



April 21, 2009

The Honorable Greg Zoeller
Office of the Indiana Attorney General
Indiana Government Center South
302 W. Washington Street
Indianapolis, IN 46204

Dear Attorney General Zoeller:

Recently, you may have received a memorandum from the office of a fellow Attorney General asking you to join a letter to Senators Kennedy and Leahy and Congressmen Waxman and Pallone (Letter to Congress) supporting enactment of the Medical Device Safety Act.

The Advanced Medical Technology Association (AdvaMed), which represents America's leading medical technology manufacturers, and the Indiana Medical Device Manufacturers Council (IMDMC) and its Indiana manufacturing members have tremendous respect for the important role that Attorneys General have in protecting consumers, and the important role that tort law can play in compensating injured persons.

However, we believe strongly that the briefing memo that you received and the letter to Congress that you were asked to sign contains information that, in our view, does not correctly address the underlying issues that supporters of the Medical Device Safety Act purport to address through the legislation.

Therefore, if you are a current signatory to this letter, we would ask you to reconsider your support. If you have not yet signed on, we would urge you not to do so.

The Letter to Congress you received suggests that device manufacturers currently receive "total immunity from liability" for certain devices. That is false.

In fact, FDA preemption over medical devices is extremely limited – only a small number of the medical devices approved every year by the FDA are subject to *limited* preemption. These products are developed to treat the most complex and most debilitating conditions and have been subjected to an assessment of safety and effectiveness by FDA, specific regulatory requirements and/or post-marketing surveillance. Even with preemption, there are circumstances even in this limited device population under which patients can sue a manufacturer.

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The U.S. Supreme Court's decision in *Riegel* was in no way a radical departure from well-established precedent. The decision merely upheld what six of seven federal circuit courts of appeal had already held—that state tort litigation constituted a “requirement” under the 1976 Medical Device Amendments –the law that created the FDA’s authority to regulate medical devices –and was therefore subject to preemption. Furthermore, the majority in *Riegel* distinguished state remedies that “parallel” rather than add to the federal requirements.

Further, the Letter to Congress omits important factual information as to the misfortune suffered by Charles Riegel, “who was injured when a Medtronic catheter burst during an angioplasty.” The letter fails to mention that the catheter was used by the attending physician in a manner contraindicated on its FDA-approved labeling, and was inflated in excess of the FDA-approved pressure.

We believe that these important facts provide much needed context for the legal and policy issues under consideration by Congress.

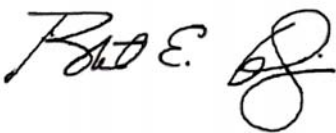
The current relationship between state tort litigation and existing federal law strikes the right balance for that small percentage of devices that endure the FDA’s most rigorous device approval process. As the 8-1 majority noted in *Riegel*:

“How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.” Riegel, p. 12.

The IMDMC and AdvaMed believe that subjecting manufacturers – including many small businesses – to the costs and risks of added tort litigation would chill medical technology innovation, reduce patients’ access to lifesaving and life enhancing therapies, and increase healthcare costs.

We would urge you not to sign on to any letter supporting this federal legislation, and we would be pleased to answer any questions that you have about our position on this important issue.

Sincerely,



Robert E. Durgin
President
Indiana Medical Device Manufacturers Council



Stephen J. Ubl
President and CEO
Advanced Medical Technology Association

IMDMC Board Member Companies

*Anson Group, Baker & Daniels, Bayer Diabetes Care, Biomet Inc., Cook Inc., DePuy Orthopaedics,
Eli Lilly and Company, Hill Rom, Inc., Johnson & Johnson Inc., Medtronic Inc., Roche Diagnostics Corp., Zimmer Inc.*

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