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**BEFORE THE HOUSE COMMITTEE ON
OVERSIGHT AND GOVERNMENT REFORM**

HEARINGS ON:

**SHOULD FDA DRUG AND MEDICAL DEVICE
REGULATION BAR STATE LIABILITY CLAIMS?**

May 14, 2008

Mr. Chairman and Members of the Committee, thank you for inviting me to be here today to set forth my views on whether FDA regulation of drugs and medical devices should bar state liability claims. This is a subject I have thought about a great deal. I am a Professor of Law at Georgetown University Law Center and also serve as a Scholar with the Center for Progressive Reform. I have written extensively on regulatory preemption, with an emphasis on the question the Committee examines today.¹

My views are these: FDA's new position on preemption — namely, that FDA regulation of drugs and certain medical devices broadly displaces state liability law — is wrong as a legal matter. I will discuss in some detail the basis for my conclusion. I also want to emphasize why FDA's position is wrong as a matter of public policy, since the ultimate decision about preemption is for Congress, not the courts, to make. Here's the bottom line: If accepted by the courts and not overturned

¹ Submitted along with this testimony are copies of a recent law review article I co-authored with David A. Kessler, M.D., former Commissioner of the Food and Drug Administration, entitled *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008), a law review article I wrote a few years ago that focused on medical device preemption, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2005), and a White Paper I prepared jointly with other scholars with the Center for Progressive Reform entitled *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety* (CPR White Paper # 704, July 2007). I would also refer the Committee to testimony I submitted to the Senate Judiciary Committee for a hearing entitled "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority," on September 12, 2007. My recent writings on preemption also include a book chapter entitled *Preemption and Regulatory Failure Risks*, which will be published in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* (William Buzbee, ed., Cambridge Univ. Press 2008) (forthcoming) and an essay entitled *The FDA and Deference Lost: A Self-Inflicted Wound of the Product of a Wounded Agency?* 93 Cornell L. R. __ (2008) (forthcoming), both of which will be published this summer.

by Congress, FDA's pro-preemption position gives consumers the worst of both worlds. On one hand, despite FDA's claims otherwise, FDA cannot single-handedly accomplish the Herculean job of assuring the safety of the 11,000 drugs and thousands of medical devices on the market. Thus, consumers cannot depend on FDA regulation alone to protect them from unsafe or defective drugs and medical devices. That is why, until recently, FDA saw the discipline the liability system places on the market as an essential complement to its work.

Despite FDA's inability to safeguard the marketplace by itself, FDA claims that consumers injured by unsafe drugs or defective medical devices should be denied the ability to seek compensation for injuries they sustained through no fault of their own. That is a right that the liability system has guaranteed to the American people since the founding of the Republic. Let's be clear about this: Under FDA's view, consumers are forced to assume the risks of unsafe drugs and medical devices. At the same time, manufacturers of drugs and medical devices who fail to take reasonable steps to assure their drug or device is safe are immunized from liability, and, these days, essentially immune from FDA enforcement. This result is not only unfair, it is bad policy. Removing economic incentives for drug and device manufacturers to act responsibly serves no legitimate end, but instead jeopardizes the health and well-being of the public.

What makes this result all the more indefensible is that the decision to wipe away state liability law was not made by Congress through legitimate, democratic means. Instead, it was made by unelected and unaccountable agency officials —

many of whom worked for drug and device companies before their government service and have returned or will return via the revolving door to represent the same companies.² These decisions were not made in a transparent, publicly accountable way. Rather, they were made in obscure regulatory documents, with no opportunity for public input, and with no regard for the clear-cut requirements of Executive Order 13,132, which disfavors preemption and requires agencies to consult with states, local governments and the public before making preemption decisions.³

Because the question posed by the Committee relates to both drugs and medical devices, and I will address those questions separately. First, I will address medical device preemption and urge Congress to act swiftly to overrule the Supreme Court's recent ruling in *Riegel v. Medtronic, Inc.*⁴ Here, I start with a brief history of the Medical Device Amendments of 1976 and explain why that history demonstrates that Congress quite clearly intended to *preserve* state liability law. I

² See, e.g., Anne C. Mulkern, *Watchdogs or Lapdogs? When Advocates Become Regulators*, The Denver Post, May 23, 2004.

³ Executive Order 13,132 provides that “[w]hen an agency foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.” *Id.* §(4)(d). The Order also directs agencies to construe federal law to preempt State law “only where the statute contains an express preemption provision or there is some other clear evidence that Congress intended the preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” *Id.* §(4)(d). The Executive Order is available at 64 Fed. Reg. 43,255, 43,257 (Aug. 10, 1999). FDA has simply ignored these requirements in accomplishing its about-face on preemption.

⁴ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

will then turn to the Court's ruling in *Riegel* and address why the Court's wooden textual approach to the Amendments — which ignored their purpose — led the Court to conclude, wrongly, that *Congress* intended the Amendments to *preempt* state liability claims for devices approved by FDA through the pre-market approval process.

I will then turn to a discussion of the debate that is raging in the courts over FDA's new contention that its approval of a drug's labeling broadly preempts state liability claims. The lower courts are deeply divided on drug preemption, although the majority of courts have rejected FDA's pro-preemption position. This question will be considered by the Supreme Court in October in *Wyeth v. Levine*, and a decision can be expected by early 2009.

In my view, the question in *Wyeth* is not a close one. The federal government has regulated the sale of drugs for one hundred years without any hint that state liability actions interfered with FDA's ability to do its job. Nothing in the statutes FDA administers suggests that they oust state liability actions for drug products. Indeed, FDA has long taken the view that state liability litigation for pharmaceuticals is an important, independent discipline on the market. And Congress has not acted to preempt or limit state liability actions, even though Congress has long been aware of the steady procession of liability actions against drug makers — including those that pre-date FDA and its forerunners. For these and other reasons I address later in my testimony, I remain hopeful that the Court will find that Ms. Levine's claim is not preempted. Should the Court reach the

wrong conclusion, however, Congress should be ready to respond with legislation to restore the right of individuals harmed by dangerous drugs to bring state liability actions for redress.

I. FDA Preemption and Medical Devices.

Preemption cases involve more than dry and arcane questions of law. They invariably involve a story like Joshua Oukrop's — a tragic death or serious injury to someone caused by a product that failed them. Joshua Oukrop, a college student, was on a spring break trip to Moab, Utah, with his girlfriend. They went for a bike ride, but Joshua soon complained of fatigue, fell to the ground, and died of cardiac arrest. Why? Joshua had a common genetic disorder that causes erratic heartbeats that, if untreated, can trigger sudden cardiac arrest. But Joshua was able to lead a normal life because of a small, pocket-watch-sized, defibrillator that had been implanted in his chest. The defibrillator — a Guidant Prizm 2 — was programmed to deliver an electrical impulse to Joshua's heart when it went into arrest and jolt his heart back into a normal rhythm. But on that day in March 2005, instead of delivering a life-saving charge to his heart, Joshua's defibrillator short-circuited and failed. A wire in the device was too close to a component, causing an arc between them when the device fired.⁵

⁵ David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2005); Thomas McGarity, *The Preemption War* (New Haven, Conn.: Yale Univ. Press 2008) (forthcoming); Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) at A1; Barry Meier, *Repeated Defect in Heart Device Exposes a History of Problems*, N.Y. Times (Oct. 20, 2005) at A1.

Joshua's doctors determined that the defibrillator's malfunction caused his death. This was no surprise to Guidant. By the time Joshua died, Guidant had received 25 reports of other failures of the device for exactly the same reason. Guidant had fixed the problem in 2002, three years *before* Joshua's death, but decided to sell its existing inventory, without first fixing the flaw. After all, defibrillators cost \$25,000. Thousands of these faulty defibrillators were sold *after* Guidant had developed a new and safer device. Nor did Guidant tell physicians or patients about the defect. Word of the defect might frighten patients into opting for potentially risky surgery to replace the device. And in Guidant's view, its data still showed the Prizm 2 to be "a highly reliable life-saving product."⁶

Shortly after his death, Joshua's doctors met with Guidant officials to discuss what the company would do for the 24,000 patients who depended on the same device. Guidant offered to replace the devices Joshua's doctors had implanted in their patients. But Guidant was unwilling to inform other doctors, fearing that they too might want replacement devices. Guidant's efforts to keep the defect quiet did not succeed. The media disclosed that the short-circuiting problem had affected other Guidant defibrillators, and that Guidant had concealed the defect. Ultimately, three years after learning of the defect, after dozens of failures (including at least one other death and several heart attacks), and prodding from FDA, Guidant decided to "recall" the Prizm 2, as well as several other defibrillator models, affecting more

⁶ See, e.g., Barry Meier, *Maker of Heath Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) A1; *The Preemption War*, at 135.

than 50,000 patients.⁷ As I'll explain in a minute, the Supreme Court's recent ruling in *Riegel v. Medtronic, Inc.*, will immunize companies like Guidant from liability for conduct such as this, notwithstanding the grave harm that it inflicted on Joshua and his family.

The statute that governs medical devices — the Medical Device Amendments of 1976 (MDA) — was enacted in response to a series of highly-publicized public health catastrophes caused by defective medical devices, like the Guidant defibrillator. Most notorious was the Dalkon Shield. It was an intrauterine device introduced and widely marketed by the A.H. Robins Company without FDA approval. At the time, FDA had limited authority over medical devices. In producing the device, Robins ignored its own experts, who urged that both ends of the device's "sheath" be sealed to prevent "wicking" of bacteria-laden fluids into the uterus. Robins touted the Dalkon Shield as a safe and effective alternative to birth control pills. Soon after it hit the market, however, women began contracting infections that caused death, infertility, and other serious injuries. Robins kept the device on the market for an additional year, but finally stopped selling it in 1974.

⁷ "Recalling" a medical device implanted into a patient's body presents its own complications. For many cardiac patients, the risk of additional surgery to explant a defective defibrillator, pacemaker or heart valve outweighs the risk of retaining a defective product. *See, e.g.,* Barry Meier, *Maker of Heath Device Kept Flaw From Doctors*, N.Y. Times (May 24, 2005) A1. Many patients decide not to undergo replacement surgery, but then endure the risk of life-threatening product failure. A young and otherwise healthy patient like Joshua likely would have opted for replacement surgery. *See generally* Barry Meier, *Faulty Heart Devices Force Some Scary Decisions*, N.Y. Times (June 20, 2005) A1.

Litigation by thousands of injured women brought to light the nature and severity of the problem and afforded women the only compensation that was available to them.⁸

To avoid a recurrence of this and similar tragedies, Congress enacted the MDA to give FDA regulatory authority over all medical devices.⁹ The MDA reserves the most rigorous regulation for “Class III” devices — devices, like defibrillators, heart valves, and pacemakers, that sustain life or pose a serious risk to patients if they malfunction. As a general rule, before marketing a Class III device, a manufacturer must submit a pre-market approval (PMA) application asking FDA’s permission to market the device for the specific uses identified in the application. There are two exceptions. First, any device manufactured prior to the passage of the MDA — a “grandfathered” device — is not subject to the PMA requirements. Second, a device manufactured *after* 1976 may bypass the PMA process if the manufacturer can show that it is “substantially equivalent” to a grandfathered device. Before granting a PMA, FDA must find that there is a “reasonable assurance” that the device is safe and effective for its intended use.

⁸ Morton Mintz, *At Any Cost: Corporate Greed, Women, and the Dalkon Shield* (New York: Pantheon Press 1985); Richard B. Sobol, *Bending the Law: The Story of the Dalkon Shield Bankruptcy* (Chicago, Ill.: U. Chi. Press 1991).

⁹ The term “medical device” includes an array of products, from cotton swabs to artificial heart valves. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). Medical devices are categorized into three classes, based on the potential risk of harm posed. Class I devices, like swabs, are subject only to general controls that provide a reasonable assurance of safety. *Id.* at 477. Class II devices, such as hearing aids, are subject to somewhat stricter controls, to ensure that they are both safe and effective for their intended use. *Id.* Class III devices are used to sustain human life or pose a serious risk to patients. *Id.* at 477-78.

Because FDA lacked authority over medical devices before 1976, states had filled the regulatory void. By the time the MDA was enacted, a number of states, especially California, were engaging in robust regulation of devices. Accordingly, to formalize the allocation of responsibilities between FDA and state regulators, Congress included an express preemption provision in the MDA. It provides that “no State . . . may establish or continue in effect with respect to a device intended for human use any *requirement* (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device . . .”¹⁰ This language is important. Nothing in it says that Congress is acting to nullify existing state damages claims. There are federal statutes that do just that. But they do so in unmistakable terms and generally provide a federal remedy in lieu of displaced state remedies.¹¹

¹⁰ 21 U.S.C. § 360k(a) (emphasis added). In an earlier ruling finding that the MDA did not preempt liability actions for devices not subject to full-scale FDA premarket approval, the Court had observed that the MDA’s preemption provision “was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions.” *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996).

¹¹ *See, e.g.*, 42 U.S.C. §§ 2210 *et seq.* (Price-Anderson Act, which federalizes all claims for personal and property damage arising from significant accidents at civilian nuclear power plants); 42 U.S.C. §§ 300aa-1 *et seq.* (Vaccine Act, which federalizes all claims arising from personal injuries relating to the administration of vaccines); Air Transportation Safety and System Stabilization Act of 2001, Pub. L. No. 107-42, 115 Stat. 230 (2001) (9/11 Compensation Fund, which substitutes a federal remedy for tort claims 9/11 victims and their families could have asserted against the airlines whose planes were hijacked); 29 U.S.C. §§ 1001 *et seq.* (Employee Retirement Income Security Act of 1974, which federalizes disputes over employment related benefits).

Nor was there any indication that Congress, which enacted the MDA in response to tragedies like the Dalkon Shield — brought to light because of liability litigation — wanted to deprive persons injured by defective devices the compensation they could obtain only through liability actions. And, for most of the MDA’s history, FDA took the position that the MDA did not preempt state liability actions.¹²

All of that changed in 2002 when the agency made a 180-degree shift in position. Abandoning its decades-old stance, FDA aggressively sought to participate in private state liability cases on behalf of device manufacturers to argue that the MDA’s preemption provision immunized device manufacturers from liability under state law. Without informing the public, states or local governments, or seeking their views on its new position, FDA filed *amicus* briefs in several cases — always on the side of the manufacturer, never on the side of the injured patient — urging the courts to find the injured patient’s claim preempted. As a result of FDA’s reversal of field, lower courts began adopting FDA’s new position, which created a split of authority among lower courts. To resolve the question, the Supreme Court granted review in *Riegel v. Medtronic, Inc.*

¹² *See, e.g.*, Brief for the United States as Amicus Curiae, *Smith Indus. Med. Sys. v. Kernats* (No. 96-1405) (arguing on behalf of FDA that the MDA preemption provision was narrow and did *not* preempt state liability cases).

On February 20, 2008, the Court ruled that the MDA expressly preempts state liability actions for PMA devices.¹³ The majority opinion does not address the *purpose* of the MDA, let alone suggest that preemption is right as a policy matter. Instead, the majority relied on the word “requirement,” which, the Court held, is a term of art that may, and in the MDA does, encompass state liability actions.¹⁴ The majority reasoned that because state liability actions seek to impose “requirements” on device manufacturers “different from, or in addition to,” those imposed by FDA, they are preempted under a literal reading of the MDA. In the majority’s view, Congress’ selection of the word “requirement” demonstrates that *Congress* made the choice to preempt state law.¹⁵

As a result of *Riegel*, thousands of cases like the one that Joshua Oukrup’s family brought against Guidant and settled will no longer be viable. FDA’s premarket approval of a device would, standing alone, require dismissal of the case, even if the device proves to be unsafe, and even if the device’s label fails to provide physicians and patients with adequate information to assess the device’s

¹³ The Court’s ruling in *Riegel* applies *only* to PMA devices. As noted, the Court had previously ruled in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state liability actions involving non-PMA devices approved by FDA were not preempted.

¹⁴ *Riegel*, 129 S.Ct. at 1007-10.

¹⁵ Justice Stevens filed a concurring opinion, in which he acknowledges that the majority’s decision is in tension with Congress’ intent in the MDA, but he nonetheless concurred in the majority’s focus on the word “requirement” and its conclusion that Congress’ use of that word expressed *Congress’* intent to preempt. *Id.* at 1011-12. Justice Ginsburg filed a dissent, arguing that the majority’s opinion “effect[s] a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices” — a result that Congress did not intend. *Id.* at 1013.

risks. The one exception noted by the *Riegel* Court is where the manufacturer violated duties imposed by FDA. In those instances, the *Riegel* ruling would “not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”¹⁶

Riegel deals a body blow to injured consumers and their families. The device industry tries to minimize *Riegel*'s impact by making two points. One is that *Riegel* applies only to PMA devices, which comprise a very small fraction of the devices on the market. The second is that *Riegel* does not preclude actions based on the manufacturer's breach of federal duties.

To be fair, both of these points are correct. But they overlook the real-life consequences of the decision. Make no mistake, the impact of *Riegel* on consumers will be severe and far-reaching. The devices specifically approved by FDA are generally the ones that sustain or support life, and failure of those devices all too often leads to dire, and at times, fatal consequences. Thus, the fact that FDA also permits other, non-PMA devices on the market is beside the point. The devices that matter most are PMA devices. Nor is the remote prospect that someone injured by a PMA device might have a claim based on a violation of a *federal* requirement much comfort. In most cases, a finding of preemption with respect to life-saving or life-sustaining PMA devices simultaneously immunizes manufacturers for their errors, removes incentives to prevent or correct errors,

¹⁶ *Riegel*, 129 S.Ct. at 1011.

and deprives consumers injured through no fault of their own of compensation that historically has been available under state law. None of these consequences is defensible as a matter of public policy.

Let me make one last point about medical devices. FDA has had to strain to suggest that its approval of a device is a warrant for its safety. In fact, premarket approval is a one-time licensing decision based on whether the device's sponsor has shown a "reasonable assurance" of safety — a standard far less rigorous than for drugs, which must be shown to be safe and effective for their intended use. Unlike drugs, which are extensively tested, medical devices are often approved on the basis of a single clinical trial, in part because of the ethical problems in testing experimental medical devices on human subjects. Once on the market, FDA engages in only limited surveillance. There is no provision in the MDA for devices to be periodically re-certified by FDA. As a result, defective devices typically remain on the market until the manufacturer commences a "voluntary" recall, often in response to adverse publicity generated by state liability litigation.

FDA's track record demonstrates the agency's inability to single-handedly protect the American people against defective and dangerous medical devices. Just in the past few years, we have seen massive recalls of defibrillators,¹⁷

¹⁷ Consider the case of the Guidant defibrillators, discussed in my Pepperdine article. By the time they were withdrawn from the market, more than 24,000 of the defective devices had been implanted in patients, who then faced the daunting decision of whether to have replacement surgery. *See generally In Re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 2007 WL 1725289 (D. Minn.

pacemakers,¹⁸ heart valves,¹⁹ and heart pumps²⁰ — which have exacted a terrible toll on the patients who have had them implanted in their bodies, and who often face the daunting prospect of explantation and replacement surgery. Post-*Riegel*, these patients will now be left with no remedy at all: no compensation for the pain and suffering they endure, no reimbursement for the expenses of surgery and a replacement device, and no recompense to their loved-ones should they die as a result of a defective device. Making matters worse, manufacturers will have little economic incentive to recall swiftly defective devices, since they are immunized

June 12, 2007); Barry Meier, *FDA Expanding Inquiry into Heart-Device Company*, N.Y. Times (Aug. 25, 2005), at C3.

¹⁸ Although Medtronic's 4004M pacemaker was approved by FDA, it was later determined to be defectively designed. Some patients died when the pacemaker's defective lead failed; many patients were forced to undergo open-heart surgery to replace the defective lead. Prior to *Riegel*, the courts were split on whether the plaintiffs' claims were preempted. Compare *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) (finding claims preempted) with *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (finding no preemption).

¹⁹ The St. Jude Silzone heart valve is another instructive case. This valve was approved on the basis of only scanty testing involving 20 human subjects. After St. Jude starting selling the valve, testing revealed that its silver coating not only did not protect against infection, but it also caused the valves to leak. Litigation publicized the risk and forced St. Jude to recall the problem valves, but not until they had been implanted in over 36,000 patients. See generally *In re St. Jude, Inc. Silzone Heart Valves Prod. Liab. Litig.*, 2004 WL 45503 (D. Minn. Jan. 5, 2004); see also *Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (class action involving 55,000 patient implanted with different defective heart valve).

²⁰ See *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (finding claim against manufacturer of device heart pump preempted, even though evidence showed that it was defectively designed and that the pump had been redesigned to correct design defect).

from liability in tort, and virtually certain to face no enforcement sanction from FDA, which has essentially withdrawn the regulatory cop from the beat.²¹

Premarket approval is an important process intended to put an end to the marketing of devices without meaningful testing and with no assurance of safety. But PMA process, by itself, cannot replace the continuous and comprehensive safety incentives, information disclosure, and victim compensation that state liability law has traditionally provided.

The Court's opinion in *Riegel* makes it clear that the decision about preemption is one for Congress. The ball is squarely in Congress' court. I would urge Congress to act swiftly to restore the historic availability of state liability law protections both to ensure that compensation is available to people injured through no fault of their own and to place economic incentives on device manufacturers to take reasonable measures to protect consumers from defective or unsafe devices.²²

²¹ The decline in enforcement activities by FDA is nothing short of stunning. In 1991 through 1993, the agency brought a total of 468 civil seizure actions, 75 injunction cases, and 121 criminal prosecutions. See Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, in FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY app. B, B-22-23 (2007). However, from 2004 to 2007, the agency brought a total of only 53 civil seizure actions, 57 injunction cases, and no criminal prosecutions. *Id.* The decline in FDA warning letters is just as steep: from 1,788 in 1993 to only 467 in 2007. *Id.*

²² Overturning the result in *Riegel* will require Congress to amend the MDA to make clear that the preemption provision, 21 U.S.C. 360k(a), does not preempt state liability action. One approach would be to define the word "requirement" to mean only positive state law (i.e., statutes and regulations); another would be to insert a "savings clause" to make explicit that nothing in the provision should be construed to displace state liability law.

II. FDA Preemption and Drugs.

As noted above, FDA's reversal of field on device preemption was part of a broad realignment by FDA on preemption more generally. Pushed by the agency's political, non-career appointees, FDA now asserts that virtually every one of its regulatory actions — from setting standards for sun-screen products to the labeling of over-the-counter drugs — preempts state law.²³

The most important and inexplicable of these shifts was FDA's about-face on the agency's long-expressed position that its regulation of drug labeling does not immunize drug manufacturers from failure-to-warn claims. FDA's prior position was not surprising. The Federal Food, Drug and Cosmetic Act does not contain, and never has contained, a preemption provision for drug products. Indeed, when the 1938 Act was being debated, Congress was told that the bill did not need to create a federal claim for damages because state law already permitted such actions to be brought.²⁴ And the Act has been amended repeatedly since then, but Congress has never given the pharmaceutical industry the immunity from liability it has long coveted. Indeed, the one preemption provision in the Act applicable to drugs cuts decidedly against FDA's position. When Congress added the efficacy requirements to the Act in 1962, it added a provision

²³ See FDA, *Sunscreen Drug Products for Over-the-Counter Human Use, Proposed Amendment of Final Monograph; Proposed Rule*, 72 Fed. Reg. 49070, 47109-10 (Aug. 27, 2007); FDA, *Over-the-Counter Human Drugs; Labeling Requirements; Proposed Rule*, 71 Fed. Reg. 74474, 74481 (Dec. 12, 2006).

²⁴ See Hearings on S. 1944 before a Subcomm. of the Sen. Comm. on Commerce, 73d Cong., 2d Sess. 400 (1933) (statement of W. A. Hines).

that states: “Nothing in the amendments . . . 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.”²⁵

Nonetheless, FDA now maintains that state failure-to-warn litigation threatens its ability to protect the public health. A determination in civil litigation that an FDA-approved label fails adequately to warn of risks may force manufacturers to add warnings not approved by FDA, or even warnings that FDA considered and rejected. For that reason, FDA asserts that most failure-to-warn litigation is preempted.²⁶ As noted, FDA’s change of position has triggered a substantial wave of preemption litigation over drug claims, with the vast majority of courts rejecting FDA’s pro-preemption position.²⁷ The Supreme Court will address this issue in October 2008 when it reviews *Wyeth v. Levine*.

This seismic shift in policy must be viewed against the backdrop of the agency’s long-held, and repeatedly expressed, position to the contrary. Let’s be clear about one thing: Litigation against drug manufacturers for failing to warn physicians and patients about the risks that attend the drug is nothing new.

²⁵ See 76 Stat. 780, 793 (1962).

²⁶ See FDA, *Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

²⁷ See also *Riegel v. Medtronic, Inc.*, 199 S. Ct. at 1019 & n.16 (Ginsburg, J., dissenting) (noting that “[c]ourts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits,” and citing cases so holding).

Perhaps the most celebrated failure-to-warn case — *Thomas v. Winchester* — was decided by the New York State Court of Appeals in 1852.²⁸ Since *Thomas*, there has been a steady stream of failure-to-warn litigation against drug companies, both pre- and post-dating the creation of the modern FDA in 1938, and its forerunner in 1908.²⁹ Notwithstanding FDA’s awareness of this litigation, until recently, FDA steadfastly took the position that its regulation of drug labeling did not preempt state failure-to-warn litigation.³⁰ Indeed, FDA took exactly the

²⁸ 6 N.Y. 397 (1852). In *Thomas*, the court held that, even though the consumer purchased the mis-labeled drug from a pharmacist, the consumer could sue the manufacturer of the drug which was responsible for the mislabeling.

²⁹ These cases are legion, but a sample includes: *Blood Balm v. Cooper*, 83 Ga. 457, 10 S.E. 118 (1889); *Valmas Drug Co. v. Smoots*, 269 F. 356 (6th Cir. 1920) (applying Michigan law); *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925) (applying Missouri law); *Halloran v. Parke, Davis & Co.*, 245 A.D. 727, 280 N.Y.S. 58 (N.Y. App. Div. 1935); *Wechsler v. Hoffman-La Roche*, 198 Misc. 540, 99 N.Y.S.2d 588 (N.Y. App. Div. 1950); *Wright v. Carter Products*, 244 F.2d 53 (2d Cir. 1957) (applying Massachusetts law). By 1964, the pace of drug litigation had accelerated to the point that one commentator called the 1960s “the era of the drug” and observed that “drugs are being withdrawn from the market in unprecedented numbers because of undesirable side effects which are deemed to outweigh whatever therapeutic value the drugs may have.” Paul Rheingold, *Products Liability – The Ethical Drug Manufacturers’ Liability*, 18 Rutgers L. Rev. 947 (1964). The reasons for this growth in litigation were (1) the fact that states had abandoned defenses based on lack of privity; and (2) the 1962 amendments to the FDCA required manufacturers to show that the drug was not just safe, but was also effective for its intended use. Post-1960, representative cases include: *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (Cal. Dist. Ct. App. 1960); *Sterling Drug v. Cornish*, 370 F.2d 82 (8th Cir. 1966) (applying Missouri law); *Love v. Wolf*, 226 Cal. App. 2d 379, 38 Cal. Rptr. 183 (Cal. Ct. App. 1964); *Lake v. Konstantinu*, 189 So. 2d 171 (Fla. Dist. Ct. App. 1966). See also *Riegel v. Medtronic, Inc.*, 199 S. Ct. at 1017 n.11 (canvassing state law drug liability cases).

³⁰ See, e.g. FDA, *Final Rule: Labeling and Prescription Drug Advertising: Content and Format for Labeling for Human Prescription Drugs*, 44 Fed. Reg. 37434, 37447 (June 26, 1979) (making clear that FDA regulation for labeling “do not

opposite position, emphasizing that it did “*not* believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency’s [drug labeling] regulations.”³¹ Thus, FDA’s current argument that state liability actions — which turn on claims that the manufacturer withheld important safety information from physicians and patients — impair FDA’s ability to protect the public health deserve especially close scrutiny.

In an article recently published in the *Georgetown Law Journal*, former FDA Commissioner David A. Kessler, M.D., and I make three key points why, in our view, FDA’s position on drug preemption cannot be sustained.

1. Failure-to-warn litigation does not challenge FDA’s decision to approve a label for a new drug, or even the agency’s final say over the form and contents of drug labeling. Instead, failure-to-warn litigation challenges the *company’s* failure to revise its labeling to warn physicians and patients about risks unknown at the time of approval, or risks that turn out to be graver than the company and FDA originally thought.

prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling and advertising of additional warnings . . . is not prohibited by these regulations.”); FDA, *Prescription Drug Product Labeling; Medication Guide Requirement*, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1988) (“FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency’s [drug labeling] regulations. FDA’s regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements”); *see also* Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7 (1997).

³¹ FDA, *Prescription Drug Product Labeling; Medication Guide Requirement*, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1988) (emphasis added).

FDA's own regulations impose a duty on drug manufacturers to modify labeling without delay when hazards emerge, and expressly authorize labeling changes without the agency's advance approval. When FDA approves a new drug, it also approves the drug's proposed labeling. The manufacturer must follow the FDA-approved label and must submit a supplemental new drug application (NDA) to FDA if it wishes to change the label.³² Ordinarily, the manufacturer waits for FDA approval before making the change. However, FDA rules create an exception in cases where a manufacturer makes a labeling change "[t]o add or strengthen a contraindication, warning precaution, or adverse reaction," or "[t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."³³ In those cases, manufacturers may

³² It is important not to overstate FDA's authority over labeling. Until the 2007 amendments, FDA lacked authority to dictate labeling changes to manufacturers. As a result, it took FDA over a year to force Merck to place a warning for heart attack and stroke on Vioxx, and even then the agency acceded to Merck's demand that the warning be a weak one and not the stronger warning the agency favored. *See FDA's Drug Approval Process: Up to the Challenge?* Hearings before the S. Comm. on Health, Educ., Labor and Pensions, 109th Cong., 23 (2005) (testimony of Sandra Kweder, M.D., Deputy Dir., Office of New Drugs, FDA) (explaining that Merck "rejected many of our proposals," and defending the lengthy delay in the labeling change by observing that "we don't have the authority to tell a company, this is how your label has to look."). To be sure, the FDA Amendments Act of 2007 makes explicit that FDA has authority to compel labeling changes, but it also requires the agency to first negotiate with the company, a process that will likely take months, even if the agency accelerates it. *See* FDAAA, Tit. IX, sec. 901(a), § 505(o)(4), 121 Stat. 924-26.

³³ *See* 21 C.F.R. § 201.80(e) (requiring labels to contain requisite warnings); 21 C.F.R. § 314.70(b)(2)(v)(A) (setting forth general rule that drug labeling must be approved by FDA); *Id.* § 314.70(c)(6) (setting forth exceptions that permit manufacturers to change the label without first obtaining FDA approval).

change labeling without first securing FDA's permission, so long as they file a supplemental NDA at the same time they make the labeling change.

Thus, the common law duty enforced in failure-to-warn litigation — namely a drug company's duty to take all reasonable measures to alert physicians and patients to previously unknown hazards — is no different than the duty FDA itself imposes on drug manufacturers. That is why the steady procession of failure-to-warn cases has not interfered with FDA's regulatory efforts for all of these years: the duties imposed by state and federal laws are parallel and mutually reinforcing.³⁴

³⁴ The Vermont Supreme Court's decision in *Levine v. Wyeth*, 2006 Vt. 107 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (2008), is a good illustration of the utility of state law in enforcing broader public policy norms. Ms. Levine was a musician who suffered through two amputations, ultimately losing an arm that ended her career, because the anti-nausea drug Phenergan, was administered through the "Push IV" method, inadvertently introducing Phenergan directly into her artery. The corrosive nature of Phenergan can lead to catastrophic tissue damage if it enters a patient's arterial blood flow. This risk was realized when an error in Levine's IV-Push procedure injected the drug into her arteries and caused her injuries. Wyeth was well aware of this risk. Yet its labeling did not clearly warn physicians or patients. Wyeth's defense was that it had submitted proposed labeling changes to FDA, which rejected them. But the Vermont Supreme Court found neither proposal sought to change the warning regarding administering the drug by intravenous injection, and thus the submissions did not provide Wyeth a defense. *Levine*, ¶ 23. FDA approved Phenergan's label over twenty-five years ago. Even assuming that Phenergan's label appropriately balanced the drug's known risks when approved, there is no evidence that FDA revisited its assessment of the IV-Push method to verify that the warnings were appropriate in light of new adverse-reaction information. Yet, by 1976, both the agency and Wyeth were aware of the risk. *See id.* The jury's verdict assessed liability for Wyeth's failure to improve the warning as the risk became increasingly clear. Because FDA never took definitive action with respect to new information about this increased risk of arterial damage, no possible conflict exists between any FDA decision and a jury verdict requiring Wyeth to pay damages. The verdict provides incentives for Wyeth to improve its warnings, but it does not *require* the

There is one more point to make about these FDA regulations, which are known as the “change being effected,” or CBE, regulations. Apparently in response to industry pressure, FDA has recently proposed modifications the CBE regulations to limit the ability of manufacturers to make changes without first securing FDA’s approval to situations in which the change is based on “new” information that had not been available previously to the manufacturer. *See* 73 Fed. Reg. 2848 (Jan. 16, 2008). Not only does this proposal run counter to fundamental notions of public health — public health is threatened if manufacturers have to wait for an FDA greenlight to warn physicians and patients of a serious, undisclosed risk — it is also transparently an effort to fortify industry’s position in *Wyeth v. Levine*. I would urge this Committee to find out whether, as many suspect, this proposal was initiated by industry and not FDA, perhaps by demanding all FDA correspondence, emails, and other records reflecting communications with individuals outside FDA on this matter.

2. More fundamentally, FDA’s preemption argument presupposes that the agency has the resources to perform the monumental task of ensuring that the labeling of drugs on the market reflects current safety information. It does not. According to the November 2007 report of a blue-ribbon panel appointed by the FDA Commissioner, “[t]he scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity

manufacturer to do anything that is inconsistent with that which FDA has instructed it to do.

of the . . . regulatory system, and hence the safety of the public.”³⁵ The Institute of Medicine reported in 2006 that FDA “lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.”³⁶ These reports are no surprise. FDA regulates products that amount to one-quarter of consumer spending in the United States,³⁷ but it has only 9,000 employees nationwide.³⁸ According to the most recent statistics, FDA’s Office of New Drugs, which reviews new drug applications, employs over 1,000 physicians and scientists to review the approximately 100 new drug applications each year and to supervise post-marketing studies. In contrast, FDA’s Office of Drug Safety, the unit charged with monitoring adverse events associated with the 3,000 prescription drugs (and 11,000 drugs altogether) on the market, has about 100 professional employees.³⁹

³⁵ FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY 1.1 (2007).

³⁶ INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193 (National Academies Press 2006).

³⁷ FDA News, *The Food and Drug Administration Celebrates 100 Years of Service to the Nation* (Jan. 4, 2006).

³⁸ Food and Drug Administration, *An Overview of the FDA*. In addition to drug safety, these employees also review applications to market new medical devices, monitor the safety of the medical devices on the market, inspect drug and device manufacturing facilities, inspect virtually all of the non-meat food products sold in this country (including a rising flood of imported foods), inspect food processing and storage facilities, regulate dietary supplements, oversee the safety of the blood supply and tissues for transplantation, regulate radiologic and biologic products, and regulate veterinary medicines and cosmetics. *Id.*

³⁹ *FDA’s Approval Process: Up to the Challenge?*, Hearings before the S. Comm. on Health, Education, Labor and Pensions, 109th Cong., 10 (2005) (Joint

I recognize that Congress has recently enacted comprehensive amendments to the Food, Drug, and Cosmetic Act, which will bolster the agency's statutory authority and shore-up, to some extent, the agency's flagging resources. But as Senator Ted Kennedy warned, even with added resources, "[t]he resources of the drug industry to collect and analyze . . . 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."⁴⁰

3. State liability litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process, and this "feedback loop" enables the agency to better do its job. FDA approval of drugs is based on clinical trials that involve, at most, a few thousand patients and last a year or two. These trials cannot detect risks that are relatively rare, affect vulnerable sub-populations, or have long latency periods. For this reason, most serious adverse effects do not become evident until a drug is used in larger population groups for periods in excess of one year.⁴¹ Time and again, failure-to-warn litigation has

Statement of Sandra L. Kweder, M.D., Deputy Director, Office of New Drugs, and Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, Food and Drug Administration, to the Committee on Health, Education, Labor and Pensions, U.S. Senate) (March 1 & 3, 2005) (reporting that for fiscal year 2005 the Office of Drug Safety had about 90 full time employees, but projecting for fiscal year 2006 an increase to about 110 full time employees).

⁴⁰ 153 CONG. REC. S11,832 (2007) (statement of Sen. Kennedy).

⁴¹ See, e.g., *Hearings on Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx*, Before the H. Comm. on Government Reform, 109th Cong., 23, 55 (2005) (testimony of Steven Galston, Acting Director, Center for Drug Evaluation and Research, FDA).

brought to light information that would not otherwise be available to FDA, to doctors, to other health care providers, and to consumers. And failure-to-warn litigation has often preceded and clearly influenced FDA decisions to modify labeling, and, at times, to withdraw drugs from the market.⁴²

Congress is, of course, acutely aware of the shortcomings in FDA's ability to police the marketplace on drug safety, which have been driven home by the recent public health failures involving widely-prescribed drugs like Vioxx, Bextra, Baycol, Rezulin, Celebrex, Avandia, and Evra Ortho. FDA's current claim that it, and it alone, can single-handedly discipline this market is a difficult claim to accept.

For the Committee's purposes, however, the key point here is that the agency's claim that it is authorized to direct the preemption of state law is not based on any mandate from Congress. Congress has not dictated preemption with respect to drug products, nor has it delegated to FDA the authority to define the borderline between federal regulation and state tort law. Nonetheless, the agency claims authority to cut off state law *now* because, at some point in the future, a state court *might* issue a ruling that undercuts the agency's regulatory authority. With all respect, that is a decision for Congress, not agency officials, to make. Congress should stand ready to ensure that its decision not to preempt state liability law is respected by both FDA and the courts.

⁴² See, e.g., Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. Am. Med. Ass'n 2215, 2218 (2002); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 287 J. Am. Med. Ass'n 308, 310 (2007) (citing examples).