Sudden Cardiac Arrest Foundation
raising awareness, saving lives

October 31, 2013

Secretary Kathleen Sebelius
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request to HHS to require the FDA to provide an evidence-based justification for its proposal to increase in regulations related to automated external defibrillators

Dear Secretary Sebelius:

By way of introduction, the Sudden Cardiac Arrest Foundation is a national 501(c)3 community benefit organization dedicated to raising awareness about sudden cardiac arrest (SCA) and saving lives. We are writing to express our concerns about a proposal by the Food and Drug Administration (FDA) to increase the level of regulation of automated external defibrillators (AEDs) from 510(k) premarket notification to premarket approval (PMA), rather than reclassifying AEDs to Class II, the level of regulation the agency has successfully implemented for this device for more than 25 years. Now, based on medical device reports and recalls, the FDA has mischaracterized the safety of this device, which rarely fails during use.[1]

Summary

We disagree with the FDA's proposal for the following reasons:

- The number of adverse events is extremely small and the risk of device failure during use is infinitesimal.
- Early defibrillation is the most effective known intervention for restoring circulation after SCA. For each minute that passes between collapse and defibrillation, survival rates decrease 7-10%.[2]
- The use of AEDs by bystanders accomplishes the earliest possible defibrillation (outside of wearable or implanted defibrillators).
- Increased use of AEDs by bystanders can only occur if the devices are more widely available and if the public is educated about its critical role in providing early defibrillation.
- The FDA's proposed regulatory changes will result in increases in device prices, thus reducing access, and will stifle innovative changes that could lead to reduced costs.
- The FDA's proposed regulatory changes are unlikely to achieve measurable safety improvements, but are very likely to mean that fewer SCA victims will be given a chance to survive.

We have expressed our concerns to the FDA in multiple communications, most recently in June in response to a solicitation for comments on the matter. (See attachments.) We are now requesting that you require the FDA to provide an evidence-based public health justification for its proposed action.

Details

By way of background information, about 1,000 people (359,400 annually) experience SCA outside hospitals each day in the U.S. and, on average, only 10 percent of victims survive.[3] However, a prospective multi-center clinical trial has demonstrated that survival rates increase to nearly 40 percent when bystanders intervene quickly by giving CPR and using AEDs before EMS arrives at the scene.[4] And, as reported just last week on NBC Nightly News, survival rates in one city (Rochester, Minnesota) now approach 60%, thanks to rapid use of AEDs by police officers.[5] If the national average survival rate increased to even 25%, more than 50,000 additional lives could be saved each year.

In contrast to the limited data presented by the FDA to support its proposal, a vast body of clinical research convincingly shows that AEDs are safe, effective, and reliable. For example, the Public Access Defibrillation trial, a prospective clinical study funded by the National Institutes of Health (NIH), 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.[6] Another NIH-funded study that looked at the use of AEDs in the home also found there were no inappropriate shocks.[7] Similarly, research conducted in Chicago area airports determined that AEDs were used safely and effectively by untrained lay responders.[8]

We are further convinced of the value of AEDs as a result of interaction with, and research conducted among, members of our growing network of SCA survivors, most of whom were saved thanks to immediate use of AEDs. In addition, 1,372 people, including many survivors, have signed a petition we initiated urging the FDA to refrain from increasing the effective level of AED regulation and instead designate AEDs as Class II devices to keep them readily accessible.[9]

Given the decades of research clearly demonstrating the safety and efficacy of AEDs, and the growing community of SCA survivors, we believe it is in the public's best interest to increase access to this lifesaving technology, not create unnecessary obstacles to access.

The proposed FDA approach, however, will inevitably decrease access to AEDs since it will lead to increases in device costs, which in turn will be passed on to AED purchasers. Although prices have declined over the years, these sophisticated devices still cost about $1,200 each, and price is a primary inhibitor to widespread access.

Furthermore, the FDA's proposed approach is unlikely to significantly improve the safety of the devices, which have already been proven by multiple studies to be safe. It is important to note that AEDs have been successfully regulated for at least 25 years under less costly and cumbersome requirements than those that are now proposed. Today, well over a million AEDs are deployed in the U.S. for use by emergency responders and laypersons in public locations (e.g., airports, schools, government office buildings) and in private homes.

In conclusion, we urge the Department of Health and Human Services to intervene in this critical public health matter and recommend that unless there is an evidence-based public health risk, the FDA should withdraw its proposed regulatory action.

Perhaps David Belkin, Esq., a cardiac arrest survivor and member of the Sudden Cardiac Arrest Foundation Board of Directors, says it best. In his testimony before the FDA he said, "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. If increasing regulations of AEDs reduces their distribution and access due to increased costs and regulatory hurdles, progress toward improving survival rates nationwide will be impeded."

Thank you for your time in considering our position.

Sincerely,

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

Mary M. Newman, MS
President

cc: Honorable, William V. Corr, HHS Deputy Secretary
David Belkin, Esq., Sudden Cardiac Arrest Foundation
Melissa Burns, Food and Drug Administration

Attachments:

- January 11, 2011 correspondence to FDA
- "Reclassifying Defibrillators, February 3, 2011 Letter to the Editor of The New York Times
- November 2, 2012 correspondence to FDA
- "AEDs Save Lives: Let's Keep Them Readily Available," December 14, 2012, Huffington Post blog
- December 17, 2012 correspondence to FDA
- June 5, 2013 correspondence to FDA

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[1] http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0234-0001
[2] http://circ.ahajournals.org/content/122/18_suppl_3/S706.full
[3] http://circ.ahajournals.org/content/127/1/e6
[4] http://www.ncbi.nlm.nih.gov/pubmed/20394876
[5] http://www.nbcnews.com/video/nightly-news/53347636/#53347473
[6] http://www.ncbi.nlm.nih.gov/pubmed/16784998
[7] http://www.ncbi.nlm.nih.gov/pubmed/18381485
[8] http://www.ncbi.nlm.nih.gov/pubmed/12393821
[9] http://www.gopetition.com/petitions/keep-automated-external-defibrillators-accessible.html

Sudden Cardiac Arrest Foundation
raising awareness, saving lives

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

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

Mary M. Newman

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

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

December 17, 2012

U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
Docket Number: FDA 2009-M-0101
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs:

As a follow-up to our letter of November 2, 2012, please find enclosed the results to date of our online petition urging the FDA to refrain from reclassifying automated external defibrillators (AEDs) as class III devices requiring pre-market approval. Please note the 33-page document includes 454 signatures and 148 comments from sudden cardiac arrest survivors, healthcare professionals, and other advocates who understand first-hand the value of the safe and effective lifesaving devices.

Also enclosed you find a copy of a blog recently published in *The Huffington Post.*

Please consider this information in your analysis of the issues.

Sincerely,

Norman S. Abramson

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

Mary M. Newman

Mary M. Newman, MS
President

Enclosures:

- November 2, 2012 correspondence
- Petition: "AEDs Save Lives: Let's Keep Them Readily Available"
- Huff Post Blog: "AEDs Save Let's Keep Them Readily Available," December 14, 2012

The Third Metric | Redefining Success Beyond Money & Power

October 28, 2013

HUFF POST IMPACT

AEDs Save Lives: Let's Keep Them Readily Available

Posted: 12/14/2012 4:30 pm

The Sudden Cardiac Arrest Foundation has launched a petition to the Food and Drug Administration to keep automated external defibrillators (AEDs) readily accessible for victims of sudden unexpected cardiac arrest, rather than increase regulatory hurdles that will hinder their deployment. The FDA is expected to make a decision before the end of the year. Please consider signing the petition today.

Background

Every day in the U.S., about 1,000 people of all ages suffer sudden cardiac arrest (SCA) outside hospitals and, on average, only one in 10 victims survives.(1) However, when bystanders provide cardiopulmonary resuscitation (CPR) and use automated external defibrillators (AEDs) before emergency medical services personnel arrive, as many as four in 10 victims survive. (2)

SCA, which differs from a heart attack, is an abrupt, unexpected pulseless condition. It is usually caused by ventricular fibrillation, an abnormality in the heart's electrical system. When SCA occurs, blood stops flowing to the brain, the heart and the rest of the body, and the person collapses. Within minutes, the victim is clinically dead and will remain so unless someone (like you or me) helps immediately.

The best way to help is to call 911, start CPR, and use the nearest AED. An AED is a portable, user-friendly device that automatically diagnoses a potentially life-threatening heart rhythm and delivers a therapeutic shock, if needed, to restore a normal heartbeat. The AED cannot hurt the victim, the rescuer or other bystanders, as long as it is used properly.

The survival of Walter "Josh" Watts is a case in point. The 21-year-old was saved from sudden cardiac death last spring through prompt CPR and use of an AED by fellow students at College of the Ozarks. Walter is a member of our growing network of SCA survivors -- people who readily attest to the value of AEDs.

The Issue

The Food and Drug Administration (FDA), however, is considering increasing regulations for AEDs by reclassifying them as Class III medical devices that require pre-market approval. This means that the lifesaving public safety devices, which have been already been proven to be safe and effective by decades of research, will have to undergo new, complicated, time-consuming, expensive clinical trials before being approved for use in the marketplace. As a result, AEDs will inevitably become much more expensive and much less readily available. The negative public health impact will be severe. Inevitably, fewer victims will survive.

A Reasonable Alternative

We urge the FDA to consider designating AEDs as Class II medical devices with special controls. This will raise the bar for all manufacturers by formalizing the hard-won experience of the last 20-plus years in key areas such as human factors and device readiness. Since AEDs place the power to save lives in the hands of laypersons, some special consideration regarding regulation is appropriate. Class II designation with special controls will not only ensure the safety and effectiveness of AEDs, it will also allow innovation to continue. As a result, the cost of AEDs will decrease and deployment will increase. Ultimately, more lives will be saved, and more families will be spared the painful loss of loved ones snatched away too quickly.

Call to Action

Please join the hundreds of individuals who have already signed a petition urging the FDA to keep AEDs accessible for victims of sudden cardiac arrest -- people like Kristin, who said, "Five years ago, the combination of bystander CPR and an AED saved by life. My children, ages 8 and 6, came so close to not knowing me. Please don't make it harder to save another life by reclassifying AEDs." Click here to sign.

For more information, click here.

References:

(1) Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics--2013 update: A report from the American Heart Assoociation. Circulation.2013: published online before print December 12, 2012, 10.1161/CIR.0b013e31828124ad:e160-161.

(2) Weisfeldt ML, Sitlani CM, Ornato JP, et al., on behalf of the ROC Investigators. J Am Coll Cardiol 2010;55:1713-1720

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. 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. Of course, this will not happen if AEDs are not readily available and the public is unaware of the safety and effectiveness of the devices and the critical need for immediate bystander intervention.

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 sudden cardiac arrest 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 stated in his testimony before the FDA, "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 sudden cardiac arrest, and emergency medical responders who have saved lives with AEDs. We urge the FDA to consider the voices of those who understand first-hand the need to keep AEDs readily available for victims of sudden cardiac arrest.

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

Sincerely,

Norman S. Abramson

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

Mary M. Newman

Mary M. Newman, MS
President

P.S. We previously sent a copy of our petition with signatures 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