PUBLIC CITIZEN
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Dr. Michael Carome, deputy director of Public Citizen's Health Research Group, is testifying today before an FDA advisory committee regarding defibrillators. (Dr. Carome's full testimony is available at www.citizen.org/hrg1929.)

He will tell the panel that there have been 68 recalls of automatic external defibrillators (AEDs) from January 2005-August 2010, 17 of which were serious enough to be Class I recalls, involving situations in which there is a reasonable probability that using the product will cause serious injury or death.

Collectively, these 17 Class I recalls alone involve well over 100,000 AEDs distributed and have resulted in deaths or life-threatening situations for many patients. The details of one such recall, involving 14,054 units and occurring only after two patients had died, are included in today's testimony.

Unless the FDA rejects the AED industry's attempt to deregulate these devices and not require the kind of premarket studies that could clearly reduce the serious dangers of these inadequately tested devices, patients using these devices will be subjected to a continuation of this de facto human experimentation, with more recalls, more deaths and more life-threatening situations.

Please let me know if you have any questions or would like to speak to Dr. Carome.

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