Multiple Studies Highlight the Safety and Efficacy of the FDA's Regulatory Pathways for Medical Technology

The FDA's regulatory pathways are the gold standard in providing safe and effective medical technologies for providers and patients. It is critically important that medical technology innovators have a predictable regulatory pathway to the market. The variability that existed over the years resulted in costly delays, and in some cases forced companies to shut down. An unpredictable and unreasonable regulatory environment leads to patients unable to access to safe and effective products.

Additionally, there has been no credible evidence to suggest that the current premarket review of medical devices is inadequate or unsafe. In fact, two studies presented before the Institute of Medicine when they examined the FDA's review process found that in approximately 99 percent of all medical device submissions, no safety issues were present. A report also highlighted that medical device recalls in Europe and the U.S. occur at the same rate, even though this U.S. process is significantly longer. Furthermore, studies have demonstrated comparable safety performance in the US vs. the European process which takes significantly less time and money to navigate.

University of Minnesota Study

A detailed analysis of FDA recall data by leading FDA expert Ralph Hall, distinguished Professor and Practitioner at the University of Minnesota Law School, resulted in a study showing that FDA has a tremendous track record of safety in reviewing medical devices and technology. The study found:

- 99.78% of 510(k) submissions did not result in a Class I (safety) recall due to premarket issues

- 99.71% of PMA approved products did do not result in a Class I (safety) recall due to premarket issues
- Manufacturing issues are the predominate reason for premarket recalls for both PMA and 510(k) products

Find the full study here.

Maisel Study

Dr. William Maisel, currently the Deputy Center Director for Science & Chief Scientist at CDRH, conducted a study demonstrating that **98.4 percent** of medical devices cleared by the F.D.A.'s 510(k) process were not subject to Class 1 recalls. The study was conducted in his role as the director of the Medical Device Safety Institute, a nonprofit, industry-independent organization.

Find the full study here.

Boston Consulting Group Study

A report by BCG showed that device recalls in Europe occur at similar rates as in the United States, noting that there is no statistical safety benefit from the more burdensome – and often slower – FDA process.

- The report examines the rate of safety recalls for medical devices in Europe from 2005-2009 and compares them with the level of similar recalls in the U.S.
- The study focused on those products recalled because of significant health risks and found an average recall rate in Europe of 21 per year, compared to the tens of thousands of devices on the market.
- This is almost identical to the rate of equivalent recalls in the U.S.

Find the full study here.