Circulatory System Devices Panel Meeting January 25, 2011

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- Almost 300,000 Americans collapse from sudden cardiac arrest every year
- "Survival depends upon a rapid sequence of rescue events that includes the successful delivery of a shock from the AEDs."
- "Rescuers have only minutes before these rhythms degenerate beyond rescue capabilities."

- “Rescuers have only minutes before these rhythms degenerate beyond rescue capabilities.”

In other words, they can die.

- “If the device is of high risk” FDA review of AEDs
- “warrants the additional controls and rigor necessary to properly determine the safety and effectiveness of the device”

High-Risk Recalls of Class III AED Devices Cleared Through 510(k)*

7/31/2009, Physio-Control, Inc, LIFEPAK CR Plus AED
2/12/2009, ZOLL Medical Corporation, AED Plus
12/15/2008, Welch Allyn Inc., AED 10 and MRL Jumpstart AED
8/28/2008, Physio-Control, Inc., LIFEPAK CR Plus AED
10/26/2007, Welch Allyn Inc., AED 10
8/24/2007, Welch Allyn Inc., AED 20
2/17/2007 Defibtech, LLC, Lifeline AED and ReviveR AED
6/15/2006, Welch Allyn Inc., AED 20
4/28/2005, Welch Allyn Inc., AED 20
2/14/2005, HeartSine Technologies, Inc., Samaritan AEDs (various models)
2/3/2005, Medtronic, LIFEPAK 500 AED (certain models)

*** From the FDA's List of Device Recalls, which is the FDA's compilation of the most serious medical device recalls**

In a soon to be published peer-reviewed journal article about FDA's high-risk medical device recalls, the National Research Center for Women & Families found that cardiovascular devices comprised the largest recall category from 2005-2009.

- GAO pointed out that the law requires Class III devices to be approved through the more stringent PMA process,
- That's why FDA needs to either start requiring PMA approval of AEDs or needs to reclassify AEDs as Class II, which means moderate risk.

- AEDs can't be classified as Class II because they are life saving devices. When they don't work, people can die or suffer permanent damage.

- The law specifies PMAs for Class III devices for a reason. The reason is to protect patients.

Researchers have reported that more than 20 percent of the almost one million AEDs in circulation were recalled by the FDA. Hundreds of people have died due to AED malfunctions.[1]

[1] Maisel WH. Medical Devices: Are Current Regulations Doing Enough for Patients? Testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives. June 2009. http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1677. Accessed August 31, 2009.

Medical Device Report (MDR) Analysis

FDA analyzed MDRs from the Manufacturers and Users Device Experience (MAUDE) database for AEDs. During the period from January 1, to March 31, 2010 there were 23,591 MDRs, classified into the following categories:

Year	Deaths	Injuries	Malfunction	Other
2005	126	11	3,084	93
2006	103	20	3,130	153
2007	118	9	3,694	18
2008	108	18	4,594	4
2009	184	15	6,484	58
2010	82	5	1,396	12
Totals	721	78	22,382	338

Source: FDA Executive Summary for the Circulatory System Devices Panel on January 25, 2010; Automated External Defibrillators 515(i) Reclassification, page 9.

Arguments Against PMA

- PMAs could slow down the process of improving AEDs.
- But up until now, the lack of PMAs has resulted in 68 recalls of a million AEDs in the last 5 years.
- Innovation in design isn't worth anything if the product doesn't work.
- PMA can make sure the product works by adding rigor to the process, including
  - better clinical data,
  - pre-market inspections,
  - post-market studies.

Innovation vs. Safety

- Innovation in design isn't worth anything if the product doesn't work when needed.
- PMA safeguards can make sure the product works by adding rigor to the process, including
  - better clinical data
  - pre-market inspections
  - post-market studies

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