



The Honorable Baron Hill
Via Fax: 202-226-6866

The Honorable Steve Buyer
Via Fax: 202-225-2267

July 21, 2009

Dear Representatives Hill and Buyer,

On behalf of the membership of the Indiana Medical Device Manufacturers Council (IMDMC), we are writing to express our concerns about the policy implications of the Medical Device Safety Act (H.R. 1346) and urge you to oppose its inclusion in the Healthcare Reform bill currently before the Energy and Commerce Committee.

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 sued manufacturers.

Removing this limited preemption protection will harm patient 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 access to valuable medical technology depending on where they live.

Beyond the harm to patients, the impact of removing preemption on our companies will be significant. 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.

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

Blake Jeffery
Executive Director
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Indianapolis, IN 46244

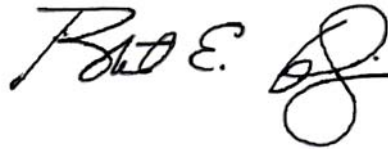
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Including this controversial bill in health care reform would run counter to two major goals of health reform: increasing access to health care and decreasing costs. As Indiana medical device companies, we urge you not to include this harmful legislation as a part of your larger health care reform efforts.

With approximately 18,500 employees, Indiana ranks third among all states in medical technology employment, behind California and Florida. Employment in this sector has increased by 32.8%, or approximately 4500 jobs, since 2001 while other manufacturing jobs in Indiana have decreased by about 66,000. These are high paying jobs, with average annual wages of approximately \$61,000. While the industry comprises several large multinational companies, the vast majority of entities are small, innovative companies.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Rob E. Durgin". The signature is fluid and cursive, with the first name "Rob" and last name "Durgin" clearly legible.

Robert E. Durgin, President

Cc: Chairman Waxman, Chairman Pallone, Ranking Members Barton and Deal

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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