BEFORE THE SENATE COMMITTEE ON THE JUDICIARY

JUNE 11, 2008

STATEMENT OF RICHARD M. COOPER

Mr. Chairman and Members of the Committee, thank you for inviting me to testify on the *Riegel* decision and federal preemption in the field of food and drug regulation. Although the law firm of which I am a partner represents a number of companies interested in the topic of this hearing, I was invited to appear, and I am appearing, on my own, and not on behalf of my law firm or any client.

The supremacy of federal law over state law, operating through the doctrines of express and implied preemption, is fundamental to our federal system. The Supreme Court's recent decision in *Riegel v. Medtronic, Inc.*[1] interprets a statute that expressly preempts any state-law requirement with respect to a device that (i) is different from or in addition to any requirement applicable under the Federal Food, Drug, and Cosmetic Act ("FDCA") to the device and (ii) relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FDCA.[2]

Riegel was decided correctly. It was not a close case. Eight Justices concurred in the Court's judgment, and seven joined the opinion of

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1 128 S. Ct. 999 (2008).

2 21 U.S.C. § 360k(a) (2000).

the Court. The decision was anticipated by a substantial majority of the federal courts of appeals that had considered the issue.[3]

The *Riegel* decision was plainly foreshadowed by prior decisions of the Supreme Court. In 1959, the Court observed that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[4] *Cipollone v. Liggett Group, Inc.* in 1992,[5] confirmed that, under the Supremacy Clause of the Constitution,[6] theories of liability that support judgments in products-liability cases can constitute state-law requirements that are preempted by federal action. A majority of the Court adhered to that holding in *Medtronic, Inc. v. Lohr* in 1996.[7] In 2002, a unanimous Court in *Sprietsma v. Mercury Marine* stated in *dictum*: "Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur."[8]

The Court also held in *Lohr* that the generality of the requirements applicable in FDA's clearance of medical devices under the

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3 Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. Tort L. 1, 14 (2006).

4 *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 246-47 (1959).

5 505 U.S. 504 (1992).

6 U.S. Const. art. VI, cl. 2.

7 518 U.S. 470 (1996). *See id.* 503-04 (Breyer, J., concurring in part and concurring in the judgment), 509-12 (O'Connor, J., joined by Rehnquist, C.J., Scalia & Thomas, JJ., concurring in part and dissenting in part).

8 537 U.S. 51, 65 (2002).

section 510(k) process[9] precluded preemptive effect for such clearances, but it explained that that generality

> make[s] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers on producers.[10]

Riegel presented that very case. FDA approval of a device pre-marketing-approval application constitutes FDA approval of the physical aspects of a device and its labeling, results from a comprehensive review of the scientific and medical information relevant to the effectiveness and safety of the particular device, and reflects FDA's detailed resolution of tensions between aspects of the device that confer therapeutic benefits and aspects that present risks to safety. Such a federal decision presents the strongest case for preemptive effect.

Where an adequately informed FDA has weighed the advantages and disadvantages of, and has approved, the design and labeling of a particular product, decision-makers applying state law should not be permitted to second-guess FDA's approval – or re-weigh benefits and risks FDA has already weighed, or revise trade-offs FDA has already found acceptable – by finding the product's design or labeling inadequate. Permitting decision-makers applying state law to do so would create conflicts

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9 *See* 21 U.S.C. § 360(k).

10 518 U.S. at 501.

with FDA-imposed requirements and would create obstacles to the achievement of the objectives of the FDCA.

Riegel and the cases that foreshadowed it did not come out of the blue. Rather, they reflect widely-supported mainstream trends in judicial and scholarly understanding of products-liability law and of the role of federal agencies in administering regulatory statutes enacted by the Congress.

Products-liability theories are widely understood as a type of regulation of manufacturers' conduct. That system of regulation is administered by judges and juries *ad hoc* and with a focus on a particular allegedly injured plaintiff or group of plaintiffs and without the presence in the courtroom of those users of the product who have benefited from it.[11] Thus, products-liability theories constitute a kind of regulation "in disguise."[12]

Moreover, it has long been obvious that regulatory agencies such as FDA are far more expert in their areas of regulatory activity than are judges and juries, and that they have the advantage of being able to apply criteria of effectiveness and safety to product design and criteria of truthfulness and adequacy to product labeling *ex ante* and with all potential users in mind, in contrast to the *ex post* perspective presented to judges and juries by an individual plaintiff or group of plaintiffs complaining of a

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11 *See generally* Nagareda, *supra* note 3, at 38-39.
12 *See id.* at 38 & n. 143.

grievous injury. In addition, since the Supreme Court's decision in *Chevron* in 1984,[13] it has been clearly understood that federal agencies administering regulatory statutes are more politically accountable as regulators than are judges and juries, and that therefore courts are to defer to them not only in their application of expertise to technical matters but also in their institutional interpretations of statutory ambiguities.[14]

Although products-liability theories are a form of regulation, they also can be a basis for compensation for injured plaintiffs. *Riegel* and similar decisions,[15] however, are consistent with the proper compensatory role of products-liability litigation.

Manufacturers are not insurers. Their liability to compensate injured plaintiffs must be based on some type of fault – most commonly, their marketing of a product that is defectively designed, manufactured or labeled or their negligence with respect to one or more of those aspects of a product. Where a manufacturer is not at fault, it should not be liable. The law of products liability is not intended to be a social safety net for all patients harmed by medical products. It is not intended to be a substitute for health, disability, and life insurance. Thus, the compensatory purpose of products-liability law is limited.

Where a properly informed FDA has specifically approved the design and labeling of a particular product, and the manufacturer is barred

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13 *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

14 *See generally* Nagareda, *supra* note 3, at 38-39.

15 *See, e.g.*, *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).

by federal law from changing the product or its labeling without prior FDA approval,[16] the manufacturer is not at fault in marketing that product, so designed and so labeled, and therefore should not be liable to a plaintiff alleging a defective design or inadequate labeling. Preemption in such circumstances is consistent with the limited compensatory purpose of products-liability litigation.

Lohr and *Riegel* leave unchanged the availability of products-liability claims relating to devices that have not gone through the PMA process, but, rather have gone through the section 510(k) process or are exempt from both – and those are all of the class I and class II devices and the vast majority of class III devices.[17] Thus, as to all but a very small percentage of devices, *Lohr* and *Riegel* provide no preemption defense based on FDA approval.

Moreover, under those cases, if a manufacturer materially violates a relevant condition of its approval, or violates some other requirement under the FDCA, it may be held liable under a traditional state-law products-liability theory that seeks to enforce the federal condition or requirement.[18] Thus, those cases leave intact the regulatory function of traditional products-liability law in providing incentives for compliance with state-law requirements that enforce FDA requirements.

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16 *See* 21 C.F.R. §§ 310.3(h), 314.70, 814.80 (2007).

17 *See Riegel*, 128 S. Ct. at 1004; *Lohr*, 518 U.S. at 479; *see also* 21 U.S.C. § 360e(a) (2000); 21 C.F.R. § 807.85 (2007).

18 Not every "violation of the FDCA will support a state-law claim," however. *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

As to drugs, biologics, and devices, FDA regulations permit manufacturers to make changes in labeling to enhance information about risk where new information warrants such changes.[19] FDA has stated that this permission extends only to situations involving information about a newly discovered risk or important new information about a known risk, where there is sufficient evidence of causal association with the drug, biologic, or device.[20] *Lohr* and *Riegel* leave open the potential for liability if a manufacturer fails to update its labeling in the narrow circumstances permitted by FDA's regulations. State courts adjudicating claims of such liability, however, would have to interpret FDA's regulations correctly.

Thus, as a practical matter, *Lohr* and *Riegel* have only a quite limited preemptive effect. As to most devices and as to most violations of traditional state-law requirements that seek to enforce FDA requirements, they leave products-liability law free to operate.

Riegel also is sound from the perspective of policy, and does not short-change patients or give short-shrift to Congress. The patients to be considered are all patients – those who need and benefit from drugs and devices, as well as those who experience adverse events and become plaintiffs.

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[19] 21 C.F.R. §§ 314.70(c)(6)(iii)(A) & (C), 601.12(f)(2), 814.39(d)(2) (2007).

[20] New Drug and Antibiotic Regulations, 47 Fed. Reg. 46,622, 46,623 (proposed Oct. 19, 1982) (to be codified at 21 C.F.R. pts. 310, 312, 314, 430, 431 & 433); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848 (proposed Jan. 16, 2008) (to be codified at 21 C.F.R. pts. 314, 601 & 814).

Riegel implements the Congress's central policy in the FDCA as to medical products. That policy has several components. First there is to be a nationally centralized agency with relevant medical, scientific, engineering, statistical, and other expertise. Second, that agency is to conduct individualized product-by-product reviews of certain devices (and certain drugs). Third, those reviews are to occur initially before marketing, and are to be in the interest of all prospective patients and for the benefit of the public health generally. Fourth, those reviews are to be based on substantial scientific information as to the aspects of the products that bear on effectiveness, safety, and labeling. Fifth, each review is to weigh a product's therapeutic benefits and risks, is to consider trade-offs between safety and effectiveness in its design and labeling, and is to take into account both what is known and what is unknown about the product's effectiveness and safety.

Finally, FDA's statutorily prescribed mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."[21] That formulation implicitly recognizes that, just as the public health is harmed by medical products that turn out to be unsafe or ineffective, the public health benefits by timely marketing of medical products that are safe and effective.

That policy serves patients well, but has unavoidable limitations. It serves patients well because FDA does a far better job of

[21] 21 U.S.C. § 393(b)(1) (2000).

deciding on product designs and labeling than judges and juries could do. Totally unpreempted regulation through products-liability litigation would erode FDA's uniform national regulatory system, would lead to inconsistent requirements from state to state and jury to jury, would create powerful incentives for inclusion in labeling of numerous additional warnings that plaintiffs' lawyers persuaded juries and judges to impose, and thereby would diminish the overall effectiveness of labeling in guiding physicians in the proper use of drugs and devices. As FDA has stated:

> [A]dditional requirements for the disclosure of risk information . . . can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug. . . . [L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to "lose its significance." (44 FR 37434 at 37447, June 26, 1979). Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.[22]

That congressional policy has limitations because there is always a trade-off between approving a device or drug for use by patients who need it and may benefit from it now and waiting for additional data that may clarify further how a device or drug may be made safer or more effective or may be labeled so as to be used more safely or more effectively, or that may show, contrary to earlier data, that a device or drug has additional risks that make it unsafe. Thus, every approved device and drug is marketed with less

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[22] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

than complete information about its optimal use and, consequently, presents risks of harm, through no fault of its manufacturer or FDA.

Preemption sometimes is opposed on the ground that FDA is ill-equipped to protect the public, that the agency is under-funded, inadequately managed, and makes mistakes.[23] The proper response to that criticism is not to declare open season for unrestrained regulation by judges and juries, but for the Congress to fund FDA adequately and to conduct effective oversight of its management and performance, so as to reduce mistakes to the minimum humanly achievable. The Congress has already taken steps, in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), to provide FDA with additional tools to improve its performance.[24]

Products-liability litigation sometimes brings to light information about medical products that was not previously known. The discovery process in litigation, however, is very costly and inefficient. FDA could obtain much the same information through effective use of tools it already has – not only required post-approval surveillance and studies,[25] and reporting of adverse events and submission of periodic reports by manufacturers,[26] but also use of its authority to inspect in a manufacturing establishment

> all things therein (including records, files, papers, . . .) bearing

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23 *See generally*, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461 (2008).

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

25 *See* FDAAA §§ 901-09, 121 Stat. at 922.

26 *See* 21 C.F.R. §§ 314.80, 314.81, 803.1-.58, 814.82 814.84 (2007).

> on whether prescription drugs . . . or restricted devices which are adulterated or misbranded . . . or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale . . . have been or are being manufactured . . . in any such place, or otherwise bearing on violation of [the FDCA].[27]

Thus, without dependence on private products-liability litigation, FDA has broad authority to obtain from manufacturers information they have and it needs to monitor the safety of marketed prescription drugs and restricted devices. That better systems and methods are needed generally to monitor the safety of medical products after they have been approved is a problem that is independent of the preemption doctrine and is not solved by litigation.

It has been argued, contrary to *Garmon* and other decisions and to other scholarly understanding of products-liability theories, that court judgments embodying such theories do not impose requirements that might conflict with FDA's requirements because the judgments merely compensate injured plaintiffs, the judgments operate against companies and not against FDA, and manufacturers can maintain their compliance with FDA requirements and satisfy court judgments by paying damages. These arguments have no merit.

Court judgments awarding damages in products-liability cases do not <u>merely</u> compensate plaintiffs; they order defendants to make payments due to a finding that those defendants violated requirements imposed by state law. That those requirements operate on companies rather

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[27] 21 U.S.C. § 374(a)(1) (2000 & Supp. V 2005).

than FDA certainly does not entail that the requirements do not conflict with contrary requirements imposed on those companies by FDA. To say that products-liability judgments don't conflict with FDA requirements because companies could continue to comply with FDA requirements and pay damages is analogous to saying that a state criminal statute that prohibited conduct required by FDA does not conflict with the FDA requirement because companies could continue to comply with the FDA requirement and pay fines and their executives could direct compliance with the FDA requirements while in state prison.

In sum, current Supreme Court jurisprudence as to preemption in the field of food-and-drug law is sound and well serves the public.