

BILL LUTHER  
6TH DISTRICT, MINNESOTA

1419 LONGWORTH HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515  
(202) 225-2271  
FAX: (202) 225-3368

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-2306

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COMMITTEES:  
SMALL BUSINESS  
SCIENCE

1811 WEIR DRIVE  
SUITE 150  
WOODBURY, MN 55125  
(612) 730-4949  
FAX: (612) 730-0507

The Honorable Thomas J. Bliley, Jr.  
Chairman  
Committee On Commerce  
2125 Rayburn HOB  
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing you on the need to adopt Food and Drug Administration (FDA) reform this year. I believe that to delay action on FDA reform this year could eliminate any chance of much-needed reform for years to come.

Much attention has been paid throughout the health and pharmaceutical industries and Congress in recent years to the prospect of FDA reform. There are several initiatives in this year's Congress to reform various functions within the FDA. Of particular concern is section 801(e) of the Federal Food, Drug and Cosmetic Act regulating the export of Class III medical devices.

The district I represent, the sixth district of Minnesota, is home to Medtronic, Incorporated, a medical device manufacturing company which holds 50 percent of the world market on implantable pacemakers. Medtronic, along with two other local firms, St. Jude Medical and CPI, are among several device manufacturers who suffer under the 801(e) policy, which effectively prohibits manufacturers from exporting Class III medical devices which are not FDA approved in this country but are approved in the importing county.

The result is that manufacturers establish facilities and business operations overseas where they can bypass the FDA and place their devices directly on foreign markets which accept them. High-paying, high-technology jobs that would otherwise go to Americans are instead taken by European workers. This policy is devastating not only in terms of American jobs lost, but also in terms of stifling technological advancements in the industry. The loss of research and development activities, which often follow manufacturing, poses a threat to innovation and American leadership in medical technology.

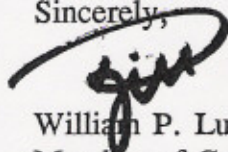
Mr. Chairman, whether it be this regulation or other regulations that impact medical device or pharmaceutical manufacturing, or whether it be general oversight, there is little doubt among many of my colleagues and constituents that the FDA is in need of serious reform. Neither Medtronic nor any device manufacturer I know advocates the abolishment of the FDA. Indeed, the FDA serves an essential regulatory function and, by and large, is very effective in protecting the public interest in the medical device, medical supply and pharmaceutical marketplaces. Yet it would

seem to be incumbent upon us to waste no time in working to improve the FDA's performance without compromising high quality standards of consumer product safety.

I believe that we are at a critical juncture on the political timeline whereby if we do not move to implement FDA reform *this year*, it may not be done at all. The effects of election-year politics on Congressional action next year could impede the ability of Congress to fairly address this issue. Therefore, I strongly urge that your committee consider acting on FDA reform measures before the end of the year. Our country can literally no longer afford to wait for effective reform while running the risk of American jobs and technology being exported abroad.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Luther", with a large, sweeping flourish above it that extends to the left and curves over the text.

William P. Luther  
Member of Congress