## SCAA urges FDA to reconsider proposed order to re-classify AEDs

If you're a sudden cardiac arrest survivor, a loved one of someone who suffered an SCA, an EMS provider, or anyone else concerned with the SCA crisis in our country, **the Sudden Cardiac Arrest Association needs your help immediately!**

The U.S. Food and Drug Administration (FDA) recently issued a proposed order that would re-classify Automated External Defibrillators (AEDs) and Advanced Life Support (ALS) defibrillators incorporating AED functionality as Class III medical devices (Docket Number FDA-2013-N-0234). Class III is the highest classification the FDA issues and would require the submission of applications for pre-market approval, which is the longest, most resource-intensive and costly scientific and regulatory pathway to market.

What will that mean? This drastic increase in regulation will have a profound negative impact on research and innovation and will most assuredly reduce the number of AEDs in every public and private venue. The SCAA and other heart-related organizations have worked for many years to ensure that AEDs will become more readily available so that we can stem the needless loss of life due to sudden cardiac arrest. **This single FDA decision will set us back immeasurably and will likely result in even higher death rates.**

What can you do? Please go immediately to www.regulations.gov, insert the docket number above (including the dashes) in the "Search" box and follow the prompts. Review the FDA's position and submit comments in opposition to the proposed order by June 24, if not before.

If you prefer, you can mail or hand-deliver your comments to the FDA at this address:

Food and Drug Administration
Division of Dockets Management (HFA-305)
Docket Number: FDA-2013-N-0234
5630 Fishers Lane, Room 1061
Rockville, MD 20852

In order to improve the national SCA survival rate we must continue to drive widespread access to AEDs. This FDA decision will be crucial in our ability to fulfill our mission. Please help convince the FDA not to proceed with this regulatory decision, a decision we're convinced will set us back several years.