NO. 09 - 1501

IN THE

Supreme Court of the United States

ACTAVIS, INC.,

Petitioner,

v.

JULIE DEMAHY,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

RICHARD A. TONRY, II
RAYMOND BRINSON
BRIAN L. GLORIOSO
KRISTINE K. SIMS
TONRY, BRINSON & GLORIOSO, L.L.C.
245 Pontchartrain Drive
Slidell, LA 70458
(985) 643-7007

LOUIS M. BOGRAD*
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th Street, N.W.
Suite 520
Washington, DC 20001
(202) 944-2803
lou.bograd@cclfirm.com

Counsel for Respondent

*Counsel of Record

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QUESTION PRESENTED

Are the states preempted under the Supremacy Clause of the Constitution from requiring additional safety information on a generic product label where the brand has not changed its label?

TABLE OF CONTENTS

QUESTION PRESENTED i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iv

RESPONDENT'S BRIEF IN OPPOSITION 1

COUNTERSTATEMENT OF THE CASE 2

FEDERAL REGULATION OF GENERIC DRUGS 4

REASONS FOR DENYING THE PETITION 7

I. THE PETITION IMPROPERLY SEEKS AN ADVISORY OPINION FROM THIS COURT 7

II. THERE IS NO CONFLICT AMONG THE UNITED STATES COURTS OF APPEALS AND/OR STATE COURTS OF LAST RESORT 9

III. THE LOWER COURTS ARE NOT CONFUSED ABOUT THE APPLICATION OF *WYETH V. LEVINE* TO CLAIMS AGAINST GENERIC DRUG COMPANIES 11

IV. PETITIONER SEEKS SPECIAL PROTECTION FROM TORT LIABILITY THAT IS NOT AVAILABLE TO OTHER MANUFACTURERS AND THAT FINDS NO SUPPORT IN THE HATCH-WAXMAN AMENDMENTS 13

CONCLUSION 16

TABLE OF APPENDICES

APPENDIX A: 21 U.S.C. § 352(f)(2) (2010) 1a

APPENDIX B: 21 C.F.R. § 201.57(e) (2005)
- excerpt 2a

APPENDIX C: 21 C.F.R. § 314.70(b) (2005)
- excerpt 3a

APPENDIX D: 21 C.F.R. § 314.70(c)(6)(iii) (2005)
..... 5a

TABLE OF AUTHORITIES

Cases

Bartlett v. Mutual Pharmaceutical Co., 659 F. Supp. 2d 279 (D.N.H. 2009) 12

Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005).....13

Couick v. Wyeth, Inc., No. 3:09-CV-210-RJC-DSC, 2009 WL 4644394 (W.D.N.C. Dec. 7, 2009).....12

Dorsett v. Sandoz, Inc., No. CV06-7821, 2010 WL 1174204 (C.D. Cal. Mar. 26, 2010).....11

Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994) 10, 11

Fulgenzi v. Wyeth, Inc., No. 5:09CV1767, 2010 WL 649349 (N.D. Ohio Feb. 19, 2010).....12

Gaeta v. Perrigo Pharmaceuticals Co., No. 09-15001 (9th Cir. filed Jan. 6, 2009) 9

Herb v. Pitcairn, 324 U.S. 117, 126 (1945).....8

In re Budeprion XL Marketing & Sales Litigation, No. 09-md-2107, 2010 WL 2135625 (E.D. Pa. May 26, 2010.....12

Kellogg v. Wyeth, 612 F. Supp. 2d 437 (D. Vt. 2009).....12

Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009), *petitions for cert. filed*, 78 U.S.L.W. 3522 (Feb. 19, 2010) (No. 09-

993), 78 U.S.L.W. 3523 (Feb. 25, 2010) (No. 09-1039)....10, 11, 14, 15

Morris v. Wyeth, Inc., No. 09-5460 (6th Cir. filed Apr. 27, 2009) 9

Munroe v. Barr Laboratories, 670 F. Supp. 2d 1299 (N.D. Fla. 2009) 12

Pustejovsky v. Wyeth, No. 4:07-CV-103-Y, 2009 WL 3336032 (N.D. Tex. Sept. 4, 2009)....12

Schrock v. Wyeth, 601 F. Supp. 2d 1262 (W.D. Okla. 2009)....12

Smith v. Wyeth, Inc., No. 09-5460 (6th Cir. filed Apr. 16, 2009) 9

Stacel v. Teva Pharmaceuticals, USA, 620 F. Supp. 2d 899 (N.D. Ill. 2009)....12

Swicegood v. Pliva, Inc., No. 1:07-cv-1671, 2010 WL 1138455 (N.D. Ga. Mar. 22, 2010)....12

Thomas v. Winchester, 6 N.Y. 397 (1852)....14

Vitatoe v. Mylan Pharmaceuticals, Inc., No. 1:08cv85, 2010 WL 1008788 (N.D. W. Va. Mar. 5, 2010) 12

Weilbrenner v. Teva Pharmaceuticals USA, Inc., No. 7:08-CV-23, 2010 WL 924915 (M.D. Ga. Mar. 10, 2010)....12

Wilson v. Pliva, Inc., No. 09-5466 (6th Cir. filed Apr. 20, 2009) 9

Wyeth v. Levine, --- U.S. ----, 129 S. Ct. 1187 (2009)..... *passim*

Statutes

21 U.S.C. § 352(f)(2) (2010)..... 4, 7

28 U.S.C. § 1292(b) (2010)..... 3

Pub. L. No. 110-85, 121 Stat. 823 (2007)..... 2

Regulations

21 C.F.R. § 201.57(c)(6)(i) (2010)..... 5, 7

21 C.F.R. § 201.57(e) (2005)..... 4, 5

21 C.F.R. § 201.80(e) (2010)..... 5, 7, 14

21 C.F.R. § 314.70 (2005)..... 6

21 C.F.R. § 314.70(b) (2005)..... 6

21 C.F.R. § 314.70(c) (2005)..... 6

21 C.F.R. § 314.80 (2010)..... 5

21 C.F.R. § 314.97 (2008)..... 6

21 C.F.R. § 314.98 (2010)..... 5

44 Fed. Reg. 37,434 (June 26, 1979)..... 7

57 Fed. Reg. 17,950 (Apr. 28, 1992)..... 5

71 Fed. Reg. 3,922 (Jan. 24, 2006)..... 4, 5

Other Authorities

Buehler, Gary, Center for Drug Evaluation and Research, FDA, Letter to ANDA holders for metoclopramide (Feb. 26, 2009) 6

Department of Health and Human Services, Food and Drug Administration, *Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use*, Form FDA 356h (Oct. 2005) 5

Korvick, Joyce, Center for Drug Evaluation and Research, FDA, Letter to NDA holders for Reglan (Feb. 26, 2009) 6

Lesser, Karen E., *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J.A.M.A. 2215 (May 1, 2002) 7

Okie, Susan, *Multinational Medicines—Ensuring Drug Quality in an Era of Global Manufacturing*, 361 New Eng. J. Med. 737 (2009) 13

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RESPONDENT'S BRIEF IN OPPOSITION

Respondent Julie Demahy respectfully requests that this Court deny the petition for review of the decision of the United States Court of Appeals for the Fifth Circuit, which held that Ms. Demahy's state products liability claims against the manufacturer of the generic drug that injured her are not impliedly preempted by the Food, Drug and Cosmetic Act (FDCA), or the Hatch-Waxman Amendments thereto.

The petition for certiorari improperly seeks an advisory opinion from this Court. The court of appeals identified three bases for denying preemption, yet Petitioner has sought review of only one. Thus, even if this Court were to agree with Petitioner, the outcome of the case would not change.

Moreover, the decision below does not conflict with any decision of any federal court of appeals or state court of last resort, and it is consistent with relevant decisions of this Court. In fact, the decision below is a straightforward application of the reasoning in this Court's decision last term in *Wyeth v. Levine*, --- U.S. ----, 129 S. Ct. 1187 (2009), to a state failure-to-warn suit brought against manufacturers of a generic drug. Every court to take up the question since the *Levine* decision has concluded that state failure-to-warn claims against generic drug companies are not preempted.

Petitioner seeks a special immunity from liability for generic drug companies, an immunity that is not available to name-brand drug companies or other manufacturers. Given that more than seventy percent of all prescriptions are now filled

with generic drugs, preemption of state tort claims against such companies would leave most persons injured by inadequately labeled drugs, including Ms. Demahy, remediless. Congress's silence regarding preemption of these cases is "powerful evidence that Congress did not intend" such a draconian result. *Id.* at 1200.

COUNTERSTATEMENT OF THE CASE

Julie Demahy developed tardive dyskinesia, a severe and irreversible neurological disorder, as a result of her long-term use of the prescription drug metoclopramide, which was prescribed to treat her gastroesophageal reflux. At the time,[1] the metoclopramide label indicated that the risk of any "extrapyramidal symptom" from metoclopramide use, including tardive dyskinesia, was "approximately 1 in 500 patients." In fact, the actual incidence of tardive dyskinesia in patients using metoclopramide long-term was many times higher, perhaps as high as 1 in 5 patients.

Despite mounting evidence that the risks of tardive dyskinesia were much greater than reflected in the product label, no manufacturer of metoclopramide ever proposed to the Food and Drug Administration (FDA) that the warnings on the metoclopramide label should be changed to reflect that greater risk. In February 2009, too late for Ms. Demahy, the FDA—acting on its own initiative pursuant to powers granted to the agency in the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (FDAAA)—ordered manufacturers of metoclopramide

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[1] Ms. Demahy took metoclopramide from October 2002 through April 2007. Pet. App. 96a-97a.

to add a "Boxed Warning" to their labels. That warning states, in relevant part: "Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia."

Ms. Demahy sued Petitioner Actavis, Inc. (Actavis), the manufacturer of the generic metoclopramide she had used, for failure to adequately warn her of the risks of long-term metoclopramide use.[2] Actavis moved to dismiss Ms. Demahy's claims on the ground of implied conflict preemption. The district court, ruling before *Wyeth v. Levine* was decided, denied Actavis's motion, but certified the issue for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) (2010).

The Fifth Circuit, following *Levine,* unanimously affirmed, ruling that Congress had not intended to preempt such state tort claims against generic drug companies. The court of appeals concluded that the plaintiff's failure-to-warn claims were not preempted because the generic-drug-company defendant could have sought to strengthen its warnings through either the "Changes Being Effected" (CBE) process or the prior approval process or by sending warnings directly to health care providers. Pet. App. 23a-35a. The court rejected the argument that the responsibility for strengthening label warnings rested solely on the name-brand drug company:

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[2] She also sued the manufacturers of the name-brand version of metoclopramide, Reglan, but voluntarily dismissed those defendants after establishing that Ms. Demahy had not taken the name-brand drug. Pet. App. 3a n.4.

> The federal interest is in maintaining safe and effective labeling that is consistent across name brand and generic bioequivalent versions of the same drug. *Who* prompts the FDA to consider necessary changes to that shared label is immaterial.

Id. at 36a (emphasis in original).

Federal Regulation of Generic Drugs

As this Court recognized in *Levine*, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate." 129 S. Ct. at 1197-98.

This principle applies with equal force to both name-brand and generic drug companies. All drug companies are under a statutory obligation to maintain adequate warnings on their labels. 21 U.S.C. § 352(f)(2) (2010) (Opp'n App. 1a) ("A drug . . . shall be deemed to be misbranded . . . unless its labeling bears . . . such adequate warnings against use . . . where its use may be dangerous . . . as are necessary for the protection of users"). Both name-brand and generic drug manufacturers have an obligation to revise their labels "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.57(e) (2005) (Opp'n App. 2a).[3] As the FDA has

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[3] In 2006, the FDA issued amended labeling regulations for prescription drugs. 71 Fed. Reg. 3,922 (Jan. 24, 2006). That

specifically instructed manufacturers of generic drugs, "[a]fter approval of an [Abbreviated New Drug Application], if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised". 57 Fed. Reg. 17,950, 17,961 cmt. 40 (Apr. 28, 1992).[4]

As this Court recognized in *Levine*, a new warning may be justified by adverse drug experience reports, 129 S. Ct. at 1197, which all drug manufacturers are required to collect and report to the FDA. 21 C.F.R. §§ 314.80 (NDA holders) & 314.98 (2010) (ANDA holders). Reports in the medical literature can also provide evidence to support a labeling change; indeed, the FDA letters

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rulemaking, which became effective on June 30, 2006, redesignated § 201.57(e) as 21 C.F.R. § 201.80(e) (2010) and it remains the regulatory standard for drugs labeled under the old labeling rules, such as metoclopramide. 71 Fed. Reg. at 3,988, 3,996. A virtually identical requirement applies to drugs labeled under the new regulation. 21 C.F.R. § 201.57(c)(6)(i) (2010) ("In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established."). 71 Fed. Reg. at 3,990.

[4] Every time a generic drug company submits an ANDA application, amendment, or supplement, it must certify to the FDA that it will, *inter alia*, "update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling." Department of Health and Human Services, Food and Drug Administration, *Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use*, Form FDA 356h (Oct. 2005), *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM082348.pdf.

ordering manufacturers of metoclopramide to add a boxed warning justified the change by referencing published studies. *See* Letter from Joyce Korvick, Center for Drug Evaluation and Research (CDER), FDA, to NDA holders for Reglan 1 & nn.1-3 (Feb. 26, 2009) *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM111376.pdf; Letter from Gary Buehler, CDER, FDA, to ANDA holders for metoclopramide 1-2 & nn.1-3 (Feb. 26, 2009), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM111378.pdf. A manufacturer's own clinical trials can also provide evidence to support labeling changes, but such studies "are in no way prerequisites to those changes." Pet. App. 41a.

There are two formal procedures by which both brand-name and generic drug companies may seek to revise their labels: (1) a Prior Approval Supplement, required for "Major Changes," 21 C.F.R. § 314.70(b) (2005) (Opp'n App. 3a), or (2) a Changes Being Effected (CBE) Supplement for "Moderate Changes," 21 C.F.R. § 314.70(c) (2005) (Opp'n App. 5a), under which a manufacturer may proceed with the change upon notification to the agency, but which the FDA may later disapprove. Labeling changes to "add or strengthen a contra-indication, warning, precaution, or adverse reaction," may be made through the CBE process. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2005).[5] Notably, 21 C.F.R. § 314.97 (2010) instructs generic drug companies to follow the procedures of § 314.70 "regarding the

[5] The petition appendix includes portions of the current version of § 314.70, rather than the version in effect during the time at issue in this litigation.

submission of supplemental applications and other changes to an approved abbreviated application."

In addition to revising a product label, a drug company may provide new warnings to health care professionals by other means, such as a "Dear Doctor" letter. 44 Fed. Reg. 37,434, 37,447 (June 26, 1979).

Thus, drug labels are not fixed as of the date of FDA approval. Nor should they be: Name-brand drugs receive initial approval based upon very limited clinical trials and there is a substantial likelihood that new risks, complications, and contraindications will only be identified or confirmed after the drug—and its generic equivalents—have been prescribed more widely. *See* Karen E. Lesser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J.A.M.A. 2215, 2218 (May 1, 2002) ("Only half of newly discovered serious ADRs are detected and documented in the Physicians' Desk Reference within 7 years after drug approval."). For this reason, FDA regulations reasonably require each drug company to provide physicians and patients with up-to-date warnings and precautions as long as the product is being marketed and prescribed to patients. 21 U.S.C. § 352(f)(2); 21 C.F.R. §§ 201.57(c)(6)(i), 201.80(e).

REASONS FOR DENYING THE PETITION

I. THE PETITION IMPROPERLY SEEKS AN ADVISORY OPINION FROM THIS COURT

This Court has repeatedly instructed litigants that it has no warrant to issue advisory opinions.

See, e.g., Herb v. Pitcairn, 324 U.S. 117, 126 (1945) ("We are not permitted to render an advisory opinion, and if the same judgment would be rendered by the state court after we corrected its views of federal laws, our review could amount to nothing more than an advisory opinion."). Here, even if this Court were to resolve the Question Presented favorably to Petitioner, the lower court's determination that Petitioner had other available means, consistent with FDA regulations, to advise health-care providers of dangers from its drug would remain unchanged and thus Ms. Demahy's claims still would not be preempted. Because the same judgment would stand, what Petitioner seeks would "amount to nothing more than an advisory opinion."

The court of appeals concluded that there were at least three separate routes Petitioner could have taken to warn health care providers of the heightened risk of tardive dyskinesia from prolonged metoclopramide use: the "Changes Being Effected" process, the Prior Approval process, or warnings sent directly to health care providers. Pet. App. 23a-35a. As the court recognized: "A finding of preemption would require that all be foreclosed to generic manufacturers." Pet. App. 23a.

Petitioner, however, has expressly limited its petition to a challenge to the court of appeals' determination that a generic drug company can invoke the CBE process. Pet. 8 n.4 (The issue whether a generic drug company "could have proposed a labeling change to the FDA . . . is raised in the *Mensing* petitions, but Petitioner has limited this petition to the issue of preemption of a state requirement that the generic change its label where the brand has not."). As the Fifth Circuit opinion

notes: "Even assuming that the CBE regulation cannot be used by an ANDA holder to amend its label without FDA pre-approval, *Levine*'s principles still apply with full force, and we agree with Demahy that generic drug manufacturers may use two other means of complying with both federal and state law . . . ." Pet. App. 36a-37a.

Because the answer to the question presented would not affect the outcome of the case, the petition seeks nothing more than an advisory opinion and should be denied.

II. THERE IS NO CONFLICT AMONG THE UNITED STATES COURTS OF APPEALS AND/OR STATE COURTS OF LAST RESORT

Review is also unwarranted because there is no conflict among the lower courts with regard to whether federal law preempts failure-to-warn claims involving generic drugs. To date, three federal courts of appeals—the Fourth, Fifth, and Eighth Circuits—have addressed the issue of generic drug companies' potential liability for failure to warn of the risks posed by their products; each has concluded, without dissent, that the federal regulatory scheme permits generic drug companies to strengthen label warnings and that such companies may be held liable under state law for inadequate warnings.[6]

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[6] As Petitioner notes, the issue of preemption of state claims against generic drug manufacturers is pending before both the Sixth and Ninth Circuits. *Morris v. Wyeth, Inc.*, No. 09-5460 (6th Cir. filed Apr. 27, 2009); *Smith v. Wyeth, Inc.*, No. 09-5460 (6th Cir. filed Apr. 16, 2009); *Wilson v. Pliva, Inc.*, No. 09-5466 (6th Cir. filed Apr. 20, 2009); *Gaeta v. Perrigo Pharm. Co.*, No. 09-15001 (9th Cir. filed Jan. 6, 2009). To Respondent's

Shortly before the decision below, the Eighth Circuit became the first court of appeals to apply *Levine* to state tort claims against generic drug companies and deny their preemption defense. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *petitions for cert. filed* 78 U.S.L.W. 3522 (Feb. 19, 2010) (No. 09-993), 78 U.S.L.W. 3523 (Feb. 25, 2010) (No. 09-1039. The Eighth Circuit rejected the argument that generic drug companies are powerless to initiate stronger warnings about the drugs they sell: "Far from prohibiting them from taking steps to warn their customers of new safety hazards, federal law requires such action." *Id.* at 614. The *Mensing* court added, "Congress could have crafted a preemption provision for generic drugs in its 1984 amendments, having done so for medical devices less than 10 years earlier. It chose not to do that." *Id.* at 607.

Even before *Levine*, the Fourth Circuit reached a similar conclusion regarding a generic drug company's potential liability for inadequate warnings. In *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), that court opined:

> When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed. . . . The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent

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knowledge, no case raising the issue has reached the highest court of any state.

> to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.

Id. at 169-70.

Every court of appeals to address this question has reached the same conclusion. The absence of conflict in the lower courts strongly supports denial of the petition for certiorari.

III. THE LOWER COURTS ARE NOT CONFUSED ABOUT THE APPLICATION OF *WYETH V. LEVINE* TO CLAIMS AGAINST GENERIC DRUG COMPANIES

As the foregoing discussion demonstrates, the Fifth and Eighth Circuits have had no problem applying the lessons of *Levine* to preemption defenses asserted by generic drug companies: both courts recognized that that decision carried "important implications" for generic drug companies as well. Pet. App. 10a. They are not alone in finding the application of preemption doctrine clear in this context. More than a dozen courts have taken up the issue of preemption of state-law tort claims against generic drug manufacturers since *Wyeth v. Levine* was decided. Every one of them has concluded that the plaintiffs' claims are not preempted. *See, e.g., Demahy*, Pet. App. 1a; *Mensing v. Wyeth*, 588 F.3d 603; *Dorsett v. Sandoz, Inc.*, No. CV06-7821, 2010 WL 1174204 (C.D. Cal. Mar. 26, 2010); *Swicegood v.*

Pliva, Inc., No. 1:07-cv-1671, 2010 WL 1138455 (N.D. Ga. Mar. 22, 2010); *Weilbrenner v. Teva Pharm. USA, Inc.*, No. 7:08-CV-23, 2010 WL 924915 (M.D. Ga. Mar. 10, 2010); *Vitatoe v. Mylan Pharm., Inc.*, No. 1:08cv85, 2010 WL 1008788 (N.D. W. Va. Mar. 5, 2010); *Fulgenzi v. Wyeth, Inc.*, No. 5:09CV1767, 2010 WL 649349 (N.D. Ohio Feb. 19, 2010); *Munroe v. Barr Labs.*, 670 F. Supp. 2d 1299, 1303 (N.D. Fla. 2009); *Bartlett v. Mutual Pharm. Co.*, 659 F. Supp. 2d 279 (D.N.H. 2009); *Stacel v. Teva Pharm., USA*, 620 F. Supp. 2d 899, 907 (N.D. Ill. 2009); *Schrock v. Wyeth*, 601 F. Supp. 2d 1262, 1265 (W.D. Okla. 2009); *Couick v. Wyeth, Inc.*, No. 3:09-CV-210-RJC-DSC, 2009 WL 4644394 (W.D.N.C. Dec. 7, 2009); *Pustejovsky v. Wyeth*, No. 4:07-CV-103-Y, 2009 WL 3336032, at *1 n.4 (N.D. Tex. Sept. 4, 2009); *see also In re Budeprion XL Marketing & Sales Litig.*, No. 09-md-2107, 2010 WL 2135625 (E.D. Pa. May 26, 2010) (rejecting preemption defense in consumer fraud class action against generic drug companies); *Kellogg v. Wyeth*, 612 F. Supp. 2d 437, 442 (D. Vt. 2009) (post-*Levine* decision declining to certify for interlocutory appeal a pre-*Levine* ruling denying preemption).

In short, the lower courts have had no difficulty applying *Levine's* teachings. Accordingly, this Court's review is not needed to provide guidance on the question presented.

IV. PETITIONER SEEKS SPECIAL PROTECTION FROM TORT LIABILITY THAT IS NOT AVAILABLE TO OTHER MANUFACTURERS AND THAT FINDS NO SUPPORT IN THE HATCH-WAXMAN AMENDMENTS

It should not be surprising, especially in the wake of *Levine*, that the lower courts have had little difficulty rejecting preemption claims by generic drug companies. Petitioner seeks a special shield against tort liability that is not available to other manufacturers, including the manufacturers of name-brand drugs. Over seventy percent of prescriptions in this country are today filled with generic drugs. Susan Okie, *Multinational Medicines—Ensuring Drug Quality in an Era of Global Manufacturing*, 361 New Eng. J. Med. 737, 738 (2009). A finding of preemption would leave all consumers of inadequately labeled generic drugs, including Ms. Demahy, without legal remedy. As the court below observed, it would be a "bizarre conclusion that Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of *any* remedy, while under *Levine*, that same plaintiff would have a state-law claim had she only demanded a name brand drug instead." Pet. App. 45a. "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

The FDCA is, first and foremost, a safety statute. As both the Fifth and Eighth Circuits recognized, the Hatch-Waxman Amendments, while providing for simplified, expedited approval of

generic drugs, did not depart from "the fundamental requirement of the FDCA that all marketed drugs remain safe." *Mensing*, 588 F.3d at 612; Pet. App. 44a. State-law remedies complement federal regulation "by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Levine*, 129 S. Ct. at 1200.

Despite the alarmist tone of the petition, the Fifth Circuit's decision does not threaten to drive generic drugs off the market or to endanger the viability of the generic drug industry. Suits against drug manufacturers for inadequate warnings have existed since long before there was an FDA, *see, e.g.*, *Thomas v. Winchester*, 6 N.Y. 397 (1852), and the generic drug industry has thrived despite the risk of tort liability.

Generic drug companies need not undertake expensive clinical trials to protect themselves from liability. All they need do is review the adverse drug experience reports they already receive, and monitor the medical literature for studies identifying new risks associated with the products they sell. Pet. App. 40a-43a; *Mensing*, 588 F.3d at 611-12. If the name-brand company is properly strengthening its label warnings "as soon as there is reasonable evidence of an association of a serious hazard with a drug," 21 C.F.R. § 201.80(e), a generic competitor can simply tag along with those label changes; but where the name-brand manufacturer fails to propose necessary warnings, the generic drug companies cannot just rely upon that inaction: "In these circumstances, § 201.57(e) [now 21 C.F.R. § 201.80(e)] does not permit generic manufacturers passively to accept the inadequacy of their drug's

label as they market and profit from it." *Mensing*, 588 F.3d at 609.

Neither the Hatch-Waxman Amendments nor its legislative history contains any hint that Congress intended to shield generic drug companies from state-law liability. Congress's decision not to include an express preemption provision in those amendments—only eight years after it had expressly preempted certain state claims against defective medical devices—"militates further against a finding of preemption here." Pet. App. 14a. As this Court said in *Levine*:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. . . . Its silence on this issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Wyeth v. Levine, 129 S. Ct. at 1200 (citations omitted).

CONCLUSION

The petition for a writ of certiorari should be denied.

July 30, 2010 Respectfully submitted,

LOUIS M. BOGRAD*
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th Street, N.W.
Suite 520
Washington, DC 20001
(202) 944-2803
lou.bograd@cclfirm.com

RICHARD A. TONRY, II
RAYMOND BRINSON
BRIAN L. GLORIOSO
KRISTINE K. SIMS
TONRY, BRINSON & GLORIOSO, L.L.C.
245 Pontchartrain Drive
Slidell, LA 70458
(985) 643-7007

*Counsel of Record

Counsel for Respondent