

Devising a Better Way to Run the FDA

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By Rep. Anna Eshoo

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The life-saving medical devices you see Dr. Ross and Greene wielding on the TV program "ER" didn't drop out of the sky into a Hollywood production studio. They were developed by high-tech companies that are dedicated to keeping American health care on the cutting edge.

Unfortunately, it's difficult for patients in this country (outside of County General Memorial Hospital) to get access to the latest devices manufactured by these companies. The Food and Drug Administration is in charge of reviewing new medical devices to determine if they're suitable for patients. But the agency's review process is so slow that many devices aren't reaching patients and their doctors in a timely manner. For the sake of maintaining good health care, the FDA needs to be made more efficient.

The FDA has a legal responsibility to ensure the safety of medical devices ranging from tongue depressors to artificial hearts. It is required to complete the approval review process for devices relatively similar to products already on the market (known as Class I and Class II devices) within 90 days. It is required to complete the process for more groundbreaking products (known as Class III devices) within 180 days. But according to the FDA's own Fiscal Year 1996 records, it takes 113 days on average to complete the review process for Class I and Class II devices, and a staggering 572 days on average for Class III products to get through the system.

There are numerous reasons why the FDA review process takes so long. The agency frequently doesn't have a good idea of what manufacturers hope to achieve with their products, nor do companies always have a clear picture of the safety and performance goals the FDA expects them to meet.

The FDA has failed to take advantage of safety and performance standards developed by industry, government and medical professionals that can provide a higher degree of safety, consistency and timeliness than the current system. And it has been unwilling to expand the use of FDA-accredited scientific organizations to review relatively noncontroversial medical devices.

Because of its bureaucratic approach to the device-review process, patients in this country have been ill-served. According to an open letter to Congress sent by health professionals, patients and research institutions, the problem from our perspective is that FDA's regulatory process for allowing patients and doctors access to these new products is cumbersome, slow and out-of-date. As a result, public health is compromised. The situation is more frustrating since new and improved versions of medical devices are introduced and available first in Europe and not in the United States.

A closer look at the U.S. medical-device industry shows why companies simply can't afford to continue doing business as usual with the FDA. Most American medical-device makers - 80 per cent of them - are small companies with fewer than 50 employees. They don't have the financial resources to wait years for the FDA to do its work. That's why 40 per cent of device manufacturers have reduced their U.S. work forces and increased their production overseas. As a result, 61 per cent of these companies are marketing or planning to market devices overseas that are not available to patients in the United States.

The Medical Device Regulatory Modernization Act, which we have introduced in the House of Representatives, would solve many of these problems by improving and streamlining the FDA regulatory process.

Among other things, our legislation would give the FDA a clear mission to ensure the safety of new medical devices, as well as promptly and efficiently review them. It would improve communication between the agency and manufacturers. It would allow device companies to use FDA-accredited scientific organizations to review most Class I and Class II devices, thereby allowing the agency to devote greater resources to examining more innovative products. And it would allow the FDA to recognize national and international performance standards and permit companies to self-certify to those standards.

Modernized FDA procedures should allow new medical devices to reach U.S. consumers sooner and encourage manufacturers to continue working in this country. The Senate Labor and Human Resources Committee shares these important goals and has already passed similar legislation on a bipartisan basis. In addition, seven states have passed resolutions calling for improved FDA review times, while three others are considering such legislation.

Medical devices have made tremendous contributions to improving the quality of life and increasing life expectancy in the United States. The Barton-Eshoo bill would help ensure that when a patient is taken to a real "E.R.," doctors have the equipment they need to do their job.

* Rep. Joe Barton (R-TX) wrote this column with Rep. Eshoo.

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[Return to Top](#)