No. 07-

IN THE

Supreme Court of the United States

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, JOSEPH MACKEN, COMMISSIONER LINDA A. WATTERS, AFSCME DISTRICT COUNCIL 47 HEALTH &WELFARE FUND, VICTORIA SCOFIELD, JANET MCGRORTY, RICHARD TIKKURI, WISCONSIN CITIZEN ACTION, UNITED SENIOR ACTION OF INDIANA, NORTH CAROLINA FAIR SHARE,

Petitioners,

v.

ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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ISSUE PRESENTED FOR REVIEW

Whether 21 U.S.C. § 352(n) and the regulations promulgated thereunder by the Food and Drug Administra-tion preempt all state-law claims for unfair and deceptive marketing of a prescription drug even though Congress stated in the legislation that created § 502(n), P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962), that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

LIST OF PARTIES TO THE PROCEEDINGS

Petitioners Pennsylvania Employees Benefit Trust Fund, Joseph Macken, Commissioner Linda A. Watters, AFSCME District Council 47 Health &Welfare Fund, Vict-oria Scofield, Janet McGrorty, Richard Tikkuri, Wisconsin Citizen Action, United Senior Action of Indiana, and North Carolina Fair Share were plaintiffs in the district court and appellants in the Court of Appeals.

Respondents Zeneca, Inc. and AstraZeneca Pharmaceuticals, L.P. were defendants in the district court and appellees in the Court of Appeals.

CORPORATE DISCLOSURE STATEMENT

None of the petitioners is a corporation.

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OPINIONS BELOW

The opinion of the Court of Appeals is reported as *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239 (3d Cir. 2007) and is reprinted in the Appendix to the Petition ("App.") A. The district court's opinion, which is unreported, is reprinted at App. B.

JURISDICTION

The Court of Appeals entered judgment on August 17, 2007. On September 19, 2007, the Court of Appeals denied a timely petition for rehearing, with three judges (in addition to Judge Cowen, who dissented from the majority decision) voting to grant the petition. App. C. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The basis for preemption is the Supremacy Clause of the Constitution, which provides in relevant part that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any States to the Contrary notwithstanding." U.S. CONST. Art. VI, cl. 2, reprinted at App. D.

The relevant provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") are reprinted at App. D. The pertinent statutory provisions are 21 U.S.C. §§ 337 and 352(n). Section 202 of The Drug Amendments Act of 1962, P.L. 87-781, 76 Stat. 780 (Oct. 10, 1962) is reprinted at App. D.

STATEMENT OF THE CASE

This petition presents an issue of exceptional importance – whether Congress clearly and manifestly intended to strip states of their traditional power to protect citizens from deceptive marketing of prescription drugs. The majority opinion denies all judicial recourse under state law to consumers and other payors who lost billions of dollars due to Zeneca's deceptive marketing of Nexium.

Defendants-Respondents AstraZeneca Pharmaceuticals, L.P. and Zeneca Inc. (collectively "Zeneca") make the prescription drugs Prilosec® and Nexium®, the latter of which Zeneca developed as a successor to Prilosec, which went off patent in 2001. Plaintiffs-Appellants ("Plaintiffs") allege that the FDA found that Zeneca's clinical studies do not support the claim that Nexium is superior to Prilosec but that Zeneca nonetheless deceptively marketed Nexium as superior to Prilosec. In a 2-to-1 decision, the Third Circuit affirmed the dismissal of the complaint on preemption grounds. *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239 (3d Cir. 2007). The Court of Appeals held that Plaintiffs' claims "would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users." *Id.* at 253. The majority held that 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." *Id.*

This Court should review the majority's decision. The holding that Congress intended § 352(n) to "protect[] the nation's prescription drug users," *id.*, by foreclosing their ability to seek redress for unfair or deceptive practices is contrary to the 1962 legislation that created § 352(n). That legislation states that

> "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962). Yet the majority points to no such "direct and positive conflict" that requires preemption of all claims under state consumer fraud laws for deceptive marketing of prescription drugs. Indeed, the majority recognizes that Plaintiffs' claims do not conflict with the federal regime: "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." 499 F.3d at 246. Moreover, Plaintiffs informed the court 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.'" *Id.* at 252 (quoting Plaintiffs' proffer). The court held that such allegations of consistency between

Plaintiffs' claims and the FDA's review of Nexium "will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumer fraud law." *Id.* at 252-53.

The conflict in this case is the one created by the majority opinion, which is at odds not only with the intent of Congress to preempt only those state-law claims that are in direct and positive conflict with the FDA's regulation of prescription drug advertising but also with decisions of this Court, other Courts of Appeals, the Third Circuit itself, and State courts of last resort, as explained in this Petition.

This Court should review the majority's flawed decision because it eviscerates the traditional role of states to protect their citizens from false marketing of prescription drugs and because of the harsh and far-reaching ramifications of that ruling, which permits pharmaceutical companies to deceptively market their products without fear of recourse from private parties.

A. Factual Background

This is a class action against Zeneca for unfair and deceptive marketing of the brand-name drug Nexium. Supplemental Appendix ("Supp. App.") ¶ 1.[1] Putting Zeneca's misconduct in context requires an understanding of Prilosec, the prescription drug it was designed to replace. Prilosec is a proton-pump inhibitor ("PPI"). *Id.* PPIs are thought of as heartburn drugs and

1. References to "¶" are to paragraphs of the Consolidated Class Action Complaint contained in the Supplemental Appendix.

are used to treat erosive esophagitis, to maintain healing of erosive esophagitis and to treat symptomatic gastroesophageal reflux disease ("GERD"). Supp. App. ¶ 33. Zeneca had a patent for Prilosec, which by the year 2000 was the most widely prescribed drug in the world, with annual sales in excess of $6 billion. Supp. App. ¶ 32.

The active ingredient in Prilosec, omeprazole, is a racemic mixture containing S- and R-enantiomers. Supp. App. ¶ 38. Enantiomers are molecules that have two non-superimposable mirror image forms, *i.e.*, a right and a left hand version. *Id.* Racemic mixtures, such as omeprazole, contain equal proportions of the two enantiomers. *Id.* Thus, 20 milligrams (mg) of Prilosec comprises 10 mg of the R-enantiomer and 10 mg of the S-enantiomer. *Id.* In humans, the S-enantiomer of omeprazole is more active than the R-enantiomer. Supp. App. ¶ 39.

The United States patent for Prilosec was set to expire in 2001. Supp. App. ¶ 40. With the looming loss of patent protection, Zeneca faced the prospect of competition from generic competitors waiting to market omeprazole. Prilosec was the best selling drug in the world, with sales of $5.9 billion in 2000, which comprised 39% of Zeneca's revenues. Supp. App. ¶ 41.

Faced with the catastrophic loss of sales from its flagship drug, Zeneca plotted a strategy to replace Prilosec. Supp. App. ¶ 45. The centerpiece of that strategy became the marketing of a new drug, Nexium. *Id.* Nexium is simply the S enantiomer of omeprazole. *Id.* In other words, Nexium is Prilosec without the less active Renantiomer. *Id.* Zeneca developed a plan to

launch Nexium and promote it as an improvement over Prilosec to migrate the Prilosec business over to Nexium and to build brand loyalty for Nexium before Prilosec's patent expired and Prilosec became subject to generic competition. Supp. App. ¶ 47.

To gain regulatory approval for Nexium, Zeneca needed only to demonstrate in clinical trials submitted to the FDA that Nexium was more effective than a placebo. Supp. App. ¶ 48. But in an attempt to prove that Nexium was superior to Prilosec, seven of the fourteen clinical trials that Zeneca conducted compared Nexium to Prilosec. Supp. App. ¶ 49.

The FDA approved Nexium for the healing of erosive esophagitis, maintenance of healing of erosive esophagitis and treatment of symptomatic GERD. However, it explicitly rejected Zeneca's contention that Nexium was superior to Prilosec. The FDA's review of Zeneca's Nexium studies ("FDA Review")[2] stated that a claim that Nexium was superior to Prilosec for healing erosive esophagitis is "NOT SUPPORTED." Supp. App. ¶ 53. With respect to three "supportive trials" submitted by Zeneca, the FDA Review stated that "[a]ll three studies failed to demonstrate superiority of [Nexium] over [20 mg of Prilosec]." Supp. App. ¶ 61. Nor did the FDA Review find support for a superiority claim for treating symptomatic GERD. Supp. App. ¶ 67 ("claims of superiority [of Nexium] to [Prilosec] are – once again – not supported. Neither H40 [Nexium 40 mg] nor H20

2. Stephen G. Hundley, *FDA Pharmacology/Toxicology Review and Evaluation*, Nexium NDA 21-154, 1-2 (Oct. 31, 2000) (*see* Supp. App. ¶ 49 n.9).

[Nexium 20 mg] could be differentiated from O20 [Prilosec 20 mg]).

A medical review conducted by the FDA confirmed there was no scientific support for a claim of Nexium's superiority over Prilosec.[3] First, the Medical Review found that the studies demonstrated no superiority of Nexium for healing erosive esophagitis:

> [A] superiority claim of Nexium over omeprazole [Prilosec] is ***not supported*** by either the comparison of H20 [Nexium 20 mg] vs. O20 [Prilosec 20 mg] or the comparison of H40 [Nexium 40 mg] vs. H20 [Nexium 20 mg].

Supp. App. ¶ 65 (emphasis added).

Second, the Zeneca studies to establish Nexium's efficacy in maintaining healing of erosive esophagitis did not compare Nexium to Prilosec and, thus, cannot support a claim that Nexium is superior to Prilosec. Supp. App. ¶ 66.

Third, the Medical Review found that the studies on treatment of symptomatic GERD showed no superiority of Nexium over Prilosec:

> [C]laims of superiority [of Nexium] to omeprazole are – once again – ***not supported.***

---

3. Hugo E. Gallo-Torres, M.D., Ph.D, Medical Team Leader, Medical Review(s), FDA Center for Drug Evaluation and Research, Application Number: 21-153/21-154, September 21, 2000 ("Medical Review"), at 3-6 (*see* Supp. App. ¶ 64 n.14).

> Neither H40 [Nexium 40 mg] nor H20 [Nexium 20 mg] could be differentiated from O20 [Prilosec 20 mg].

Supp. App. ¶ 67 (emphasis added).

The "SUMMARY OF BENEFITS VS RISKS" section of the FDA's Medical Review stated:

> It is important to point out that in order to determine whether one compound is superior to another, these drugs need to be tested at comparable amounts: H20 [Nexium 20 mg] vs. O 20 [Prilosec 20 mg]; H40 [Nexium 40 mg] vs. O 40 [Prilosec 40 mg]. The sponsor's comparisons of H 40 to O 20 do not yield valid conclusions about the superiority of H [Nexium] over O [Prilosec], although these comparisons are adequate to demonstrate that [Nexium] is active in the assessed indications. ***Therefore the sponsors conclusions that [Nexium] has been shown to provide a significant clinical advance over [Prilosec] in the first-line treatment of patients with acid-related disorders is not supported by data.***

Supp. App. ¶ 68 (emphasis added). The FDA concluded it would not allow Zeneca to claim that Nexium demonstrated any advantage to Prilosec:

> In addition, it is recommended not to allow the sponsor to claim that [Nexium] has any significant clinical advantage over [Prilosec]

> in the first-line treatment of these acid-related disorders because no data in support of such a claim have been submitted.

Supp. App. ¶ 69.

Zeneca launched a massive promotional campaign aimed at doctors, which was intended to and did create the impression that Nexium, the "new purple pill," was an improvement over Prilosec. Zeneca flew its entire sales force of 6,000 to Hawaii, where they spent an intensive training session on how to convince physicians to prescribe Nexium. Supp. App. ¶ 87. Zeneca trained the sales force to push Nexium as more effective than Prilosec even if doctors were resistant to using Nexium or were happy with Prilosec. *Id.* Teleconferences were held whereby the sales force rehearsed, before Zeneca sales executives, the sales pitch to be made to doctors. *Id.*

After those training sessions, Zeneca's sales force flooded doctors' offices with free samples and claims of Nexium's superiority. Supp. App. ¶ 88. A *Wall Street Journal* article reported this campaign, describing how Zeneca sales representatives promoted Nexium to a doctor, Peter Halper, touting Nexium as superior to Prilosec in "healing rates" and safety. *Id.*

Zeneca's 2000 Annual Report articulated Nexium's central marketing theme:

> ***Nexium is the first PPI to offer significant clinical improvements over*** [***Prilosec***] in terms of acid control and clinical efficacy,

> shown in clinical studies involving over 30,000 patients performed across 20 countries. It is expected to establish a ***new, improved treatment standard for the PPI class.***

Supp. App. ¶ 89 (emphasis added).

Zeneca misleadingly promoted Nexium to doctors as the first PPI to offer significant improvements over Prilosec and its main competitors. Supp. App. ¶ 91. The Zeneca sales force also misleadingly told doctors that Nexium offered more effective acid inhibition than all other PPIs. *Id.* Advertisements directed to doctors suggested that Nexium was more powerful than Prilosec, stating that "we've captured the essence of Prilosec and created a new PPI" and "introducing Nexium the powerful new PPI from the makers of Prilosec." Supp. App. ¶¶ 92, 123, 124 ("We captured the ESSENCE of Prilosec® . . . and created a NEW PPI . . . Introducing NEXIUM™ .. . The POWERFUL new PPI from the makers of Prilosec®"). Zeneca made those claims even though the FDA found that Zeneca's clinical trials showed that claims of superiority are "not supported." Supp. App. ¶ 93. In sales pitches to doctors, Zeneca employees also falsely conveyed the message that Nexium was the first PPI to offer improvements over Prilosec and that Nexium was "improved treatment for the PPI class." *Id.* at ¶ 95.

Zeneca built the Nexium campaign around the brand identity already established with Prilosec. Zeneca had long heavily advertised Prilosec as "the purple pill" to relieve heartburn. It then capitalized on that brand identity by marketing Nexium in a way that connected

it to, yet distinguished it from, Prilosec, *e.g.*, as the "new" purple pill, "today's" purple pill, the "healing" purple pill, or by stating that relief is "possible with the purple pill called Nexium." Supp. App. ¶¶ 116, 117. Nexium advertisements targeting physicians and consumers conveyed the false and misleading message that Nexium was a clinical advance over, and a superior drug to Prilosec, which by comparison became ***yesterday's*** purple pill, the ***old*** purple pill.

In 2003, the administrator of the federal Centers for Medicare and Medicaid Services, Tom Scully, told doctors at a convention of the American Medical Association that they should not prescribe Nexium because Prilosec, which had just become available in generic form, cost less and provided the same level of treatment. Supp. App. ¶ 106. Indeed, Mr. Scully scolded doctors, "You should be embarrassed if you prescribed Nexium" because it increased costs without medical benefits. "The fact is, Nexium is Prilosec," Mr. Scully said. "It is the same drug. It is a mirror compound." Aptly describing Zeneca's scheme, Mr. Scully stated that "Nexium is a game that is being played on the people who pay for the drugs making it one of the most successful launches ever of a new medicine." Supp. App. ¶ 106.

Sales of Prilosec plummeted in response to generic competition. Supp. App. ¶ 107. After establishing Nexium's position and capitalizing on brand loyalty, Zeneca raised the price of Nexium while the price of Prilosec dropped. Supp. App. ¶ 108. As of 2005, Nexium sold for more than $4.00 per pill versus $0.67 per pill or less for Prilosec. *Id.* Sales figures reveal the success of

Nexium in replacing Prilosec. Supp. App. ¶ 109. For example, sales of Prilosec in the United States dropped from $3.694 billion in 2001 to $867 million in 2003, while sales of Nexium rose from $580 million in 2001 to $2.477 billion in 2003.

B. Proceedings Below

Plaintiffs allege violations of the Delaware Consumer Fraud Act (6 Del. C. § 2511, *et seq.*) and consumer-protection statutes of 48 states, and assert claims for unjust enrichment and negligent misrepresentation. The district court dismissed the complaint.

The Third Circuit Court of Appeals affirmed the dismissal in a 2-to-1 decision. The majority held that "[b]y 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." 499 F.3d at 253. The majority also stated:

> 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.

Id. at 251-52. The majority held that state-law claims for deceptive marketing are preempted even if the claims are wholly consistent with FDA regulations and findings:

> [T]he 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 consumers fraud law, as explained in part III.

Id. at 252-53.

In dissent, Judge Cowen explained that the majority opinion rests on a ground never raised by Zeneca (*id.* at 254 n.13) and is contrary to well-established Supreme Court principles. Judge Cowen stated:

> 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.

Id. at 253.

The dissent further explained why Plaintiffs' claims would not frustrate any federal policy:

> 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.

Id. at 258 (Cowen, J., dissenting).

Judge Cowen also exposed the flaw in the majority's conclusion that Congress intended to preempt all state law claims for deceptive marketing of prescription drugs:

> 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 *Silk-wood* [v. *Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)], "[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.

Id. at 258-59.

REASONS FOR GRANTING THE PETITION

I. THIS CASE PRESENTS THE IMPORTANT QUESTION OF WHETHER CONGRESS INTENDED 21 U.S.C. § 352(n) TO PREEMPT ALL STATE-LAW CLAIMS FOR UNFAIR AND DECEPTIVE MARKETING OF PRESCRIPTION DRUGS

A. The Majority's Decision that Congress Intended 21 U.S.C. § 352(n) to Preempt All Claims Under State Law for Deceptive Marketing of Prescription Drugs is Directly At Odds With Congress's Explicit Statement that § 352(n) Preempts Only State Laws that are in "Direct and Positive Conflict" with § 352(n)

This petition involves the critically important issue of whether Congress has clearly and manifestly stripped states of their historical power to protect their citizens from unfair and deceptive marketing of prescription drugs. The majority in this case held that by enacting 21 U.S.C. § 352(n), Congress intended to preempt ***all*** state-law claims for false advertising of prescription drugs, even if those claims do not conflict with any regulation of or finding by the FDA. Specifically, the majority held that by "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." 499 F.3d at 253.

The majority's holding overlooks a clear statement of congressional intent to ***preserve*** state regulation of drug advertising. In 1962, Congress enacted the "Drug Amendments of 1962." P.L. 87-781 § 131, 76 Stat. 780 *et seq.* (Oct. 10, 1962). Section 131 of Public Law 87-781 amended § 502 of the FDCA by adding subsection (n), which was codified as 21 U.S.C. § 352(n). *Id.*, 76 Stat. 791-92. Subsection (n) states, in pertinent part, that:

> [N]o 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 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. §§ 52-57).[4]

The majority relied on this provision in holding that Congress intended to strip states of their historical authority to regulate prescription drug advertising. *See* 499 F.3d at 253.

The majority's ruling should be reviewed because it directly conflicts with Congress's clear statement to the contrary. Section 202 of the Drug Amendments of 1962, 76 Stat. 793, states:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic

4. The FDA regulations for prescription drug advertising are set forth in 21 C.F.R. § 202.1.

> Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.

Despite § 202 of the Drug Amendments of 1962, the majority held that 21 U.S.C. § 352(n) preempts Plaintiffs' claims even though Plaintiffs' claims are not in direct and positive conflict with any FDA regulation or any FDA finding. The majority held that § 352(n) preempts Plaintiffs' claim even though the Court also stated: "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." 499 F.3d at 246.

Given the clear statement of Congress that state law claims are preempted only if they are in "direct and positive conflict" with § 352(n), there is no need to consult the legislative history for the Drug Amendments Act of 1962. Nonetheless, the legislative history of P.L. 87-781 shows that the majority's holding that Congress intended § 352(n) to preempt all state-law claims for false advertising of prescription drugs is misguided. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 n.26 (2005) ("the lengthy legislative history is barren of any indication that Congress meant to abrogate most of the common-law duties long owed by pesticide manufacturers"). For example, the Senate Report focused on widespread deceptive marketing of prescription drugs and does not suggest that all state-law claims for false advertising are preempted.

See S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2904 ("Eminent medical authorities testified that much of the drug advertising is misleading and some is false. They further emphasized that when a doctor is misled his patient's health is endangered.").

In addition, the floor debate in the House supports the conclusion that Congress did not intend to preempt all state-law claims for false advertising. Congressman Smith of California stated that "if we are going to pass this law, someone ought to offer an amendment to make certain that the passage of this bill, which gives all of this power to the Department of Health, Education, and Welfare and the Food and Drug Administration, will not preempt any State laws." 108 Cong. Rec. 21046 (1962). Shortly thereafter, Congressman Harris of Arkansas, the primary House sponsor of the bill, stated that "there is nothing in this bill that in any way preempts the authority and prerogatives of the States." *Id.* at 21047. Congressman Schenck of Ohio agreed, stating that "[m]any very helpful State laws are in effect; many such laws in some instances are even stronger than Federal laws for the protection of human health in the public interest." *Id.* at 21056.

In light of the clear language of congressional intent ***not*** to strip states of their authority to protect their citizens from deceptive prescription drug advertising and the lack of any indication in the legislative history to the contrary, this Court should review the majority's erroneous interpretation of 21 U.S.C. § 352(n) in this case.

Finally, the majority's interpretation of § 352(n) should be reviewed for an additional reason. The majority held that § 352(n) preempts oral misrepresentations to doctors even though § 352(n) addresses only written matter. By its terms, § 352(n) applies only to "advertisements and ***other descriptive printed matter*** issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug. . . ." (Emphasis added.) Thus, § 352(n) cannot preempt state-law claims for oral misrepresentations to physicians, because it does not cover such claims.

B. The Majority's Holding that FDA Regulation of Prescription Drug Advertising Preempts All State Claims Conflicts With Decisions by this Court

The majority's conclusion that Plaintiffs' claims are preempted because of the nature of the regulations adopted by the FDA, 499 F.3d at 251-52, conflicts with this Court's preemption decisions. For instance, in *Bates*, this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* (2000 ed. and Supp. II) did not preempt the plaintiffs' state-law claims for damages. This Court looked only to the language of 7 U.S.C.S. § 136v(b) to determine whether the plaintiffs' claims were preempted. This Court stated: "Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed, even if its alternative were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors pre-emption." 544 U.S. at 449. This Court further explained that the "long history of tort litigation against manufacturers of poisonous

substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.*[5]

Under the analysis set out in *Bates*, preemption cannot be found in this case based solely on the extent of the FDA regulations, because Congress established that state laws must be in "direct and positive conflict" with § 352(n) in order to be preempted. Thus, the only pre-emption issue in this case is whether Plaintiffs' claims directly and positively conflict with § 352(n). Nonetheless, the Third Circuit held that Plaintiffs' claims were barred by the doctrine of implied conflict preemption as a result of the FDA regulations concerning prescription drug advertising. This Court should review that ruling.

The majority's holding that FDA regulation of prescription drug advertising preempts Plaintiffs' claims is at odds with other decisions by this Court. In *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707 (1985), this Court stated:

> To infer pre-emption whenever an agency deals with a problem comprehensively is

5. Moreover, this Court held in *Bates* that FIFRA does not preempt state-law claims for sales agents' oral misrepresentations. 544 U.S. at 445 n.17 ("Because FIFRA defines labeling as 'all labels and all other written, printed, or graphic matter' that accompany a pesticide, § 136(p)(2), any requirement that applied to a sales agent's oral representations would not be a requirement for 'labeling or packaging.'").

> virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence. *See Jones v. Rath Packing Co.*, 430 U.S., at 525. [¶] Moreover, because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive.

Id. at 717-18. Here, the FDA has not taken the position that its regulations preempt all state-law claims for deceptive advertising of prescription drugs. *See In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500, at *71 (N.D. Cal. Aug. 18, 2006) ("The FDA has been silent with respect to the preemption of lawsuits challenging false claims in prescription drug advertisements. This silence suggests that the FDA does not intend its review of promotional materials to preempt false advertising claims."). *See also Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 888 (8th Cir. 2005) ("In light of the dearth of evidence about the EPA's intent, we cannot conclude that it was the 'clear and manifest purpose of [the EPA]' to prohibit states from requiring that pesticides used exclusively on hopper box seeds be colored or discolored"); *Ford Motor Co. v. Ins. Comm'r of Penn.*, 874 F.2d 926, 939 (3d Cir. 1989) ("precisely

because the regulatory scheme at issue in these cases is so detailed, we interpret the absence of clear preemptive language as indicative that Congress did not intend to displace state law entirely.").

Further, the authority cited by the majority does not support its holding that the FDA regulation of prescription drug advertising preempts Plaintiffs' claims. The majority relies on *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 369 (1986), in which this Court stated that "a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation. *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984)." *See* 499 F.3d at 249. Neither *Louisiana* nor either of the two cases cited therein stands for the proposition that federal regulations preempt state-law claims that are consistent with the regulations. In *Louisiana*, this Court held that § 220 of the Communications Act of 1934 "does not operate to pre-empt state depreciation regulation for intrastate ratemaking purposes." 476 U.S. at 378 (footnote omitted). In *Fidelity*, this Court held that the Federal Home Loan Bank Board's "due-on-sale regulation was meant to pre-empt ***conflicting*** state limitations on the due-on-sale practices of federal savings and loans." 458 U.S. at 159 (emphasis added). Finally, in *Capital Cities*, this Court held that states could not prohibit cable operators from carrying alcoholic beverage commercials, because the FCC had taken the formal position that the "subject areas this agency has preempted include, of course, signal carriage, pay cable, leased channel regulations, technical standards, access, and several aspects of franchisee responsibility." 467 U.S.

at 703 n.8. In contrast, the FDA has not taken the position that its regulations of prescription drug advertising preempt all state-law claims for false advertising of such drugs.

The majority also relies on *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), but *Geier* undermines the majority's holding. In *Geier*, the plaintiffs sought to compel the defendants to install airbags, even though federal regulations permitted the defendants to install "other passive restraint systems, such as automatic belts or passive interiors." *Id.* at 881. This Court held that the plaintiffs' claim "would have presented an obstacle to the variety and mix of devices that the federal regulation sought." *Id.* In contrast to *Geier*, Plaintiffs do not claim that Zeneca should be required to take steps that would frustrate the FDCA's purposes. To the contrary, this case concerns Zeneca's deceptive touting of Nexium as superior to Prilosec – an assertion that the FDA found lacking in support. Thus, Plaintiffs' claims do not stand as an obstacle to the enforcement of FDA regulations.

Further, the majority's reliance on § 337 of the FDCA, 499 F.3d at 252, is contrary to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), in which this Court held that fraud-on-the-FDA claims under state law are preempted. This Court explained that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such as to warrant a presumption against finding federal preemption of a state-law cause of action." *Id.* at 347. This Court then held that "the plaintiffs' state-law fraud-on-

the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law." *Id.* at 348. As this Court explained, "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case." *Id.* at 353.

Judge Cowen's dissent below explains why *Buckman* does not support the majority's opinion:

> 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.

499 F.3d at 257. As Judge Cowen recognized, Plaintiffs do not claim that Zeneca should take steps that would frustrate the FDCA's purposes or FDA regulation. To the contrary, this case concerns Zeneca's deceptive marketing of Nexium as superior to Prilosec. Plaintiffs' claims are fully consistent with the FDA's explicit findings that Zeneca's clinical studies do not support a claim that Nexium is superior to Prilosec. Thus,

Plaintiffs' claims do not stand as an obstacle to the FDA's enforcement of its regulations.

In short, this case presents the important question of whether the majority misapplied established preemption doctrine in holding that Congress intended to preempt all state regulation of prescription drug advertising.

II. THE MAJORITY'S HOLDING THAT 21 U.S.C. § 352(n) AND THE REGULATIONS PROMULGATED THEREUNDER PREEMPT ALL STATE-LAW CLAIMS FOR UNFAIR AND DECEPTIVE MARKETING OF PRESCRIPTION DRUGS IS IN CONFLICT WITH DECISIONS BY STATE COURTS OF LAST RESORT AND BY FEDERAL COURTS OF APPEALS

The majority's holding is in conflict with decisions by federal courts of appeals and state courts of last resort. First, the majority's construction of § 352(n) is at odds with that of two state courts of last resort. In *Levine v. Wyeth*, 2006 Vt. 107 (2006), the Vermont Supreme Court affirmed a judgment for the plaintiff, who was injured as a result of being injected with the prescription drug Phenergan.[6] The Court rejected the defendant's argument that the "claims conflict with defendant's obligations under federal law regulating

6. A petition for a writ of certiorari is pending in this Court in *Wyeth v. Levine*. *See* 127 S. Ct. 2451 (May 21, 2007) ("The Soli-citor General is invited to file a brief in this case expressing the views of the United States.").

prescription drug labels." *Id.* at ¶ 1. In particular, the Court stated:

> Congress has expressed its purposes clearly, not only in the general sense that the statute was intended to "protect the public, "but also more specifically, with respect to the FDCA's preemptive effect. In the 1962 amendments to the FDCA, Congress included a clause expressly limiting the preemptive effect of the statute: "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law ... unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).
>
> This amendment essentially removes from our consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress. Congress intended that the FDCA would leave state law in place except where it created a "direct and positive conflict" between state and federal law. Drug Amendments § 202. This language "simply restates the principle that state law is superseded in cases of an actual conflict with federal law such that 'compliance with both federal and state regulations is a physical impossibility.'" *See S. Blasting Servs., Inc. v.*

> *Wilkes County*, 288 F.3d 584, 591 (4th Cir. 2002) (interpreting "direct and positive conflict" language in the preemption clause of a federal statute governing explosive materials to allow states to "impose more stringent requirements than those contained in the federal regulations") (quoting *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985)). In other words, under any circumstances where it is possible to comply with both state law and the FDCA, the state law in question is consistent with the purposes and objectives of Congress. Thus, our discussion above regarding defendant's impossibility argument, *supra* 21-23, provides a complete answer to the question of pre-emption.

Id. at ¶¶ 26-27 (footnote omitted).

The majority's interpretation of § 352(n) also is in conflict with the New Jersey Supreme Court's decision in *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1, 734 A.2d 1245 (1999). In *Perez*, the Court held that the learned intermediary doctrine "does not confer on pharmaceutical manufacturers a license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to such consumers." *Id.* at 32, 734 A.2d at 1264. The Court noted that the "FDA is authorized to regulate advertisements for prescription drugs pursuant to 21 U.S.C.A. Section 352(n) of the Food, Drug and Cosmetic Act." *Id.* at 22, 734 A.2d at 1258. The Court did not hold that § 352(n)

preempted the plaintiffs' state-law claims but rather explained that "FDA regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers with respect to direct-to-consumer advertising." *Id.* at 24, 734 A.2d at 1259. The Court then held that a "rebuttable presumption [of legality] should apply when a manufacturer complies with FDA advertising, labeling and warning requirements." *Id.*

Thus, the holding by the New Jersey Supreme Court in *Perez* is in conflict with the holding by the majority in this case. Plaintiffs in this case allege that the FDA found that Zeneca's studies do not support the assertion that Nexium is superior to Prilosec. Nonetheless, Zeneca advertised and otherwise marketed Nexium as superior to Prilosec. Under *Perez*, the rebuttable presumption of lawful behavior would not apply, because Zeneca did not comply with FDA requirements. Indeed, the Third Circuit stated that "[t]o 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." 499 F.3d at 246. Nonetheless, the Third Circuit held that § 352(n) pre-empted Plaintiffs' claims. Thus, Plaintiffs' claims could be brought in New Jersey state court but not in the United States District Court for New Jersey.

Moreover, in the forty-five years since enactment of § 352(n), no court other than the majority in this case has held by enacting § 352(n), Congress intended to preempt all state-law claims for deceptive marketing of prescription drugs. Federal and state courts have long

permitted state-law claims for deceptive marketing of prescription drugs. *See, e.g., Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 350 (2d Cir. 2003) (reversing dismissal of action under state law for false advertising of prescription drug Rezulin, because "courts have long recognized the right of [plaintiffs] to recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices"). Thus, courts have routinely permitted claims under state law for false advertising of prescription drugs.[7]

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7. *See In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 523 (3d Cir. 2004) (approving settlement of a case for violation of the Sherman Act and the Delaware Consumer Fraud Act, in which "DuPont allegedly issued a variety of false and misleading communications to convince health care professionals, government agencies, and the public that Coumadin was safer and more effective than Barr's generic warfarin sodium product"); *Hill v. Searles Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (reversing summary judgment for pharmaceutical company in product liability case, in part because "IUD manufacturers, through mass advertising and merchandising practices, generated a general sense of product quality, making it difficult for con-sumers to fully understand the risks involved with the use of an IUD"); *Mirkin v. Wasserman*, 5 Cal. 4th 1082, 1112-13 (1993) ("Courts in California and other states have applied the principle of indirect reliance to the situation in which a manufacturer of a prescription drug or medical device has misrepresented its product's safety and effectiveness to the medical profession."). *Cf. Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) (rejecting defendant's argument that "plaintiffs may not bring Lanham Act false advertising claims involving FDCA or FDA regulations because there is no private right of action to enforce these provisions, Congress did not intend for the Lanham Act to be a vehicle for enforcing the provisions indirectly, and the area is within the expertise of the FDA").

The majority's decision in this case is also at odds with numerous decisions in which courts have held that the phrase "direct and positive conflict" demonstrates that Congress intended ***not*** to preempt state-law claims. For example, the "Firearms" chapter of the criminal code contains 18 U.S.C. § 927, which states:

> No provision of this chapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision operates to the exclusion of the law of any State on the same subject matter, unless there is a direct and positive conflict between such provision and the law of the State so that the two cannot be reconciled or consistently stand together.

In *Thrall v. Wolfe*, 503 F.2d 313, 317 (7th Cir. 1974), the Seventh Circuit explained that § 927 "was doubtless inserted for the purpose of avoiding a claim of preemption." The highest courts of three states agree. *See City of Gary v. Smith & Wesson Corp.*, 801 N.E.2d 1222, 1237 (Ind. 2003) ("But federal legislation has expressly denied any intent to preempt state laws regulating guns. 18 U.S.C. 927 (2000)."); *State v. Hernandez-Mercado*, 124 Wn.2d 368, 879 P.2d 283 (1994) (citing 18 U.S.C. § 927 in holding that "RCW 9.41.170 does not directly conflict with, nor is it inconsistent with, the federal provision prohibiting possession of a firearm by non-citizens (aliens) who are 'illegally or unlawfully in the United States'. RCW 9.41.170 is thus not pre-empted by federal firearms laws."); *Carfield v. State*, 649 P.2d 865, 873 (Wyo. 1982) (quoting 18 U.S.C. § 927 in rejecting argument that federal law preempted state law

banning certain felons from possessing a firearm and explaining that "comparison of the Wyoming statute with the federal laws demonstrates no conflict. Indeed the statutes are complementary in their application and can be easily reconciled. Since the clear intention of Congress was not to preempt this field, but rather to supplement existing state law in the area, and because of the difference in the statutory elements, we find no merit in this contention of the appellant.").

A similar preemption provision is contained in the federal law governing explosive materials, which is codified at 18 U.S.C. §§ 841-848 (2000). Section 848, entitled "Effect on State law," provides:

> No provision of this chapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision operates to the exclusion of the law of any State on the same subject matter, unless there is a direct and positive conflict between such provision and the law of the State so that the two cannot be reconciled or consistently stand together.

In *S. Blasting Servs., Inc. v. Wilkes County*, 288 F.3d 584 (4th Cir. 2002), the Fourth Circuit rejected the plaintiffs' argument that federal law preempts ordinances regulating the use of explosives. After quoting § 848, the court stated:

> This statutory language makes clear that Congress did not intend to occupy the field of licensing and regulating explosives operations.

> In preemption analysis, "the purpose of Congress is the ultimate touchstone." *Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103, 11 L. Ed. 2d 179, 84 S. Ct. 219 (1963). Here Congress has stated in the clearest of terms that it was not preempting local efforts to regulate the explosives industry, absent a direct and positive conflict with the federal standards. In fact, as the district court recognized, "§ 848 is designed to limit the preemptive scope" of the federal law and expressly "disclaims any intent to occupy the field." *S. Blasting*, 162 F. Supp. 2d at 462.

Id. at 590. Thus, the majority decision in this case is at odds with the holdings of numerous other courts.

CONCLUSION

Petitioners' petition for a writ of certiorari should be granted.

Respectfully submitted,

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