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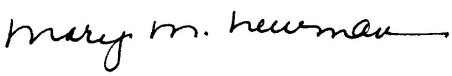
[1] American Heart Association. Heart Disease and Stroke Statistics – 2009 Update. Dallas, Texas: American Heart Association, 2009.
[2]Weisfeldt ML, Sitlani CM, Ornato JP, et al., on behalf of the ROC Investigators. J Am Coll Cardiol 2010;55:1713-1720.
[3]Ibid.

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
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