether
Drug, and Cosmetic Act (FDCA) does not contain an express preemption provision applicable to prescription drugs; therefore, determining whether Congress intended for the FDA prescription drug regulations to preempt conflicting state claims has become the center of the debate.27

A. Use Preemption Only as Directed

The FDA has been responsible for the federal regulation of prescription drugs for over a century.28 In 1906, Congress enacted the first federal drug law, the Pure Food and Drug Act (PFDA),29 to ensure that only safe and accurately labeled drugs were sold in interstate commerce.30 Initially, pharmaceutical companies were not required to submit any information

Congress intended preemption); Cipollone, 505 U.S. at 517 (discussing how express preemption does not require courts to infer congressional intent); Coronato & Lanza, supra note 25, at 368 (explaining that express preemption provisions set forth preemptive scope of legislation if they provide "reliable indication of congressional intent"). In the absence of express preemptive language, congressional intent to preempt can be implied by either field or conflict preemption. See Cipollone, 505 U.S. at 516 ("In the absence of an express congressional command, state law is preempted if [the] law actually conflicts with federal law or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it."). Under implied field preemption, the regulation's scope indicates that Congress intended to occupy an entire field of regulation and has left no room for states to supplement the federal law. See Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230-31 (1947) (explaining that where acts of Congress "touch a field in which the federal interest is so dominant[,] . . . the federal system will be assumed to preclude enforcement of state laws on the same subject"). Implied conflict preemption occurs when compliance with both state and federal law is impossible or "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Sprietsma v. Mercury Marine, 537 U.S. 51, 64-65 (2002) (internal quotations omitted); see also Cipollone, 505 U.S. at 516 (explaining how implied conflict preemption renders state law without effect when state law conflicts with federal law).

27. Compare Pa. Employees Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 253 (3d Cir. 2007) (finding congressional intent to preempt because Congress gave FDA exclusive authority), with Desiano v. Warner-Lambert & Co., 467 F.3d 85, 95 (2d Cir. 2006) (declining to find congressional intent where Congress has not made "explicit expression of intent").


29. Pure Food and Drug Act, §§ 1-13 (1934) (setting forth drug labeling requirements). The Pure Food and Drug Act, which created the FDA, "limited the agency's regulatory reach to preventing untruthful labeling, promotion, and advertising of food and drugs." Shaeffer, supra note 5, at 630.

to the FDA before marketing a drug.\textsuperscript{31} In fact, "[t]he burden of proof was on the [federal] government to show that a drug's labeling was false and misleading before it could be taken off the market."\textsuperscript{32} In addition, states retained the power to protect their citizens from false or deceptive conduct with respect to food and drugs sold in interstate commerce.\textsuperscript{33}

Over the years, the FDA's regulatory authority over drug safety and promotion powers expanded.\textsuperscript{34} Congress, cognizant of the states' historical police powers, was careful not to upset the harmonious relationship between state and federal regulations.\textsuperscript{35} For example, when Congress enacted the Food, Drug and Cosmetic Act (FDCA) of 1938, it determined that a private right of action for damages was "unnecessary" because a "common law right of action exists."\textsuperscript{36} Nonetheless, the FDCA greatly extended the FDA's control over drug manufacturers by requiring manufacturers to show that a drug was safe and to submit a marketing application to the FDA before placing the drug on the market.\textsuperscript{37}

Congress did not expressly address the relationship between state and federal regulations in enforcing drug regulations until the adoption of the Fair Packaging and Labeling Act (FPLA) of 1966.\textsuperscript{38} Under the FPLA, "Congress specifically provided that States could not enforce different or less stringent laws with respect to disclosures of quantity on the label of any food, drugs, or cosmetic."\textsuperscript{39} In 1976, when Congress enacted the Medical Device Amendments (MDA) to the FDCA, Congress explicitly addressed the states' regulatory powers in enforcing such regulations.\textsuperscript{40}

\begin{itemize}
  \item \textsuperscript{31} See Meadows, \textit{supra} note 30, at 2 (explaining marketing requirements under PFDAMA).
  \item \textsuperscript{32} Id.
  \item \textsuperscript{33} See Shaeffer, \textit{supra} note 5, at 634 (explaining states' historic roles in regulation of prescription drugs).
  \item \textsuperscript{34} See generally Davis, \textit{supra} note 7, at 1100-08 (describing how FDCA increased labeling requirements over years); Shaeffer, \textit{supra} note 5, at 650-37 (explaining expansion of FDA regulation over prescription drug advertising).
  \item \textsuperscript{35} See Shaeffer, \textit{supra} note 5, at 633-37 (noting Congress's continuous adoption of "harmonization" language in federal drug amendments).
  \item \textsuperscript{36} Louis M. Bograd, \textit{Taking on Big Pharma-and the FDA}, 43 \textit{Trial} 30, 30 (Mar. 2007) (quoting \textit{Hearing on S. 1944 Before the S. Subcomm. of the Comm. on Commerce, 73rd Cong., 2d Sess. 400, 403 (1934)}); see also Leslie C. Kendrick, \textit{FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption}, 62 \textit{Food & Drug L.J.} 227, 238 (2007) ("When Congress first enacted the FDCA in 1938, it considered a proposal to include in the statute a private cause of action for injury caused by products regulated by the act. Congress rejected the proposal precisely because state common law already provided such a cause of action.").
  \item \textsuperscript{37} See Meadows, \textit{supra} note 30, at 2 (explaining impact of FDCA of 1938 on drug manufacturers).
  \item \textsuperscript{38} See Shaeffer, \textit{supra} note 5, at 635 (explaining Congress's continued use of "harmonization language" in its subsequent amendments).
  \item \textsuperscript{39} See id. at 634.
  \item \textsuperscript{40} See 21 U.S.C. § 360k(a)(1) (2006) (limiting states' enforcement and regulation of medical devices); see also Shaeffer, \textit{supra} note 5, at 634 (explaining how language in MDA differed from other express preemption legislation).
\end{itemize}
Under the MDA, Congress expressly precluded states from enforcing any requirements "which were different, from or in addition to, any requirement" of the MDA.41

In 1997, Congress enacted the Food and Drug Administration Modernization Act (FDAMA).42 Similar to the MDA, the FDAMA expressly precluded states from regulating the packaging and labeling of nonprescription drugs.43 Although Congress enacted a national uniform system of regulation under the FDA, it still envisioned the states playing a vital role in the enforcement of nonprescription drug regulations.44 Thus, Congress provided that the FDAMA did not preempt state product liability claims or false advertising claims not related to product safety for nonprescription drugs.45 Specifically, Congress stated that although the FTC is responsible for the regulation of nonprescription drug advertisements, "advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of the preemption" unless they conflict with or frustrate federal regulations.46 Congress, however, did not include a comparable provision regarding the preemption of prescription drug advertisements.47 Thus, courts are left to determine congressional intent when applying the preemption doctrine to prescription drug advertisement cases.48


43. See 21 U.S.C. § 379r(a) (2006) (prescribing national uniformity for regulation of prescription drugs) (emphasis added); see also Shaeffer, supra note 5, at 635 (discussing effect of FDAMA on nonprescription drugs).

44. See H.R. Rep. No. 105-399, at 103 (1997) (Conf. Rep.) ("The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption."). Significantly, the FTC, not the FDA, is responsible for regulating nonprescription drug advertisements. See 36 Fed. Reg. 18, 539 (Sept. 16, 1971) (designating responsibility to FTC).

45. See 21 U.S.C. § 379r(e) (2006) ("Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.").


48. See, e.g., Pa. Employees Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 253 (3d Cir. 2007) ("By specifically excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising."); Desiano v. Warner-Lambert & Co., 467 F.3d 85, 95 (2d Cir. 2006) (declining to find preemption because to do so "would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between
B. Warning! Broadcasting this Advertisement May Subject You to Common Law State Fraud Claims

Today, through its Center for Drug Evaluation and Research (CDER), the FDA oversees advertising, marketing and promotional materials relating to prescription drugs. In order to ensure that pharmaceutical companies provide accurate and truthful advertisements, the FDA has enacted precise and detailed regulations. Specifically, the FDA regulates not pharmaceutical companies and their consumers); see also Shaeffer, supra note 5, at 636 (distinguishing legislative history regarding prescription drugs and nonprescription drugs). Shaeffer explained:

It is a supportable conclusion that, because it excluded prescription drugs, Congress did not intend to preempt state regulation of the labeling, packaging, promotion, or advertising of prescription drugs. Such a construction, however, is not appropriate here. The legislative history indicates that Congress would be willing to extend similar—if not broader—federal superiority with respect to prescription drugs.

Id.


To protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program and by fostering better communication of labeling and promotional information to both health care professionals and consumers.

Id. Originally, the Federal Trade Commission (FTC) was responsible for regulating prescription drug advertisements. See generally Shaeffer, supra note 5, at 690 (outlining transfer of regulation of prescription drug advertising from FTC to FDA). In 1938, Congress enacted the Wheeler-Lea Act, which gave the FTC jurisdiction over unfair and deceptive advertising of food, drugs and cosmetics. See id. (explaining effect of Wheeler-Lea Act). The FDA, on the other hand, was responsible for regulating labeling and branding. See id. (describing division of responsibility between FDA and FTC in regulating prescription drugs). In 1938, Congress enacted the FDCA and expanded the FDA’s role by requiring drug companies to retain FDA approval prior to marketing the drug. See Pub. L. No. 717, 52 Stat. 1040 (1938) (as amended at 21 U.S.C. § 301) (setting forth marketing requirements for drug manufacturers). In 1962, Congress expressly transferred this responsibility to the FDA under the Kefauver-Harris Amendments. See 21 U.S.C. § 393(b)(1) (2006) (“The [FDA] shall . . . promote the public health by . . . taking appropriate action on the marketing of regulated products in a timely manner . . . .”).


[1]In the case of an advertisement for a drug . . . presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

only what information can be included in an advertisement, but also the
method of presentation.\textsuperscript{51} For example, all advertisements must contain a
“brief summary relating to side effects, contraindications, and effective-
ness.”\textsuperscript{52} Although the FDA can regulate the advertisement itself, Con-
gress, concerned with First Amendment issues, has expressly precluded
the FDA, except in extraordinary situations, from enacting regulations
that would require pre-approval of any advertisement.\textsuperscript{53} Thus, the FDA
only requires submissions for approval for any promotional material pre-
pared in connection with the launch of any new drug or label change.\textsuperscript{54}

Although the FDA retains exclusive federal authority over regulating
prescription drug advertisements, states have assisted the FDA in the en-
forcement of these standards.\textsuperscript{55} Specifically, states have provided citizens
with a private right of action against pharmaceutical companies for false
or misleading advertisements under state consumer protection acts
(CPAs).\textsuperscript{56} The elements necessary to bring a CPA claim vary from state to

FDA regulations provide that an advertisement is considered false, lacking in fair
balance or misleading if it “[c]ontains a representation or suggestion, not ap-
proved or permitted for use in the labeling, that a drug is better, more effective,
useful in a broader range of conditions.”\textsuperscript{51} See 21 C.F.R. § 202.1(e)(6)(i). Fur-
thermore, the act specifically penalizes any party who disseminates false or misleading
direct-to-consumer advertisements by imposing a civil penalty of up to $250,000 for
the first violation in any three year period, and $500,000 for any subsequent viola-
tions within the three year time period. See 21 C.F.R § 901(d)(4)(g)(1) (2008)
(setting forth penalties).

\textsuperscript{51.} See Requirements on Content and Format of Labeling for Human Pre-
scription Drug and Biological Products, 71 Fed. Reg. 3922, 3960 (Jan. 24, 2006) (to
be codified at 21 C.F.R. pts. 201, 314, 601) (“[S]tatements made in promotional
labeling and advertisements must be consistent with all information included in
labeling under proposed 201.57(c) to comply with current 201.100(d)(1).”). \textsuperscript{52.} 21 C.F.R. § 202.1 (e)(1) (2008).

\textsuperscript{53.} See 21 C.F.R. § 202.1(j)(4) (2008) (“Any advertisement may be submitted
to the Food and Drug Administration prior to publication for comment.”) (em-
phasis added). See generally Shaeffer, supra note 6, at 642-43 (discussing First
Amendment considerations involved in regulation of prescription drug
advertisements).

\textsuperscript{54.} See 21 C.F.R. § 202.1(j)(1) (2008) (listing circumstances requiring ap-
proval by FDA prior to market dissemination); see also Shaeffer, supra note 5, at 632
(explaining difference between FDA pre-approval of labeling and drugs).

\textsuperscript{55.} See Shaeffer, supra note 5, at 629 (discussing relationship between FDA
and states in regulating and enforcing prescription drug advertising).

\textsuperscript{56.} See Schwartz & Silverman, supra note 5, at 15-16 (providing historical de-
velopment of CPAs). During the 1960s and 1970s, a number of states concerned
with the dissemination of misleading and false advertisements enacted state con-
sumer protection acts (CPAs), modeled after the Federal Trade Commission Act
(FTC Act). See id. at 15 (explaining enactment of CPAs). The CPAs, designed
broadly to prohibit conduct that is “unfair” or “deceptive,” provided consumers
with a private right of action. See id. at 17 (setting forth elements necessary for
bringing private claim). The FTC, envisioning CPAs as complementary to the fed-
eral laws in place, welcomed and encouraged states to adopt CPAs. See id. at 16
state; however "CPAs often do not explicitly require the traditional elements of common law fraud and negligent misrepresentation claims, such as reliance, intent, injury, and damages." Therefore, plaintiffs' attorneys are able to bring claims that have a lower burden of proof than typical common law tort claims.

The majority of states, cognizant of the important balance between state and federal regulation, have inserted "safe harbor" provisions in their CPAs. The safe harbor provisions "defer to the expertise of state and (discussing historical relationship between FTC and state consumer protection act laws). Today, every state has enacted one or more statutes to protect consumers. See Joseph J. Leghorn et al., Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation, 61 FOOD & DRUG L.J. 519, 519 (2006) (discussing development of state consumer protection statutes).

57. Schwartz & Silverman, supra note 5, at 3.
58. See Leghorn et al., supra note 56, at 519 (explaining difference between traditional products liability claims and consumer fraud actions).
59. See id. at 522 (explaining widespread use of safe harbor provisions in CPAs). The majority of state CPAs specifically exempt acts that are regulated by, authorized by or in compliance with regulations of a federal government agency. See, e.g., Colo. Rev. Stat. § 6-1-106 (2007) ("This article does not apply to [c]onduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency"); Fla. Stat. § 501.212 (2007) ("This part does not apply to . . . [a]n act or practice required or specifically permitted by federal or state law."); Ga. Code Ann. § 10-1-374 (West 2007) ("This part does not apply to . . . [c]onduct in compliance with the orders or rules of or a statute administered by a federal, state, or local governmental agency."); Idaho Code Ann. § 48-605 (2007) ("Nothing in this act shall apply to [a]ctions or transactions permitted under laws administered by the state public utility commission or other regulatory body or officer acting under statutory authority of this state or the United States."); Ind. Code Ann. § 24-5-0.5-6 (West 2007) ("This chapter does not apply to an act or practice that is: (1) required or expressly permitted by federal law, rule, or regulation; or (2) required or expressly permitted by state law, rule, regulation, or local ordinance."); Ky. Rev. Stat. Ann. § 367.176(2) (West 2007) ("KRS 367.175 shall not apply to activities authorized or approved under any federal or state statute or regulation."); Mass. Gen. Laws Ann. ch. 93A, § 3 (West 2006) ("Nothing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States."); Mich. Comp. Laws Ann. § 445.904(1)(a) (West 2007) ("This act does not apply to . . . [a]ct or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States."); Minn. Stat. Ann. § 325D.46 (West 2004) ("Sections 325D.43 to 325D.48 do not apply to conduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency."); Neb. Rev. Stat. Ann. § 598.0955 (LexisNexis 2007) ("Consumer Protection Act shall not apply to actions or transactions otherwise permitted, prohibited, or regulated under laws administered by the Director of Insurance, the Public Service Commission, the Federal Energy Regulatory Commission, or any other regulatory board or officer acting under statutory authority of this state or the United States."); Nev. Rev. Stat. § 598.0955 (2007) ("The provisions of NRS 598.0903 to 598.0999, inclusive, do not apply to [c]onduct in compliance with the orders or rules of, or a statute administered by, a federal, state or local governmental agency."); N.M. Stat. Ann. § 57-12-7 (West 2008) ("Nothing in the Unfair Practices Act shall apply to actions
federal government agencies by exempting regulated conduct from the CPA, particularly when the conduct is explicitly authorized by law. Although some states have specifically provided an exemption for advertisements that are subject to and comply with FTC regulations, no state has provided a similar exclusive provision for FDA regulations. Thus, a

or transactions expressly permitted under laws administered by a regulatory body of New Mexico or the United States, but all actions or transactions forbidden by the regulatory body, and about which the regulatory body remains silent, are subject to the Unfair Practices Act); OHIO REV. CODE ANN. § 1345.12 (West 2008) ("Sections 1345.01 to 1345.13 of the Revised Code do not apply to [a]n act or practice required or specifically permitted by or under federal law, or by or under other sections of the Revised Code . . . "); OR. REV. STAT. ANN. § 646.612 (West 2007) ("ORS 646.607 and 646.608 do not apply to [c]onduct in compliance with the orders or rules of, or a statute administered by a federal, state or local governmental agency."); R.I. GEN. LAWS § 6-13.1-4 (2007) ("Nothing in this chapter shall apply to actions or transactions permitted under laws administered by the department of business regulation or other regulatory body or officer acting under statutory authority of this state or the United States."); S.C. CODE ANN. § 39-5-40 (2007) ("Nothing in this article shall apply to [a]ctions or transactions permitted under laws administered by any regulatory body or officer acting under statutory authority of this State or the United States or actions or transactions permitted by any other South Carolina State law."); S.D. CODIFIED LAWS § 37-24-10 (2007) ("Nothing in this chapter shall apply to acts or practices permitted under laws of this state or the United States or under rules, regulations, or decisions interpreting such laws."); TENN. CODE ANN. § 47-18-111(a) (2007) ("The provisions of this part do not apply to [a]cts or transactions required or specifically authorized under the laws administered by, or rules and regulations promulgated by, any regulatory bodies or officers acting under the authority of this state or of the United States."); UTAH CODE ANN. § 13-11-22(1)(a) (2007) ("This act does not apply to an act or practice required or specifically permitted by or under federal law, or by or under state law."); WASH. REV. CODE ANN. § 19.86.170 (West 2008) ("Nothing in this chapter shall apply to actions or transactions otherwise permitted, prohibited or regulated under laws administered by the insurance commissioner of this state, the Washington utilities and transportation commission, the federal power commission or actions or transactions permitted by any other regulatory body or officer acting under statutory authority of this state or the United States . . . "); WYO. STAT. ANN. § 40-12-110 (2007) ("Nothing in this act shall apply to . . . [a]cts or practices required or permitted by state or federal law, rule or regulation or judicial or administrative decision.")

60. Schwartz & Silverman, supra note 5, at 31.

61. See, e.g., ARIZ. REV. STAT. ANN. § 44-1523 (2007) ("Nothing contained in this article shall apply to any advertisement which is subject to and complies with the rules and regulations of, and the statutes administered by the federal trade commission."); ARK. CODE ANN. § 4-88-101 (2007) ("This chapter does not apply to [a]dvertising or practices which are subject to and which comply with any rule, order, or statute administered by the Federal Trade Commission."); DEL. CODE ANN. tit. 6, § 2513(b) (2008) ("This section shall not apply . . . [t]o any advertisement which complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission."); IOWA CODE § 714.16 (2008) ("Nothing herein contained shall apply to any advertisement which complies with the rules and regulations of, and the statutes administered by the Federal Trade Commission."); LA. REV. STAT. ANN. § 51:1406 (2006) ("The provisions of this Chapter shall not apply to . . . [a]ny conduct which complies with section 5(a)(1) of the Federal Trade Commission Act [15 U.S.C. § 45(a)(1)], as from time to time amended, any rule or regulation promulgated thereunder and any finally adjudi-
problem arises where the advertisement complies with FDA regulations but does not fall within the "safe harbor" provision. \(^6^2\) Currently, there is an intense debate about whether this problem can be solved by applying the implied preemption doctrine to prescription drug advertisements. \(^6^3\)

C. Ask the Supreme Court if Preemption is Right for You

Although the Supreme Court has yet to address whether the implied preemption doctrine applies specifically to FDA approved pharmaceutical drug labeling and advertisements, it has provided some guidance over the years on the application of the preemption doctrine. \(^6^4\) The Supreme Court's interpretation of the MDA's express preemption provision in Medtronic v. Lohr \(^6^5\) and Riegel v. Medtronic, Inc. \(^6^6\) is important because it first recognizes and then applies preemption to common law tort claims in the device industry. \(^6^7\) In addition, the Supreme Court's holdings in Geier v. American Honda Motor Co. \(^6^8\) and Buckman v. Plaintiff's Legal Committee \(^6^9\) provide guidance for courts struggling with the application of the implied preemption doctrine in light of the FDA's current views on preemption. \(^7^0\)
Specifically, Geier addresses the amount of deference to be afforded to an agency's position when applying the preemption doctrine, although not in the prescription drug context. Moreover, the Court's analysis in Buckman recognizes the conflict between the FDA's regulatory regime and state tort law.

1. Medtronic, Inc. v. Lohr and Riegel v. Medtronic, Inc.

In both Lohr and Riegel, the Supreme Court addressed whether the express preemption provision provided in the MDA preempted state tort claims. In Lohr, the Court considered whether the MDA preempts state tort claims for injuries related to medical devices approved under the 510(k) process. The 510(k) process permitted medical devices to be approved by a pre-market notification process, allowing approval if a device was substantially equivalent to one currently on the market. The defendants, Medtronic, argued that the express preemption provision found in MDA preempted any common law state claims. Focusing on legislative history and the statute's language, the Court determined that not all common law state claims were precluded. The Court concluded, however, that the importance of agency opinions in determining scope of preemption doctrine in complicated federal regulations.

71. See Geier, 529 U.S. at 883-87 (giving deference to agency views). For a discussion of Geier, see infra notes 85-91 and accompanying text.

72. See Buckman, 531 U.S. at 347-48 (analyzing implied conflict preemption as it relates to FDA regulations). For a further discussion of Buckman, see infra notes 92-98 and accompanying text.

73. See Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1006 (2008) (concluding that MDA preempts common law claims that impose different or additional requirements); see also Medtronic v. Lohr, 518 U.S. 470, 487 (1996) (explaining possibility of statute preempting common law damages claims). The express preemption in the MDA provided that:

[N]o State or political subdivision of a State may 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 this chapter 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 this chapter.

Lohr, 518 U.S. at 481-82 (quoting 21 U.S.C. § 360k(a)).

74. See id. at 474 (evaluating whether MDA "pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device").

75. See id. at 478-79 (discussing approval of medical devices under 510(k) process).

76. See id. at 486-87 (setting forth defendant's preemption argument).

77. See id. at 487 (finding Medtronic's argument "not only unpersuasive but implausible"). In Medtronic, the Supreme Court refused to grant "complete immunity from design defect liability to an entire industry." Id. The Court determined that "at least some common law claims against medical device manufacturers may be maintained after the enactment of the MDA." Id. at 491. Specifically, the Court concluded that Congress's use of the terms "additional" or "different" requirements in the MDA did not manifest an intent to preclude all state tort claims. Id. (interpreting congressional intent).
ever, that state 510(k) processes “escape[] preemption” because “their generality leaves them outside the category of requirements that express preemption provision envisioned to be ‘with respect to’ specific devices.”

After Lohr, a majority of circuit courts determined that express preemption was applicable if the device was subject to the premarket approval process. Under the premarket approval process, the FDA subjects the device to a “rigorous” process and only approves the device if there is a “reasonable assurance” of the device’s “safety and effectiveness.” In Riegel, the Supreme Court endorsed the majority view and held that the MDA preemption clause “bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval” by the FDA. In Riegel, the plaintiffs alleged that the catheter inserted into the patient’s coronary artery was “designed, labeled, and manufactured in a manner that violated New York Common Law.” The Supreme Court found that a “State tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect” and thus preemption was appropriate. The Court emphasized, however, that the express preemption provision did not “prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”


Recently, the Court addressed whether to apply deference to an agency position in a products liability claim. In Geier, the Supreme Court found that a federal safety standard promulgated by the Depart-

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78. Id. at 502.
79. See, e.g., Cupek v. Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005) (holding that FDA’s regulation of medical devices subject to premarket approval process gave rise to preemption); Horn v. Thoratec Corp., 376 F.3d 163, 179-80 (3d Cir. 2004) (same); Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001) (reaffirming that “medical device manufacturer’s compliance with the FDA’s PMA process will preempt state tort law claims brought with respect to that approved device and relating to safety, effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval”). But see Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1382 (11th Cir. 1999) (concluding that “FDA’s approval of a medical device pursuant to the PMA process, standing alone, imposes no specific federal requirement applicable to a particular device and, therefore, has no preemptive effect under section 360k(a) of the MDA”).
81. Id. at 1007.
82. Id. at 1004-05 (stating plaintiff’s claims).
83. Id. at 1008.
84. Id. at 1011.
ment of Transportation under the Motor Safety Vehicle Act preempted a state negligence claim.\textsuperscript{86} The safety standard required that some, but not all, automobiles contain passive restraint devices, such as airbags.\textsuperscript{87} The plaintiff sued the automobile manufacturer after an accident, alleging that the lack of a driver-side airbag amounted to a negligent or defective product design.\textsuperscript{88}

Although the Motor Vehicle Safety Act contained an express preemption provision stating that the federal standard preempted state or local safety standards, its effect on common law tort claims was removed because of a "savings" clause.\textsuperscript{89} Nevertheless, the Court found the common law claims impliedly preempted because they conflicted with the federal regulation by standing as "an obstacle to the gradual passive restraint phase-in that the federal regulation deliberately imposed."\textsuperscript{90} In determining the statute's preemptory scope, the Supreme Court placed weight on the agency's interpretation of the statute, emphasizing the importance of the agency's views in the preemption analysis.\textsuperscript{91}

3. Buckman v. Plaintiff's Legal Committee

Next, in \textit{Buckman}, the Supreme Court found that the FDAC, as amended by the MDA, impliedly preempted the plaintiff's "fraud-on-the-FDA" claim.\textsuperscript{92} In \textit{Buckman}, the plaintiffs claimed injuries from the implantation of orthopedic bone screws into their spines.\textsuperscript{93} Specifically, the plaintiffs alleged that the consultant company that assisted the manuf-

\textsuperscript{86} See id. at 865 (holding that federal standard preempts common law tort claim).

\textsuperscript{87} See id. at 864-65 (noting that safety standard under Act required some vehicles to be equipped with restraints).

\textsuperscript{88} See id. at 865 (explaining facts of case).

\textsuperscript{89} See id. at 867-68 (employing narrow reading of preemption provision to find not all common law torts claims preempted). The "savings" clause in the Motor Vehicle Safety Act stated that "'[c]ompliance with' a federal safety standard 'does not exempt any person from any liability under common law.'" \textit{Id.} at 868 (quoting 15 U.S.C. § 1397(k) (1988 ed.)).

\textsuperscript{90} \textit{Id.} at 881.

\textsuperscript{91} See id. at 883-87 (considering views of Department of Transportation in its preemption analysis). The Supreme Court explained its reasons for placing weight on the agency's interpretation of the statute:

\begin{quote}
Congress has delegated to DOT [the Department of Transportation] authority to implement the statute; the subject matter is technical; and the relevant history and background are complete and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is "uniquely qualified" to comprehend the likely impact of state requirements.
\end{quote}

\textit{Id.} at 883.


\textsuperscript{93} See \textit{Buckman}, 531 U.S. at 344 (describing nature of plaintiff's claims).
turer in receiving FDA approval made fraudulent representations to the FDA that played a substantial role in their injuries. The Supreme Court determined that federal regulations impliedly preempted "[p]olicing fraud against [a] federal agency." The Court reasoned that implied conflict preemption "stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA], and that this authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objectives." In addition, the Supreme Court recognized the possibility of implied preemption under the FDA's regulatory regime by acknowledging the increased burden pharmaceutical companies would face in "complying with the FDA's detailed regulatory regime in the shadow of the fifty states' tort regimes." Recently, however, the Supreme Court, in a four-to-four decision, limited Buckman by affirming an appeals court ruling that a "fraud on the FDA" exception to drug manufacturer immunity statutes was not preempted by Buckman.

III. ACCEPTING THE RISKS: THE THIRD CIRCUIT APPLIES PREEMPTION IN PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND v. ZENECA, INC.

A. Facts and Procedural Background

Although no other circuit court has yet to address whether FDA regulations preempt consumer fraud claims, the Third Circuit in Zeneca reminded consumers and practitioners that the FDA—and not the states—is responsible for regulating misleading drug advertisements. In 2005, Pennsylvania Employee Benefit Trust Fund and two private plaintiffs jointly filed a putative class action against Zeneca alleging deceptive mar-

94. See id. (same).
95. Id. at 347.
96. Id. at 341.
97. Id. at 350; see also Leghorn et al., supra note 6, at 524-25 (discussing impact of Buckman on implied preemption arguments).
98. See Warner-Lambert Co. v. Kent, 128 S. Ct. 1168 (2008) (per curiam) (discussing scope of Buckman), aff'g Desiano v. Warner-Lambert & Co., 467 F.3d 85, 87 (2d Cir. 2006). Desiano involved a challenge to legislation enacted in Michigan that provided drug manufacturers with immunity from products liability lawsuits where the FDA had approved the drug at issue, except where the manufacturer had defrauded the FDA. See 467 F.3d at 86-87 (explaining facts of case); see also MICH. COMP. LAWS § 600.2946(5) (2007) (explaining requirements for drug manufacturers to receive immunity). The Second Circuit found that under the rationale of Buckman, "the Michigan immunity exception is not prohibited through preemption." Desiano, 467 F.3d at 98. The Supreme Court, after the excusal of Chief Justice Roberts, upheld the decision with no opinion, due to a 4-4 tie. See Warner-Lambert Co., 128 S. Ct. at 1168 (affirming lower court's decision).
99. See Pa. Employee Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 251-52 (3d Cir. 2007) ("[T]he purpose of protecting prescription drug users in the FDCA 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.").
Marketing campaign of the drug Nexium. The plaintiffs alleged that Zeneca committed unlawful advertising under the Delaware Consumer Fraud Act (DCFA) and violated the consumer protection statutes of all fifty states for false, misleading and deceptive advertising. Specifically, the plaintiffs claimed that Zeneca's promotional campaign for Nexium, consisting of physician-directed marketing and direct-to-consumer advertising, was misleading because it incorrectly represented that Nexium was superior to Prilosec, another drug manufactured by Zeneca. The district court granted Zeneca's motion to dismiss for failure to state a claim; Employee Benefit subsequently appealed.

B. The Third Circuit's Analysis

1. The Majority Opinion

In a two-to-one decision, the United States Court of Appeals for the Third Circuit affirmed the district court's decision. Judge Smith found that the appeal in Zeneca presented two important issues: (1) whether the DCFA exemption for advertising regulated by the FTC extended to FDA regulations; and (2) whether federal law preempted the plaintiffs' state consumer protection claims. The Third Circuit rejected the district court's decision.

100. See id. at 241 (stating facts of Zeneca). The drug Nexium treats acid reflux disease and heartburn. See id. (discussing medical use of drug). The Pennsylvania Employees Benefit Trust Fund was joined in the action by two private plaintiffs, Joseph McCraken and Linda Watters. See id. at 240.

101. See id. at 241-42 (setting forth plaintiffs' claims). The Delaware Consumer Fraud Act's (DCFA) purpose is to "protect consumers and legitimate business enterprises from unfair or deceptive merchandising practices in the conduct of any trade or commerce in part or wholly with this State." 6 DEL. CODE ANN. tit. 6, § 2512 (2008). The DCFA forbids the use of deception, fraud, misrepresentation or omission of a material fact in connection with the sale or advertisement of any merchandise, regardless of whether the person has actually been misled, deceived or damaged. See id. § 2513(a), invalidated by State ex rel. Brady v. Preferred Florist Network, Inc., 791 A.2d 8, 20 (Del. Ch. June 07, 2001) (finding DCFA provision unconstitutional). The DFCA, however, included an exemption clause which stated that "[t]his section shall not apply . . . [t]o any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission." Id. § 2513(b) (2). In addition, the plaintiffs brought claims alleging unjust enrichment and state claims under Delaware common law for restitution, disgorgement and constructive trust and negligent misrepresentation. See Zeneca, 499 F.3d at 241-42 (setting forth plaintiffs' claims).

102. See id. (describing plaintiffs' claims).

103. See id. at 242 (setting forth procedural history of case).

104. See id. at 253 (affirming decision of United States District Court for District of Delaware that claims under state consumer protection laws were preempted by federal law). Circuit Judge Smith delivered the opinion of the court and was joined by Judge Siler, Senior Circuit Judge for the United States Court of Appeals for the Sixth Circuit, sitting by designation. See id. at 240. Judge Cohen provided the dissenting opinion. See id. at 253 (Cohen, J., dissenting) (opining that federal regulations do not preempt state claims because there is no conflict).

105. Id. at 241.
court's broad interpretation that the DCFA exemption provision included the rules and regulations administered by the FDA. The court, however, affirmed the district court's conclusion that "Nexium advertisements that complied with the FDA-approved label were not actionable under the state consumer protection laws because those laws were preempted by federal law." The majority determined that "[t]o allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users."

Relying on Supreme Court precedent, the Third Circuit placed great emphasis on the FDA's purpose when determining whether to preempt the claim. Specifically, the court interpreted Lohr and Geier as "suggesting that state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority." In addition, the court reasoned that although the FDCA was not a "critical element" like the plaintiff's claim in Buckman, the state claims here would "unnecessarily frustrate the FDCA's purpose and FDA regulations, as the extent of agency involvement in regulating pre-

106. Id. at 253 (declining to extend DFCA exemption to FDA regulations and rules). After carefully examining the relationship between the FTC and FDA, the Third Circuit determined that the FDA is primarily responsible for prescription drug advertisements. See id. at 243 (analyzing responsibilities of FDA and FTC in regulating prescription drug advertisements). The Third Circuit explained:

Reading the exemption in Sec 2513(b)(2) to exclude from the scope of the DCFA marketing practices that are subject to the rules and regulations of the FDA, and which are required to be based on labeling that is expressly approved and required by the FDA, improperly broadens the reach of the exemption beyond its explicit limitation to practices that are compliant with FTC rules and regulations. We will not rewrite the text of the exemption to include regulation of activities that are not within the FTC's authority.

Id. at 246-47.

107. Id. at 247 (affirming district court's implied conflict preemption analysis and conclusion).

108. Id. at 253.

109. See id. at 249-51 (discussing and applying Supreme Court precedent). The Third Circuit explained its reliance on Supreme Court precedent when determining deference to FDA:

Medtronic and Geier suggest the sort of confluence between congressional purpose and agency purpose that had previously been recognized in Fidelity Federal Savings and Loan Ass'n v. de la Cuesta: 'Federal regulations have no less pre-emptive effect than federal statutes. Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily.'

Id. at 250 (quoting Fidelity Fed. Sav. Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153-54 (1982)) (citation omitted).

110. Id. at 250 (citing Kendrick, supra note 36, at 240-41).
scription drug advertising is extensive and specific." The court explained that where the:

FDA approved-labeling is the basis for the allegedly fraudulent representations made in prescription drug advertising . . . the purpose of protecting prescription drug users in the FDCA 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.

Therefore, the Third Circuit concluded that the FDA regulations preempted the plaintiff's state fraud claims.

2. The Dissenting Opinion

In his dissent, Judge Cohen criticized the majority for "ignor[ing] the teaching of the Supreme Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists." Judge Cohen disagreed with several components of the majority's rationale that consumer fraud laws stand as an obstacle to the federal regulation in prescription drug advertisements. First, Judge Cohen opposed the "majority's heavy reliance upon the high level of specificity in the federal regulations as a basis for a finding of preemption." Next, Judge Cohen found that Congress's purpose would not be frustrated because the FDA had not determined the "veracity" of the statement in the advertisement at issue.

111. Id. at 251.
112. Id.
113. See id. at 253 ("Accordingly, the state consumer fraud laws are preempted by the extensive federal legislative and regulatory framework.").
114. Id. at 253 (Cohen, J., dissenting) (internal citations omitted). Judge Cohen, applying the presumption against preemption and the conflict analysis, determined that preemption was not applicable. See id. at 253 (disagreeing with majority's determination of preemption).
115. See id. at 254-59 (setting forth points of disagreement with majority opinion).
116. Id. at 254-60. According to Judge Cohen, "it is well-established that a preemption inquiry 'cannot be judged by reference to broad statements about the comprehensive nature of federal regulations.'" Id. at 254 (quoting Head v. N.M. Bd. Of Exam'rs in Optometry, 374 U.S. 424, 429-30 (1963)).
117. See id. at 255-56 (declining to find frustration of purpose). Judge Cohen explained:

In summary, because the FDA has not approved or disapproved the veracity of the advertising statements that plaintiffs challenge in this case, and plaintiffs' particular challenge does not question the veracity of any statements in the labeling approved by the FDA, there is no likelihood that plaintiffs' claims would conflict with the FDA's responsibility in protecting prescription drug users.

Id. at 256.
In addition, the dissent declined to find a congressional intent to pre-empt state consumer fraud laws. Moreover, the dissent criticized the majority's broad reading of *Buckman* to find in favor of preemption. Lastly, the dissent argued that state law parameters for false advertisement are parallel and not in conflict with FDA determinations. Judge Cohen concluded by noting that "Congress's failure to provide a private remedy for persons injured by false and misleading advertisements further convinces me that the state law remedies are not preempted."

IV. SIDE EFFECTS: HOW ZENECA WILL IMPACT THE USE OF PREEMPTION DOCTRINE IN THE THIRD CIRCUIT

The Third Circuit's acceptance of the implied conflict preemption doctrine in *Zeneca* was a big win for drug manufacturers nationwide. Not only did the Third Circuit shut the door on state law deceptive advertising claims, but it opened the door for even greater use of the implied preemption doctrine. For example, in April 2008, the Third Circuit extended the use of the preemption doctrine in *Colaccio v. Apotex* to a consolidated appeal grounded on whether FDA approval of a label preempted a failure-to-warn products liability claim. In *Colaccio*, the Third Circuit determined that the FDA's continued public rejection of a stronger warning preempted a plaintiff's failure-to-warn claims.

118. See id. (finding "exclusion of prescription drug advertisements from coverage under the federal statute does not approach the required 'clear and manifest' congressional purpose to preempt state law" (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))).

119. See id. at 256-57 (differentiating *Buckman* because there was "no cited risk that the availability of state-law remedies would conflict with a particular federal objective or a careful balancing interests that the federal government has achieved in policing prescription drug advertising").

120. See id. at 257-58 ("I cannot agree that the mere presence of state law standards for false and misleading advertisements would present a conflict with the federal law.").

121. Id.

122. For a discussion of the holding and rationale of *Zeneca*, see supra notes 99-121 and accompanying text.


124. 521 F.3d 253 (3d Cir. 2008).

125. See id. at 271 (concluding FDCA impliedly preempted state law failure-to-warn claims).

126. See id. (explaining holding of case).
The debate over preemption of tort and fraud claims, however, is far from over. In fact, on January 18, 2008, the Supreme Court granted certiori to Levine v. Wyeth, another preemption case. In Levine, the Court will review a Vermont Supreme Court decision, which found that FDA regulations do not preempt a failure-to-warn products liability claim. The Court's decision in this case will greatly impact the use of the preemption doctrine generally and will provide circuit courts with additional guidance when applying the implied conflict preemption doctrine.

Nevertheless, pharmaceutical companies in the Third Circuit, armed with the Zeneca and Colacicco decisions, should continue to assert the preemption defense for fraud and tort claims. Litigators defending phar-

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127. Compare Richard A. Epstein, Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagared, 1 J. TORT L. 1, 3 (2006) (advocating preemption where agency "undertakes its authorized comprehensive review"), with Kendrick, supra note 36, at 247 (arguing that preemption applies to claims but is more limited than FDA asserts in preamble), and Jonathan V. O'Steen & Van O'Steen, The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs, 48 Ariz. L. Rev. 67, 93-95 (2006) (determining that preemption should not be applied to prescription drugs because of policy reasons).


129. See Wyeth, 128 S. Ct. at 1118 (granting certiori and requiring petitioner to file brief by Feb. 25, 2008).

130. See Levine, 944 A.2d at 194 (determining that failure-to-warn claim was not preempted by federal law). In Levine, the plaintiff brought negligence and failure-to-warn claims, alleging that Wyeth was negligent in providing adequate warnings of the dangers of injecting the drug Phenergan directly into a patient's vein. See id. at 182 (explaining facts of case). Although the FDA had rejected a stronger warning, the Vermont Supreme Court rejected the defendant's preemption argument. See id. at 183-84 (describing court's conclusion). The court reasoned that the defendants could have "warned against IV-push administration without prior FDA approval . . . because federal labeling requirements create a floor, not a ceiling, for state regulation." Id. at 184.

131. For a discussion of the preemption issues presented in Levine, see supra notes 127-30 and accompanying text.

132. See Karen Barth Menzies, Focus on Facts to Defeat Preemption, 43 TRIAL 44, 44 (March 2007) (explaining that "preemption attack . . . is a win-win proposition for the defendant"). Menzies explained that "[i]f the attack fails, the defendant has lost nothing—it is simply in the same position it was before filing the motion. And if the attack succeeds, the defendant avoids having to submit to potentially damaging discovery, or more significant, any rulings on the merits of the plaintiff's claims." Id. at 45. The doctrine of preemption is asserted as an affirmative defense to state law claims. See Stephen Torline & Derek Teeter, Federal Preemption in Products Liability Case, 76 J. KAN. B. ASS'N. 32, 32 (July-Aug. 2007) (explaining use of preemption as affirmative defense). The party seeking to use preemption as a defense bears the burden of both overcoming the presumption against preemption and affirmatively establishing preemption. See id. (commenting that substantial burden often requires use of "canons of statutory construction to convince the court of the preemptive effect of federal law"). Therefore, in the context of FDCA preemption, pharmaceutical companies have the burden of establishing conflict preemption. See Leghorn et al., supra note 56, at 523 (discussing use of preemption doctrine under FDCA in motions to dismiss).
maceutical companies against claims similar to the fraud claim presented in *Zeneca* should emphasize the significance that the Third Circuit placed on the FDA’s specific and detailed advertising regulations. By comparing the specificity of the FDA regulations to the general state claims, litigators can illustrate how the state claim directly conflicts with the FDA regulations.

In addition, pharmaceutical defense attorneys should use the broad language in *Zeneca* favoring preemption to argue preemption of traditional products liability claims filed against their clients. Defense attorneys should focus on arguing that any common law claim based on FDA approval labels should be preempted because it frustrates the FDA’s purpose. Litigators should highlight how extensive FDA regulation of labeling and approval of drugs is even more detailed than its regulation of advertisements. Therefore, the FDA’s purpose in regulating prescription drugs would be “frustrated” if the states demanded a warning that the FDA did not find substantiated. In addition, pharmaceutical companies should continue to employ additional safeguards to shield themselves from liability for false or misleading advertisements. For example, drug manufacturers should take extra care to comply with FDA regulations and take the precaution of having their advertisements pre-approved by the FDA.


135. See *Zeneca*, 499 F.3d at 251 (“An even stronger case for preemption occurs when FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertisement.”); see also Third Circuit Issues Expansive Preemption Ruling, PHARMACEUTICAL & MED. DEVICE LITIG. ALERT (Shook, Hardy & Bacon, LLP), Sept. 28, 2007, at 2, available at http://www.shb.com/fileUploads/pharmaalert-092807_1944.pdf (noting *Zeneca’s* importance because it “speaks of implied preemption in broad terms—suggesting that the defense may apply to other state law claims as well”).

136. See *Zeneca*, 499 F.3d at 244 (explaining strong correlation between drug labeling and marketing); see also 21 C.F.R. § 202.1(e)(4)(i)(a) (2008) (“The advertisement shall present information from labeling, required, approved, permitted, or granted in a new-drug ... application ... relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised dosage form(s) ... .”).

137. See Dorfman et al., supra note 9, at 611 (“Given the rigorous process involved in label approval, preemption is a reasonable response to this conflict. Accordingly, FDA’s policy of preemption is both within its broad statutory mandate and a reasonable accommodation to address a conflict of policies affecting its ability to fulfill that mandate.”).

138. See *Zeneca*, 499 F.3d at 251 (explaining how state imposed claims would frustrate FDA’s purpose).

139. See Menzies, supra note 132, at 45 (highlighting importance of seeking FDA approval of asserting preemption defense).

Although the pharmaceutical company’s use of the preemption doctrine prevailed in the Third Circuit on a consumer fraud and failure-to-warn claim, plaintiffs can still defeat the preemption defense for other state claims by employing various strategies.\textsuperscript{141} First, it is important for plaintiffs’ attorneys to distinguish their claims from the claims presented in \textit{Zeneca} and \textit{Colacicco}.\textsuperscript{142} For example, consumer fraud claims based on deceptive advertising actions like the one asserted in \textit{Zeneca} are “much more regulatory than compensatory in nature, and the regulatory component is much more likely to conflict with FDA action.”\textsuperscript{143} In contrast, tort litigation provides compensatory relief and serves as “an important means for the identification and dissemination of new information concerning product risk.”\textsuperscript{144} Second, given the important role of tort litigation in promoting product safety, practitioners should advocate for courts to apply the presumption against preemption and find against preemption.\textsuperscript{145}
Lastly, plaintiffs’ attorneys should focus on how the Third Circuit limited the holding in Colacicco to cases “in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires.”

V. PREEMPTION RESULTS NOT TYPICAL

The Third Circuit’s opinion in Zeneca is important to the current debate regarding the use of preemption in prescription drug cases because it marks the first time that a circuit court has applied the FDA preemption position. Although the Zeneca decision preempted consumer fraud claims based on deceptive advertising practices, the preemption doctrine may not have the same success when applied to other state claims. The full impact of the Zeneca decision and its application to other state claims will depend heavily on the outcome of Levine v. Wyeth, which is currently pending before the Supreme Court. Meanwhile, litigators on both sides of the debate will continue to concentrate on the similarities and differences of the claims in order to win their cases.

Although the Zeneca rationale in favor of preemption may not be extended to other common law claims, the Third Circuit correctly concluded that the FDA’s regulatory authority preempts advertising-based doctrinal limits on federal preemption by reviving the traditional presumption against preemption and developing rules to limit which federal actors can preempt state law”.


149. For a discussion of Wyeth v. Levine, see supra notes 128-30 and accompanying text.

150. See generally Menzies, supra note 132, at 45 (noting that success of preemption claim depends upon factual claims asserted).
state consumer protection claims. Historically, state and federal regulations were thought to complement one another; however, the increasing scope and specificity of federal regulation has challenged the states' roles in enforcing federal prescription drug advertising regulations. The debate about whether states or the federal government should determine if advertisements are false or misleading should be resolved in favor of preemption. If states and juries were permitted to determine whether an advertisement was misleading or deceptive, the FDA's purpose in protecting the health and safety of prescription drug users would be frustrated. The Third Circuit's finding in favor of preemption of drug advertisements is best suited to ensure that drug manufacturers comply with a uniform national regulatory standard that determines whether or not advertisements are misleading or deceptive. Thus, the preemption doctrine

151. For a discussion of the holding in Zeneca, see supra notes 104-14 and accompanying text.
152. For a discussion of the historical relationship between the federal and state governments, see supra notes 28-49 and accompanying text.
153. See generally Shaeffer, supra note 5, at 630 (arguing in favor of preemption of prescription drug advertisements). Shaffer explained: Unlike the perceived "peaceful coexistence" between a state-based compensatory system for physical injury and FDA's regulation of the safety and efficacy of prescription drugs, state action relating to prescription drug advertising necessarily will conflict with FDA's role. If FDA is the best judge of the veracity of prescription drug advertising, that agency's determination should hold sway, and courts should not let state regulation become an obstacle.

Id.; see also W. Wylie Blair, Implied Preemption of State Tort Law Claims Against Prescription Drug Manufacturers Based Upon FDA Approval, 27 J. LEGAL MED. 289, 301 (2006) (suggesting amendment to FDCA to include express preemption clause).
154. Cf Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1008 (2008) (explaining how "tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation"). Justice Scalia explained the problems underlying a jury determination of the safety of a medical device:
A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Id.

155. For a discussion of the majority's holding in Zeneca, see supra notes 105-14 and accompanying text; cf. Shaeffer, supra note 5, at 648 ("Our federal system does not permit one State to decide for the nation when an advertisement is deceptive, especially where Congress has expressly empowered an expert agency with exclusive federal jurisdiction to police such conduct."). In addition to national uniformity, the preemption doctrine benefits patients. See Daniel E. Troy, The Patient's Interest in FDA Preemption, 1-5 (Mar. 31, 2006) (unpublished article), available at http://www.federalismproject.org/preemption/papers/Troy_Patients_Interest_in_FDA_Preemption.pdf (discussing how preemption serves "long-term health interest of all Americans" by "encourag[ing] the development of new drugs, preserv[ing] the availability of existing drugs, reduc[ing] upward pressure on drug prices, and assur[ing] rational prescribing").
should be adopted and employed by the courts in prescription drug advertisement cases based on an FDA-approved label.

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