Sudden Cardiac Arrest Foundation
raising awareness, saving lives

June 5, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0234

Dear Sir or Madam:

The Sudden Cardiac Arrest Foundation is a national community benefit organization whose mission is to raise awareness about sudden cardiac arrest and help save lives. Our signature program is the Sudden Cardiac Arrest Survivor Network, a growing community with members from throughout the U.S. and abroad whose lives were saved thanks to early CPR and defibrillation.

As noted in our previous correspondence (Jan. 18, 2011, Nov. 2, 2012, and Dec. 17, 2012) and in our testimony before the Circulatory System Devices Panel on Jan. 25, 2011, we urge the Food and Drug Administration to reconsider its proposal to reclassify automated external defibrillators (AEDs) and related accessories as class III medical devices requiring pre-market approval or a notice of completion of a product development protocol. We are concerned that this designation will be excessively burdensome and costly and will not only result in reduced access to the life-saving devices, but will stifle innovation. Further, increased regulations may not effectively address the issue of adverse events.

We recommend, instead, that the FDA regulate AEDs as class II medical devices with special controls, such as testing to industry standards, device labeling, guidance documents and post-market surveillance. We believe that this designation—along with initiatives to raise public awareness, increase CPR-AED training among laypersons, increase AED deployment, and improve systems to ensure device readiness—will have a much more beneficial impact on public health.

As you know, sudden cardiac arrest strikes about 1,000 people every day in the U.S. and only 10 percent of victims survive.[1] Those who do make it invariably have received immediate CPR and treatment with a defibrillator. In fact, research shows that survival rates of nearly 40 percent can be achieved when bystanders intervene quickly with CPR and AEDs before EMS arrives at the scene.[2]

Imagine! If the national average survival rate increased to 40 percent, as many as *100,000 additional lives* could be saved each year. Needless to say, this is unlikely to happen if AEDs are not readily available and if the public doesn't understand that AEDs are safe and effective and that immediate bystander intervention can mean the difference between life and death.

We recognize that reports of adverse events are important and should be vigorously scrutinized. However, we want to ensure that any increased regulations do not impede access to and use of AEDs, which would dramatically reduce the chances of survival for thousands of victims each year. We are concerned that such changes could negatively impact schools, colleges, businesses, places of worship, and other venues where AEDs should be readily available to help victims of sudden unexpected cardiac death.

In our opinion, research convincingly shows that AEDs are safe, effective and reliable. The Public Access Defibrillation trial, a prospective clinical study funded by the National Institutes of Health, for example, found that "AEDs have an exceptionally high safety

profile when used by trained lay responders." Investigators from multiple centers reported there were no inappropriate shocks and no failures to shock when indicated.[3] Another NIH-funded study, which looked at the use of AEDs in the home, also found there were no inappropriate shocks.[4] Similarly, research conducted in Chicago area airports determined that AEDs were used safely and effectively by untrained lay responders.[5]

According to David Belkin, Esq., a cardiac arrest survivor and Foundation board member, "It's essential to keep in mind that AEDs do not *cause death*. By definition, they are used to help *restore life* for people who die suddenly." As he testified before the FDA panel in Jan. 2011, "If designating AEDs as class III devices reduces their distribution and access—due to increased costs and regulatory hurdles—progress toward improving survival rates nationwide will be stymied."

Last November we initiated an online petition[6] urging the FDA to refrain from reclassifying AEDs as class III devices requiring pre-market approval. More than 1,000 individuals have signed the petition—including survivors, people who have lost family members to cardiac arrest, and emergency responders who have saved lives with AEDs. We urge the FDA to listen to the voices of those who understand first-hand the need to keep AEDs readily available for victims of sudden cardiac arrest.

Additional information on our position may be found here: http://www.sca-aware.org/sca-news/will-proposed-fda-action-reduce-access-to-defibrillators-for-victims-of-sudden-cardiac-arre.

Thank you for the opportunity to comment on this critical issue.

Sincerely,

Norman S. Abramson, MD, FACEP, FCCM
Chairman, Board of Directors

Mary M. Newman, MS
President

P.S. We previously sent a copy of our petition with signatures and comments in December. We will send an updated copy under separate cover.

[1] http://circ.ahajournals.org/content/127/1/e6
[2] http://www.ncbi.nlm.nih.gov/pubmed/20394876
[3] http://www.ncbi.nlm.nih.gov/pubmed/16784998
[4] http://www.ncbi.nlm.nih.gov/pubmed/18381485
[5] http://www.ncbi.nlm.nih.gov/pubmed/12393821
[6] http://www.gopetition.com/petitions/keep-automated-external-defibrillators-accessible.html