BEFORE THE SUBCOMMITTEE ON HEALTH
OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE

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STATEMENT OF RICHARD M. COOPER

Mr. Chairman and Members of the Subcommittee, thank you for inviting me to testify on H.R. 1346, The Medical Device Safety Act of 2009, a bill to amend the Federal Food, Drug, and Cosmetic Act ("FDCA") with respect to liability under State and local requirements respecting devices. 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.

I was Chief Counsel of FDA during the Carter Administration. Since then, I have practiced food and drug law at the law firm of Williams & Connolly LLP, have taught food and drug law at Georgetown University Law Center, and have served on committees, published articles, and edited or co-edited books in the field.

H.R. 1346 would overturn the Supreme Court's decision last year in *Riegel v. Medtronic, Inc.*[1] That decision interpreted a provision of the FDCA that expressly preempts any state-law requirement with respect to a device that (i) is different from or in addition to any requirement applicable

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1 128 S. Ct. 999 (2008).

under the 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] The Court held that the FDCA's preemption provision bars common-law claims challenging the safety or effectiveness of a medical device marketed in accordance with a premarket approval application ("PMA") approved by FDA.

I want to make seven points.

First, the supremacy of federal law over state law, operating through the doctrines of express and implied preemption, is fundamental to our federal system, and is expressly authorized by the Constitution. Without preemption, the 50 States and other American jurisdictions would apply their own bodies of law, businesses and other organizations operating in interstate commerce could be subjected to conflicting duties, and the many benefits of a national legal system and a national economy would be greatly diminished.

Second, *Riegel* was not an innovation in the law, and was decided correctly. It was not a close case. Eight Justices concurred in the Court's judgment, and seven joined the opinion of the Court. The decision was anticipated by a substantial majority of the federal courts of appeals that had considered the issue.[3]

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[2] 21 U.S.C. § 360k(a) (2006).

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

Riegel also was plainly foreshadowed by prior decisions of the Supreme Court that stretch back to the period before the enactment of the Medical Device Amendments of 1976 ("MDA").[4] 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."[5] *Cipollone v. Liggett Group, Inc.*, decided in 1992,[6] confirmed that, under the Supremacy Clause of the Constitution,[7] 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.[8] 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."[9]

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4 Pub. L. No. 94-295, 90 Stat. 539 (1976).

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

6 505 U.S. 504 (1992).

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

8 518 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).

9 537 U.S. 51, 65 (2002).

Moreover, *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.[10] Thus, products-liability theories constitute a kind of regulation "in disguise."[11]

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 grievous injury. In

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

11 *See id.* at 38 & n. 143 (internal quotation omitted).

addition, since the Supreme Court's decision in *Chevron* in 1984,[12] it has been clearly understood that federal agencies administering regulatory statutes are more politically accountable as regulators (including to congressional committees and subcommittees, such as this one) 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.[13]

The *Harvard Law Review*, after a thorough analysis, concluded that *Riegel* strikes the proper balance between the interest of patients generally in having a single, authoritative federally-managed system for regulating medical devices and the interest of individual patients in receiving from state tort systems compensation for injuries from devices:

> Despite criticisms that it leaves tort victims uncompensated, preemption is necessary to ensure that federal regulatory agencies, like the Food and Drug Administration (FDA), are the only governmental actors able to impose requirements on manufacturers — thereby ensuring a nationally standardized system of safety regulations without myriad local variations. *Riegel* extends an evolving MDA jurisprudence that empowers this federal system, while preserving common law claims when the regulation systematically provides inadequate safety assurances . . . .
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> *Riegel* is the most recent step in a body of preemption precedent pertaining to medical devices; these cases must balance the effective regulatory power of the federal government and the ability of tort victims to seek compensation for their injuries.

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

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

While acknowledging the supremacy of federal regulation, the Supreme Court's preemption jurisprudence has recognized that the FDA does not strictly regulate all medical devices on the market, nor can it ensure safety in all situations. Common law claims have thus been allowed to proceed when the federal regulatory system is systematically avoided — as when the device is not subject to regulation — or when it is unable to protect the public — as with manufacturer noncompliance. The Court has repeatedly decided cases according to the underlying principle that state law claims are only precluded if federal safety requirements have been satisfied . . . .

Through the MDA, Congress created a superseding federal system of regulation to ensure the safety of medical devices. In so doing, Congress vested the FDA with the power to approve — through a rigorous process — new devices before they may be marketed. Through its express preemption, the MDA made the FDA the only arbiter of appropriate regulation. (In fact, some commentators have suggested increasing the role of the FDA in determining the outcome of product liability suits.) As Justice Scalia argued, to allow state common law claims to proceed against a properly screened medical device in the face of the preemption provision would grant a single jury greater power than even state legislatures — a "perverse distinction" not mandated by the MDA. By precluding some tort suits, *Riegel* accepted that some consumers hurt by pre-approved products will be uncompensated, which is a necessary cost of prioritizing the federal system.

However, preemption does not automatically apply to all medical devices. As a threshold matter, the MDA does not preempt suits relating to devices that are not subject to the extensive federal regulation at issue in *Riegel*. If the device was not required to comply with the most stringent federal safety requirements, its manufacturer cannot use FDA approval as a liability shield. As the *Riegel* majority discussed, the *Lohr* Court preserved causes of action against products that did not go through the premarket approval process, but only through "substantial equivalence" review . . . . Thus, if the federal regulatory system has not approved the medical device, regulation through common law claims is allowed — and expected — to fill this gap.

Even if a device has been screened by the premarket approval process, the tort system catches some cases that fall through the cracks in federal safety regulation — if the cracks are

> the result of manufacturer noncompliance. Manufacturers are not immunized from tort suits if they violate FDA regulations. Importantly, the MDA does not preempt "parallel" state claims; nothing in the statute "prevent[s] a State from providing a damages remedy for claims premised on a violation of FDA regulations." . . .
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> Although *Riegel* appears to be a broad preemption precedent, its scope is couched within a system of supreme federal regulation and supplementary common law claims. The Court's finding that the MDA's express preemption provision precluded the Riegels' state tort claims was the next step in a jurisprudence that finds preemption when federal requirements have been satisfied. However, this preemption only applies to medical devices that undergo the extensive premarket approval process; manufacturers who do not comply or who perpetrate fraud are likely to find themselves still subject to tort liability. Rather than completely deprive consumers of the protection provided by state common law actions, the Supreme Court's MDA-related decisions have struck a balance — protecting consumer safety through a complementary system of federal regulation and state civil actions.[14]

The Supreme Court also held in *Lohr* that the generality of the requirements applicable in FDA's clearance of medical devices under the section 510(k) process[15] 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 or producers.[16]

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14 *The Supreme Court 2007 Term – Leading Cases*, 122 Harv. L. Rev. 405, 410-12, 414-15 (2008) (footnotes omitted), *available at* http://www.harvardlawreview.org/issues/122/nov08/leadingcases/riegel_v_medtronic.pdf.

15 *See* 21 U.S.C. § 360(k) (2006).

16 518 U.S. at 501.

Riegel presented that very case.

Third, as interpreted and applied in *Riegel*, medical device preemption of products liability claims has very limited scope. *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 – less than 1%[18] – *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 a state-law requirement that adopts, or otherwise is the same as, the federal condition or requirement.[19] Thus, those cases leave intact the regulatory function of traditional products-liability law in providing incentives for compliance with state-law requirements that, in effect, enforce FDA requirements. In sum,

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17 *See Riegel*, 128 S. Ct. at 1004; *Lohr*, 518 U.S. at 479; *see also* 21 U.S.C. § 360e(a) (2006); 21 C.F.R. § 807.85 (2008).

18 Statement of Dr. Randall Lutter before the H. Comm. on Oversight and Government Reform 7 n.2 (May 14, 2008), *available at* www.fda.gov/ola/2008/stateliability051408.html.

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

Riegel and the current overall judicial interpretation of medical-device preemption do not grant manufacturers blanket immunity. Far from it: 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.

H.R. 1346 is not needed to provide appropriate compensation under products-liability law for injured users of medical devices. Under products-liability law, manufacturers are not insurers. Their liability to compensate injured plaintiffs always is to 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. Under products liability law properly applied, where a manufacturer is not at fault, it should not be liable. A manufacturer that complies with requirements imposed by FDA through the PMA-approval process is not at fault for so complying without doing something additional or different. Thus, *Riegel* is fully consistent with the limited compensatory purpose of products-liability law.

Fourth, as described by FDA, the PMA process under section 515 of the FDCA[20] is

> the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient

[20] 21 U.S.C. § 360e (2006).

> valid scientific evidence to assure that the device is safe and effective for its intended use(s)."[21]

The Supreme Court has described the process as "rigorous"[22]:

> A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts and may request additional data from the manufacturer.
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> The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives . . . .
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> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading.[23]

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21 FDA Device Advice, Review Process Overview (Nov. 21, 2002), *available at* http://www.fda.gov/cdrh/devadvice/pma/.

22 *Lohr*, 518 U.S. at 477.

23 128 S. Ct. at 1004 (citations omitted).

Thus, FDA approval of a PMA for a medical device constitutes FDA approval of the physical aspects of the device and its labeling, results from a comprehensive review of the scientific and medical information relevant to the effectiveness and safety of the device, and reflects FDA's detailed resolution of tensions between those aspects of the device that confer therapeutic benefits and those 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 with FDA-imposed requirements, and would create obstacles to the achievement of the objectives of the FDCA.

Fifth, FDA has broad authorities and regulatory systems to monitor the safety of medical devices after approval, to require changes to enhance safety, and to bring about withdrawal of a product from the market if new information warrants such action.[24] The means available to FDA to

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[24] *See generally* FDA, Center for Devices and Radiological Health, *Ensuring the Safety of Marketed Medical Devices[:] CDRH's Medical Device Postmarket Safety Program* (Jan. 18, 2006), *available at* www.fda.gov/cdrh/postmarket/mdpi-report.pdf.

obtain safety-related information include: FDA inspections[25]; mandatory reports of adverse experiences by device user facilities, manufacturers, and importers[26]; other reports by manufacturers[27]; voluntary reports of adverse events by healthcare providers and patients; postmarket surveillance[28]; review of medical literature, monitoring certain listservs, and cooperative arrangements with other organizations, both governmental and private, that are concerned with public health. Remedial actions available to FDA include: restrictions on distribution[29]; notification, repair, replacement, refund, and recall.[30] The agency can conduct a variety of risk-communication and other educational activities directed to manufacturers, healthcare providers, and patients. FDA can bring about changes in labeling through enforcement action against a device it considers misbranded.[31] As a practical matter, FDA can end the use of a product immediately by exercising its authority to call publicly for an end to such use.[32] The agency can also suspend or withdraw

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25 *See* 21 U.S.C. § 374 (2006).

26 *See* 21 U.S.C. § 360i(a)-(c) (2006); 21 C.F.R. pt. 803 (2008).

27 See 21 U.S.C. § 360i (2006); 21 C.F.R. pt. 806, § 814.84 (2008).

28 *See* 21 U.S.C. § 360l (2006); 21 C.F.R. § 814.82, pt. 822 (2008).

29 *See* 21 U.S.C. § 360j(e) (2006).

30 *See* 21 U.S.C. § 360h (2006); 21 C.F.R. pt. 810 (2008).

31 *See* 21 U.S.C. §§ 331(a), 332-334, 337, 352 (2006).

32 *See* 21 U.S.C. § 375 (2006).

its approval of a device,[33] or ban it.[34] Congress has also specifically provided for FDA to make use of an advisory committee on communication of information on product-related risks.[35]

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 – mandatory reporting of adverse events and submission of periodic reports by manufacturers,[36] and use by FDA of its authority to inspect in a manufacturing establishment

> all things therein (including records, files, papers, . . .) bearing on whether . . . 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].[37]

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 restricted devices. FDA can also receive voluntary reports of adverse events associated with devices

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33 *See* 21 U.S.C. § 360e(e) (2006).

34 *See* 21 U.S.C. § 360f (2006); 21 C.F.R. pt. 895 (2008)

35 *See* 21 U.S.C.A. § 360bbb-6(a) (West 2009).

36 *See* 21 C.F.R. §§ 803.1-.58, 814.82, 814.84 (2008).

37 21 U.S.C. § 374(a)(1) (2006).

from physicians, healthcare facilities, and patients. 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. Significant improvements are likely, moreover, when medical records are stored and transmitted electronically rather than in hard copies, and FDA's Sentinel Initiative seeks to make such improvements.[38]

Sixth, H.R. 1346 is not justified by arguments that FDA is ill-equipped to protect the public, that the agency is under-funded, inadequately managed, and makes mistakes.[39] The proper response to those criticisms is not to declare open season for unrestrained regulation by judges and juries (who lack FDA's expertise and broad public-health perspective), 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[40]; and the President's budget

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38 *See* FDA's Sentinel Initiative, *available at* www.fda.gov/oc/initiatives/advance/sentinel/.

39 *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).

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

for FY 2010 proposes significant additional resources for FDA's safety-related activities.[41]

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

Riegel implements the Congress's central policy in the FDCA as to medical devices. That policy has several components. There is to be a nationally centralized agency with relevant medical, scientific, engineering, statistical, and other expertise. That agency is to conduct individualized product-by-product reviews of certain devices. 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. Each review is to be based on substantial scientific information as to the aspects of the device that bear on its effectiveness, safety, and labeling. Each review is also to weigh a device's therapeutic benefits and risks, is to consider trade-offs between effectiveness and safety in its design and labeling, and is to take into account both what is known and what is unknown about the device's effectiveness and safety.

FDA's statutorily prescribed mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking

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41 Press Release, FDA, President's FY 2010 Budget for FDA Invests Substantially in Food and Medical Product Safety (May 7, 2009), *available at* www.fda.gov/bbs/topics/NEWS/2009/NEW02013.html.

appropriate action on the marketing of regulated products in a timely manner."[42] That formulation implicitly recognizes that, just as the public health is harmed by medical products that turn out to be ineffective or unsafe, the public health benefits by timely marketing of medical products that are effective and safe.

That policy serves patients well, but has unavoidable limitations. It serves patients well because FDA, under congressional oversight, does a far better job of 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 medical devices. The diminished effectiveness of labeling – indeed, the diminished willingness of physicians to wade through labeling drafted to provide legal protections as well as to guide medical decision-making – would make devices in actual use less effective and less safe than they would be if considerations of products liability did not intrude. The totally unpreempted tort system would also increase the costs of medical devices by building in additional costs not only

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[42] 21 U.S.C. § 393(b)(1) (2006).

to compensate plaintiffs injured through no fault of the manufacturer but also to pay for lawyers' fees and other costs incurred in litigation.

H.R. 1346 might well lead to a reduction in medical device effectiveness and safety. Increased manufacturer exposure to litigation risks might well lead to increased defensive statements in product labeling and, as a result, decreased usefulness of such labeling and decreased willingness of doctors to consult such labeling. It might also deter the development of devices for medical needs that carry high risks of litigation.

As FDA has stated with respect to drugs, in language equally applicable to devices:

> [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.[43]

The problem of potentially inconsistent jury verdicts in multiple states is worse as to devices than it is as to drugs. Devices share with drugs the risk of claims of inadequate labeling, inadequate testing, and inadequate manufacturing. Because devices are engineered products, however, they face a much greater risk of claims of inadequate design. Thus, without preemption, a design that FDA experts have approved as constituting an

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

appropriate trade-off between aspects that provide therapeutic effectiveness and aspects that present risks of harm, juries could conclude that the FDA-approved design is inadequate. Different juries could find different inadequacies; one jury could find that a design different in one respect should have been adopted, and other juries could find that designs different in other respects should have been adopted. The result would be chaos – or, perhaps the withdrawal of the FDA-approved device from the market, even though FDA would still find it effective and safe.

This congressional policy for approval of devices has limitations because there is always a trade-off between approving a device 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 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 has additional risks that make it unsafe. Thus, every approved device is marketed with less than complete information about its optimal use and, consequently, presents risks of harm, through no fault of its manufacturer or FDA.

In sum, current Supreme Court jurisprudence as to device preemption is sound and well serves the public. H.R. 1346 would destroy the balance achieved by current device jurisprudence and, overall, would harm the interests of patients who need and use medical devices that have gone through the PMA process.