Sudden Cardiac Arrest Foundation
raising awareness, saving lives

November 2, 2012

U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
Docket Number: FDA 2009-M-101
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs:

The Sudden Cardiac Arrest Foundation is a national nonprofit 501(c)(3) organization whose mission is "to raise awareness and support programs that give 'ordinary people' the power to save a life."

We are writing to express our concern that the Food and Drug Administration is considering reclassification of automated external defibrillators (AEDs) as Class III Devices requiring pre-market approval. We believe that increased regulation of the user-friendly lifesaving devices—proven irrefutably safe and effective by decades of research—would demonstrate a lack of understanding about the life-threatening condition of sudden cardiac arrest and would have a profoundly harmful effect on unsuspecting victims, greatly reducing their chances of survival.

As you are certainly aware, sudden cardiac arrest is a leading cause of death in the U.S., affecting more than 1,000 people each day (382,500 people annually) and on average, only eight percent of victims survive. [1] Survival rates increase slightly when victims receive bystander CPR, however, survival rates increase dramatically to 38 percent when victims receive both CPR and treatment with AEDs by bystanders. If all SCA victims had timely access to treatment with AEDs and the average survival rate increased to 38 percent, more than 100,000 additional lives could be saved each year. [2]

We believe the FDA would be prudent to reconsider the proposed increase in regulations, and instead focus on ensuring that AEDs are widely deployed and the public is informed about the importance of using the lifesaving devices—without hesitation—in cases of sudden unexpected cardiac death. We urge the FDA to redirect its energy and resources to help raise awareness about the need for immediate bystander intervention with AEDs.

Our Sudden Cardiac Arrest Survivor Network is a testament to the fact that a quick combination of CPR and defibrillation is nothing less than the key to survival. Earlier this fall, we co-hosted a gathering of survivors from around the U.S., who would be quick to point out they owe their lives to the timely use of AEDs.

Perhaps our national spokesperson, TV news anchor and sudden cardiac arrest survivor, Susan Koeppen, 39, says it best: "If it were not for the bystanders who rushed to help me, I would not be here today. I can't stress enough the importance of learning CPR and how to use an AED."

Robust AED safety and performance standards already exist that capture more than 20 years of hard-won clinical, regulatory, and industry experience. We urge the FDA to consider alternative pathways that ensure the safety and effectiveness of AEDs, and at the same time support efforts to drive widespread access to early defibrillation.

It has taken decades to get this far. We cannot afford to decrease the odds that victims in need will have timely access to definitive care.

Best regards,

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

Mary M. Newman, MS, President

[1] Roger VL, et al. Heart Disease and Stroke Statistics-2012 update. A report from the American Heart Association. Circulation. 2012;125(1):188-197.
[2] Weisfeldt ML, et al. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. J Am Coll Cardiol. 2012;55(16):1713-1720.

Attachments:

- Correspondence from Sudden Cardiac Arrest Foundation to John Paul Swink, FDA, January 18, 2011
- Letter to Editor of New York Times from Mary Newman, Sudden Cardiac Arrest Foundation on "Reclassifying Defibrillators," February 3, 2011

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January 18, 2011

James Paul Swink
Designated Federal Officer
Medical Devices Advisory Committee
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: January 25-26, 2011: Food and Drug Administration, Health and Human Services, Circulatory Devices Panel of the Medical Devices Advisory Committee Meeting

Dear Mr. Swink:

The Sudden Cardiac Arrest Foundation is a national nonprofit organization whose mission is "to raise awareness and support programs that give 'ordinary people' the power to save a life." We are writing to express our support for the reclassification of automated external defibrillators (AEDs) as Class II Devices, with special controls designed to ensure safety and efficacy. We are concerned that a Class III designation could impede access to AEDs, thus dramatically reducing the chances of survival for thousands of sudden cardiac arrest victims each year.

As you may know, 295,000 cases of out-of-hospital cardiac arrest are treated by emergency medical services annually in the United States[1], and only 7% of victims survive.[2] Survivors inevitably have three things in common: Someone immediately called 9-1-1, started CPR (cardiopulmonary resuscitation), and treated the victim with the nearest defibrillator. In fact, research shows when AEDs are *applied* before EMS arrives, survival rates increase to 24%, and when AEDs are *used* before EMS arrives, survival rates increase to 38%.[3]

Last month, we co-hosted a workshop for 50 SCA survivors from around the U.S., along with their families and other advocates. These individuals are living proof that early CPR and early defibrillation can make the difference between life and death. One of them, David Belkin, Esq., a member of our Board of Directors, expressed the prevailing sentiment when he said: "If it were not for immediate use of an AED in the school where I had my SCA, I would not be here today."

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[1] American Heart Association. Heart Disease and Stroke Statistics – 2009 Update. Dallas, Texas: American Heart Association, 2009.
[2]Weisfeldt ML, Sitlani CM, Ornato JP, et al., on behalf of the ROC Investigators. J Am Coll Cardiol 2010;55:1713-1720.

We urge the FDA to reclassify AEDs as Class II devices.

Sincerely,

Norman S. Abramson, MD, FACEP, FCCM
Chairman, Board of Directors
Professor Emeritus, University of Pittsburgh, Department of Emergency Medicine, Pittsburgh, PA

Mary M. Newman
President

cc: Bobby V. Khan, MD, PhD
Immediate Past Chairman, Board of Directors
Executive Director, Atlanta Vascular Research Foundation, St. Joseph Translational Research Institute, Atlanta, GA

David Belkin, Esq., Member, Board of Directors
David Belkin Consulting, LLC, Bethesda, MD

Andrew R. Roszak, JD, MPA, EMT-P, Member, Advisory Council
Senior Health Policy Counsel, Office of Special Health Affairs, Health Resources and Services Administration, Department of Health and Human Services, Washington, DC

February 3, 2011

Reclassifying Defibrillators

To the Editor:

Re "Stricter Oversight Urged for Defibrillators" (Business Day, Jan. 26):

The Food and Drug Administration's recommendation to reclassify automated external defibrillators as high-risk devices is shortsighted and could cost thousands of lives each year.

While there were 22,000 malfunction reports over the last five years, most resulted from routine device self-checks, not the actual use of A.E.D.'s. Further, considering that more than one million A.E.D.'s have been deployed in the United States, that's an extremely low failure rate.

A.E.D.'s do not cause death — they are used to bring dead people back to life. While they cannot save everyone, they give many victims a second chance, particularly when used quickly by bystanders.

If regulatory hurdles increase, public access to A.E.D.'s will decrease. That would be devastating news for the 295,000 people who suffer sudden death outside hospitals each year — and a giant step backward in the quest to improve survival from the nation's leading killer.

Mary Newman
President
Sudden Cardiac Arrest Foundation
Wexford, Pa., Jan. 27, 2011