PRECEDENTIAL

THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Case No: 05-5340

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND
on behalf of itself and all others
similarly situated; JOSEPH MACKEN;
COMMISSIONER LINDA A. WATTERS,

Appellants

v.

ZENECA INC; ASTRAZENECA PHARMACEUTICALS
LP;

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On Appeal from the United States District Court
for the District of Delaware
District Court No.: 05-cv-00075
District Judge: The Honorable Sue L. Robinson

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Argued June 5, 2007

Before: SMITH, COWEN, and SILER, *Circuit Judges*,[*]

(Filed: August 17, 2007)

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[*]The Honorable Eugene E. Siler, Senior Circuit Judge for the United States Court of Appeals for the Sixth Circuit, sitting by designation.

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OPINION OF THE COURT

SMITH, *Circuit Judge*.

The Pennsylvania Employees Benefit Trust Fund, Joseph Macken, and Linda Watters ("plaintiffs") sued Zeneca, Inc. and AstraZeneca Pharmaceuticals, L.P. (collectively referred to as "Zeneca") in the United States District Court for the District of Delaware, asserting that Zeneca engaged in deceptive conduct

in the advertising of its new drug Nexium. Claim One alleged unlawful advertising under the Delaware Consumer Fraud Act ("DCFA"). The second claim alleged violations of the consumer protection statutes of the 50 states for false, misleading, and deceptive advertising. Claim Three alleged unjust enrichment, and stated claims under Delaware common law for restitution, disgorgement, and constructive trust. The fourth claim was for negligent misrepresentation, and it alleged that the company released misleading advertisements for the prescription drug Nexium. The District Court dismissed the complaint with prejudice.

This appeal presents two principal questions: (1) whether the DCFA exemption for advertising regulated by the Federal Trade Commission applies to the facts of this case; and (2) whether federal law preempts the plaintiffs' state consumer protection claims. The plaintiffs also assert that primary jurisdiction was an improper basis for dismissal, that their unjust enrichment claim was improperly dismissed on the ground that they had not pled individual reliance, and that they should have been allowed to amend their complaint. We will affirm the judgment of the District Court.[1]

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[1]The District Court had diversity jurisdiction under 28 U.S.C. § 1332(d)(2) and (6), which confers federal jurisdiction over class actions where "any member of a class of plaintiffs is a citizen of a State different from any defendant" and the amount in controversy exceeds $5,000,000. This Court has jurisdiction

I.

On February 11, 2005, the plaintiffs[2] filed a putative class action against Zeneca, alleging that Zeneca's marketing campaign for Nexium[3] was deceptive because it misleadingly advertised Nexium as an improvement on Prilosec. Nexium and Prilosec are both proton-pump inhibitors, drugs that treat gastroesophageal reflux disease ("GERD") and erosive esophagitis, conditions that are commonly known as acid reflux disease and frequent heartburn. Prilosec was a profitable drug for Zeneca, and had sales of $6 billion in 2000. The patent for Prilosec was due to expire in 2001, at which point it would be available for sale as the generic drug omeprazole. On February 14, 2001, Zeneca obtained approval from the Food and Drug Administration ("FDA") for final labeling on Nexium for

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pursuant to 28 U.S.C. §§ 1291 and 1294.

[2]On April 13, 2006, Zeneca filed a motion to dismiss the appeal as to seven of the original ten plaintiffs on the ground that the notice of appeal included only the Pennsylvania Employees Benefit Trust Fund, Joseph Macken, and Linda Watters. The three named plaintiffs contested the motion to dismiss, which is now before us. Because of our disposition of this case, we need not reach this issue. We will deny the motion to dismiss as moot.

[3]Nexium is the proprietary name for esomeprazole magnesium.

healing of erosive esophagitis, maintenance of healing of erosive esophagitis, and treatment of symptomatic GERD (i.e., heartburn).

One published clinical study of Nexium compared both 20 mg and 40 mg doses of Nexium to the approved 20 mg dose of Prilosec. The data from this study showed that 40 mg of Nexium had a statistically significant healing rate over 20 mg of omeprazole. This study was among those used to obtain FDA approval of Zeneca's new drug application for Nexium. The FDA later determined that Nexium should be approved at recommended dosages of 20 mg or 40 mg once daily, for four to eight weeks, for the healing of erosive esophagitis, and at 20 mg for both maintenance of healing of erosive esophagitis and symptomatic GERD.

In their complaint, plaintiffs alleged that the large-scale promotional campaign for Nexium, which included both physician-directed marketing and direct-to-consumer advertising, was misleading because it incorrectly represented that Nexium was superior to Prilosec. The plaintiffs asserted that a dose of 40 mg is not needed in most patients and a fair comparison of 20 mg of Nexium to 20 mg of Prilosec would not have proven Nexium to be superior. The plaintiffs also contended that Zeneca initially sold Nexium at a price below Prilosec in order to establish brand loyalty, but "then raised the price of Nexium while the price of Prilosec dropped. [Nexium] now sells for $4.09 per pill versus $0.67 per pill or less for

Prilosec." On November 8, 2005, the District Court granted Zeneca's motion to dismiss for failure to state a claim.

We review the grant of a motion to dismiss de novo, accepting all well-pleaded allegations as true and drawing all reasonable inferences in favor of the plaintiffs. *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 273 (3d Cir. 2004); *In re Alpharma Sec. Litig.*, 372 F.3d 137, 146 (3d Cir. 2004). Review of the denial of leave to amend is for abuse of discretion. *Hill v. City of Scranton*, 411 F.3d 118, 134 (3d Cir. 2005).

II.

The Application of the DCFA Exemption

The first issue raised on appeal is whether FDA approval of prescription drug labeling and regulation of advertising brings the plaintiffs' claims within the DCFA exemption of "any advertising or merchandising practice" that is compliant with Federal Trade Commission regulations. The purpose of the DCFA 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 within this State." 6 DEL. CODE ANN. § 2512. The DCFA proscribes

> The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment,

> suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby....

6 DEL. CODE ANN. § 2513(a). The exemption language in the DCFA at issue states 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…." 6 DEL. CODE ANN. § 2513(b)(2). The District Court concluded that all of the advertising materials cited by the plaintiffs in their complaint "are related to the safety and efficacy of Nexium, are consistent with the FDA-approved labeling and, therefore, are not actionable under the DCFA pursuant to 6 Del. C. § 2513(b)(2)."

Plaintiffs argue that the exemption should be read more narrowly than the District Court read it, and that, properly construed, the exemption did not protect Zeneca's conduct. In particular, plaintiffs assert that (1) the exemption is limited to conduct expressly approved by the FTC; (2) the FDA did not explicitly approve Zeneca's marketing campaign; and (3) Zeneca's marketing deviated from statements approved by the FDA for Nexium's label. Zeneca points to the broad prohibitions in 15 U.S.C. §§ 45 and 52, which declare unlawful unfair methods of competition and the dissemination of false

advertisements, as proof that prescription drug advertising is subject to the statutes administered by the FTC.

As a preliminary matter, we decline to read the DCFA exemption to require that an advertisement or merchandising practice must be expressly approved by the FTC in order to qualify for the exclusion. The plain language of § 2513(b)(2) requires only that the conduct be subject to and compliant with rules and regulations created by the FTC and the statutes administered by that agency. Accordingly, the lack of express FTC approval of the Nexium marketing campaign is not a basis for declaring the statutory exemption inapplicable.

We are left, then, with the thornier question presented by plaintiffs' assertion that the exemption's reach does not extend to matters subject to FDA oversight. By congressional decree, the FTC and the FDA originally shared jurisdiction over prescription drug advertising. *See* Pub. L. No. 87-781, 76 Stat. 791-92 (1962) (codified as amended at 21 U.S.C. § 352(n)); *see also* 15 U.S.C. §§ 45 and 52; 21 U.S.C. § 352(n) (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) ("The [FDA] shall ... promote the public health by ... taking appropriate action on the marketing of regulated products in a timely manner"). Because Congress gave the agencies concurrent jurisdiction with respect to regulating prescription

drug advertising until the FDA promulgated regulations, the FDA and FTC established their own interim division of responsibilities.[4] In the Working Agreement Between FTC and Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971), the two agencies agreed that "[t]he Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising." This statement does not preclude FTC regulation of prescription drug advertising, but rather notes the agencies' mutual understanding that the FDA will take the lead in regulating such activities, subject to the concurrent jurisdiction of both agencies. The statement explicitly limits the FDA's primary responsibility to determining the veracity of the advertising claims; it does not suggest that regulating technically true, but potentially misleading, advertisements is the exclusive domain of the FDA. Accordingly, this arrangement alone does not remove the claims regarding Nexium advertising from the purview of regulations and statutes administered by the FTC. However, the FDA's subsequent promulgation of regulations for prescription drug advertising effectively eliminated the FTC's authority in this area.

Even if Zeneca can show that the marketing was almost identical to the specifically authorized labeling, the FDA is not

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[4]The FDA promulgated preliminary regulations on prescription drug advertising in 1975. 40 Fed. Reg. 14106 (Mar. 27, 1975).

merely acting as the FTC's proxy in regulating prescription drug advertising. The FDA has responsibility for regulating the advertising of prescription drugs that is independent of any delegation from the FTC.[5]

Although there is an affinity between FTC and FDA

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[5]In *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), we summarized the division of regulatory authority in this manner: "the FDA regulates the labeling of OTC drugs while the FTC monitors the advertising for these drugs." *Id.* at 227. The facts and law at issue in *Sandoz* are distinguishable and we need not follow its dicta in this case. In *Sandoz*, the Court was concerned with the question of whether a Lanham Act plaintiff needs to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines, or whether the plaintiff must also show that the claims are literally false or are misleading to the public. *Id.* at 224, 229. The dispute in Sandoz was also over the marketing of an over-the-counter drug. OTC drugs and prescription drugs are subject to different rules and regulations. *Compare id.* at 227 ("The FTC has the authority under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 & 52, to find that an inadequately substantiated advertising claim regarding a non-prescription drug is deceptive or misleading, and thus illegal."), *with* 21 C.F.R. § 202.1. Thus, our opinion in *Sandoz* has little applicability to this case.

guidance[6] and the scope of the Federal Trade Commission Act ("FTCA") is broad, the reasoning of the District Court rests on the premise that advertising that is based upon labeling approved by the FDA falls within the DCFA exemption. This is an unsupportable extension of the language of § 2513(b)(3).

The distinction between labeling and marketing is significant for regulatory purposes. Although there is often a strong correlation between a drug's labeling and marketing[7],

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[6]For example, Zeneca points to FDA guidance that expressly permits drug manufacturers to describe newly approved drugs as "new" for six months after their launch, see http://www.fda.gov/cder/ddmac/FAQS.HTM (explaining that "DDMAC [the Division of Drug Marketing, Advertising and Communications] generally considers that 'New' is an accurate description of the marketing phase for six months from the time a product is initially marketed"), and the FTC's similar opinion that there is a "tentative outer limit for use of the claim [that a product is 'new'] ... [of] a period of time no longer than 6 months." Permissible Period of Time During Which New Product May Be Described as "New," 32 Fed. Reg. 6023, 6023 (Apr. 14, 1967). The mere fact that the agencies have similar interpretations only shows inter-agency consistency; it does not show that the FTC was the regulating entity.

[7]21 C.F.R. § 202.1(e)(4)(i)(a) ("The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the

federal approval of labeling does not necessarily authorize marketing practices. Labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). It functions as "the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81082 (Dec. 22, 2000); *see also* 21 C.F.R. § 202.1(*l*)(2) (stating that material such as "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, [etc.] ...

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uses of the advertised drug dosage form(s)...."); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3960 (Jan. 24, 2006) ("[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) and 202.1(e)."); Professional Product Labeling; Public Meeting, 60 Fed. Reg. 52196, 52196 (Oct. 5, 1995) ("The approved labeling serves as the basis for fulfilling the requirement of the Federal Food, Drug, and Cosmetic Act ... that prescription drug advertising include 'information in brief summary relating to side effects, contraindications, and effectiveness.' (section 502(n) of the Act (21 U.S.C. § 352(n))).").

descriptive of a drug and references published (for example, the 'Physicians Desk Reference') *for use by medical practitioners, pharmacists, or nurses*, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling" (emphasis added)).

In contrast, advertisements are published in journals, magazines, and newspapers, and are broadcast through media such as television and radio. Advertisements also come in the form of physician-directed pitches by sales representatives, computer programs, and electronic media. *See* 21 C.F.R. § 202.1(*l*)(1). Although advertising may also serve as a mechanism to distribute safety information about a drug, its primary purpose–unlike labeling–is not to promote safety but rather to promote market expansion. *See, e.g.*, Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs, 72 Fed. Reg. 11889, 11889 (March 14, 2007) ("Although advertising of prescription drugs was once primarily addressed to health professionals, increasingly consumers have become a target audience, as DTC advertising has dramatically increased in the past few years. ... Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert,

professional labeling, or prescribing information). This labeling is written for health professionals, using medical terminology."). Zeneca has shown, through documentary evidence, that the FDA approved its labeling. However, the plaintiffs contend that the advertising differed sufficiently from the labeling such that it cannot also be considered to have been approved by the FDA.

Approval of a new drug application occurs "after [the FDA] determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, *and labeling*...." 21 C.F.R. § 314.105(c) (emphasis added). The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, requires that applicants for new drug applications submit "[c]opies of the label and all labeling for the drug product," 21 C.F.R. § 314.50(e)(2)(ii), and it specifically prohibits misbranding of drugs. "A drug or device shall be deemed to be misbranded ... if its labeling is false or misleading in any particular." 21 U.S.C. § 352(a); 21 C.F.R. § 1.21(a)(i)-(ii) ("Labeling of a ... drug ... shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or (2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual."). The FDA may refuse to approve an application on the grounds that "[t]he proposed labeling is false or misleading in any particular." 21 C.F.R. § 314.125(b)(6). Thus, to the extent that the advertising

statements regarding Nexium were consistent with statements used in the labeling approved by the FDA, the FDA has determined that they are not false or misleading.[8]

The FDA's Division of Drug Marketing, Advertising and Communications advises drug makers on proposed advertising and promotional labeling, in accordance with 21 C.F.R. § 202.1(j)(4). However, this review process is largely voluntary.

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[8]The FDA's determination that a statement is not false or misleading is, of course, distinct from a determination that the presentation of that statement is not misleading. The regulations provide that

> An advertisement may be false, lacking in fair balance, or otherwise misleading ... if it ... [f]ails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

21 C.F.R. § 202.1(e)(7)(viii). Through these regulations, the FDA has gone beyond the mere supervision of veracity in advertising statements to examine how the information is presented.

Id. ("Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment."); *but see* 21 C.F.R. § 314.81(b)(3) ("The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."). Section 352(n) of the FDCA exempts the content of any advertisement from pre-release Secretarial scrutiny, except in "extraordinary circumstances." 21 U.S.C. § 352(n)(A).

Whether Zeneca is correct in its assertion that the complaint is fundamentally "based on" the labeling is a legal question. The complaint attacks both the actual marketing tactics used by Zeneca, as well as the studies upon which FDA approval was based. To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading. Although we need not decide this question now, we note that the FDA's regulations require prescription drug advertisements to comport with approved labeling. *See, e.g.*, 21 C.F.R. § 202.1(e)(3)(iii) ("The information relating to side effects and contraindications shall disclose each specific side effect and contraindication ... contained in required, approved, or permitted labeling for the advertised drug...."); Thomas A. Hayes, *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51

FOOD & DRUG L.J. 57, 62 (1996) (explaining that, under the regulations, "advertising claims may be based either on substantial evidence or on substantial clinical experience," but the standard for labeling is substantial evidence); *see* 21 C.F.R. § 201.56(a)(3) (disallowing claims or suggestions of drug use on labeling if there is a lack of substantial evidence).

Congress expressly gave the FDA authority over prescription drug advertising in the FDCA. The FDCA lists a number of required elements of prescription drug advertising and states that "no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of Title 15." 21 U.S.C. § 352(n). Section 52 of Title 15 declares unlawful the dissemination of false advertisements. Subsection 352(n) of the FDCA was added in 1962. Pub. L. 87-781, § 131(a).

The DCFA became law in 1965. *See Brandywine Volkswagen, Ltd. v. State Dept. of Community Affairs and Econ. Dev., Div. of Consumer Affairs*, 312 A.2d 632, 633 (Del. 1973) (citing 55 Del.L., Ch. 46.). In enacting this statute, the Delaware General Assembly expressed its intent "to protect consumers and legitimate business enterprises from unfair or deceptive merchandising practices." 6 DEL. CODE ANN. § 2512. The legislature also explicitly declared its "intent ... that such

practices be swiftly stopped and that this subchapter shall be liberally construed and applied to promote its underlying purposes and policies." *Id.* Reading the exemption in § 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. Accordingly, we hold that the District Court erred in ruling that the plaintiffs' claims were not actionable under the DCFA.

III.

Preemption

The District Court further concluded that the Nexium advertisements that complied with the FDA-approved labeling were not actionable under the state consumer protection laws because those laws were preempted by federal law. The District Court correctly analyzed this issue under the rubric of implied conflict preemption. Plaintiffs assert that the District Court's application of federal preemption is incorrect because there is not an irreconcilable conflict between the state consumer fraud laws and the FDCA. In particular, the plaintiffs argue that the

approval of Nexium's labeling did not extend to an assertion of Nexium's superiority over Prilosec.

Implied conflict preemption renders state law "without effect" when, without "express congressional command," state law conflicts with federal law. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). As the Supreme Court has explained, "[t]his question is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State? If so, the Supremacy Clause requires courts to follow federal, not state, law." *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996). The Court has "found implied conflict pre-emption ... where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 64-65 (2002) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941))). Thus, the question presented here is whether state consumer fraud laws pose an obstacle to the FDA's congressionally-mandated regulation of prescription drug advertising.

For purposes of this case, the critical characteristic of the FDCA is that it regulates the safety of drugs. The FDCA states that the mission of the FDA is to "(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products

in a timely manner; (2) with respect to such products, protect the public health by ensuring that ... (B) human ... drugs are safe and effective." 21 U.S.C. § 393(b). Prior to the introduction of a new drug, the FDA must find that the "drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d) (explaining in detail the seven-part test that the FDA uses in determining whether to approve a drug); *see also Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987). As part of this process, the FDA must find that there is "substantial evidence that the drug will have the effect it purports or is represented to have...." *Id.* During the approval process, the Secretary may determine, "based on relevant science, that data from *one* adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness...." *Id.* (emphasis added). Such data and evidence constitute "substantial evidence" under 21 U.S.C. § 355.

Section 352(n) lists three items that prescription drug advertising must include: (1) the actual name of the drug, if a trade or brand name is used; (2) the ingredient list and quantitative formula for each ingredient; and (3) a brief summary of side effects, contraindications, and effectiveness. The subsection is called the "brief summary" provision. It requires a true statement of these three items in the brief summary included in advertisements. The statute explains that, to the extent that an advertisement complies with subsection (n)

in listing the three items, it is not subject to the false advertising provisions of the FTCA. However, as noted above, § 352(n) requires only pre-release approval of advertisements in "extraordinary circumstances."

Pursuant to its regulatory authority over prescription drug advertising, the FDA promulgated regulations that lay out the specific requirements for advertising prescription drugs. *See* 21 C.F.R. § 202.1. In particular, the regulations stipulate that an advertisement does not include a "true statement" if it is

> [F]alse or misleading with respect to side effects, contraindications, or effectiveness; or [i]t fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness ... is not fairly balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug ...; [or] [i]t fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.

21 C.F.R. § 202.1(e)(5). The regulation includes an extensive, but non-exhaustive, 20-factor list of reasons why "[a]n advertisement for a prescription drug is false, lacking in fair

balance, or otherwise misleading...." 21 C.F.R. § 202.1(e)(6)(i)-(xx).[9] The subsequent subsection explains the circumstances under which "[a]n advertisement *may* be false, lacking in fair balance, or otherwise misleading...." 21 C.F.R. § 202.1(e)(7) (emphasis added). The regulations further state that "[d]issemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded...." 21 C.F.R. § 202.1(j)(3). The FDA explains that "[a]ny advertisement may be submitted to the Food and Drug Administration prior to publication for comment," but does not require that manufacturers submit their ads for preapproval. 21 C.F.R. § 202.1(j)(4). However, the FDA does require manufacturers to submit advertising specimens "at the time of

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[9]Subsection (e)(6)(ii) deems an advertisement misleading if it "[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 C.F.R. § 202.1(e)(6)(ii). Although the FDA did not explicitly approve Zeneca's advertising, the FDA did approve Nexium's labeling, which included clinical studies that showed statistically significant healing rates for 40 mg of Nexium as compared to 20 mg of omeprazole. The regulations explain that the clinical studies section "must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively. Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s)...." 21 C.F.R. § 201.57(c)(15).

initial publication of the advertisement for a prescription drug product." 21 C.F.R. § 314.81(b)(3)(i) (requiring transmittal of the advertisement with Form FDA-2253).

The degree of discretion inherent in the regulations demonstrates that the FDA envisioned itself occupying an ongoing and extensive role in the supervision of prescription drug advertising. *See, e.g.*, 60 Fed. Reg. at 44210 ("In order to carry out the public health protection purposes of the act, FDA: ... (3) monitors drug labeling and prescription drug advertising to help ensure that they provide accurate information about drug products."); Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677, 36,677 (Sept. 9, 1985) ("FDA will continue to regulate prescription drug advertising, regardless of its intended audience, in accordance with section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) and the implementing regulations (21 CFR Part 202)."). Furthermore, Congress shared that vision. *See* 21 U.S.C. § 352(n); 21 U.S.C. § 393(b)(1).[10]

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[10]Congress did not always concede jurisdiction over prescription drug advertising to the FDA. When the FDCA was passed in 1938, Congress left the authority to police "unfair or deceptive acts or practices in or affecting commerce" with the FTC. Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. § 301 *et seq.*; Wheeler-Lea Act, 52 Stat. 111, ch. 49 (1938) (amending section 5 of the FTCA, Pub. L. No. 63-203, 38 Stat. 717, 719 (1914) (prohibiting "unfair methods of

However, neither the language of the FDCA nor the regulations explicitly preempt state consumer fraud law.

The central tenet of preemption analysis is that "'[t]he purpose of Congress is the ultimate touchstone'" in determining whether state law is preempted. *Cipollone*, 505 U.S. at 516 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).[11] However, the Supreme Court has long indicated that

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competition in commerce")). It was not until the 1962 Kefauver-Harris Drug Amendments, which enacted section 502(n) of the FDCA, that regulatory authority over prescription drug advertising was transferred to the FDA. Pub. L. No. 87-781, § 131(a), 76 Stat. 791-92 (1962). For a more complete recitation of the history of direct-to-consumer advertising, see Francis B. Palumbo and C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 424-31 (2002).

[11]The dissent correctly notes that "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The prevention of consumer fraud has traditionally been within the purview of the states. This historical preference does not foreclose the possibility of preemption, where applicable. *See, e.g.*, *Gen. Motors Corp. v. Abrams*, 897 F.2d 34, 36 (2d Cir. 1990) ("While the protection of consumers from unfair practices is a traditional state police power function, federal laws and administrative regulations may

agency regulations are also a source of preemptive law. *See, e.g.*, *Louisiana Public 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 acting within the scope of its congressionally delegated authority may pre-empt state regulation."). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court considered FDA regulations in the course of its preemption analysis and noted that, under the regulations, "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or ... other specific requirements applicable to a particular device.'" *Id.* at 498 (quoting 21 C.F.R. § 808.1(d)). While the Court emphasized congressional intent in determining whether preemption was appropriate, *id.* at 485-86, the Court also looked to the "statutory and regulatory language" in evaluating "the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement...." *Id.* at 500.

Similarly, in *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), the Court examined whether the National Traffic and Motor Vehicle Safety Act of 1966, and a standard promulgated under it by the Department of Transportation, preempted a state common law tort action "in which the plaintiff claims that the defendant auto manufacturer, who was in compliance with the standard, should nonetheless have equipped

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operate in tandem with–or even preempt–state law under the Supremacy Clause....").

a 1987 automobile with airbags." *Id.* at 865. The Court concluded that "the Act, *taken together with* FMVSS 208 [the agency-promulgated standard], pre-empts the lawsuit." *Id.* (emphasis added). Both *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 Association v. de la Cuesta*, 458 U.S. 141 (1982):

> 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. *United States v. Shimer*, 367 U.S. 374, 381-82 (1961). When the administrator promulgates regulations intended to pre-empt state law, the court's inquiry is similarly limited.

Id. at 153-54; *see also Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) ("[S]tate laws can be pre-empted by federal regulations as well as by federal statutes."). *Medtronic* and *Geier* add to the preemption analysis by 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. Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 FOOD & DRUG L.J. 227, 240-41 (2007).

Following *Medtronic* and *Geier*, the Supreme Court examined conflict preemption in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The Court determined that fraud-on-the-FDA claims in state tort law were preempted by the Medical Device Amendments, 21 U.S.C. § 360c, *et seq*. *Id.* at 348. The Court explained that "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* In so holding, the Court emphasized the flexibility inherent in the statutory and regulatory framework, and noted that such flexibility was necessary for the FDA to pursue "difficult (and often competing) objectives." *Id.* at 349. The Court distinguished *Medtronic*, noting that "the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Id.* at 352. Because the "existence of these federal enactments [was] a critical element in [the plaintiffs'] case," the Court held that to allow the claims to proceed "would exert an extraneous pull on the scheme established by Congress...." *Id.* at 353. In the plaintiffs' claims against Zeneca under state consumer fraud laws, the FDCA is not as clearly a "critical element," because plaintiffs may not need to show non-compliance with the FDCA in order to prevail. However, allowing these claims to proceed would unnecessarily frustrate the FDCA's purpose and FDA regulations, as the extent of agency involvement in regulating

prescription drug advertising is extensive and specific. *See* 21 C.F.R. § 202.1(e)(6)(i)-(xx) and (e)(7)(i)-(xiii); Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Withdrawal; Availability, 69 Fed. Reg. 6308-01 (Feb. 10, 2004) ("FDA has responsibility under the Federal Food, Drug, and Cosmetic Act (the act) for regulating advertising for prescription drugs.").

An even stronger case for preemption occurs when FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising. The essential affinity between advertising and labeling is clear in the composition of the FDCA and its associated regulations. 21 U.S.C. § 321(n) (explaining criteria for "determining whether the labeling or advertising is misleading"); 21 U.S.C. § 352(n) (requiring that all advertisements include "the formula showing quantitatively each ingredient of such drug to the extent required for labels"); *see, e.g.*, 21 C.F.R. § 202.1(a)(2) ("The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product."); 21 C.F.R. § 202.1(e)(3)(ii) ("[W]hen an advertisement contains a broad claim that a drug is an antibacterial agent, the advertisement shall name a type or types of infections and microorganisms for which the drug is effective clinically as specifically as required, approved, or permitted in the drug

package labeling."). Although labeling is often directed at medical practitioners, the rules that govern labeling form the basis for the advertising regulations. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3961 (Jan. 24, 2006) ("The purpose of prescription drug labeling is to provide health care practitioners information necessary for safe and effective use."); Prescription Drug Advertising; Content and Format for Labeling of Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,460 (June 26, 1979) ("The use of quantitative statements of safety or effectiveness is permitted in drug advertisements when the representation has been approved as part of the labeling...."). Accordingly, 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.

Implied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. Congress specifically determined that "all ... proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising. *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R.

§ 314.81(b)(3). Accordingly, the plaintiffs' state consumer fraud claims are preempted.[12]

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[12]Plaintiffs also assert that the District Court erred in utilizing the doctrine of primary jurisdiction in dismissing their complaint because they had no opportunity to argue the applicability of primary jurisdiction to their claims. Although the plaintiffs are correct that a district court may not dismiss a complaint on grounds that the plaintiffs had no opportunity to address, see *Mortensen v. First Federal Savings and Loan Association*, 549 F.2d 884, 893 n.18 (3d Cir. 1977), invocation of primary jurisdiction was, at most, an alternative holding. Because "we [can] affirm the district court on any basis which finds support in the record," any error that may have occurred is harmless and does not require reversal. *United States v. Maker*, 751 F.2d 614, 627 (3d Cir.1984) (quoting *Bernitsky v. United States*, 620 F.2d 948, 950 (3d Cir. 1980)).

Likewise, the plaintiffs' unjust enrichment claims are untenable as a result of our holding regarding the preemption of the DCFA. The unjust enrichment claims do not rest on any sounder footing than the fraud claims. Delaware defines unjust enrichment as "the unjust retention of a benefit to the loss of another, or the retention of money or property of another against the fundamental principles of justice or equity and good conscience." *Schock v. Nash*, 732 A.2d 217, 232 (Del. 1999) (quotation omitted). Because no fraud claim exists under the DCFA due to the operation of preemption, there was no deception by Zeneca cognizable in state law and therefore no retention of money against the fundamental principles of justice at issue in this case. *See Bober v. Glaxo Wellcome PLC*, 246

IV.

Leave to Amend

The decision whether to grant leave to amend is within the discretion of the district court. *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 654 (3d Cir. 1998). The Supreme Court has explained that

> In the absence of any apparent or declared reason–such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.–the leave sought should, as the rules require, be 'freely given.'

Foman v. Davis, 371 U.S. 178, 182 (1962). The District Court did not rule on appellants' request for leave to amend.

The plaintiffs amended their complaint once in response to a motion to dismiss dated March 31, 2005 that advanced the same arguments presented in the motion to dismiss at issue here.

F.3d 934, 943 (7th Cir. 2001).

We have considered the other arguments raised, and conclude that they are without merit and compel no separate discussion.

Plaintiffs had an opportunity to revise their complaint in response to the renewed objections, but failed to cure the deficiencies. Additionally, although the plaintiffs suggest that some additional facts might be pled in order to cure the defects of the complaint, amendment would be futile. In particular, the plaintiffs state that they could allege that "in negotiations between the FDA and AstraZeneca regarding Nexium labeling, the FDA stated it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec, and AstraZeneca responded it would not make any such statement." This will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumer fraud law, as explained in part III.

V.

The DCFA exemption for advertisements or merchandising practices which are subject to and compliant with the rules and regulations of, and the statutes administered by, the FTC, 6 DEL. CODE ANN. § 2513(b)(2), does not preclude the plaintiffs' suit. The language of the exemption circumscribes the federal agencies to which advertisers may look in seeking to exclude their conduct from the prohibition of § 2513(a). The FDA is not referenced in subsection (b)(2), nor does the FDA act as a proxy for the FTC in its regulation of prescription drug advertising. We therefore decline to read that section more broadly than the Delaware General Assembly plainly drafted it.

Although the DCFA exemption does not bar the plaintiffs' suit, their state consumer fraud claims are preempted by federal law. 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. The FDA has established specific regulations regarding such advertising. To 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. Accordingly, the state consumer fraud laws are preempted by the extensive federal legislative and regulatory framework. We will affirm the judgment of the District Court.

Pennsylvania Employees Benefit Trust Fund, et al. v. Zeneca, Inc., et al., No. 05-5340

Cowen, Circuit Judge, dissenting.

The majority's conclusion that the FDCA and the implementing regulations displace the Delaware Consumer Fraud Act and the consumer protection statutes of the fifty states "ignore[s] the teaching of th[e] [Supreme] Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists." *Huron Portland Cement Co. v. City of Detroit, Mich.*, 362 U.S. 440, 446 (1960). Because the state laws do not "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives" of the federal law, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), I respectfully dissent.

I.

In areas of traditional state regulation, we start with "the

assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[B]ecause the States are independent sovereigns in our federal system, [it] ha[s] long [been] presumed that Congress does not cavalierly pre-empt state-law causes of action."). The protection of consumers against deceptive business practices is an area traditionally regulated by the States. *California v. ARC Am. Corp*., 490 U.S. 93, 101 (1989) ("Given the long history of state common-law and statutory remedies against . . . unfair business practices, it is plain that this is an area traditionally regulated by the States." (footnote omitted)); *Fla. Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146 (1963) (statute to "prevent the deception of consumers" within scope of state's police powers); *Plumley v. Commonwealth of Mass*., 155 U.S. 461, 467 (1894) (recognizing state's power to "prevent[] deception or fraud in the sales of property within their respective limits"). Similarly, "[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens." *Medtronic*, 518 U.S. at 475. As such, a presumption against a finding of preemption clearly applies in this case. Applying the presumption against preemption and general principles of conflict preemption, I cannot agree with the majority's finding of preemption, as discussed below.

II.

A

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My first point of disagreement lies with the majority's heavy reliance upon the high level of specificity in the federal regulations as a basis for a finding of preemption. While the prescription drug advertising regulations are unquestionably detailed and extensive, it is well-established that a preemption inquiry "cannot be judged by reference to broad statements about the 'comprehensive' nature of federal regulation." *Head v. N.M. Bd. of Exam'rs in Optometry*, 374 U.S. 424, 429-30 (1963) (citations omitted); *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990) ("Ordinarily, the mere existence of a federal regulatory scheme, even one as detailed as § 210, does not by itself imply pre-emption of state remedies."); *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985) ("[I]f an agency does not speak to the question of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to pre-empt.").[13]

[13] Incidentally, the assertion that the mere "volume and complexity" of agency regulations demonstrates an implicit

Despite the volume and specificity of the federal regulations, "state statutes, otherwise valid, must be upheld unless there is found 'such actual conflict between the two schemes of regulation that both cannot stand in the same area, []or evidence of a congressional design to preempt the field.'" *Head*, 374 U.S. at 430 (quoting *Fla. Lime*, 373 U.S. at 141); *Fla. Lime*, 373 U.S. at 143 (finding "no inevitable collision between the two schemes of regulation").[14] As discussed further below, no such actual conflict has been demonstrated or found in this

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intent to displace all state law in a particular area is a field preemption argument, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000), which was never raised in this case.

[14] This is not an area of the law inherently requiring national uniformity and ousting all related state law. As the Supreme Court has explained, "every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law." *Hillsborough*, 471 U.S. at 719. Thus while prescription drug advertising merits national concern, Congress has not taken drug advertising from a health and safety issue into a field of inherently national concern. *See id.* at 720-22 (federal regulations governing collection of blood plasma do not preempt local ordinances on the same subject matter). Indeed, even the FDA has acknowledged that "regulation of drug labeling will *not* preempt all State law actions." *See* Labeling Rule, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (emphasis added).

case.

B.

My second point of contention is with the majority's statement, at least within the context of this case, that Congress's purpose of protecting prescription drug users would be frustrated if plaintiffs were permitted to question the veracity of statements approved by the FDA. It is undisputed that the FDA has not approved the veracity of the particular advertisements in question, and, as discussed in greater detail below, plaintiffs are not attacking, directly or indirectly, the labeling approved by the FDA.[15]

[15] Even assuming *arguendo* that Congress wanted labeling statements approved by the FDA to be immune to attack, that federal interest would be served by preempting state law to the extent that it afforded recovery to plaintiffs attacking the labeling. Similarly, if Congress wanted advertisements approved by the FDA to be immune to attack, that federal interest would be served by preempting state law to the extent that it afforded recovery to plaintiffs attacking the advertisements. Here, plaintiffs are not attacking the labeling of Nexium. There is also no record evidence that the FDA approved the Nexium advertisements which they are challenging. Specifically, the

The majority refers to the "essential affinity" between advertising and labeling in support of its preemption finding. Admittedly, in defining the scope and substance of certain information to be included in drug advertisements, the FDA regulations refer to the information required or permitted in the approved labeling. *See, e.g.*, 21 C.F.R. § 202.1(a)(1) (order of listing of ingredients), (e)(3)(iii) (side effects and contraindications), (e)(6)(xi) (conditions of drug use). Consequently, a state-law claim, alleging that an advertisement consistent with the approved labeling contains inadequate disclosures or warnings regarding such matters as ingredients, side effects, contraindications, and conditions of use, might indirectly present a conflict with the FDA's labeling determination. That kind of case would present a more difficult preemption question than the one presented here.

In the instant case, on the other hand, plaintiffs claim that advertisements of Nexium contain a false and misleading *drug comparison*. The labeling of a prescription drug does contain or require a showing of a drug's superiority over other drugs on the

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FDA has not determined the veracity of advertisements touting Nexium's effectiveness as "compared with Prilosec"and indicating the benefits of Nexium in "efficacy in short-term healing" and "system control" in head-to-head studies with Prilosec.

market. Unsurprisingly, then, the FDA has not rendered an official opinion approving or disapproving a claim of superiority of Nexium over Prilosec.[16] As a result, there is no risk that a successful state-law claim, alleging that Nexium advertisements contain false and misleading drug comparisons, would conflict with the FDA's approval of the statements in the Nexium labeling.

The FDA's own prescription-drug advertising regulations demonstrate as much. The regulations categorize as false and misleading any advertisement that "[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 C.F.R. § 202.1(e)(6)(ii). Unlike the labeling-related provisions in the regulation, *see, e.g.*, 21 C.F.R. § 202.1(a)(1), (e)(3)(iii), (e)(6)(xi), the false and misleading drug

[16] To be sure, the approved labeling for Nexium reproduces the results of clinical studies comparing the two treatments. According to FDA guidelines, however, the Clinical Studies section of labeling is intended to "facilitate an understanding of how to use the drug safely and effectively." Inclusion of the clinical studies are not intended to serve as an implicit agency determination about the superiority of one drug over another.

comparison provision does not turn on the approved labeling, but on the existence of "substantial evidence or substantial clinical experience." 21 C.F.R. § 202.1(e)(6)(ii). The "essential affinity" between advertising and labeling, therefore, does not subsist in a claim attacking a statement of drug superiority in an advertisement.

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. As stated by the late Chief Justice Rehnquist, "merely identifying a purpose is not enough [for conflict preemption]; it must also be shown that the state law inevitably frustrates that purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 545 (1977) (Rehnquist, J., dissenting). Emphasizing that point, he noted:

> We must also be careful to distinguish those situations in which the concurrent exercise of a power by the Federal Government and the States or by the States alone may possibly lead to

> conflicts and those situations where conflicts will necessarily arise. "It is not . . . a mere possibility of inconvenience in the exercise of powers, but an immediate constitutional repugnancy that can by implication alienate and extinguish a pre-existing right of (state) sovereignty."

Id. (quoting The Federalist No. 32, p. 243 (B. Wright ed. 1961)). Only if the purpose of the federal law cannot be accomplished–if its operation must be frustrated and its provisions be refused their natural effect–must the state law yield to the regulation of Congress. *Savage v. Jones*, 225 U.S. 501, 533 (1912).

While the majority has identified the congressional purpose of protecting prescription drug users, it has not articulated how the state law must inevitably frustrate that purpose. There is certainly no "immediate constitutional repugnancy" between an extra-agency finding that a claim of drug superiority in an advertisement is false and misleading and the congressional purpose of protecting prescription drug users. *Jones*, 430 U.S. at 545 (Rehnquist, J., dissenting) (internal quotations marks and citation omitted). As such, I cannot agree with the majority's finding of preemption on that basis.

C.

My third concern relates to the majority's finding that Congress's exclusion of prescription drug advertisements from the scope of 15 U.S.C. § 52 signals a congressional intention to preempt state consumer fraud laws. The text of 21 U.S.C. § 352(n) only excludes coverage under 15 U.S.C. § 52 and does not purport to bar state-law tort actions. Nor does the legislative history to § 352(n) indicate a congressional purpose to supplant state-law actions. *See English*, 496 U.S. at 88. Most importantly, the 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. *See Rice*, 331 U.S. at 230.

D.

Fourth, I disagree that the majority's attempt to analogize this case to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), where the Supreme Court found preemption based upon specific conflicts between certain FDA objectives and state-law fraud-on-the-agency claims and the

interdependency between the state claims and FDCA requirements. In *Buckman*, the Court found that the plaintiffs' fraud-on-the-agency claims would have had the effect of deterring beneficial off-label uses, despite the FDA's objective not to regulate the practice of medicine, and would have caused a deluge of information concerning off-label uses, resulting in administrative burdens and delays. *Id.* at 350-51. In addition, the Court found that unlike the traditional state tort claims, the fraud-on-the-agency claims existed solely by virtue of FDCA disclosure requirements, which Congress had given the FDA the exclusive responsibility to enforce. *Id.* at 352. For these reasons, the Court held that the plaintiffs' state-law claims were preempted. *Id.* at 353.

Unlike the claims in *Buckman*, plaintiffs' claims here do not exist by virtue of a violation of FDCA disclosure requirements. The state consumer protection statutes at issue existed long before the federal enactments. Moreover, the majority does not identify any actual conflicts between the federal regime and the state statutes. There is, for example, no cited risk that the availability of state-law remedies would conflict with a particular federal objective or a careful balancing of interests that the federal government has achieved in policing prescription drug advertising. For these reasons, the claims in this case cannot be reasonably analogized to the claims in *Buckman*, and, thus, the majority's use of the reasoning in

Buckman to support its preemption finding is misguided.

E.

Fifth, I disagree with the majority's finding of preemption to the extent it is based upon the presence of state-law parameters for false and misleading advertisements. As discussed below, the mere presence of state law standards would not inevitably lead to a collision with the federal regime.

As an initial matter, the majority characterizes plaintiffs' claims as both interposing state-law standards and vindicating federal requirements. Implicit in this dual characterization is, necessarily, the recognition that the state standards and federal requirements are not inconsistent. Yet, it is well-established that the mere presence of state-law claims that *parallel* federal requirements is not sufficient to support a preemption finding. *See Medtronic*, 518 U.S. at 495 ("The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law.");

Cipollone v. Liggett Group, Inc., 505 U.S. 504, 529 (1992) ("State-law prohibitions on false statements of material fact do not create 'diverse, nonuniform, and confusing' standards. Unlike state-law obligations concerning the warning necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity.").

On a number of occasions, the Supreme Court has upheld state laws that provide remedies parallel to the remedies provided by the federal law. *See, e.g.*, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 257 (1984) ("Paying both federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible. Nor does exposure to punitive damages frustrate any purpose of the federal remedial scheme."); *Hayfield N. R.R. Co. v. Chi. and N. W. Transp. Co.*, 467 U.S. 622, 636 (1984) ("Although it may seem unfair to allow a shipper a 'second bite at the apple' in state condemnation proceedings . . . , that second opportunity does not frustrate the purpose of the federal valuation scheme."); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974) ("[T]he patent policy of encouraging invention is not disturbed by the existence of another form of incentive to invention."). As explained by the Supreme Court, "state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law." *California*, 490 U.S. at 105;

English, 496 U.S. at 89 (same). *But see Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 706 (1984) ("Since the Oklahoma law . . . compels conduct that federal law forbids, the state ban clearly stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal regulatory scheme." (internal quotation marks and citation omitted)); *Franklin Nat. Bank v. New York*, 347 U.S. 373, 378 (1954) (finding a "clear conflict" between federal law, which authorized national banks to receive savings deposits but did not specifically permit– much less require–advertising by such banks, and New York law, which forbade them from using the word "savings" in their advertising or business).

The state statutory damages remedies for false and misleading advertisements would not frustrate the federal policy of protecting prescription drug consumers. The veracity of drug advertisements is essential to the protection of consumers. As stated in the legislative history to 21 U.S.C. § 352(n), "when a doctor is misled his patient's health is endangered." S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2904. Given that there are limitations to the FDA's oversight over prescription drug advertisements–both congressionally-imposed limitations, such as the lack of authority to require preapproval, 21 U.S.C. § 352(n), and practical limitations attendant to the sheer volume of drug advertisements in the media, *see* Donna U. Vogt, *CRS Report for Congress: Direct-to-Consumer*

Advertising of Prescription Drugs 20 (Congressional Research Service, The Library of Congress 2005) (noting that in 2003 alone, the FDA received 38,000 advertisements from drug sponsors)–the supplementation of state-law remedies would seem to aid the FDCA's objectives and purposes, not frustrate them.

For these reasons, I cannot agree that the mere presence of state law standards for false and misleading advertisements would present a conflict with the federal law.

F.

Of final note, 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. As the Supreme Court stated in *Silkwood*, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." 464 U.S. at 251; *see also Bates v. Dow Agrosciences LLC*., 544 U.S. 431, 450 (2005) ("[I]t seems unlikely that Congress considered a relatively obscure provision

like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability.").

In addition, where the state law in question provides a long available form of compensation, it would be expected that Congress would express an intent to deprive injured parties of that compensation even more clearly. *See Bates*, 544 U.S. at 449. Here, the long history of state consumer protection statutes in this country (which, incidentally, were modeled after and coexisted with the FTCA, the FDCA's predecessor insofar as prescription drug advertising is concerned) adds force to the basic presumption against preemption. *See id.* at 449-50. That presumption has not been rebutted in this case.

In summary, because congressional intention to remove all judicial recourse for parties injured by deceptive business practices is far from clear, a finding of preemption is not permitted under Supreme Court precedent.

III.

Based upon the foregoing, I respectfully dissent, insofar as the majority concludes that the state claims are preempted.[17]

[17] Apart from my general disagreement with the majority's preemption analysis, I also disagree with the majority's summary conclusion that the FDA's prescription drug advertising regulations preempt the plaintiffs' claims to the extent based upon false and misleading presentations and "detailing," as it is not clear that the regulations apply to those kinds of promotional activities.