

Testimony to the House Committee on Energy and Commerce (Health Subcommittee)

My name is Steven E. Nissen, M.D. I am Chairman of the Department of Cardiovascular Medicine at Cleveland Clinic and former President of the American College of Cardiology (ACC). My testimony does not reflect the views of either the Cleveland Clinic or the ACC.

I agree with the underlying premise for these hearings. For decades, the American medical products industry has been responsible for innovations that have saved lives, reduced suffering, and sometimes even lowered medical costs. I also agree that this industry creates high-quality jobs that contribute to the nation's economic health. For these reasons and many others, strengthening a vibrant and vital medical device industry is an important national priority.

The dilemma posed by today's hearings is how to best promote innovation, while protecting the health of the American people. Medical devices are regulated via an antiquated regulatory system originally devised in 1976 that employs two very different pathways to market.

Premarket Approval is a rigorous standard similar to the approach used to regulate pharmaceutical products, often involving careful testing in patients with a full regulatory review. The 510(k) provision allows products to be "cleared" for market if they are deemed "substantially equivalent" to a "predicate" device already marketed, many before 1976. Surprisingly, 35 years later, the 510(k) pathway has become the primary approach used by FDA to clear products for market, now utilized for 98% of all medical devices. Devices approved under the 510(k) provision rarely undergo any testing in patients and manufacturing facilities are not subject to FDA inspections.

Often, new medical devices are very dissimilar to previously-marketed products, use different materials and manufacturing processes, have different mechanisms of action and have different intended uses. It is no longer reasonable to compare modern medical products with devices marketed as long as 35 years ago.

The abbreviated 510(k) process was never intended for use for clearing Class III medical devices, defined by the Code of Federal Regulations as products used for life-supporting or life-sustaining indications, for preventing impairment of human health, or presenting a potentially unreasonable risk of illness or injury. However, FDA has sometimes cleared Class III devices for market using the 510(k) provision, a policy that was sharply criticized by the GAO in a January 2009 report.

In recent years, several high profile withdrawals of medical devices have resulted in serious injuries or death. In a particularly poignant example, a faulty lead used in an implantable defibrillator frequently failed, resulting in inappropriate shocks or worse, a failure to function during a cardiac arrest, resulting in death. When this problem was identified, patients were presented with an agonizing choice, to undergo an operation to remove the defective device, or take their chances that it wouldn't fail when needed to save their life.

Automated external defibrillators (AEDs) were approved under the 510(k) provision. These devices are used to permit bystanders to resuscitate victims of cardiac arrest. During the last 5 years, FDA has received more than 28,000 reports of AED failures resulting in hundreds of deaths. Many AED devices were recalled for manufacturing defects.

An artificial hip joint used in 13,000 patients rapidly failed, often releasing toxic metal debris, which sickened thousands of patients. Again, patients faced the choice of a painful and risky repeat operation or accepting the possibility of serious health complications from this faulty device.

Colleagues at the National Research Center for Women and Families, Dr. Diana Zuckerman and Paul Brown, and I analyzed all 113 high-risk medical device recalls from 2005-2009. FDA designated these recalls as high risk because the devices could cause serious injury or death. Surprisingly, 71% of these high-risk recalls involved devices initially cleared using the 510(k) provision. Only 19% had undergone full PMA approval. 7 % were intentionally exempt from any FDA review because they were considered so low risk.

This finding represents a paradox. Federal regulations require devices used to support or sustain life to undergo a full PMA approval process. By law, these life-sustaining devices should not be cleared using the 510(k) provision. Yet 71% of recalls for defects that could “cause serious health problems or death” were originally approved using the 510(k) pathway.

The total number of devices recalled during this interval exceeded 112 million. According to the FDA data, there have been more than 2,000 deaths reported each year from medical devices, rising to almost 5,000 in 2009. The number of annual injuries is much higher –over 100,000 in 2006, according to the FDA statistics.

These findings illustrate the need for a balanced approach to approval of medical devices. Although, we all want to stimulate innovation and job creation, we cannot afford to allow deregulation to place the American public at risk for serious health consequences from defective products not adequately studied prior to human use.

I believe that we need a more nuanced approach to device regulation that appropriately balances the need for timely approval with patient safety. Components of reform should include:

- 1) A more accurate definition of a high risk device, which takes into account the likely risks if the device is defective.
- 2) An intermediate regulatory category more rigorous than 510(k), but short of a full PMA process, for moderate risk devices.
- 3) Better funding for FDA Center for Devices to enable timely, but thorough, evaluation of the risks and benefits of medical devices.