



April 7, 2014

The Honorable David L. Deen
Vermont State House
Montpelier, VT 05602

Dear Representative Deen:

On behalf of the members of the Advanced Medical Technology Association, AdvaMed, I want to share our concerns with S. 239, relating to regulating toxic chemicals.

AdvaMed is a national trade association that leads efforts to advance medical technology to achieve healthier lives and healthier economies around the world. AdvaMed represents 80 percent of medical technology firms in the United States. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 40 percent purchased annually around the world. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies.

You should know that:

- The federal Food and Drug Administration is responsible for ensuring the safety and effectiveness of medical devices on the market.
- All aspects of medical devices, including their components, manufacturing, labeling, packaging, and sale are closely regulated by the FDA.
- Any changes to a device's make-up, labeling, or packaging would require FDA approval. Making those changes and seeking FDA approval could be costly and impact patient access to technologies.
- Most device manufacturers are in compliance with ISO 14000, an international standard, which addresses numerous aspects of environmental management and provides a framework for measuring, minimizing, and improving their environmental impact.



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Advanced Medical Technology Association

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For these reasons, we must respectfully oppose the bill in its current form. We would be pleased to further discuss our concerns with you.

Sincerely,

Thomas E. Tremble
Vice President, State Government Affairs