PATIENT SAFETY BLOG

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Posted On: **February 18, 2011** by Patrick A. Malone

Is Grandfathering of Medical Devices Bad for Your Health?

The vast majority of medical devices recalled by the U.S. Food and Drug Administration (FDA) were subject to a less stringent regulatory process that requires only that the device prove that it's similar to something already on the market, according to a recently published study.

Of the 113 devices recalled from 2005 to 2009 because the FDA determined they could cause serious health problems or death, 80 (71%) were reviewed using the “510(k) process,” which is meant to assess devices deemed to involve low or moderate risk.

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Only 21 devices (19%) had been approved through the more rigorous premarket approval (PMA) process, which requires clinical testing and inspections. (Eight other devices were exempt from any FDA regulation.)

Cardiovascular devices, chiefly external defibrillators, made up nearly a third of the recalled medical products from 2005 through 2009, the time covered by the review. A 2006 study linked defibrillator failure to more than 300 deaths over a 10-year period.

Originally, the 510(k) process was specifically intended for devices with less need for scientific scrutiny, such as surgical gloves and hearing aids. It did not require clinical trials or manufacturing inspections to demonstrate safety and efficacy. Instead, it only required proof that the device was substantially equivalent in materials, purpose, and mechanism of action to another device that was already on the market, with the previous device serving as the “predicate” device with which the new device would be compared.

This approach was justified as a way to give manufacturers the opportunity to make small improvements on the devices already on the market and to allow companies with new products to compete with very similar devices without using the more extensive PMA process. If the FDA determined that the product was reasonably safe and effective according to the 510(k) review, it was said to be cleared for market rather than approved.

However, in 2002, Congress passed the Medical Device User Fee and Modernization Act, which shifted the regulatory standard to "the least burdensome approach in all

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areas of medical device regulation." This had the practical effect of making 501(k) the dominant mechanism for new device clearance, with the FDA now reviewing only 1% of medical devices using the more rigorous PMA process.

To decrease the number of high-risk recalls, the study recommends:

1. The FDA fully implements current law that subjects "life-saving and life sustaining" (Class III) devices to the PMA process.

2. The FDA's definition of a high-risk device takes into account the potential risks if the device fails.

3. The FDA expands the use of their authority to inspect the manufacturing of 510(k) devices just as they do for devices approved through the PMA process; and

4. The FDA strengthens their authority to use special controls for 510(k) devices as they do for PMA devices, such as postmarket surveillance, performance standards, and product-specific and general guidance documents.

Source: The Los Angeles Times

You can read the complete study here.

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