



**National Center for
Early Defibrillation**

Community Resources to Help Save Lives

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January 26, 2004

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

Re: Docket No. 1994N-0418 Reclassification of Automated External Defibrillators

To Whom It May Concern:

The National Center for Early Defibrillation (NCED) supports the above-referenced reclassification of automated external defibrillators (AEDs) from Class III to Class II devices.

The NCED is a non-profit, independent organization based in the Department of Emergency Medicine at the University of Pittsburgh. (See www.early-defib.org.) NCED promotes improved access to early defibrillation and greater implementation of the Chain of Survival (early recognition, early call to 9-1-1, early CPR, early defibrillation, early advanced care, early follow-up care). NCED leadership consists of Mary M. Newman, BS, Executive Director, Vincent N. Mosesso, Jr, MD, Medical Director and associate professor, and Paul M. Paris, MD, Associate Medical Director and professor and chair of the department of emergency medicine. All have extensive experience and are respected researchers on the topic of sudden cardiac arrest (CVs enclosed).

As you may be aware, NCED recently hosted a national conference, the Congress of Champions and Survivor Summit, that featured a pre-conference workshop on "Regulations in Defibrillation: An AED Issues Forum." This forum addressed the reclassification question and included participation from FDA Center for Devices and Radiological Health representatives Carole Carey, Bev Gallauresi, Megan Moynahan, Dale Tarvis, MD, Oscar Tovar, MD, and Geretta Wood.

The following outlines our position. AEDs provide significant clinical benefit in the fight to reduce mortality from sudden cardiac arrest (SCA), allowing bystanders to provide the critical intervention of defibrillation. This is in most cases the only hope these victims have for survival, since it is often impossible for first responders or emergency medical services (EMS) to provide defibrillation within the therapeutic window. There is now a large body of human clinical research that shows the effectiveness and safety of AEDs in the hands of both public safety first responders and minimally trained laypersons. These studies have documented impressive and unprecedented survival rates among SCA

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victims in airplanes, airports and casinos. The recently reported Public Access Defibrillation (PAD) Trial found twice as many survivors at study locations where responders were trained and equipped with AEDs compared with locations where responders were trained only in CPR. (Dr. Mosesso of NCED served as principal investigator of the Pittsburgh site for this trial.)

Perhaps most important is that in the studies mentioned above and in many others, serious adverse events were extremely rare. AEDs were used by a variety of non-medical persons safely and effectively. Rhythm analysis was extremely accurate with sensitivity for shockable rhythms at or over 90% and specificity near or at 100%. Even in the PAD Trial, which enrolled nearly 10,000 volunteer responders at 1,000 different locations, there were no inappropriate shocks. Further, there were no reports of AEDs causing significant injury or harm to patients or users.

The above experience argues that AEDs now have a 20-year track record of safety and efficacy that warrants reclassification. However, since these devices are increasingly deployed in locations where they may be used by persons without formal device training, and especially if such down classification is associated with loss of prescription requirement, it is even more important that all devices marketed perform at extremely high levels of safety and efficacy. We feel this means that the FDA must ensure, in particular, the quality of the following:

- For Safety
 - Accuracy of rhythm analysis (quality of signal attainment, processing and algorithm)
 - Features to reduce risk of electrical shock to user (active and passive)
 - Use of non-harmful defibrillation waveform
- For Efficacy
 - Easy-to-follow real-time user instructions (visual and auditory)
 - Features to ensure proper shock delivery
 - Effective defibrillation waveform
 - Functional reliability of electronic and mechanical components.

Further we suggest consideration of the feasibility of including in the packaging not only device instructions but information on appropriate deployment. This would include information for determining installation location, ensuring device utilization at the time of the event (i.e., response planning and proper awareness among on-site personnel), training options and response review. NCED is willing to develop or review such materials.

We believe all of this can be accomplished through special controls and labeling provisions under Class II. This will facilitate more rapid availability of improved and advanced features as AEDs evolve, a development that would likely be inhibited by the expense and time inherent to the Class III process. This would in turn lead to more rapid widespread deployment and bystander utilization, which should save many lives.

We support the reclassification of the AED as a Class II device based on our review of the literature, extensive discussion with AED users, clinical and research experience and the safeguards already developed to address potential device risks.

Thank you for the opportunity to share our views. Please feel free to contact us if you would like any further information.

Sincerely,



Vincent N. Mosesso, MD
Medical Director



Mary M. Newman
Executive Director



Paul M. Paris, MD, FACEP
Associate Medical Director

Enclosures.