

March 31, 2009

The Honorable Harry Reid
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
United States House
of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
United States Senate
Washington, DC 20510

The Honorable John Boehner
United States House
of Representatives
Washington, DC 20515

Dear Majority Leader Reid and Speaker Pelosi, Minority Leader McConnell and
Minority Leader Boehner:

As a group, we represent thousands of individuals and companies that develop medical technology as well as the venture capitalists who help to provide the essential financing for innovations that save lives and provide greater value in health care. We are writing to express our concerns about the policy implications of the Medical Device Safety Act (S. 540 & H.R. 1346).

We believe this legislation does not advance patient safety, will limit patient access to lifesaving medical technologies, increase health care costs by delaying innovation, and dilute the regulatory effectiveness of the FDA.

The Medical Device Amendments of 1976 – the law that helped to create the modern medical device industry has balanced the interests of patient safety and patient access to medical technology extremely well for more than three decades. Only a subset of all medical devices reviewed by the FDA each year is subject to 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 and specific regulatory requirements including post-marketing surveillance. In addition, the preemption protection is not blanket immunity – there are circumstances under which patients can and have been suing manufacturers.

The impact of removing preemption on the integrity of this process and our industry will be significant.

NEED FOR A STRONGER, CENTRAL FEDERAL AUTHORITY

As former FDA Chief Counsel and Carter-appointee Richard Cooper recently testified before Congress:

"Totally unpreempted regulation through product-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." (Statement before the Senate Committee on the Judiciary, June 11, 2008)

The creation of a lawsuit-driven, state court-based compliance scheme imposes two potentially significant costs on our industry: multi-jurisdictional compliance, as well as the additional costs of mass tort litigation.

This flawed legislation contemplates a regulatory scheme that would undermine the safety and effectiveness determinations of the FDA with respect to complex medical devices – for reasons that may or may not be medically and scientifically sound. The manufacturer of a product with the potential to save millions of lives, but with known and properly disclosed risks, will no longer be able to create tomorrow's next wave of medical technology on the fair playing field of a national standard set and enforced by the FDA.

It is much more effective to continue to make the FDA more independent, stronger and accountable than it is to allow states to create a patchwork of regulations that preempt innovation and fail to protect the safety and rights of all Americans.

IMPACT ON PATIENTS

Beyond the harm to innovation, Congress should also consider the harm done to the health and rights of patients who will no longer be assured a national standard for safety under the FDA. Eliminating preemption will create a patchwork system of state laws and regulations that may help some citizens and leave others without options depending on where they live.

For nearly 30 years, the current system for regulating medical technology has worked extremely well in three areas: it has fostered the development of an industry in which the United States has unparalleled leadership; it has fostered innovations that have safely enhanced and prolonged patients' lives; and it has provided avenues for recovery in the tort system for injured patients.

IMPACT ON SMALL BUSINESSES

A significant percentage of these costs will be borne by small businesses. For example, from 2003-2007, nearly one-in-five applications for pre-market approval were submitted by a small business. These small businesses are not only catalysts for growth and innovation within our industry, but in these challenging economic times – when access to capital already threatens their business model – their success is critical to our nation's overall economic recovery.

These small companies develop cutting-edge technologies such as devices to close heart defects, non-invasively treat uterine fibroids, non-invasively manage diabetes, better detect fetal heartbeats, and destroy contaminated needles. Such products allow for the better management of chronic disease, the better treatment of expectant mothers and their babies, and the better management of cardiovascular diseases such as stroke.

If preemption is rolled-back, many of these business will face two equally unappealing alternatives. They can bring products to market with the harbinger of unfettered tort litigation on the horizon, a prospect nearly guaranteed to drive higher insurance premiums, or they can shelve the product. The notion, suggested by some, that only unsafe products would go on the shelf is nonsensical. Venture capital firms will be less willing to fund even the most promising and safe breakthroughs unless there is the level playing field of a national standard for safety. In this case, innovation wouldn't be shelved, it would never get off the drawing board.

We would urge you to exercise your respective leadership positions in Congress to ensure that no action is taken on this harmful legislation – and that the FDA is given the resources it needs to guarantee the health and safety of the nation.

Sincerely,

Advanced Medical Technology Association (AdvaMed)
Arizona BioIndustry Association
BioOhio
BIOCOM
California Healthcare Institute (CHI)
Florida Medical Manufacturers' Consortium
The Health Industry Council
HealthCare Institute of New Jersey
Indiana Health Industry Forum
Indiana Medical Device Manufacturers Council (IMDMC)
LifeScience Alley
Massachusetts Medical Device Industry Council (MassMEDIC)
Medical Device Manufacturers Association
MedTech
National Venture Capital Association
North Carolina Biosciences Organization
Texas Healthcare and Bioscience Institute
Washington Biotechnology & Biomedical Association