No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,
v.
KAREN L. BARTLETT,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF FORMER FDA COMMISSIONERS DR. DONALD KENNEDY AND DR. DAVID A. KESSLER AS AMICI CURIAE IN SUPPORT OF RESPONDENT

JONATHAN S. MASSEY
Counsel of Record
MASSEY & GAIL, LLP
1325 G St. N.W., Suite 500
Washington, D.C. 20005
(202) 652-4511
jmassey@masseygail.com

— Additional counsel listed on the inside cover. —

Dated: February 20, 2013

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

JOHN EDDIE WILLIAMS, JR.
JOHN T. BOUNDAS
WILLIAMS, KHERKHER, HART, BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, TX 77017
(713) 230-2200

MICHAEL S. BURG
PETER W. BURG
BURG SIMPSON ELDREDGE
HERSH & JARDINE, P.C.
40 Inverness Dr. East
Englewood, CO 80112
(303) 792-5595

SEAN P. TRACEY
SHAWN P. FOX
TRACEY LAW FIRM
440 Louisiana, Suite 1901
Houston, Texas 77002
(713) 495-2333

KEITH L. ALTMAN
THE LAW OFFICE OF KEITH ALTMAN
32250 Calle Avella
Temecula, CA 92592
(516) 456-5885

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BRIEF OF FORMER FDA COMMISSIONERS DR. DONALD KENNEDY AND DR. DAVID A. KESSLER AS AMICI CURIAE IN SUPPORT OF RESPONDENT

INTEREST OF AMICI CURIAE

This brief in support of respondent is filed on behalf of Dr. Donald Kennedy and Dr. David A. Kessler, each of whom served as Commissioner of Food and Drugs at the Food and Drug Administration (FDA).[1]

Dr. Donald Kennedy, a biologist, served as FDA Commissioner from 1977 to 1979. Dr. Kennedy then returned to Stanford University, where he had previously been a member of the faculty. From 1980 to 1992, Dr. Kennedy served as President of Stanford University. When he stepped down he returned to the faculty and is currently a professor emeritus. From 2000 until 2008, Dr. Kennedy also served as editor-in-chief of SCIENCE, the weekly magazine published by the American Association for the Advancement of Science. In 2010 he received Wonderfest's Carl Sagan Prize for Science Popularization.

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[1] Pursuant to Rule 37.6, amici state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

Dr. David A. Kessler was appointed by President George H.W. Bush in 1990 to serve as FDA Commissioner. Dr. Kessler was reappointed to that position by President William J. Clinton. After serving as Commissioner for seven years, Dr. Kessler left the FDA in 1997 to join the Yale School of Medicine as Dean, a position he held until 2003. From 2003 through 2007, Dr. Kessler served as Dean and Vice-Chancellor of the University of California, San Francisco, Medical School. Dr. Kessler remains on the medical school faculty. In 2009, he published THE END OF OVEREATING: TAKING CONTROL OF THE INSATIABLE AMERICAN APPETITE, and in 2012 he published YOUR FOOD IS FOOLING YOU: HOW YOUR BRAIN IS HIJACKED BY SUGAR, FAT, AND SALT.

Amici file this brief because the preemption position urged by petitioner threatens to undermine, not advance, the underlying goal of our nation's drug safety laws, which is "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

Amici previously expressed their views in a brief filed in *Wyeth v. Levine*, No. 06-1249, which was cited by the Court in its opinion. *See* 555 U.S. 55, 579 n.12 (2009). Both Dr. Kennedy and Dr. Kessler have also set forth their opinions in publications: Dr. Kennedy in an editorial, *Misbegotten Preemptions*, 320 SCIENCE 585 (May 2, 2008), and Dr. Kessler in a law review article, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Effort to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008) (hereinafter "Kessler & Vladeck").

SUMMARY OF ARGUMENT

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. (FDCA), does not have the preemptive effect petitioner claims. The Act does not automatically bar state-law strict liability claims asserting that FDA-approved drugs are unreasonably dangerous for their approved uses. This conclusion applies to a drug approved via a "new drug application" (NDA), as well as to a generic version approved under an "abbreviated new drug application" (ANDA). *See* 21 U.S.C. §§ 355(a), (b) and (j).

The nation's drug safety laws have never placed the responsibility for drug safety solely on FDA. To the contrary, they place primary responsibility for safety squarely on the shoulders of drug manufacturers. To be sure, FDA also plays an important role. It oversees, and when necessary compels, compliance with safety standards. But the ultimate responsibility remains with the manufacturer. Amici submit that the preemption arguments pressed by petitioner and its amici turn that understanding upside down, improperly relieving manufacturers of front-line responsibility for the safety of their drugs and handing that job to FDA.

FDA does not have the resources or practical ability to serve as the sole guarantor of public safety and the statutory scheme has never operated under the assumption that FDA could successfully perform such a demanding role. The situation with respect to generics is no different. The Hatch-Waxman Amendments were not intended to compromise

public safety. Indeed, an important objective of the Amendments was to ensure that generics are just as safe as brand-name drugs, so that consumers will accept generics as substitutes, without worry that they are risking their health or their ability to seek compensation in the case of an injury.

In recent years, study after study has documented severe limitations in FDA's ability to ensure drug safety, as this Court recognized in *Wyeth v. Levine*, 555 U.S. 555, 578 n.11 (2009). The studies include:

• The Institute of Medicine of the National Academies, Ethical and Scientific Issues in Studying the Safety of Approved Drugs (May 2012);

• Institute of Medicine of the National Academies, The Future of Drug Safety: Promoting and Protecting, the Health of the Public (2007) ("IOM 2007 Report");

• FDA Science Board, FDA Science and Mission at Risk: A Report of the Subcommittee on Science and Technology (2007) ("FDA Science and Mission at Risk");

• GAO, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 5 (GAO–06–402, 2006), http:// www. gao. gov/ new. items/ d 06402. Pdf.

State tort litigation has always played an important role in ensuring that manufacturers bear responsibility for the safety of their drugs. Time and time again, such litigation has uncovered problems with long-term use of drugs, such as Vioxx, Bextra, Celebrex, Avandia, Rezulin, Baycol, Halcion, and

Zomax. State tort litigation preceded the enactment of the first federal drug safety law, the Federal Pure Food and Drug Act of 1906, and it has been a complement to federal enforcement of drug safety laws throughout the history of FDA and its predecessor agencies. Congress's unwillingness to cut off state tort claims is in keeping with FDA's longstanding judgment that this litigation supplements the agency's regulatory and enforcement activities. For decades, FDA consistently took the position that state tort claims were an important adjunct to federal regulation.

Congress has been particularly attentive to the federalism issues relating to FDA regulation of drugs and medical devices, but has never seen fit to preempt state damages actions against drug manufacturers. Congress has, over the years, provided limited preemption of state-law claims for medical devices specifically approved by FDA, over-the-counter drugs, and vaccines. Although Congress has repeatedly revisited the FDCA, including a significant overhaul in the 2007 Food and Drug Administration Amendments Act, Congress has never given drug companies the immunity from liability they now seek from this Court.

ARGUMENT

I. FDA IS NOT EQUIPPED TO SERVE AS THE SOLE GUARANTEE OF PUBLIC HEALTH.

The preemption arguments advanced by petitioner and its amici significantly overstate FDA's ability to police the marketplace on its own, without the backstop of state tort litigation. The question before this Court is whether state tort litigation jeopardizes the fulfillment of the FDCA's goal, namely, "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. at 696.

The short answer to that question is "no." State tort litigation plays an indispensable role in achieving the congressional goal. The fundamental problem FDA faces is that, by necessity, drugs are approved on the basis of less-than-perfect knowledge. The emergence of safety hazards that were unknown or not well understood at the time of a drug's approval is commonplace. FDA's approval process is not a warrant of the drug's absolute safety, but is an assessment of whether the drug's benefits outweigh its potential risks based on the evidence available to FDA at the time. As this Court has observed, "risk information [regarding pharmaceuticals] accumulates over time and that the same data may take on a different meaning in light of subsequent developments." *Wyeth v. Levine*, 555 U.S. 555, 569 (2009). This Court has also noted that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new

risks emerge." *Id.* at 578-79. This Court's observations are correct, and they confirm that the federal regulatory process cannot serve as the sole guarantee of consumer safety.

A. The Approval Process For Both New Drugs And Generics Puts The Responsibility On The Manufacturer To Assure Safety.

To obtain approval for a new drug, a manufacturer must submit a new drug application (NDA) for the agency's review. 21 U.S.C. § 355; *see generally* Kessler & Vladeck, 96 GEO. L.J. 470-73. The NDA must include, among other things, full results of all clinical studies performed on human subjects. But risks that are rare, have long latency periods, result from drug interactions, or have adverse impacts on subpopulations often go undetected in clinical testing.

Pre-market human studies generally involve only a few thousand subjects and last only a year or so. Drugs are generally tested on no more than 600 to 3,000 patients prior to approval. *See* IOM 2007 Report, at 36. To control for conditions that might distort the study's findings, subjects who take other drugs or have other diseases or infirmities are excluded. *See* Kessler & Vladeck, 96 GEO. L.J. at 471. Because of these limitations, preapproval testing is generally incapable of detecting adverse effects that have long latency periods, result from drug interactions, occur infrequently, or affect sub-populations excluded from or not adequately represented in the clinical studies (for example, the elderly, ethnic minorities, and pregnant women). *Id.*

Moreover, FDA's assessment of risks-versus-benefits is generally done population-wide, not sub-group by sub-group, because there are rarely enough clinical trial participants in a sub-group to permit that degree of refined analysis. *Id.* As the IOM has commented:

> Preapproval trials typically are too small to detect even significant safety problems if they are rare. An adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug.

IOM 2007 Report at 37-38 (citations omitted).

For these reasons, FDA approval of a drug is no guarantee that the drug will not cause serious adverse effects even if properly used for its approved purposes. As the IOM explains, "FDA approval does not represent a lifetime guarantee of safety and efficacy," and drugs enter the U.S. market with "incomplete safety profiles." IOM 2007 Report at 2, 37. It is estimated that "as many as half of all new drugs have at least one serious adverse effect that is unknown at the time of drug approval."[2] An FDA historian has noted that "[i]n the years since 1962 literally thousands of prescription drug items have

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[2] Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 430 (2010) (citing Bengt D. Furberg & Curt D. Furberg, EVALUATING CLINICAL RESEARCH 8 (2d ed. 2007)).

been taken off the U.S. market because they lacked evidence of safety and/or effectiveness, or they have had their labeling changed to reflect the known medical facts."[3] Professor and former FDA General Counsel Richard A. Merrill once quipped, "All consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry."[4]

The situation with respect to generics is no different. Under the Hatch-Waxman Amendments, once a brand-name drug has been approved by FDA, any drug company may seek permission to market a generic version through a significantly simplified process, known as the abbreviated new drug application procedure, or ANDA Generic drug manufacturers must establish the generic drug's bioequivalence with the name brand drug. 21 U.S.C. § 355(j)(2)(A)(iv). The ANDA must also show that the "labeling proposed for the [generic] drug is the same as the labeling approved for" the brand-name drug. *Id.* at § 355(j)(2)(A)(v).

The Hatch-Waxman Amendments were not intended to compromise consumer safety. The House Energy and Commerce Committee Report cited "the policy objective" of the bill as "getting *safe* and *effective* generic substitutes on the market as quickly as possible after the expiration of the patent." H. Rep. No. 98-857, pt. 2, 98th Cong. 2d sess. 9 (1984)

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[3] Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER (June 1981), available at http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

[4] *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 20 (1973).

(emphasis added). The sponsors of the Amendments also stressed the pro-consumer nature of the bill. Rep. Waxman explained:

> The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate reduction in drug prices when a generic is on the market as a competitor.

130 Cong. Rec. 24430 (Sept. 6, 1984) (statement of Rep. Waxman). Sen. Hatch added:

> This is a good bill. *Without compromising the public safety or welfare in the least* it will significantly lower the price of off-patent drugs, by many times in some cases, through increased generic competition.

Id. at 15847 (June 12, 1984) (statement of Sen. Hatch) (emphasis added).

The Hatch-Waxman Amendments are premised on the idea that consumers should be just as willing to accept generic pharmaceuticals as brand-name drugs. Consumers must have confidence that generics will be every bit as safe and effective as brand-name drugs, that manufacturers of generic drugs will be held to the same high standards as those of brand-name drugs, and that any violation of these standards can be addressed with an identical set of legal tools.

Manufacturers of generics retain the responsibility for assuring safety. Both brand-name and generic manufacturers are statutorily required to keep records of clinical experiences and ensure that their products remain safe and effective as

labeled. *See* 21 U.S.C. § 355(k). FDA regulations mandate that all manufacturers record and report adverse events. *See* 21 C.F.R. § 314.80(a) and (c) (brand-name manufacturers); 21 C.F.R. § 314.98(a) (generic manufacturers). Manufacturers must submit annual reports including, *inter alia*, a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and a "description of actions the applicant has taken or intends to take as a result of this new information." *Id.* at § 314.81(b)(2)(i).

In commentary accompanying FDA's implementation of the Hatch-Waxman Amendments, the agency repeated the manufacturer's responsibility:

> If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, 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. 17950, 17961 cmt. 40 (Apr. 28, 1992).

At hearings on the Hatch-Waxman Amendments, representatives of the generic drug

industry stressed that they would keep FDA informed of the risks of their products.[5]

B. Practical Considerations Require That FDA Cannot Be The Sole Guarantor Of Consumer Safety.

FDA cannot singlehandedly perform the Herculean job of monitoring the safety of every one of the 11,000 or so drugs on the market. FDA does not have timely access to safety information and other resources to enable it to engage in a day-by-day monitoring of the safety profile of every one of the thousands of drugs on the market (not to mention medical devices, food products, blood products and other biologics, and the hundreds of other consumer products FDA regulates), let alone

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[5] *See New Drug Application*: Hearings on H.R. 3605, The Drug Price Competition Act, House Committee on Energy & Commerce, Subcommittee on Health and the Environment, 98th Cong., 1st sess. 45 (July 15, 1983) ("I, too, would like to comment on this adverse reaction issue that was brought up. I can speak as a manufacturer and for two other generic companies in whose representatives are in attendance that are sensitive to the importance of looking at adverse reactions. We are sensitive and responsible. The generic manufacturers of today will respond to those needs. As far as I know we have not been remiss in that responsibility. If it demands a higher level of knowledge on our part we are prepared to meet and respond to the need.") (testimony of Kenneth N. Larsen, chairman of the Generic Pharmaceutical Industry Association); *id*. at 50-51 ("[G]eneric companies . . . also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reaction.") (testimony of Mark Haddad, member of the board of directors of the Generic Pharmaceutical Industry Association).

the capacity to monitor the safety profile of an individual drug that is even remotely equivalent to that of the drug's manufacturer.

A long series of investigations and expert reports has documented the challenges that FDA faces. For example, the Institute of Medicine of the National Academies (IOM) recently concluded that "[t]he FDA's current approach to drug oversight in the post-marketing setting is not sufficiently systematic and does not ensure that it assesses the benefits and risks of drugs consistently over a drug's life cycle." Ethical and Scientific Issues in Studying the Safety of Approved Drugs (Report Brief) 3 (May 2012).

That finding echoed the conclusion of a 2007 IOM Report, which warned that FDA "lacks the resources to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future." IOM 2007 Report at 193. "[T]he existing regulatory framework is structured around the premarketing testing process; few tools are available for addressing postmarketing issues, short of the blunt instruments available to respond to clear-cut adulteration and misbranding." *Id.* at 153. *See also* GAO, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 5 (GAO–06–402, 2006), http:// www. gao. gov/ new. items/ d 06402. pdf ("FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket safety issues"); Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 932 (2011) ("FDA epitomizes 'the hollow government syndrome—an agency with expanded

responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.'") (quoting Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 431 (2008)).

Similarly, a report issued in November 2007 by a blue-ribbon advisory panel appointed by FDA concluded, "The scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence to the safety of the public." FDA Science and Mission at Risk, at § 1.1. The report found that the agency has "serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at 2-3.

As the FDA advisory panel observed, the agency's appropriations have not kept pace with its enormous and growing responsibilities. When the FDCA was enacted in 1938, Congress gave FDA a mandate "to review and approve prior to marketing, the safety of color additives, human food additives and animal feed additives, as well as to review and approve the safety and effectiveness of new human drugs, new animal drugs, human biological products and medical devices for human use." FDA Science and Mission at Risk, § 2.1. Since 1938, Congress has enacted "125 statutes that directly impact FDA's regulatory responsibilities," by requiring "the development of implementing regulations, guidance or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific

knowledge or expertise for the agency to address them." *Id.*

Despite the addition of all of these requirements, Congress did not provide "an appropriation of new personnel and increased funding designed to allow adequate implementation." *Id.* Indeed, during the past two decades, the agency's funding and staffing levels have remained static. For these and other reasons, the report concludes that "[t]his reality, combined with a burgeoning industry . . . has made it increasingly impossible for the FDA to maintain its historic public health mission." *Id.*

Although the Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) ("2007 FDCA Amendments") attempted to address the challenges facing FDA, the reforms under the Amendments will take considerable time to implement and their success is uncertain. *See* Kessler & Vladeck, 96 GEO. L.J. at 489-91. For example, a recent study in the British Medical Journal reported that, in 2009, only 22% of clinical-trial sponsors posted their results within one year of completion, as the 2007 FDCA Amendments require.[6] Although FDA has disputed that finding, it concedes that compliance is not complete.

The chief Senate sponsor of the 2007 FDCA Amendments explained that even a strengthened

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[6] Prayle, A. P., Hurley, M. N. & Smyth, A. R., *Compliance With Mandatory Reporting Of Clinical Trial Results On Clinicaltrials.Gov: Cross Sectional Study*, 344 BR. MED. J. d7373 (Jan. 3, 2012).

FDA should not be expected to assume exclusive responsibility for consumer safety:

> Clearly, the resources of the drug industry to collect and analyze post-market safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does. It is absurd to argue that the FDA, even with the enhanced resources and authorities provided by this legislation, commands the field when it comes to postmarket safety. The drug companies have the capacity to do a far more comprehensive job . . . [and] cannot be allowed to ignore their responsibilities and wait for the FDA to act.

153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (remarks of Sen. Kennedy).

The bottom line is that FDA and manufacturers have highly unequal access to information about drug safety hazards. The annual revenues for a single prescription drug can be more than two hundred times the entire FDA budget dedicated to post-marketing surveillance for the same time period. *Id.* Manufacturers invariably obtain safety information before FDA and have access to a great deal of data that is not available to FDA.

The proof of the information imbalance between FDA and drug manufacturers is in the pudding. FDA has recently faced a flood of high-profile regulatory failures with approved drugs. For example, in 2007, eight years after FDA approval, the diabetes drug Avandia was found to increase the risk of heart

attacks.[7] In 2006, thirteen years after FDA approval, the medication Trasylol (used to reduce bleeding during surgery) was found to increase the risks of kidney failure, heart attack, and stroke.[8] And in 2004 and 2005, four and five years, respectively, after their initial approval, Cox-2 inhibitors[9] Bextra and Vioxx were withdrawn from the market after discovery that they increased the risks of heart attack and stroke and (in Bextra's case) serious skin reactions (such as SJS/TEN).[10] Millions of consumers were exposed to serious risks.[11] In the words of an FDA official, "Vioxx was [an] enormous national catastrophe. Up to 60,000 Americans, most over the

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[7] Steven E. Nissen, M.D. & Kathy Wolski, M.P.H., *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, 356 NEW ENG. J.MED. 2457, 2458, 2467 (2007).

[8] Dennis T. Mangano, Ph.D., M.D., Iulia C. Tudor, Ph.D. & Cynthia Dietzel, M.D., *The Risk Associated with Aprotinin in Cardiac Surgery*, 354 NEW ENG. J. MED. 353, 361 (2006).

[9] Cox-2 inhibitors are a type of nonsteroidal anti-inflammatory drug (NSAID). *See, e.g.*, David J. Graham, M.D., M.P.H., *Cox-2 Inhibitors, Other NSAIDs, and Cardiovascular Risk: The Seduction of Common Sense*, 296 JAMA 1653, 1653 (2006).

[10] *Cox-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103420.htm.

[11] *See* Rodney Kristopher Miller, *Sacrificial Lambs: Compensating First Subscribers to FDA-Approved Medications for Postmarketing Injuries Resulting from Unlabeled Adverse Events,* 62 CATH. U. L. REV. (forthcoming) (available at SSRN: http://ssrn.com/abstract=2114394).

age of 50, died from Vioxx-related heart attacks . . . . Another 80,000 suffered nonfatal, but nonetheless life-threatening heart attacks."[12]

All of these examples demonstrate shortcomings in FDA regulation. In the case of Avandia, the danger was discovered not by FDA but by a third party's analysis of the publicly available data, and evidence suggests that the manufacturer had previously identified the cardiac risks at issue but did not disclose them to FDA.[13] Likewise, Trasylol's manufacturer withheld from FDA information pointing to a link between the drug and increased risk of stroke and heart attacks.[14] In the case of Vioxx, FDA did not understand the cardiovascular risks posed by the drug at the time of approval, and

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[12] *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply*: Hearings Before the Subcomm. on Oversight & Investigations of the H. Comm. On Energy & Commerce, 110 Cong. 59 (2007) (testimony of David J. Graham, M.D., M.P.H., Assoc. Dir., Science and Medicine, FDA Office of Surveillance and Epidemiology).

[13] Gardiner Harris, *Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, at A1 ("The heart risks from Avandia first became public in May 2007, with a study from a cardiologist at the Cleveland Clinic who used data the company was forced by a lawsuit to post on its own Web site.").

[14] *Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 109 Cong. 41 (2006) (statement of Jim Guest, Pres. of Consumers Union) (noting that Trasylol's manufacturer, Bayer, "failed to inform the FDA Advisory Committee (which had convened 8 days earlier on September 21, 2006 to discuss Trasylol) of a new study that revealed an increased risk of death, serious kidney damage, congestive heart failure and stroke").

Merck withheld information relating to the drug's cardiovascular risks from FDA to avoid a stronger warning on the label.[15]

Congress is well aware of the limitations faced by FDA. Congressional hearings and reports have documented that FDA's resources are not commensurate with the agency's enormous task.[16]

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[15] *See* Thomas O. McGarity, THE PREEMPTION WAR 1-17 (2008) (detailing Vioxx's regulatory history); *McDarby v. Merck*, 949 A.2d 223, 231-47 (N.J. App. Div. 2008) (same); *see also Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry*: S. Hearing Before the Special Comm. on Aging, 110th Cong. 50 (2007) (testimony of Peter Lurie, M.D., M.P.H., Deputy Dir. of Public Citizen's Health Research Group, Wash. D.C.) (noting publication of incomplete trial data on Celebrex by the drug's manufacturer, Pfizer, "because [Pfizer] knew that the full data set that it had in its possession didn't show the benefit that half the data set showed").

[16] *See, e.g.*, *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?* Hearing Before the House Committee on Oversight and Government Reform, 110th Cong. 2d Sess. (May 14, 2008) ("*House FDA Preemption Hearing*"); *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?* Hearing Before the Senate Committee on the Judiciary, 110th Cong. 1st Sess. (Sept. 12, 2007); *Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx: Hearing Before the House Comm. on Government Reform*, 109th Cong. (2005); *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the Senate Comm. on Health, Educ., Labor and Pensions*, 109th Cong. (2005); *FDA, Merck and Vioxx: Putting Patient Safety First?: Hearing Before the Senate Comm. on Finance*, 108th Cong. (2004); U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 10, *available at* www.gao.gov/cgi-bin/getrpt?GAO-06-402.

Hearings have also confirmed the importance of state tort litigation. For example, Gregory Curfman, executive editor of the New England Journal of Medicine, warned that "preemption of common-law tort actions against drug and medical device companies is ill advised and will result in less safe medical products for the American people." *House FDA Preemption Hearing* (testimony of Dr. Curfman). Another expert advised a House Committee that:

> Preempting lawsuits against pharmaceutical manufacturers would remove a check on pharmaceutical manufacturers that is essential to prescription drug safety and the public health. Without the possibility of litigation against manufacturers and their executives, we are likely to see greater misrepresentation of safety-related data and more inappropriate use of potentially harmful medications.

Id. (testimony of Aaron S. Kesselheim, Brigham & Women's Hospital and Harvard Medical School).

Experience and practical considerations demonstrate that FDA cannot be the sole guarantor of consumer safety.

II. THE STATUTORY FRAMEWORK AND HISTORY SHOWS THAT THE FDA'S ROLE IN ENSURING SAFETY IS NOT EXCLUSIVE.

In *Wyeth v. Levine*, this Court observed that "Congress enacted the FDCA to bolster consumer protection against harmful products" and "did not

provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." 555 U.S. at 574. "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." *Id.* "Its silence on the 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." *Id.* at 575.

This Court's observations were correct, and they compel affirmance of the judgment below. Indeed, it is telling that following this Court's decision in *Wyeth v. Levine*, FDA's analysis of "post marketing reports of severe tissue injury" with respect to promethazine (the generic form of Phenergan) led it to require a boxed warning of the adverse event that afflicted Diana Levine – the plaintiff in that case.[17] Hence, the very state tort suit that this Court

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[17] *See* FDA, *Information for Healthcare Professionals - Intravenous Promethazine and Severe Tissue Injury, Including Gangrene*, http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm182169.htm (Sept. 16, 2009) (explaining that "FDA is requiring manufacturers of these products to revise the labeling for promethazine, including addition of a Boxed Warning describing the risk of severe tissue injury, including gangrene, requiring amputation following intravenous administration of promethazine").

addressed in 2009 demonstrates that state claims complement federal regulation.

A. The History of the FDCA Confirms That It Does Not Have The Preemptive Effect Petitioner Claims.

Federal drug labeling regulation began with the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)). Prior to 1906, "the States provided the primary and possibly the exclusive source of regulatory control over the labeling of foods and drugs." *In re Vioxx Prods. Liab. Litig.,* 501 F. Supp. 2d 776, 782 (E.D. La. 2007). State courts recognized common-law causes of action for consumers injured by medicines and related products.[18]

Nothing in the Pure Food and Drug Act of 1906 displaced traditional state-law tort remedies. The Act was part of the progressive agenda of the trust-busting reformer, Theodore Roosevelt,[19] and it was intended solely to protect consumers – not to deny

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[18] *See, e.g.*, *Boyd v. Coca Cola Bottling Works,* 177 S.W. 80, 81 (Tenn.1915); *Willson v. Faxon, Williams & Faxon*, 208 N.Y. 108, 112, 101 N.E. 799, 801 (1913); *Blood Balm Co. v. Cooper*, 83 Ga. 457, 10 S.E. 118, 119 (1889); *Thomas v. Winchester,* 2 Seld. 397, 1852 WL 4748 (N.Y.1852); *Fleet v. Hollenkemp*, 52 Ky. (1 B. Mon.) 219, 220 (1852).

[19] *See* Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, § 3, 34 Stat. 768, 768–69, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 201(d), 52 Stat. 1040, 1040 (codified in scattered sections of 21 U.S.C.).

state tort remedies to victims of unsafe drugs.[20] For example, in 1913, this Court considered the effect of a Wisconsin statute providing that mixtures or syrups offered for sale "shall have upon them no designation or brand . . . other than that required by the state law." *McDermott v. Wisconsin,* 228 U.S. 115, 127 (1913). Although this Court held that Wisconsin could not require that federally approved labels "shall be removed from the packages," the Court also "[c]onced[ed] to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs." *Id.* at 133.

The history of federal food and drug regulation has been an evolutionary process, in which existing (and sometimes longstanding) remedies have been removed from the market as new knowledge reveals health risks or other problems associated with them. For example, mercury, lead salts, arsenic, strychnine, and many other substances were once all regarded as widely useful therapies but are now considered obsolete.[21]

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[20] Dennis R. Johnson, *The History of the 1906 Pure Food and Drugs Act and the Meat Inspection Act*, 37 FOOD DRUG COSM. L.J. 5, 8–9 (1982); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Muckrakers and the Enactment of the First Federal Food and Drug Law in the United States*, 36 FOOD DRUG COSM. L.J. 647, 648–51 (1981).

[21] *See* John Fry, *Therapeutic Habits & Customs*, 56 PROCEEDINGS OF THE ROYALTY SOC'Y OF MEDICINE 127, 127-29 (1963).

In 1938, after the deaths of more than 100 people from elixir of sulfanilamide, Congress enacted the FDCA, which prohibited false therapeutic claims and for the first time required FDA premarket notification for drugs, although it did not impose a prescription requirement.[22] As this Court has long recognized, the purpose of the statute was to increase consumer protection. *See United States v. Dotterweich,* 320 U.S. 277, 280, 282 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection").

Congress considered including in the FDCA a private federal cause of action for damages caused by faulty or unsafe products. *See* H.R. Rep. No. 73-6110, pt. 1, § 25 (1933) ("Liability for Personal Injuries - a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act."). As this Court noted in *Wyeth v. Levine*, 555 U.S. at 574 n.7, the Senate deleted this proposed private cause of action from the bill on

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[22] Not until 1951 did Congress impose the familiar requirement that "prescription drugs be dispensed only upon a physician's prescription." *Christopher v. SmithKline Beecham Corp.*, 132 S.Ct. 2156, 2163 (2012). As originally enacted in 1938, the FDCA allowed manufacturers to designate certain drugs as prescription only, but it did not provide which drugs were to be sold by prescription. *Id.* at 2163 n1. Prior to Congress' enactment of the FDCA, a prescription was not needed to obtain any drug other than certain narcotics. *Id.*

the ground that it was unnecessary because "[a] common-law right of action exists" under state law.[23]

Congress has never seen fit to enact a preemption provision with respect to drugs. Indeed, Congress explicitly declined to do so in the 1962 amendments to the FDCA, which require FDA to ensure that a drug is effective as well as safe before the drug is approved. The purpose of the legislation was "to strengthen and broaden existing laws in the drug field so as to bring about better, safer, medicine and to establish a more effective system of enforcement of the drug laws." S. Rep. No. 87-1744, 87th Cong., 2d Sess. 1 (1962). The catalyst of the reforms was the thalidomide tragedy in Europe in the late 1950s and early 1960s, in which thousands of children were born with birth defects. *See* IOM 2007 Report, at 22, 152. In the 1962 Amendments, Congress made clear its intent not to preempt claims relying on state common law: "Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in

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[23] Hearing on S. 1944 Before a Subcomm. of the Comm. on Commerce, 73d Cong., 2d Sess. 400, 403 (1933). *See also Consumer Fed'n of Am. v. Upjohn,* 346 A.2d 725 (D.C. 1975) (explaining that private right of action was omitted from bill because "it would create an *unnecessary* federal action *duplicative of state remedies*" and concluding that Congress "*rejected* [] setting up a nationally uniform law for such" actions) (emphasis added); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok,* 59 MO. L. REV. 895, 924 & n.130 (1994) ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages [for injuries caused by prescription drugs] because 'a common law right of action [already] exists.'").

the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. 87-781, § 202, 76 Stat. 780, 793.[24]

Congress' assumption that state-law causes of action would remain under the FDCA – coupled with its decision not to provide a federal remedy – is strong evidence that it did not mean to displace traditional state tort actions. Where Congress displaces state law, it typically provides an alternative federal remedy.[25] As the Court has acknowledged, "[i]f 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,*

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[24] The provision's language underscores Congress's judgment not to displace state product liability law, but to preserve it. *See California Federal Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 283 n.12 (1987) (explaining antipreemption thrust of phrase "a direct and positive conflict"); *Swift & Co. v. Wickham*, 382 U.S. 111, 132 n.3 (1965) (Douglas, J., dissenting) (same). The provision explicitly displaces only positive state law only where there is "a direct and positive conflict" between the FDCA's new effectiveness requirements and state law. Congress refrained from using broader language that might encompass other types of state law, such as tort law.

[25] *See, e.g.*, 42 U.S.C. § 2210 (Price-Anderson Act); 42 U.S.C. §§ 300aa-10 to 300aa-34 (National Vaccine Injury Compensation Program); 49 U.S.C. § 40101 (Supp. 2004) (Air Transportation Safety and System Stabilization Act of 2001, also known as the September 11th Victim Compensation Fund); 29 U.S.C. § 1144 (Employee Retirement Income Security Act of 1974).

544 U.S. 431, 449 (2005). *See also Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251 (1984) ("This silence [of Congress in enacting and amending the Atomic Energy Act] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

B. Congress Confirmed Its Understanding In a Series of Amendments To The FDCA.

When Congress has wished to preempt state law in the FDCA, it has done so explicitly. For example, in 1976, Congress enacted an express preemption provision for medical devices. *See Riegel v. Medtronic, Inc.,* 552 U.S. 312 (2008) (considering the effect of the express preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(a)). As this Court opined in *Riegel*, "Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices." *Id.* at 327.

In addition, in the National Vaccine Injury Compensation Program ("VICP"), Congress provided an administrative remedy for vaccine-related injuries as an alternative to state tort liability, with the possibility of an opt-out to state court if the injured person wishes to pursue a state-law products liability remedy. 42 U.S.C. § 300aa-21(a). VCIP includes a specific provision that "[n]o vaccine manufacturer shall be liable in a civil action for

damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." *Id.* at § 300aa–22(b)(1).

In *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011), this Court held that the statutory language of the VCIP preempts design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects. But if there were no potential for non-warning claims against manufacturers of prescription drugs in the first place, there would have been no need for this Court's decision in *Bruesewitz*. Vaccines are approved under the Public Health Service Act, 42 U.S.C. § 300aa-1 to -6, but otherwise regulated as drugs. *E.g.*, 21 C.F.R. § 600 *et seq*. The regulatory treatment of vaccines thus confirms Congress' understanding that FDA regulation of a drug does not preempt state-law tort liability.

Further confirming the absence of preemption in this case are the express *anti*-preemption provisions for nonprescription or "over-the-counter" ("OTC") drugs, FDCA Section 751, 21 U.S.C. § 379r, and for the labeling and packaging of cosmetics, FDCA Section 752, 21 U.S.C. § 379s. These provisions prohibit any State or political subdivision from establishing or continuing "any requirement" relating to the regulation of an OTC drug or the labeling or packaging of a cosmetic that is "different from or in addition to, or that is otherwise not

identical with," a requirement under the FDCA, the Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 *et seq*., or the Fair Packaging and Labeling Act, 15 U.S.C. § 1451 *et seq*. *See* 21 U.S.C. § 379r(a), 379s(a). However, the OTC and cosmetic anti-preemption provisions expressly exempt state product liability actions from federal displacement: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e), 379s(e).

Thus, although Congress has provided for some degree of preemption for state requirements regarding OTC drugs and cosmetics labeling, it has also specifically preserved state-law products liability, at least in part. The statutory framework demonstrates Congress' clear understanding of the potential for state-law products liability actions against manufacturers of OTC drugs, and cosmetics. The absence of any analogous express preemption provision for prescription drugs is significant. If Congress had wanted to take the extraordinary step of according drug manufacturers immunity from personal tort actions, it would have done so expressly. As this Court opined in *Wyeth v. Levine*, "Congress has repeatedly declined to pre-empt state law," and "Congress did not regard state tort litigation as an obstacle to achieving its purposes." 555 U.S. at 575, 581.

Moreover, the relationship between OTC and prescription drugs makes the lack of an express preemption provision for prescription drugs even more significant. Some OTC drugs are initially approved as prescription drugs under the FDCA and

are "switched over" to OTC status after several years of marketing, as in the cases of Claritin and Zyrtec. Thus, a drug initially receiving FDA approval may later become an OTC drug governed by Section 751, which explicitly contemplates products liability claims under state law. It is implausible to suggest that Congress silently created immunity through federal preemption for prescription-drug-related claims but then affirmatively negated that immunity when the same drug became OTC. Rather, it is plain that Congress has always assumed that the fact of FDA approval would not preclude state-law product liability actions.

Other provisions of the FDCA also acknowledge Congress' understanding of the potential for state tort liability. For example, Section 756 of the FDCA provides that certain safety reports to FDA may not be considered admissions for liability purposes. *See* 21 U.S.C. § 379v (manufacturer's submission of a safety or adverse event report is not "an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness"). This provision indicates a congressional recognition of the potential for state tort suits, because it's evident purpose is to prohibit the use of safety reports in product liability litigation.

The same view of non-preemption is reflected in the 2007 FDCA Amendments, Pub. L. No. 110-85, 121 Stat. 823 (2007). The Amendments do not contain any express preemption provision barring state-law damages claims. The sole preemption language included in the Amendments precludes

states and their political subdivisions from "establish[ing] or continu[ing] in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database." 42 U.S.C. § 282(d).

Given the statutory structure, courts have long held that FDA approval does not preempt design-defect claims. *See, e.g.*, *Riegel*, 552 U.S. at 340 n.11 & 343 n.16 (Ginsburg, J., dissenting) (collecting cases); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390-91 (7th Cir. 2010) ("Until the early 2000s, prescription drug companies infrequently invoked the preemption defense, and when they did, it rarely succeeded."); *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993) ("We reject the argument that FDA approval preempts state product liability claims based on design defect.") (citing *Hurley v. Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-77 (5th Cir. 1988)).

Of course, some courts have declined, as a matter of state law, to recognize strict-liability claims based on the design of a prescription drug.[26] Those states' courts have taken the view that prescription drugs are, by definition, "unavoidably

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[26] *See, e.g.*, *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003); *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996); *Martin v. Hacker*, 628 N.E.2d 1308 (N.Y. 1993); *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla.1997); *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010) (Ohio law); *Tatum v. Schering Corp.*, 795 F.2d 925, 926 (11th Cir. 1986) (Alabama law); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658 (D. Md. 2011) (Maryland law).

unsafe" within the meaning of Restatement (Second) of Torts § 402A cmt. k (1965).[27] But the decision by some states not to recognize design-defect claims for prescription drugs hardly militates in favor of a finding of preemption. The longstanding assumption of the federal regulatory scheme, and judicial interpretations under it, is that the FDCA does not displace state tort actions. A state's choice to interpret its own tort law in a particular manner demonstrates that state law has a role to play with respect to approved drugs.

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[27] *See Bruesewitz*, 131 S. Ct. at 1077 n.41 (noting that, as of 1986, "a large number of courts" took comment k to mean that manufacturers "did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings"); *Kurns v. Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) (discussing Restatement (Third) of Torts: Products Liability § 2(c), at 14 (1998) (Third Restatement)). In general, comment k does not entail a categorical pronouncement that a particular product is unavoidably unsafe in all circumstances. *See* Nitin Shah, Note, *When Injury Is Unavoidable: The Vaccine Act's Limited Preemption Of Design Defect Claims*, 96 VA. L. REV. 199, 235 (2010) ("The longstanding majority approach is to analyze Comment k's applicability on a case-by-case basis."); AM. L. PRODS. LIAB. 3d § 17:47 (1987) ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether a particular drug is unavoidably unsafe should be determined on a case-by-case basis.").

C. The FDA's Longstanding Position Recognized That The FDCA Does Not Have The Preemptive Effect Petitioner Claims.

As this Court opined in *Wyeth v. Levine*, "[i]n keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." 555 U.S. at 578. "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id.* at 579. "Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.*

In 1974, for example, FDA adopted a regulation providing for confidential treatment of any identifying information relating to physicians (and other health care professionals) included in adverse drug reaction reports (ADRs) submitted by the manufacturer to the FDA. 21 C.F.R. § 314.80(h). FDA adopted this regulation precisely because it recognized that federal law permits products liability lawsuits in which plaintiffs' counsel would seek such identifying data:

> Large numbers of requests are received from plaintiff's attorneys in product liability lawsuits, requesting records relating to any other injuries caused by the product that is the subject of the lawsuit.

39 Fed. Reg. 44629 (Dec. 24, 1974).

In a 1979 preamble accompanying a drug rule, the agency explained that state tort law does not interfere with federal regulation: "It is not the intent of the FDA to influence the civil tort liability of the manufacturer." 44 Fed. Reg. at 37437 (1979).

Similarly, in a 1998 Final Rule relating to labeling provided directly to patients for certain prescription drugs and other biological products, the FDA indicated that state tort law did not interfere with its regulations:

> Tort liability cannot be a major consideration for FDA which must be guided by the basic principles and requirements of the act in its regulatory activities. Nevertheless, FDA does not believe this rule would adversely affect civil tort liability....
>
> * * *
>
> FDA does not believe that the evolution of state tort law will cause the developments of standards that would be at odds with the agency's regulations.

63 Fed. Reg. 66378, 66384 (1998).

In 1997, a former chief counsel of the FDA explained that this Court's no-preemption ruling in *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), was

consistent with the FDA's "longstanding ... presumption against preemption." Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 10 (1997). She added that:

> Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers.

Id. at 9. Although the article concerned medical devices specifically rather than pharmaceuticals, its explanation of FDA's longstanding view of limited preemption applies *a fortiori* with respect to drugs.

In December 2000, the FDA proposed a new regulation to address the form and content of drug labeling, the principal purpose of which was to require a "Highlights" section on drug labels. At that time, the agency explained that "this proposed rule does not preempt state law," and "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." 65 Fed. Reg. 81082, 81103 (2000).

Both FDA and Congress have long rejected the preemption position of petitioner and its amici. FDA is not the sole guarantor of public safety.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted.

JONATHAN S. MASSEY
Counsel of Record
MASSEY & GAIL, LLP
1325 G St. N.W., Suite 500
Washington, D.C. 20005
(202) 652-4511
jmassey@masseygail.com

JOHN EDDIE WILLIAMS, JR.
JOHN T. BOUNDAS
WILLIAMS, KHERKHER, HART, BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, TX 77017
(713) 230-2200

MICHAEL S. BURG
PETER W. BURG
BURG SIMPSON ELDREDGE
HERSH & JARDINE, P.C.
40 Inverness Dr. East
Englewood, CO 80112
(303) 792-5595

SEAN P. TRACEY
SHAWN P. FOX
TRACEY LAW FIRM
440 Louisiana, Suite 1901
Houston, Texas 77002
(713) 495-2333

KEITH L. ALTMAN
THE LAW OFFICE OF KEITH ALTMAN
32250 Calle Avella
Temecula, CA 92592
(516) 456-5885

February 20, 2013