

**H. Thomas Wells, Jr.**  
President

AMERICAN BAR ASSOCIATION

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December 29, 2008

The Honorable Senator Edward M. Kennedy  
Chairman  
Committee on Health, Education, Labor, and Pensions  
U.S. Senate  
Washington, DC 20510

Dear Mr. Chairman:

On behalf of the American Bar Association and its over 400,000 members, I write to express support for S. 3398, the “Medical Device Safety Act” that you introduced in the 110<sup>th</sup> Congress and to urge you to reintroduce this legislation in the next Congress.

Earlier this year, the Supreme Court in *Riegel v. Medtronic* ruled that a product liability lawsuit filed against *Medtronic* in a state court was pre-empted because the device had received approval from the U.S. Food and Drug Administration (FDA). It found that the Medical Devices Amendments of 1976 allow the FDA to preempt the state liability laws for medical devices. S. 3398 would address that decision by allowing injured patients to hold negligent medical device manufacturers liable for damages in state courts under state laws for product related deaths and injuries, as had been the case prior to the holding in the *Riegel* case. S. 3398 recognizes the value of over 30 years of experience that the United States has had in utilizing both FDA regulations *and* state tort laws to ensure the safety of medical devices.

State product liability law holds manufacturers accountable for injuries caused by their products when they are negligent or irresponsible. These laws permit an injured consumer to be compensated by a manufacturer found to be negligent. In addition, a manufacturer has a financial incentive to be vigilant in making its product as safe as possible and has an incentive to quickly recall a product from the market if it discovers that its product is dangerous even if the product or its label has been approved by the FDA.

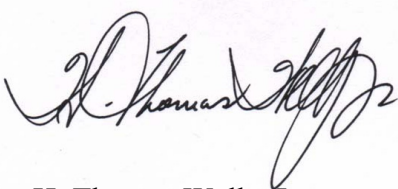
S. 3398 is consistent with ABA policy supporting the continued right of the states and territories to regulate product liability law with discrete exceptions. For example, we support enactment of narrowly drawn federal legislation on compensation that addresses the issues of liability and damages with respect to claims arising out of occupational diseases (such as asbestosis) with long latency periods in certain cases. In addition, we support federal legislation allocating product liability risks between the federal government and its contractors.

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December 29, 2008  
Page 2

The ABA is committed to sustaining a legal system in America that is not only effective and just, but also one that protects the rights of consumers and manufacturers, plaintiffs and defendants. We continually work on many fronts to develop recommendations and pursue projects aimed at improving our civil justice systems at both the federal and state level.

We look forward to working with you toward enactment of this very important legislation in the 111<sup>th</sup> Congress.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Thomas Wells, Jr.", written in a cursive style.

H. Thomas Wells, Jr.