

March 30, 2009

TO THE MEMBERS OF THE UNITED STATES CONGRESS:

On behalf of the undersigned companies and organizations and the thousands of members they collectively represent, we are writing to express our concern with what is likely a series of efforts to dilute the preemptive authority of Congress to regulate interstate commerce. As we collectively seek to restore our economy to strong fiscal health, we are especially concerned about efforts to devolve regulatory authority to state tort systems.

These systems serve an important role in redressing wrongs and compensating injured persons, but they are a poor proxy for a strong, uniform regulatory environment that sends clear prospective signals to businesses and consumers about the integrity of the products they develop, market, sell, and buy. The creation of a lawsuit-driven, state-court-based compliance scheme would impose potentially significant costs on our companies and members in the form of state based litigation and the cost of multi-jurisdictional compliance. Moreover, we believe that such state based litigation would limit the availability of many, including life-saving, products for Americans.

Given this broad concern, we write specifically to express opposition to H.R. 1346 and S. 540, the “Medical Device Safety Act of 2009,” which represents the opening salvo of a broader campaign by personal injury lawyers to replace uniform federal regulation with tort litigation. This bill seeks to undo the U.S. Supreme Court’s 2008 nearly unanimous ruling in *Riegel v. Medtronic*, which held that certain state tort suits based on injuries from medical devices that were approved through the FDA’s premarket approval (PMA) process are expressly preempted by federal law. *See Riegel v. Medtronic*, 128 S. Ct. 999 (2008). As set forth below, we believe that enacting legislation to repeal the preemption provision at issue in the *Riegel* case would stifle innovation, compromise the safety of American consumers, and threaten the preeminence of the U.S. medical device industry in the world community.

In 1976, Congress enacted the Medical Device Amendments Act (MDA) to create a uniform national process for evaluating the safety and efficacy of medical devices. Prior to enactment of the MDA, medical device manufacturers were subject to various state regulatory regimes and were frequently sued over alleged device failures in state courts around the country. Congress enacted the MDA and incorporated an express preemption provision in that statute in response to this hopelessly complex regulatory environment. Thus, the MDA ensures intensive federal review of new and innovative medical devices and provides manufacturers with clear guidance from a single source, the Food and Drug Administration (FDA), on the safety and efficacy standards applicable to new medical devices. Under the MDA’s uniform regulatory environment, medical innovation has thrived and patients have received cutting-edge medical technologies like pacemakers, arterial stents, and heart valves.

Last year, the Supreme Court confirmed in *Riegel* the MDA’s uniform regulatory framework by holding in an 8-1 decision that the express preemption clause in the MDA limited certain state tort lawsuits against medical devices that have gone through PMA review, a

particularly rigorous FDA approval process. The decision clearly allows claims to move forward in a variety of instances including in cases where the device was not manufactured to specification, or a company misled FDA. The Medical Device Safety Act of 2009 seeks to undo the *Riegel* decision by amending the MDA to revoke preemption with respect to such medical devices.¹

We strongly urge you to reject the proposed legislation for several reasons:

First, the pending legislation would stifle innovation of new medical devices thus limiting the availability of lifesaving technologies. As it currently stands, the PMA approval process Congress established in 1976 (which is specific for certain medical devices) benefits both manufacturers and consumers. Consumers are protected by a rigorous safety review procedure conducted by expert regulators. The approval process is an intense one, during which the FDA typically spends over a thousand hours reviewing volumes of clinical and safety data about a proposed device. Even after a device is approved, regulatory review is not complete. Rather, the manufacturer is required to report to the FDA on any changes to the device and provide a summary of new information from scientific literature and unpublished reports about that device. This regulatory scheme assures that only products whose benefits to potential patients outweigh their risks can go to market. Although the process is extremely burdensome on manufacturers, the MDA's express preemption provision assures that manufacturers that complete the PMA process will not be subject to later tort liability. This balance of intense regulation, coupled with protection from state law liability, has fostered the invention and marketing of countless devices that have saved American lives.

The proposed legislation would upend this comprehensive regulatory framework. Many manufacturers would inevitably determine that it is too costly to go through the PMA approval process and still be forced to comply with 50 different state tort regimes. Thus, they will simply stop developing new, innovative medical devices, preferring to market older technologies for which the litigation risks are known. Such a result would hurt not only manufacturers and their employees but it would also prevent patients from gaining access to life-saving, cutting-edge medical devices.

Second, the proposed legislation, notwithstanding its title, would provide no real safety benefits to American consumers. Instead, the result of the legislation would be to replace the judgment of expert regulators with that of lay juries. Under the current regime, FDA is able to weigh the risks and benefits of a particular device, and to assure that when the former are outweighed by the latter, the device reaches the market. Replacing expert regulators with lay jurors would result in conflicting and suboptimal regulation and ultimately prevent important medical technologies from reaching the patients who need them.

Finally, the pending legislation would impose significant additional costs on American business at a time of economic crisis. Many medical device manufacturers are relatively small

¹ The Supreme Court's recent decision in *Wyeth v. Levine* – which rejected a claim of implied preemption with respect to prescription drugs – has no relevance to the pending legislation. The question in *Wyeth* was whether certain FDA regulation had preemptive effect *absent* express preemption by Congress. The *Wyeth* Court did not make any policy judgments regarding whether and to what extent preemption of state tort claims against either drug or medical device manufacturers was appropriate.

companies without large research and development budgets. These companies rely on often-scarce, venture capital to fuel innovation and cannot afford the risk of increased lawsuits. *See* S. Rep. No. 33, 94th Cong., 2d Sess. 18 (1976) (noting the importance of the MDA for “small manufacturer[s] of medical devices,” with “limited financial resources”). In fact, in 2002, Congress created a mechanism for small device manufacturers to receive a discount on the application fees associated with a PMA. In the last five years, 20% of all PMA applications were from small businesses. For more than 30 years, the United States has been a leader in innovation in medical technology. Now is not the time to threaten the viability of an important American industry – especially one that has saved countless American lives.

For all of these reasons, we strongly urge you to oppose the Medical Device Safety Act of 2009.

Sincerely,

Abbott
Acorn Cardiovascular
AdvaMed
Aesculap, Inc.
American Health Care Association
American Insurance Association
American Tort Reform Association
ATS Medical, Inc.
B. Braun Medical Inc.
Bayer
Beckman Coulter
Biomet, Inc.
Boston Scientific Corporation
Business Roundtable
C. R. Bard, Inc.
Cardinal Health
CaridianBCT, Inc.
ConvaTec Inc.
Edwards Lifesciences
Elemé Medical, Inc.
Eli Lilly and Company
GE Healthcare
Hill-Rom
Hollister
Hospira, Inc.
Ikaria
Johnson & Johnson
3M
Medical Device Manufacturers Association
Medtronic, Inc.
MicroCube, LLC
National Association of Manufacturers

RetireSafe
Roche Diagnostics
Sleep Solutions
Smith and Nephew
St. Jude Medical, Inc.
STERIS Corporation
U.S. Chamber of Commerce
U.S. Chamber Institute for Legal Reform
Vietnam Veterans of America
Welch Allyn
Zimmer, Inc.