Written by **Brian Koenig** on August 1, 2011

Institute of Medicine Calls for More Regulation of Medical Devices

Originally commissioned by the FDA, the Institute of Medicine urged FDA officials last Friday to foster "a new framework that used both premarket clearance and improved postmarket surveillance of device performance to provide reasonable assurance of the safety and effectiveness of Class II devices." The IOM protests that premarket screenings are far too lax, as current standards neglect to provide a thorough examination of the safety and effectiveness of medical devices.

The 227-page report was anticipated to carry heavy weight with the FDA, but immediate action to scrap current FDA medical device standards, known as the 510(k) approval process, has met unanticipated resistance from FDA officials. Dr. Jeffrey Shuren, the FDA's director of the Center for Devices and Radiological Health, commented that "the 510(k) process should not be eliminated" but that the FDA is "open to additional proposals and approaches for continued improvement of our device review programs."

The IOM is not advocating minor adjustments, but a comprehensive reconstruction of the 510(k) process:

> "It's not clear that the 510(k) process is serving the needs of either industry or patients, and simply modifying it again will not help," said committee chair David Challoner, emeritus vice president for health affairs, University of Florida, Gainesville. "The 510(k) process cannot achieve its stated goals — to promote innovation and make safe, effective devices available to patients in a timely manner — because they are fundamentally at odds with the statutes that govern how FDA must implement the process. While current information is not adequate to immediately start designing a new framework, we believe the agency can get the necessary data and establish a new process within a reasonable time frame."

"We startled a lot of people, including ourselves," asserted Challoner. "We realize we are suggesting a paradigm shift that will be disquieting to a number of constituencies." The report's decisive proposal has spurred widespread rejection from industry leaders. The Advanced Medical Technology Association, one of the industry's leading trade groups, branded the IOM's proposal a grave "disservice to patients,"

alleging that "the report's conclusions do not deserve serious consideration from the Congress or the Administration."

As a whole, the debate over the degree of FDA regulatory powers is a slippery balancing act. Consumer advocates say current regulations are not comprehensive enough to ensure safety and efficacy, while private-sector corporations and advocacy groups claim burdensome regulations make drugs and medical devices too expensive to develop.

A great many pharmaceutical companies and private-sector industry leaders postulate that the FDA has a fatal track record, as heightened regulation and extended clinical testing delay new drugs from entering the market — and sometimes eliminate them altogether. Indeed, the average time a drug takes to receive FDA approval has nearly doubled since the 1960s. Expenditures have also nearly doubled, as pre-clinical and clinical testing for a single drug burns an average of 12 to 15 years, while costing upwards of $800 million.

In August 2007, the D.C. Circuit Court of Appeals reversed a previous ruling that restricted a patient's right to take investigational, FDA-unapproved drugs. The leukemia drug Gleevac passed its first phase of testing in 1998 — being ruled both safe and effective — but when physicians requested the drug for treatment in June 2001, the FDA denied their request. The clinical trials of Gleevac bear testimony to the overwhelming success it has had with leukemia patients, as nearly 80 percent of the test subjects are still alive today. Despite conclusive evidence, Gleevac did not receive approval until March 2003, after 3,600 patients had been denied the drug — many of whom died while waiting for it.

Likewise, the FDA has delayed countless lifesaving cancer drugs over the decades, which health experts claim leave thousands of cancer victims to die every year. Ronald Trowbridge and Steven Walker documented this medicinal roadblock in the *Wall Street Journal*:

> The American Cancer Society reports that some 550,000 cancer patients die annually, making the number of cancer deaths from 1997 to 2005 about 4.8 million. Over that same period, the FDA reports granting individual access to an investigational drug to not more than 650 people per year for all diseases and drugs — a pathetic, even cruel, pittance. A few thousand more patients managed to gain access by enrolling in relatively small clinical trials or exceedingly rare expanded access programs.

The FDA's fatal performance in pharmaceuticals could, arguably, parry the effects of heightened medical device regulation, except instead of denying a cancer patient a lifesaving drug, it would mean denying a heart bypass patient a new and technologically-improved pacemaker.

Engineer Robert Fischell summed up this side of the argument a couple of weeks ago when he told a subcommittee of the House Energy and Commerce Committee,

> It is not technology, science, ingenuity or the economy that is standing in the way of success in developing new medical technologies. In my opinion, it is today the FDA.