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LEGAL IMPLICATIONS OF LAY USE OF AUTOMATIC EXTERNAL DEFIBRILLATORS IN NON-HOSPITAL SETTINGS

*Karen F. Petersen**

INTRODUCTION

Sudden Cardiac Arrest (SCA), the largest single cause of death in the United States, strikes up to 350,000 Americans each year and takes a life every two minutes.¹ Studies have shown that two out of three deaths occur before the victims even reach the hospital, usually at home, work or in a public place like a mall.² What is more troubling is that ordinary citizens do not know that they could be doing more to help victims of SCA. Technology has produced a relatively inexpensive device that is indispensable in treating SCA, but most Americans have not even heard of it. Considering the prevalence of public education campaigns on Acquired Immune Deficiency Syndrome (AIDS), drug addiction and depression, why is the majority of the public unaware of the small device that is capable of saving thousands of lives during the onset of a cardiac arrest?

This Comment's purpose is to heighten the reader's awareness of the merits of lay use of Automated External Defibrillators (AEDs) and to

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1. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

SCA – Sudden Cardiac Arrest is the loss of an effective pumping action of the heart, so that blood flow ceases to the vital organs. The heart muscle may continue to have some activity, but it is fragmented and disorganized, weak or very slow, and is therefore ineffective. The patient quickly loses consciousness and stops breathing. Within several minutes irreversible damage to body organs begins to occur. *Id.*

2. *Id.*

explain the potential barriers facing their use and the issues involved in advancing implementation of employer programs supporting the lay use of AEDs. Part I of this Comment provides a comprehensive review of the legal, ethical and policy issues surrounding the development of widespread lay use of AEDs. Part II of this Comment discusses the current state of lay use of AEDs, particularly the need for public access to defibrillation devices. Part III explains how, in the context of the American Heart Association's (AHA) "chain of survival" construct, greater use of AEDs increases survival rates for victims of sudden cardiac arrest. Part IV reviews the current law governing the manufacture and use of AEDs and examines recent and progressive state and federal legislation that would allow non-medical personnel to operate AEDs under revised Good Samaritan laws. Part V analyzes the potential legal liability for employers as a result of the use, or non-use, of AEDs by lay persons. It addresses the employer liability problem by reviewing the experiences of three distinct industries, casinos, health and fitness centers, and airlines. Part VI briefly summarizes some of the ethical concerns surrounding the use of AEDs, including the concern for those victims with "do not attempt resuscitation" orders. Finally, this Comment concludes by arguing that greater public awareness of the availability of AEDs and increased acceptance and use of such devices by the public, in concert with Emergency Medical Services (EMS), will ultimately save human lives.

A. *Medical Background on SCA*

Most cardiac arrests are due to rapid or chaotic activity of the heart - ventricular tachycardia or fibrillation; some are due to extreme slowing of the heart.³ These events are called life-threatening arrhythmias and are responsible for sudden death.⁴ Ventricular fibrillation (VF) occurs when the nerves embedded in the heart malfunction causing the main pumping chamber, the left ventricle, to quiver or fibrillate, thus it can no longer pump oxygenated blood effectively throughout the body, and most importantly, to the brain.⁵ Many of us have heard of cardiopulmonary resuscitation (CPR), possibly even taken a CPR class. However, when you think back on your experiences in first aid or CPR classes would the medical definitions above

3. *Sudden Cardiac Death: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/sudden.htm (last visited Oct. 18, 1999).

4. *Id.*

5. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

help you to determine if a person is in cardiac arrest? Early bystander CPR and rapid defibrillation are the two major contributors to survival of adult victims of sudden cardiac arrest.⁶

A twelve year old study in the *New England Journal of Medicine*⁷ cited the following obstacles to a nation-wide program of on-the-spot defibrillation: medical need for highly trained users, legal concerns about the liability of users, logistic and economic problems associated with defibrillation, and a serious lack of public education about sudden cardiac death.⁸ Advances in technology and an innovative medical devices industry have made the logistic and economic problems much less burdensome. The latest AEDs have nearly eliminated logistic and economic concerns since they weigh about five pounds and range in price from \$3000 to \$5000.⁹ Although public education campaigns have been mounted in the intervening years, the resulting public response has been less than enthusiastic.

B. Use and Development of AEDs

Emergency Medical Technicians (EMTs) have, for the most part, led the battle for utilization of AEDs in the field. EMTs have fought to have AEDs available to first responders no matter their level of medical expertise. Proponents of widespread AED use, especially by lower level EMTs, fire and rescue personnel and police, have clashed with groups who want to limit defibrillation to highly trained medical personnel. The debate centers on the objective need for medical training in order to provide early defibrillation. Some first responders believe that the more highly trained paramedics feel threatened and thus are less likely to support relinquishing the initial shock to someone with less training.¹⁰ AEDs not only recognize an arrhythmia, but also can deliver the needed shock with little specialized knowledge on the part of users. The AHA and many other interested groups profess that anyone can use an AED with minimal training.¹¹ According to the AHA,

6. Myron L. Weisfeldt et al., *Public Access Defibrillation: A Statement for Healthcare Professionals From the American Heart Association Task Force on Automatic External Defibrillation*, AHA Medical/Scientific Statement, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Scientific/statements/1995/21952222.html> (last visited Oct. 18, 1999).

7. Jeremy N. Ruskin, *Automatic External Defibrillators and Sudden Cardiac Death* (editorial), *N. ENG. J. MED.*, Sept. 15, 1988, at 713.

8. *Id.*

9. David Herbert, *Heart in the Right Place*, *J. AM. FITNESS*, Mar/Apr 1999.

10. A.J. Heightman, *Shocking News from Chicago*, 8 *J. EMERGENCY MED. SERVICES* 24 (1999).

11. *See generally*, A Memorandum from the University of North Carolina at

“[d]espite their diagnostic capabilities, current laws in many states may limit [AED] use to highly trained health care providers.”¹² This is due, in part, to concerns surrounding liability of first responders and lay users of the devices. The AHA has stated that, “[d]espite potential legal problems, an effort is underway to lobby state legislatures for the amendment of current statutes allowing non-medical personnel to operate defibrillators.”¹³

At the federal level, the Cardiac Arrest Survival Act of 2000 was passed by the 106th Congress.¹⁴ It provides “for recommendations of the Secretary of Health and Human Services regarding the placement of automatic external defibrillators in Federal buildings in order to improve survival rates of individuals who experience cardiac arrest in such buildings, and to establish protections from civil liability arising from the emergency use of the devices.”¹⁵ In the absence of other federal standards regarding AED use, this appears to be a step in the right direction. A 1995 poll of EMS directors revealed that a lack of enabling legislation in many states is a major problem in implementing early defibrillation programs, one which national standards would help remedy.¹⁶ Section four of the Cardiac Survival Act,

Chapel Hill, *AED Safety: A Review of the Data*, UNC-CH, at http://www.padl.org/html/articles/current/praed_uncch.htm, (May 24, 2000); see also Weisfeldt, *supra* note 6.

12. Herbert, *supra* note 9.

13. *Id.*

14. See Cardiac Arrest Survival Act of 2000, 106th Cong. (2000).

Support for the Cardiac Arrest Survival Act in the 106th Congress is broad. A diverse cross-section of national health and safety groups endorse the proposal, including the American Heart Association, American Red Cross, American Academy of Pediatrics, American College of Emergency Physicians, American Association of Respiratory Care, American College of Cardiology, Emergency Nurses Association, International Association of Firefighters, International Association of Fire Chiefs, the North American Society Pacing and Electrophysiology and the National Association of State EMS Directors.

Frequently Asked Questions About the Cardiac Arrest Survival Act, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/HEART/CPR/PAD/quest.html> (last visited Oct. 18, 1999).

15. Alexandra Trinkoff, *AHA Calls for Increased Access to Automatic External Defibrillators*, NEW YORK HEALTH LAW UPDATE, Feb. 1998.

16. See *Frequently Asked Questions about the Cardiac Arrest Survival Act*, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/HEART/CPR/PAD/quest.html> (last visited Oct. 18, 1999). The Cardiac Arrest Survival Act of 2000 was passed by both houses of Congress on October 26, 2000. available at <http://thomas.loc.gov/cgi-bin/bdquary/D?106:20:/temp/~bdZfgh:@@L&summ2=m&>. As this Comment goes to print the bill was signed by President

“Liability Regarding Emergency Use of Automated External Defibrillators,” addresses the legal concerns of acquirers and users of AEDs.¹⁷ It provides immunity from civil liability for any person who provides emergency medical care through the use of an AED.¹⁸

Knowledge about CPR is widespread, but defibrillation, a powerful electrical shock to the heart, is less known, even rare. According to the AHA, “[an] A.E.D., helps reestablish normal contraction rhythms in a heart that is not functioning properly.”¹⁹ Portable AEDs give one or more jolts of electricity (defibrillation) designed to interrupt the disorganized activity so that an orderly heartbeat can re-emerge.²⁰ A “massive heart attack” is the phrase commonly used in the media to describe sudden death, but it is often not the cause. Heart attack, or myocardial infarction, more properly refers to the death of the heart muscle tissue due to the loss of blood supply, therefore, a heart attack may cause cardiac arrest and sudden cardiac death, however, the terms are not synonymous.²¹ Unlike a heart attack, which is

Clinton on Nov. 13, 2000. *Id.* (no public law number is available) Section 4 of the Act amends Part B of Title II of the Public Health Service Act by adding:

§248.(a) Good Samaritan Protections Regarding AEDs: Except as provided in subsection (b), any person who uses or attempts to use an automated external defibrillator device on a victim of a perceived medical emergency is immune from civil liability for any harm resulting from the use or attempted use of such a device; and in addition, any person who acquired the device is immune from such liability, if the harm was not due to the failure of such acquirer of the device –

- (1) to notify local emergency response personnel or other appropriate entities of the most recent placement of the device within a reasonable period of time after the device is placed;
- (2) to properly maintain and test the device; or
- (3) to provide appropriate training in the use of the device to employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that such requirement of training does not apply if –
 - a. the employee or agent was not an employee or agent who would have been reasonably expected to use the device; or . . .H.R.2498 Title IV §248.

17. See Cardiac Arrest Survival Act of 2000, 106th Cong. (2000).

18. *Id.*

19. *Defibrillation: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/defib.html (last visited Oct. 18, 1999).

20. Paul C. Sorum, *Limiting Cardiopulmonary Resuscitation*, 57 ALB. L. REV. 617 (1994).

21. *Sudden Cardiac Death: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Zguide/

caused by blocked blood flow to the heart muscle, SCA is ventricular fibrillation, a life threatening condition in which the heart's normal electrical signals become disorganized and erratic, causing the heart to cease pumping blood effectively.²² "Other forms of cardiac arrest - ventricular standstill, in which there is no electrical activity in the heart, and pulseless electrical activity, cannot be treated with a defibrillator."²³

AEDs were developed in the 1980s after advances in solid-state circuitry and micro-computers allowed defibrillators to recognize ventricular fibrillation (VF),²⁴ the sudden onset of chaotic electrical activity in the muscle wall of the ventricle, that leads to disorganized quivering of the heart with no forward movement of blood.²⁵ Defibrillation can be compared to rebooting a "frozen" computer; it can eliminate VF and allow a coordinated rhythm to resume.²⁶

AEDs are lightweight, easy to carry and handle and have built-in computers that guide users through the defibrillation procedure.²⁷ The first out-of-hospital defibrillation device weighed 110 pounds; today they weigh about five pounds.²⁸ The cost of an AED, currently between \$3000-\$5000, is a small price to pay to save a life.²⁹ Today's automatic external defibrillators analyze heart rhythms, then deliver verbal prompts to users to stop using the machine when the rhythm returns to normal. A computer algorithm makes

sudden.htm (last visited Oct. 18, 1999).

22. *American Red Cross Leads the Fight Against Sudden Cardiac Arrest in the Workplace*, AMERICAN RED CROSS, at <http://www.redcross.org/news/inthenews/99/3%2dl%2d99.html> (last visited Oct. 18, 1999).

23. Jennifer Fitzenberger, *State Gives Law Officers Defibrillators to Help Save More Lives: Rochester's Success with Police Officers Treating Cardiac Arrest led to Funding for Distributing More Machines*, STAR-TRIBUNE NEWSPAPER OF THE TWIN CITIES, Dec. 31, 1998.

24. *Cardiac Arrest and the Need for Early Defibrillation: When every Second Counts*, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/Brochure.html> (last visited Oct. 18, 1999).

25. See Sorum, *supra* note 20.

26. *Cardiac Arrest and the Need for Early Defibrillation: When every Second Counts*, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/Brochure.html> (last visited Oct. 18, 1999).

27. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

28. *Cardiopulmonary Resuscitation (CPR) Statistics*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart/_and_stroke_A_Z_Guide/cprs/html (last visited Oct. 18, 1999).

29. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

the decision, and it is rarely wrong.³⁰ Diagrams show where to place the pads and visual displays coupled with audible voice prompts give instructions to users. The algorithm automatically detects and assesses the heart's rhythm and determines whether or not defibrillation is needed.³¹ The AED will not shock an "unshockable" rhythm.³² Special low-energy electrical waves are used by AEDs in order to decrease potential damage to the heart.³³

AEDs have increasingly been viewed as a critical public health advance.³⁴ The AHA estimates that 20,000 or more deaths could be prevented each year if AEDs were widely available to first-line responders, such as police officers and fire department personnel.³⁵ Researchers have examined not only "return of spontaneous circulation and survival to hospital admission and discharge, but also neuralgic function among survivors."³⁶ In other words, not only were the results of the initial use of the defibrillator to shock the heart studied, but the study also focused on useful information about the functioning of the patient after recovery. Experts can determine the economics associated with intervention and estimate the financial costs of their use by analyzing cost per life saved.³⁷

In one such study, public health officials in Seattle studied the cost of a life saved.³⁸ They found that if 276 AEDs were located in the airport, county jail, shopping malls, stadiums, industrial sites, golf courses, homeless shelters, train and ferry terminals, health clubs and senior centers, up to thirty-two lives could be saved.³⁹ At a volume discounted price of \$2500 per AED, which equals \$690,000, the initial cost of the device is less than \$22,000 per

30. Ken Garber, *Porta Pulse*, HOSP. & HEALTH NETWORKS, American Hospital Publishing, Inc. (June 1999).

31. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

32. *Id.*

33. Alexandra Ravenelle, *On-the-Job Lifesavers Small, Portable Defibrillators are Becoming Popular in the Workplace*, GREENSBORO NEWS & RECORD, July 13, 1999 at D1.

34. Donald C. Drake, *A Jump Start for the Heart: Little Device Saves Lives*, PHILADELPHIA INQUIRER, July 2, 2000 at A1.

35. *A Matter of Life and Death*, AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdfacts.html> (last visited Oct. 18, 1999).

36. I.G. Stiell et al., *Improved Out-of-Hospital Cardiac Arrest Survival Through the Inexpensive Optimization of Existing Defibrillation Program: OPALS Study Phase II*, 281 JAMA 13, 1175 (1999).

37. Carin Olson et al., *Advancing Cardiac Resuscitation: Lessons From Externally Controlled Trials*, 281 JAMA 13, 1220, 1221 (1999).

38. See Drake, *supra* note 34, at A1.

39. *Id.*

life saved.⁴⁰

At \$3000-\$5000 a machine, the cost of equipping first responders is not the issue. The threat of civil liability for users and owners of AEDs seems to be the biggest reason for slow implementation of AED programs nationwide. Few public places have AEDs and only certain first responders have legal authority to use AEDs.⁴¹ According to the Washington Post, “[t]oday, Las Vegas gambling halls are about the safest public places in the world, at least in terms of their preparation for cardiac disaster.”⁴² Casinos are leading the way in the movement to make AEDs as indispensable as life jackets and seat belts - pieces of technology that we cannot imagine ever living without.⁴³

I. CURRENT USE OF AEDS IN THE WORKPLACE

AEDs that accurately analyze cardiac rhythms and, if appropriate, advise the operator to deliver an electric countershock were introduced in 1979.⁴⁴ But only recently have they become commonplace on emergency vehicles, including police and fire vehicles. Nearly 40,000 AEDs will be sold this year, and the market doubles about every eighteen months.⁴⁵ One researcher believes that “[t]echnology may be cutting out the middleman and woman - specially trained medical personnel in order to beat the clock.”⁴⁶

[Highly trained] medical personnel [do not] really need an AED

40. *Id.* “The researchers thought it would cost too much to cover lower-incidence sites, such as restaurants, retail stores, hotels, and government offices. This would require 71,000 AEDs at a cost of \$177 million or about \$2 million per life saved.” *Id.*

41. *A Matter of Life and Death*, AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdfacts.html> (last visited Oct. 18, 1999).

42. David Brown, *A Heart Jump Starting Trend: Americans Move to Put Defibrillators in Public Places*, WASH. POST, Oct. 2, 1999, at A11.

43. *Id.*

44. Richard Kerber et al., *Automatic External Defibrillators for Public Access Defibrillation: Recommendation for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety*, A Statement for Health Professional from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy, at <http://www.americanheart.org/scientific/statement/1997/039701.html> (last visited Sept. 20, 2000). Endorsed by the Board of Trustees of the American College of Cardiology.

45. See Brown, *supra* note 42.

46. Gloria Butler Baldwin, *Shocking Advances*, THE CLARION LEDGER, THE DES MOINES REGISTER, Mar. 1998.

because it might slow them down telling them step-by-step what to do. They already know what to check for and can do it faster. But for the basic services ambulances where there are not medically trained people, an AED is simple to use and helpful.⁴⁷

Thus, AEDs are easy for co-workers to use in an office setting, or for bystanders to use in other public venues. Considering that most sudden cardiac arrest incidents occur on Monday, closely followed by Friday, the two most stressful days of the workweek: American companies are quickly responding to this reality by equipping employee lay rescuers with AEDs.⁴⁸ According to the Washington Post, "USX Corporation recently got automated defibrillators for two steel mills near Pittsburgh, and over the next year will outfit four more plants as well as all four oil refineries run by its subsidiary Marathon Oil . . . John Hancock Life insurance Co. has them in five office buildings at its Boston headquarters."⁴⁹ R&B Falcon Corp., an oil drilling contractor in Houston, also purchased eighty-eight AEDs for its rigs and offices, stating, "[w]e want to make certain that we give our employees the best possible care. The defibrillator is as important to us on a rig as any other safety equipment," said Robert B. Carvell, the company's director of risk management.⁵⁰ Employees in industries such as construction and manufacturing face increased risk of sudden cardiac arrest because of their exposure to high and low-voltage currents.⁵¹

Community-wide efforts sponsored by survivors of successful AED uses, cardiologists, EMS personnel and local media outlets, i.e. radio and television, are proving the most successful in bringing AEDs to the public's attention. Many communities have started pilot programs to raise awareness and public access to AEDs. According to an article in the *Virginian Pilot*, many public places in Norfolk and Virginia Beach will soon have them.⁵² Norfolk Southern Railway, Raytheon and Lillian Vernon, all large private employers, have implemented AED programs.⁵³ Individuals are also touting the benefits of AEDs. Rabbi Daniel Kovobkin, in Allentown, Pennsylvania, wrote a letter to the local newspaper

47. *Id.*

48. *American Red Cross Leads the Fight Against Sudden Cardiac Arrest in the Workplace*, AMERICAN RED CROSS, at <http://www.redcross.org/news/inthnews/99/3-1-99.html> (last visited Oct. 18, 1999).

49. Brown, *supra* note 42.

50. *Id.*

51. See Ravenelle, *supra* note 33.

52. Marc Davis, *Keeping the Beat: Defibrillation in Public Places Could Saves Lives, Officials Say*, THE VIRGINIAN PILOT, June 22, 1999, at 33.

53. *Id.*

recommending that places of worship obtain AEDs after a congregant was saved during services in July 1999.⁵⁴ A widower in Palm Beach, Florida donated an AED in memory of his wife who died of SCA at her desk in the Clerk of Court's Office; it was later used to save an elderly man who collapsed in the lobby of the administration building.⁵⁵

Three manufacturers⁵⁶ of the devices also finance pilot programs around the country and routinely issue press releases announcing dramatic rescues with their particular brands.⁵⁷ AED manufacturers have teamed up with the American Red Cross (ARC) to instruct lay users by including AED training as part of its standard CPR training course for U.S. businesses.⁵⁸ The new AED training component will help businesses ensure that employee lay rescuers are trained and equipped to save lives in the workplace, where Americans spend the majority of their waking hours.⁵⁹ Unfortunately, many companies still rely on the EMS system, which faces obstacles such as traffic, staircases, elevators, crowds of people, as well as remote office locations, slowing response times.⁶⁰

A. Public Access To Defibrillation

The AHA, as well as other public health groups including the Department of Health and Human Services, has recommended public access to AED technology for on-the-spot defibrillation. Dr. Joseph Kozina established the Public Access Defibrillation League™ (PADL) in response to media reports about lives lost to incidents of SCA.⁶¹ The group is composed of prestigious cardiologists, paramedics and volunteers from many walks of life.⁶² One purpose is to bring the need for AEDs to the

54. Daniel N. Korobkin, *Be prepared, save lives with defibrillators*, CPR, THE MORNING CALL (Allentown), July 21, 1999, at A10.

55. Jeri Butler, *Man "so lucky" to survive this heart trauma*, THE PALM BEACH POST (Martin/St. Lucie Edition), Aug. 13, 1999, at F1.

56. The three largest AED manufacturers are: SurvivaLink™, Hewlett Packard/Agilent Technologies™ and Physio-Control™.

57. Mark Fritz, *Putting A Heart Saver in the Hands of Novices*, L. A. TIMES, July 16, 1998, A1.

58. *American Red Cross Leads the Fight Against Sudden Cardiac Arrest in the Workplace*, AMERICAN RED CROSS, at <http://www.redcross.org/news/inthenews/99/3-1-99.html> (last visited Oct. 18, 1999).

59. *Id.*

60. *Id.*

61. See Fritz, *supra* note 57, see also PADL available at <http://www.padl.org/html>.

62. *Id.*

public's attention by publicizing successful uses throughout the country. By noting the survival rates of people treated by AEDs, the awareness of the benefits of public access to these devices should become apparent. The general public should have access to defibrillators in highly populated areas such as office buildings, stadiums and airports, where survival rates from sudden cardiac arrest are less than one percent.⁶³ An important determination to be made is the length of time it would take EMS to reach a victim in an emergency. If it is likely to take longer than five to seven minutes, placement of an AED in the immediate area becomes critical to saving lives.

Since the purpose of an AED is to make early defibrillation possible, it is essential that a defibrillator be available immediately to personnel responding to a cardiac arrest. As a result, "all emergency ambulances and other emergency vehicles that respond to or transport heart patients should be equipped with a defibrillator."⁶⁴ The latest technology combined with a competitive medical devices industry, have helped minimize economic costs and make logistics more manageable by making AEDs truly portable. A logical extension of the AED concept is "public access defibrillation" or widespread distribution and use of AEDs by non-medical, minimally trained personnel. This group would include security guards and spouses of cardiac patients.

Public access to defibrillation poses unique challenges. AEDs need to be simple to operate, because in many cases the operator is a first-time user with minimal or no training.⁶⁵ Not only must the device be portable, it must also accurately diagnose lethal arrhythmias under unfavorable conditions that may degrade its performance.⁶⁶ Fears are that AEDs can be misused, either inadvertently while patients are conscious and breathing or possibly even deliberately when placed in the hands of "lay" users.⁶⁷ Safety must be

63. *Cardiac Arrest and the Need for Early Defibrillation: When Every Second Counts*, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/brochure.html> (last visited Oct. 18, 1999). A next step will be to place AEDs in the houses of high-risk patients and to train family members to use them. Other citizens will also be trained to use AEDs to extend bystander-initiated defibrillation in rural and congested urban areas. These settings often have low survival rates because defibrillators do not reach victims in time.

64. *Defibrillation: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/defib.html (last visited Oct. 18, 1999).

65. See Kerber, *supra* note 44.

66. *Id.*

67. *But cf.* Kenneth J. Searcy, *Debunking the Myths About Automated*

strongly emphasized, in order to minimize the risk of injury to both patient and rescuer. Existing Food and Drug Administration (FDA) safety standards for AED construction and performance recognize these inherent challenges associated with AEDs.⁶⁸ Analysis of Agency regulations shows that

AEDs are in a class of devices known as intelligent medical devices. These devices include internal decision-making electronics (microcomputers and special software) that allow the devices to interpret physiologic signals, make medical diagnoses, and, in many cases, automatically apply therapy. Complete testing of this class of device is extremely difficult because of the wide range of possible signals that the device may see.⁶⁹

In public access defibrillation, the technology of AEDs and training for their use are brought into the community. In order to save the lives of more victims who experience SCA outside of the hospital, defibrillation with AEDs should become the next important element. Perhaps increased use by bystanders having access to an AED at the site of an emergency, either at the workplace or in some other place where the public gathers, will result in a larger percentage of SCA survivors in non-hospital settings.

The debate continues between critics who argue that AEDs are dangerous and proponents who proclaim that the technology has progressed so far as to make them "foolproof." Critics say that the evidence does not support the theory that putting an AED in every police car or public

External Defibrillators, 10 NURSING SPECTRUM 17, (Sept. 2000).

68. *Id.*

69. *Intelligent Medical Devices Evaluation*, FDA, at <http://www.verity.fda.gov/search97cgi/index.html>. (last visited Sept. 15, 2000).

Test System Development Project is intended to provide CDRH with the ability to objectively assess the performance of AEDs using a small set of simulated waveforms as the input signals (as opposed to actual physiologic signals collected in the clinic). In addition, this project is intended to demonstrate to the medical device community the feasibility of developing a bench test method for assessing the arrhythmia detection capability of AEDs.

A test system for AEDs was developed in FY 95. In FY 96, this test system was improved by increasing the fidelity of cardiac signal simulation. A database of simulated cardiac signal segments was developed which allowed comparative testing of AEDs. Public domain literature, patents, and standards were accumulated in order to ensure that the cardiac signals generated by the test system will accurately simulate the wide variety of signals that AEDs are expected to encounter.

Id.

building is worth the cost.⁷⁰ One cardiologist says there is “[l]ittle good scientific evidence that peppering a community with defibrillators works. For every successful increase in survival rates in cities such as Seattle and Rochester, Minn., where defibrillators were put in police cars, there are places such as Cincinnati and Memphis, where the impact was negligible.”⁷¹ In fact, a three year pilot program sponsored by the Institute of Critical Medicine, which distributed fifty AEDs to local gated communities, golf courses, senior citizen buses, country clubs, museums and mobile home parks and trained hundreds of people to use them, found that it would need hundreds of them to account for the random and sudden nature of SCA.⁷² The Institute’s director said that “[a]fter investing more than \$100,000 over more than three years, the devices have been used eight times and saved two lives.”⁷³ Because most cardiac arrests happen in the home, AEDs in public places will not necessarily save most victims.⁷⁴ Two-thirds of the cases that Virginia Beach EMS responded to were in private homes in contrast to only ten SCA cases in public malls and restaurants.⁷⁵ However, some mall safety managers state that large malls can expect a cardiac arrest to happen one or two times a year in their facility and believe the investment is worth it.⁷⁶

II. THE FOUR LINKS IN THE “CHAIN OF CARDIAC SURVIVAL”

One physician remarked, “I think it’s unreasonable to think that every business and every school should purchase one of these machines . . . they serve a purpose, but they are only one link in the chain of survival.”⁷⁷ In contrast, an article in *Nursing Spectrum Magazine* calls public access defibrillation a “public necessity,” which is long overdue.⁷⁸ The article states that “[t]hough AEDs are not a panacea, they represent a perfect fit among the AHA’s chain of survival.”⁷⁹ The “chain of survival” concept includes four progressive steps: 1) early access to the emergency medical services system; 2) early CPR when needed; 3) early defibrillation when indicated;

70. See Fritz, *supra* note 57.

71. *Id.*

72. *Id.*

73. *Id.*

74. See Davis, *supra* note 52, at B3.

75. *Id.*

76. *Id.*

77. Chris Meehan, *Smaller Size, Ease of Use Leads to Surge in Heart Defibrillators*, THE GRAND RAPIDS PRESS, June 26, 1999.

78. See Searcy, *supra* note 68.

79. *Id.*

and 4) early advanced cardiac care.⁸⁰ According to experts and the AHA, this sequence of actions, done in a timely manner is essential to the patient's survival.

Receiving immediate attention is of the greatest importance for victims of SCA. The cardiac chain of survival has been established as the standard for successful medical intervention. Unless a SCA victim can be diagnosed and transported to a hospital within a few minutes, chances of survival without defibrillation are relatively nonexistent. AEDs are helping to save lives every day. The beauty of AED technology is that a minimally trained individual who relies on the machine can easily utilize the device's prompt to complete the steps necessary to deliver an electrical shock to the patient. Medical training is not required.

The AHA expanded its early-defibrillation standard of care in the 1990s. Nursing Magazine states that "[h]istorically, as a first responder, you could provide only [CPR] until the code team arrived; they'd then initiate defibrillation and advanced cardiac life support (ACLS). Now, the AHA recommends the use of [AEDs] by first responders trained in basic life support (BLS)."⁸¹ Professional journals give instructions to

80. See generally, *Defibrillation: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/defib.html (last visited Oct. 18, 1999). See also AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999) stating

[s]tarting these procedures quickly may determine whether one lives or dies. 1. **Early Access to Care** in most communities, dialing 911 activates the emergency medical system, which dispatches the appropriate emergency personnel to the scene. 2. **Early Cardiopulmonary Resuscitation** (kar"de-o-PUL'mo-na-re re-sus"i-TA'shun) if performed properly, CPR can add a few minutes to the time available for successful defibrillation. Millions of people have learned the breathing and chest compression techniques of CPR, but it does not replace defibrillation in saving lives. 3. **Early Defibrillation** the critical link in treating victims in VF is delivery of an electrical shock. Each minute of delay in returning the heart to its normal pattern of beating decreases the chance of survival by ten percent. After as little as ten minutes, very few resuscitation attempts are successful. 4. **Early Advanced Care** After successful defibrillation, some patients require more advanced treatments, such as airway control or intravenous drugs, on the way to the hospital.

81. Mary E. Mancini & William Kaye, *Learning the Latest About AEDs*, NURSING, Sept. 1, 1999.

To use it, you need only to perform the standard BLS patient assessment (recognize that the patient is unresponsive, apneic, and pulseless), activate the AED, and place electrode pads on the patient's chest. The

nurses on use of AEDs based solely on basic life support (BLS) standards.⁸² The AHA believes that greater access to AEDs by the public is the next step in strengthening the chain of survival.⁸³ The current national rate of survival of SCA is five percent, however, some communities with strong chains of cardiac survival report survival rates as high as thirty percent or more.⁸⁴

A. *First Link—Early Access To EMS*

Linking AED programs with EMS is the only way to monitor success and produce usable data that can be studied to further improve programs. The Journal of the American Medical Association reports two studies of sudden cardiac death, in which groups of investigators gathered data consistently and systematically during the preintervention and intervention periods by using EMS report forms.⁸⁵ EMS administration of AED programs would call for monitoring and refinements to the AED program, as well as EMS responses in general. The AED program medical director is responsible for the following: 1) ensuring compliance with the standardized reporting format for cardiac arrests; 2) accomplishing a case by case analysis of each AED application, 3) using dual channel analysis and written reports; and 4) establishing and monitoring an effective quality improvement (QI) program.⁸⁶ The AED

AED, not you, then analyzes the cardiac rhythm. Assuming the device detects a shockable rhythm (VF or pulseless ventricular tachycardia with a rate of 200 or greater), what happens next depends on the type of AED you're using. A semiautomatic AED will prompt you to push the shock button. Voice prompts will also tell you to stand clear during rhythm assessment and defibrillation and to check the patient's pulse after defibrillation. After defibrillation you push another button to initiate rhythm reassessment. A fully automatic AED delivers the shock and assesses the subsequent rhythm automatically, without requiring you to push any buttons. This AED has similar voice prompts to that of semiautomatic AEDs. *Id.*

82. *Id.*

83. See Weisfeldt, *supra* note 6.

84. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

85. See Olson, *supra* note 37.

86. See *Implementation of Early Defibrillation/Automated External Defibrillator Programs, Policy Resource and Education Paper*, AM. C. EMERGENCY PHYSICIANS, at <http://www.acep.org/POLICY/PR400144.htm> (last visited Oct. 18, 1999). (Including the following: breakdown of response interval from first call for help to application of device, including dispatch times; witnessed

program coordinator is also responsible for planning for an AED maintenance program and a QI program that interfaces with a system-wide QI program including evaluation of outcome data.⁸⁷ The AED program medical director should also approve early defibrillation programs and AED providers and instructors.⁸⁸ These protocols are outlined in a "Statement for Healthcare Professionals" by the AHA task force on AEDs include oversight and evaluation of the feasibility and desirability of their use by healthcare professionals in concert with the lay public.⁸⁹

B. The Second Link – CPR

CPR breathes life into a victim, keeping oxygenated blood flowing to vital organs, such as the brain and heart, essentially buying time until help arrives.⁹⁰ There are no reliable national statistics on CPR because no single agency collects information on the number of people trained, the number of successful uses, or deaths resulting from non-use.⁹¹ In cities where CPR training is widespread and EMS response is rapid, the survival rate increased from nine to thirty percent when AEDs were made available to first responders.⁹²

CPR needs to be initiated within four minutes to keep the brain and heart viable.⁹³ Resuscitation research has proceeded steadily in the forty years since CPR was first described in medical journals. Despite numerous studies involving various therapies for cardiac arrest, CPR and defibrillation are the only interventions that have demonstrated improving long-term survival.⁹⁴

Until 1994, responding firefighters focused on immediate defibrillation,

versus unwitnessed; bystander CPR; field performance of providers and machines; estimate of interval between collapse and call.)

87. *See id.*

88. *See id.* ("Early defibrillation programs should be administered with appropriate medical direction including quality improvement programs utilizing a standard reporting format for cardiac arrest resuscitations.")

89. *See Weisfeldt, supra* note 6.

90. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

91. *Cardiopulmonary Resuscitation (CPR) Statistics*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart/_and_stroke_A_Z_Guide/cprs/html (last visited Oct. 18, 1999).

92. *See id.*

93. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

94. *See Olson, supra* note 37.

although CPR was recommended if it could be carried out by available personnel while the AED was charged.⁹⁵ The 1984 standing orders stated that “application of the AED is to have the highest priority.”⁹⁶ The routine was modified by provisions requiring approximately ninety seconds of CPR prior to delivery of a shock through an AED. Evidence showed increased survival rates in cases where ninety seconds of CPR were administered first when response times were four minutes or longer.⁹⁷ Since CPR maintains a minimal blood flow and can bridge the time until defibrillation, advocates are in the race to get a stopped heart started again by putting AEDs into the hands of the public.⁹⁸

C. Third Link—Early Defibrillation

Within one minute of the onset of ventricular fibrillation, defibrillation results in an 80 to 90 percent chance of survival; at three minutes survival is 50 to 60 percent; at five minutes survival is 40 percent; at seven minutes survival is 30 percent; and at 10 to 15 minutes, chances of survival are five percent or less.⁹⁹

CPR alone postpones life rather than saving it because CPR can artificially circulate only up to thirty percent of the body’s original blood volume, therefore, restoration of normal circulation is the key to survival.¹⁰⁰ Early defibrillation is the only thing that restores normal circulation. Since children as well as adults can be helped through public access defibrillation, these programs should be prominent in schools and nearly anywhere that the public gathers. Public education about access to AEDs will bring the third link in the chain of survival, early defibrillation, to the forefront. Proponents urge that volunteers should be educated about the use of AEDs so that the initial response to witnessing a cardiac arrest will be to start CPR and look for an accessible AED. Critics insist that AEDs are not one hundred percent foolproof and could theoretically, actually give people a heart attack. Proponents say that those who do not need a shock are not likely to receive one.¹⁰¹ The AHA

95. See generally Leonard Cobb et al., *Influence of Cardiopulmonary Resuscitation Prior to Defibrillation in Patients with Out-of-Hospital Ventricular Fibrillation*, 281 JAMA 13, 1182 (1999).

96. *Id.* at 1183.

97. *Id.* at 1182.

98. See Fritz, *supra* note 57.

99. Trinkoff, *supra* note 15.

100. See Searcy, *supra* note 67.

101. See Fritz, *supra* note 57.

advises that “[e]arly defibrillation programs must be integrated into EMS systems that are designed to efficiently deliver this technology in a manner, which maximizes the potential for survival.”¹⁰² “All four components [of the chain of survival] are critical to ensure that EMS system can treat victims of cardiac arrest with a maximum potential for survival.”¹⁰³

Although regional variations in medical care have been widely documented in recent years, few are as dramatic as those seen in the treatment of SCA.¹⁰⁴ In the U.S., recommended protocols for SCA treatment vary not only among states but among counties as well. The Department of Transportation establishes national standards of proficiency. However, each region decides which standards are applied at each level of its own EMS hierarchy. EMTs are allowed to use AEDs in all states. Some states allow first responders, such as police, fire fighters and other law enforcement personnel to use AEDs. More states are now enacting state and local legislation to permit lay rescuers with proper training and medical supervision to use AEDs.¹⁰⁵

The time interval between the cardiac arrest and the activation of the EMS system can be decreased by public education regarding when to call for help and by ensuring efficient emergency medical dispatching procedures.¹⁰⁶ Methods for ensuring prompt activation of EMS include the implementation of 911 programs, utilization of centralized dispatch and close examination of dispatch intervals.¹⁰⁷ One example of an effective program of public information and education is the “phone first” program, which teaches the public to call EMS immediately in potential cardiac arrest situations.¹⁰⁸

102. *Implementation of Early Defibrillation/Automated External Defibrillator Programs*, Policy Resource and Education Paper, AM. C. OF EMERGENCY PHYSICIANS, at <http://www.acep.org/POLICY/PR400144.htm> (last visited Oct. 18, 1999).

103. *Id.*

104. *See* Brown, *supra* note 42, at A11, col. 1.

105. *American Red Cross Workplace Training Programs: Adult CPR/AED Training*, AMERICAN RED CROSS, at <http://www.redcross.org/hss/cpraed/html> (last visited Oct. 18, 1999).

106. *Implementation of Early Defibrillation/Automated External Defibrillator Programs*, Policy Resource and Education Paper, AM. C. OF EMERGENCY PHYSICIANS, at <http://www.acep.org/POLICY/PR400144.htm> (last visited Oct. 18, 1999).

107. *Id.*

108. *Id.*

D. *Fourth Link - Advanced Cardiac Life Support (ACLS)*¹⁰⁹

Even if there is widespread access by the public to AEDs, the fourth link in the chain of survival, ACLS, is critical. It seems logical that public access to AEDs be the first step towards full implementation of the cardiac chain of survival with ACLS following when resources become available in a community. "What we do know is that each day nearly 1,000 Americans suffer from sudden cardiac arrest—usually away from a hospital. More than [ninety-five] percent of them die, in many cases because life-saving defibrillators arrive on the scene too late, if at all."¹¹⁰

Certainly defibrillation is a *sine qua non* for the effective treatment of VF. But it is also clear that defibrillation alone by no means ensures survival, restoration of circulation, or even establishment of an organized rhythm, particularly when there have been delays in initiating treatment, as typically occurs with cardiac arrest outside the hospital.¹¹¹ Therefore, immediate follow-up with ACLS after AED use is indicated in every case. The goal of increasing survival rates can be achieved if a defibrillator is carried in all emergency vehicles or is available to any person likely to arrive first at an emergency scene and its use is followed with ACLS. According to the Department of Transportation and the AHA, "[a] broad range of people can be first responders, including EMTs, police officers, fire department personnel, security personnel and flight attendants."¹¹² Those first on the scene should begin CPR, use the AED as indicated, activate the EMS system and relinquish the patient on to highly skilled

109. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Sept. 15, 2000). (stating "Advanced Cardiac Life Support (ACLS) includes airway intubation for proper ventilation, drug therapies, monitoring, and other advanced skills. This essential treatment not only stabilizes the patient but also provides further diagnosis, more supportive medical cardiac care and helps to prevent recurrence of cardiac arrest.")

110. "Cardiac Arrest and the Need for Early Defibrillation: When Every Second Counts", AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/brochure.html> (last visited Oct. 18, 1999).

111. See Cobb, *supra* note 95.

112. "Cardiac Arrest and the Need for Early Defibrillation: When Every Second Counts", AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/brochure.html> (last visited Oct. 18, 1999). ("Any person trained in a program using the U.S. Department of Transportation's National Highway Traffic Safety Administration First Responder National Curriculum is considered a first responder. First responders use a limited amount of equipment to perform an initial assessment and intervention. They are trained to assist other EMS providers.")

medical personnel who can follow the chain of survival to its conclusion with ACLS. An AED is not enough, in itself, to properly treat a SCA victim, but it is a start, to be followed up by ACLS protocols with drug treatment.¹¹³

Currently about fifty percent of ambulances and a smaller percentage of fire department vehicles used for emergencies have portable external defibrillators.¹¹⁴ The AHA claims that “[i]f the chain of survival were strengthened across the nation, almost 3000 lives could be saved every day.”¹¹⁵ For every minute that goes by without defibrillation, the chances of survival decrease by ten percent, so after ten minutes without defibrillation, the chances of survival are practically nonexistent.¹¹⁶

When Walter Pritchard, a guest at the Ramada Inn in Portland, Maine, collapsed in the hotel lobby, two employees started CPR while another summoned EMS.¹¹⁷ They continued CPR until EMS arrived and took over with an AED and advanced cardiac life support, so that by the time Walter arrived at the hospital his heartbeat had been restored.¹¹⁸ The hotel workers had put the cardiac chain of survival into action to save his life.¹¹⁹ This is just one example of how lay responders are already employing the first link in the chain of cardiac survival. Efforts to make AEDs more accessible to the public should also help to activate the chain or survival.

E. Cardiac Disease in Children

At least one-half million children in the United States have some form of cardiac problem (not including high blood pressure).¹²⁰ However, the

113. See Davis, *supra* note 52.

114. *Id.*

115. AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdlearn.html> (last visited Oct. 18, 1999).

116. *Id.*

117. *Hotel Employees Save Victim of Sudden Cardiac Arrest* AMERICAN RED CROSS, at <http://www.redcross.org/hss/notes/hotel.html> (last visited Oct. 18, 1999).

118. *Id.*

119. *Id.*

120. *Cardiac Disease in Children*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/cardk.html (last visited Sept. 14, 2000).

About 77 million people under age 20 live in the United States. About 32,000 infants born each year have congenital cardiovascular defects. When mortality and spontaneous defect improvement are factored into live birth data, it's estimated that 300,000 children under age 21 will have congenital cardiovascular disease by 1997. Thirty-eight percent of them

use of AEDs has been limited almost exclusively to adults due to the lower occurrence of ventricular arrhythmias in children. Another factor is that delivered energy doses are automated to 100 or 200 Jules, higher than standard dosages for children.¹²¹ However, studies furnish evidence that AEDs provide accurate rhythm detection and shock delivery to children and young adolescents, and that their use is potentially as effective for children as it is for adults.¹²²

Like adults, children's survival rates improve when they are treated by rapid response EMS; children experiencing ventricular arrhythmias have the highest survival rates.¹²³ The benefit of earlier detection and treatment of VF afforded to adult patients needs to be evaluated in pediatric patients.¹²⁴ With current equipment design, children weighing as little as twenty kilograms (approximately forty-five pounds) could potentially be safely shocked with 200 Jules. Alternatively, all AEDs, or special pediatric AEDs, could be equipped to deliver 50, 100, and 200 Jules.¹²⁵ Because the mass of a child's heart is smaller, accuracy of rhythm detection will not be as high in younger children.¹²⁶ Preliminary studies conducted by the American Medical Association (AMA) show that AEDs provide; 1) accurate rhythm detection and shock delivery to older children and young adolescents, 2) VF was identified correctly and treated eighty-eight percent of the time, and 3) all other rhythms were analyzed accurately, and no inappropriate shocks were delivered.¹²⁷

The Atkins AMA study demonstrates that current AEDs accurately recognize the cardiac rhythms observed in pediatric cardiac arrest. Among the findings are that AEDs are potentially as effective for

will have had one or more surgical procedures.

Other children will develop acquired heart disease, such as: Arrhythmias.

The projected incidence estimate for supraventricular tachycardia alone is between one and four per 1000. Cardiomyopathies, Kawasaki disease; Rheumatic fever; Familial hypercholesterolemia will affect the future of an unknown but probably large number of children; Acquired Immunodeficiency Syndrome (AIDS) with its myocarditis. *Id.*

121. Dianne L. Atkins et al., *Accurate Recognition and Effective Treatment of Ventricular Fibrillation by Automated External Defibrillators in Adolescents*, PEDIATRICS, Mar. 1998, at 393.

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

children and adolescents as for adults in increasing survival rates.¹²⁸ Also, special pediatric paddles are not necessary for AED use in children as young as eight years of age.¹²⁹ Some of the aspects to be considered are equipment and design modifications, especially the rhythm detection algorithm, energy dose, and electrode paddle size,¹³⁰ in situations where children would be the primary victims on whom AEDs would be used.

Atkins states that “[i]f an episode of unexpected cardiac arrest is successfully stopped, the person is said to have survived an “aborted” sudden cardiac death. If the cardiac arrest was due to ventricular tachycardia or fibrillation, survivors are at risk for another arrest, especially if they have underlying heart disease.”¹³¹ Most deaths due to cardiovascular disease, in particular coronary artery disease, are often sudden and unexpected. Regardless of the underlying disease, half of all deaths are due to degeneration of the heart muscle, or to cardiac enlargement for patients with high blood pressure.¹³² However, people who survive a sudden cardiac arrest have a good long-term outlook. About eighty percent are alive one year after cardiac arrest and as many as fifty-seven percent are alive after five years.¹³³

III. FEDERAL AND STATE REGULATION OF AEDS

A. *Federal Legislation*

The Cardiac Survival Act directs the Secretary of Health and Human Services to promote the outfitting of all federal buildings with AEDs and to

128. *Id.*

129. *Id.*

130. *Id.*

131. *Sudden Cardiac Death: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Zguide/sudden.htm (last visited Oct. 18, 1999). “Survivors of aborted SCD must have all causes corrected to prevent future episodes. Possible causes are myocardial ischemia, arrhythmia, etc. Possible test and treatments include cardiac catheterization, electrophysiologic test, coronary artery bypass surgery, balloon angioplasty or PTCA, antiarrhythmic medicine, implantable cardiovascular/defibrillator, implantable pacemaker, and heart transplant.” *Id.*

132. *Id.*

133. *Cardiac Arrest and the Need for Early Defibrillation: When every Second Counts*, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/brochure.html> (last visited Oct. 18, 1999).

train users.¹³⁴ Congress has recognized that AEDs use a technology that non-medical personnel, who are properly trained, can employ in emergency situations. Congress' promotion of their placement throughout government buildings implies that AEDs are simple to use, since they walk the user through the process with easy-to-follow prompts. AEDs are programmed to shock only specific heart rhythms where a shock is necessary.¹³⁵ Even with these protections against inappropriate use, especially by lay people, training in their proper use and maintenance is recommended. In many states, only highly trained medical personnel are allowed to use them, however, in the majority of SCA cases, the first people on the scene are ordinary bystanders. Legislators are currently attempting to make the first person at the scene *legally* capable of using the AED, through proposed legislation aimed at limiting the liability of lay users. Minutes count in saving lives, especially when SCA is involved. "Victims collapse and quickly lose consciousness; death usually follows unless the responder restores a normal heart rhythm within [five to seven] minutes."¹³⁶

AEDs are medical devices subject to governmental regulations administered by the FDA.¹³⁷ At this time there are three companies that manufacture AEDs: Heartstream, Laerdal and PhysioControl.¹³⁸ On September 15, 1993, the United States filed a complaint in the U.S. District Court of Oregon against Laerdal Manufacturing, alleging violations of regulations relating to good manufacturing practices (GMP) and medical device reporting (MDR)¹³⁹ which implement the Federal

134. *Id.*

135. *A Matter of Life and Death*, AMERICAN HEART ASSOCIATION, at <http://www.chainofsurvival.com/bdfacts.html> (last visited Oct. 18, 1999).

136. *Cardiac Arrest and the Need for Early Defibrillation: When Every Second Counts*, AMERICAN HEART ASSOCIATION, at <http://www.americanheart.org/Heart/CPR/PAD/brochure.html> (last visited Oct. 18, 1999).

137. *United States v. Laerdal Manufacturing Corporation*, 853 F. Supp. 1219 (D. Or. 1994) (citing the Federal Food, Drug and Cosmetic Act regulations implementing the act, which include the Good Manufacturing Practices (GMP) regulations, 21 C.F.R. §820.1-820.198 (1993) and the Medical Device Reporting (MDR) regulations, 21 C.F.R. §803.1-803.36 (1993)). Commonly referred to as the Medical Devices Amendments Act of May 28, 1976 P.L. 94-295, 90 Stat. 539 (1976) was enacted in response to the proliferation of new and increasingly complex medical devices. See 1976 U.S. Code Cong. and Admin News, P. 1070 et seq.

138. *Id.* at 1219 (citing Federal Food, Drug and Cosmetic Act section 302(a), as amended, 21 U.S.C.A. § 332(a) (2000)).

139. *Id.* (citing Federal Food, Drug and Cosmetic Act regulations

Food, Drug and Cosmetic Act. The manufacturer was granted partial summary judgment.¹⁴⁰ The court stated that GMP requires an AED manufacturer to establish and maintain a consistent quality assurance program based upon current industry standards, but went on to explain that FDA regulations did not prescribe a step-by-step approach for compliance.¹⁴¹ To establish that Laerdal violated GMP, the government had to prove by a preponderance of the evidence that the quality assurance program prepared and implemented was not adequate to “assure and verify confidence in the quality of the process used”¹⁴² or that specific minimum legal requirements were inadequate or missing from the quality assurance program. Since 1993, no product liability actions have been pursued against manufacturers of AEDs. In fact, their safety has been proven through rigorous testing regulations, outlined by the FDA.¹⁴³ Many cardiologists and health care experts vouch for the safety of AEDs, as is demonstrated by the approach found in an open memorandum from the University of North Carolina at Chapel Hill, which published a review of AED safety.¹⁴⁴

Despite the fact that there have been no instances of lay users or their employers being sued for use of AEDs, fears of potential liability suits have weighed heavily in the debates between those who advocate acquiring AEDs and those who object. The Los Angeles Times reminds us that “[f]or every AED that is put in place, somebody has to assume responsibility for using it.”¹⁴⁵ Proponents see an AED as a necessary piece of safety equipment. The opposition fears the liability and a possible increase in standard of care that acquirers may have to provide. Not only is it important to indemnify users but it is also prudent to indemnify acquirers, trainers and maintenance personnel as well. Existing

implementing the act, which include the Good Manufacturing Practices (GMP) regulations, 21 C.F.R. §820.1-820.198 (1993), and the Medical Device Reporting (MDR) regulations, 21 C.F.R. §803.1-803.36 (1993)).

140. *Id.*

141. *Id.* (citing Federal Food, Drug and Cosmetic Act section 302(a), as amended, 21 U.S.C.A. § 332(a)).

142. *See id.*

143. *See Intelligent Medical Devices Evaluation*, FDA, at <http://www.verity.fda.gov/search97cgi/index.html>. (last visited Sept. 15, 2000).

144. A Memorandum from the University of North Carolina at Chapel Hill, *AED Safety: A Review of the Data*; at http://www.padl.org/html/articles/current/praed_uncch.htm (May 24, 2000). Published data from manufacturers on specificity and sensitivity in the lab and in the field, shows all AED manufacturers have far exceeded the AHA requirements..

145. *See Fritz, supra* note 57, at A1.

Good Samaritan laws do not go far enough for some industry leaders to achieve the level of comfort that would allow them to endorse and participate in public access defibrillation. Many communities will wait for federal regulations to limit liability before they expend the necessary resources to equip their police and other possible first responders or to station AEDs in public venues. It becomes a political question in many communities, due to the necessity of cross-training paramedics and firefighters.¹⁴⁶ The AHA has established a model for states to follow regarding AED legislation, which is discussed in the following sections.

B. *Progressive Legislation*

Despite potential legal problems, an effort is underway to lobby state legislatures to adopt the AHA model legislation or to amend current statutes to allow non-medical personnel to operate AEDs. The Nevada legislature addressed private companies' concerns over litigation if victims die by extending the state's Good Samaritan law to cover non-medical workers, such as security guards, who defibrillate people on the job.¹⁴⁷ However, a recent California proposal failed to get out of committee due to opposition by trial lawyers who represent injured parties.¹⁴⁸ Trial lawyers' interests opposed provisions in the bill that would limit the number of lawsuits arising from the use of such devices by lay individuals.¹⁴⁹ Rick Simmons of Consumer Attorneys of California, said the group lobbied against the legislation because it would have granted legal immunity to people who violated state regulations that required training.¹⁵⁰ AED advocates argue that California's training regulations are typical of laws that have not kept pace with technology, and new AEDs are easier for the layperson to use than performing CPR.¹⁵¹ Illinois is somewhere in the middle, in terms of liability protections because lay people may use AEDs as long as they are certified in adult CPR and receive training from the Red Cross, AHA, certified paramedics or

146. See Megan O'Matz, *Fireman Do A Burn Over Heart Machines*, THE CHI. TRIBUNE, June 24, 1999, at A1.

147. See Brown, *supra* note 42, at A5.

148. See Herbert, *supra* note 9.

149. *Id.*

150. See Fritz, *supra* note 57 (stating that California's Good Samaritan law protects people from lawsuits if they render medical care in an emergency situation yet state health code provisions specifically require that anyone who uses an AED must be trained at least four hours).

151. *Id.*

medical experts.¹⁵²

In recent years, forty-three states have enacted laws protecting rescuers using defibrillators (and in some cases, the companies who own them) from liability suits.¹⁵³ Maryland and Virginia both have such laws, but the District of Columbia does not.¹⁵⁴ One of the initial versions of The Cardiac Arrest Survival Act of 2000 provided that an AED may be used by an individual “trained in its use, pursuant to an established medical protocol or under medical control, which can be achieved by contacting EMS either before or immediately after its use.”¹⁵⁵ In the meantime the number of AEDs in federal offices is proliferating. Congress and the Supreme Court have them, and the Washington, DC headquarters of the Departments of Health and Human Services (HHS) and Labor, the Environmental Protection Agency, and several other executive branch agencies are getting them.¹⁵⁶ The Internal Revenue Service and the Federal Deposit Insurance Corporation are putting them in “selected” buildings nationwide.¹⁵⁷

In selecting the federal buildings in which AEDs should be placed, the Secretary of HHS has been directed, by the President, to take into account the typical number of employees and visitors, the extent and need for security measures, special conditions such as high electrical voltage and extreme heat and cold in each building.¹⁵⁸ This list is not exhaustive, nor does it preclude other factors from being considered during the decision-making process. Response times and physical accessibility of the location and the distance to be traveled by EMS personnel when responding to an emergency situation can be studied from data gathered from past emergency responses. The type of employees that work in a specific location may also play a factor in the appropriateness of locating AEDs for their use.

AEDs are apparently “idiot proof” since they diagnose distress and indicate whether an external shock is necessary. Despite their diagnostic capabilities, current laws in many states may limit their use to highly

152. See Terri Tabor, *Life-Saving Defibrillators no Longer Just for Paramedics, Hospitals*, CHI. DAILY HERALD, Aug. 1, 1999.

153. See *AED Legislation in the U.S.*, at <http://www.padl.org/html/legislation/law-us.htm> (last visited Apr. 2, 2000).

154. See Brown, *supra* note 42, at A11.

155. See Herbert, *supra* note 9.

156. *Id*

157. See Brown, *supra* note 42, at A11.

158. Cardiac Survival Act of 2000, S. 1488, 106th Cong. §3(d)(1) (2000).

trained health care providers.¹⁵⁹ The Journal of American Fitness states that “[t]he New York law regarding use of AEDs is stricter than federal standards. Food and Drug Administration regulations require only that the user be trained and the use be under medical control.”¹⁶⁰ A New York Affiliate of AHA is sponsoring a task force on rapid access defibrillation.¹⁶¹ The task force has recommended modification of New York laws to remove liability from individuals who use AEDs and to promote the placement of AEDs in office buildings, bus and train terminals, airports, and other public sites.¹⁶² In conjunction with the greater access to AEDs, new policies would allow trained individuals, in addition to certified first responders, to use AEDs.

Alarming, even in light of the dismal realities of time spent waiting for emergency vehicles to arrive, New York law prohibits the use of AEDs by any individual who is not trained as a certified first responder, an emergency medical technician, or an advanced emergency medical technician.¹⁶³ Certification for these positions requires in excess of fifty hours of training, while effective training in the use of AEDs and CPR can be accomplished in a fraction of this time.¹⁶⁴ In addition, in New York State, only about one-half of all ambulances, and even fewer fire companies are equipped with AEDs.¹⁶⁵ They are not available in public places, and only limited categories of individuals are authorized by law to use them.

Upgrading local EMS to provide every vehicle with an AED should be a relatively non-controversial issue, however, many communities lag behind. In Chicago, for example, only one quarter of the department’s ninety-nine engines and none of its sixty hook and ladder trucks have defibrillators.¹⁶⁶ The Los Angeles Times stated “[w]hen no defibrillator is available, firefighters perform CPR while awaiting a truck or ambulance

159. See Herbert, *supra* note 9; *but cf.* Fritz, *supra* note 57 (critics insist that AEDs are not 100% foolproof and could theoretically, actually give people a heart attack. Proponents say they are more likely not to shock people who really need it rather than the reverse).

160. Trinkoff, *supra* note 15.

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. See Fritz, *supra* note 57 (Note: “Instead of installing defibrillators on each truck, the department has a more ambitious long term plan to convert all 99 engines to advanced life support units.”)

with one.”¹⁶⁷ Community outcry may erase some of this inertia. In Michigan, a local fire station was allocated paramedics with advanced life support equipment based upon community needs, “[s]tatistics showed the station had 187 fire calls and 647 emergency medical service calls; fifty-seven percent of these EMS calls needed advance life support previously supplied by other stations.”¹⁶⁸ The International Association of Fire Chiefs recommends having defibrillators on emergency response vehicles both for the protection of the community, as well as for firefighters who may suffer cardiac arrest while on duty.¹⁶⁹

Philadelphia’s sports arenas do not have AEDs. In accordance with Pennsylvania regulations, paramedics who carry defibrillators handle crowd rescue situations.¹⁷⁰ Ten thousand people attending an event rate one ambulance with a defibrillator; sixty thousand people rate three ambulances with three defibrillators and one emergency physician.¹⁷¹ Other venues where crowds gather, such as Universal Studios, Florida have AEDs at first aid stations throughout the park.¹⁷² Universal Studios and Sea World staffers take an AED with them whenever they respond to a call, and trained personnel with at least one AED are present at all stadium events, such as whale and waterski shows.¹⁷³ The Orlando area also has medical personnel armed with AEDs at all major events at the Florida Citrus Bowl and TD Waterhouse Arena; although there is no law requiring defibrillators at big events, insurance companies typically require EMS personnel to be on hand.¹⁷⁴

Do public safety teams at these venues face increased legal risk by not having an AED? In 1996, a Florida jury found the amusement park, Busch Gardens, negligent, because it lacked a defibrillator, and awarded the plaintiff \$500,000 in damages for the death of her daughter.¹⁷⁵ In light of this, the Florida legislature passed a progressive law on early defibrillation. The Florida law permits a medical doctor to prescribe an AED for use by a layperson.¹⁷⁶ It allows any person properly trained in

167. *Id.*

168. Jon Wilson, *I Was Dead*, ST. PETERSBURG TIMES, July 18, 1999.

169. *Id.*

170. See Drake, *supra* note 34.

171. *Id.*

172. Harry Wessel, *Instant Lifeline Push is on to Make Defibrillators as Commonplace as First-Aid kits*, ORLANDO SENTINEL, June 6, 2000 at E1.

173. *Id.*

174. *Id.*

175. See Garber, *supra* note 30, see also Herbert, *supra* note 9.

176. See Garber, *supra* note 30.

CPR who has demonstrated proficiency in the use of an AED to use it to treat another person.¹⁷⁷ Florida extends protection to good faith users of AEDs under its Good Samaritan Law. The law provides that “any individual, including a medical doctor, who in good faith provides treatment by using an AED is not liable for any civil damages resulting from such use provided that the individual acted reasonably.”¹⁷⁸ The Florida law goes further by encouraging owners of AEDs to register their location with local EMS directors, which increases public access to AEDs throughout the community and facilitates the collection of data regarding their use and maintenance.¹⁷⁹ Registration and clearly identifying the location of AEDs will raise public awareness.

Once legislation is in place, all that remains is the proper training of AED users. Training lay users who are likely to be in a position to render aid during a cardiac arrest, such as security guards, health and fitness instructors, hotel and restaurant workers, and airport and cruise ship personnel, makes using on-site AEDs a very real possibility. Throughout Chicago’s O’Hare and Midway Airports, AEDs are strategically placed within sixty seconds of walking distance from any point.¹⁸⁰ They are mounted in recessed compartments next to fire extinguishers and are easily identified by an icon of a heart with a lightning bolt through it.¹⁸¹ Over 2000 airport employees including all public safety employees, secretarial staff, food service vendors and custodial staff have been trained in the use of AEDs; combine them with airline employees and they comprise a dynamic force to battle SCA in some of the world’s busiest airports.¹⁸²

The AHA offers HeartSaver AED, a training course that integrates CPR and AED use. This four-hour course is designed for the lay rescuer and first responder.¹⁸³ Designed especially for business and industry, the American Red Cross Adult CPR/AED course focuses on training the lay rescuer in the workplace. It combines OSHA-compliant Adult CPR training with instruction in automated external defibrillation - the two

177. See Trinkoff, *supra* note 15.

178. *Id.*

179. *Id.*

180. See Heightman, *supra* note 10.

181. *Id.*

182. *Id.*

183. *Defibrillation: AHA Scientific Position*, AMERICAN HEART ASSOCIATION, at http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/defib.html (last visited Oct. 18, 1999).

skills needed to save the life of a sudden cardiac arrest victim.¹⁸⁴ One of the most exceptional aspects of the Chicago HeartSaver program is its mission to train any resident or visitor, on designated dates, in CPR and the operation of an AED.¹⁸⁵ The program training coordinator says “travelers might be able to use the knowledge and skills as they pass through our facility or take the concept back to their community.”¹⁸⁶

AEDs’ notable success in reviving Las Vegas’s downed gamblers is attributable to two things—access and speed, both of which are provided by employees in proximity when the emergency occurs.¹⁸⁷ This concept is exemplified in the programs sponsored by Chicago’s O’Hare and Midway Airports. These airports place high priority on public access to AEDs and training of all employees who could possibly witness and aid someone who is the victim of cardiac arrest. As these examples illustrate, AED training is convenient, of relatively short duration and requires very little logistical support.

IV. POTENTIAL LIABILITY CONCERNS FOR EMPLOYERS

As we have seen, no lawsuits have been brought over deaths following the use of an AED by lay rescuers. Most experts, in fact, believe that the risk to employers lies elsewhere. “If there’s any threat of litigation, it is more for not providing the device,” said Richard Hamburg, director of government relations for the AHA.¹⁸⁸ Mainly, employers are opting to adopt an AED program and train employees instead of going without and continuing to rely on an overworked EMS.

Jim Young, a fifty-nine year-old-retiree of Michelin, North America is glad his employer chose an AED program.¹⁸⁹ He suffered cardiac arrest in 1998 while he was exercising at Michelin’s corporate wellness center, when a fitness staff member initiated CPR until just minutes later Michelin emergency personnel arrived with an AED.¹⁹⁰ Generally, a bystander has no legal duty to provide affirmative aid to an injured

184. American Red Cross Workplace Training Programs: Adult CPR/AED Training, AMERICAN RED CROSS, at <http://www.redcross.org/hss/cpraed/html> (last visited Oct. 18, 1999).

185. Heightman, *supra* note 10.

186. *Id.*

187. *See* Brown, *supra*, note 42.

188. *Id.*

189. *American Red Cross Leads the Fight Against Sudden Cardiac Arrest in the Workplace*, AMERICAN RED CROSS, at <http://www.redcross.org/news/inthenews/99/3-1-99.htm> (last visited Oct. 18, 1999).

190. *Id.*

person, even if the bystander has the ability to help. In New Jersey, and other states, however, proof of the existence of a relationship between the victim and a person in position to render aid may create an affirmative duty to render assistance.¹⁹¹

A. *Is there a Duty to Provide Assistance?*

If a company has an AED on the premises and has trained employees to use it, is it increasing its potential for liability? In the case of *Lundy v. Adamar of New Jersey Inc.*¹⁹² the Court of Appeals held that “[u]nder New Jersey law, the casino owner did not voluntarily assume [the] duty to provide [a] level of care encompassing intubation¹⁹³ of a patron who suffered [a] heart attack by contracting with [a] physician to have intubation tube on [the] premises.”¹⁹⁴ The plaintiff argued that, by having the equipment on-site and contracting with a physician, the casino had a preexisting duty. But, the court held that the “preexisting duty exception to New Jersey’s Good Samaritan Act did not subject [the] casino owner to liability.”¹⁹⁵ The casino’s “preexisting duty was limited to summoning aid and, in the interim, taking reasonable first aid measures, and did not include [the] duty to provide medical equipment and personnel necessary to perform intubation on [a] patron.”¹⁹⁶ The “purpose of New Jersey’s Good Samaritan Act is to encourage rendering of assistance to victims by providing that [the] voluntarily rendering of aid will not give rise to any liability that would not otherwise exist.”¹⁹⁷ The district court held that “the casino’s duty was, at most, to provide basic first aid to the patron when the need became apparent and to take reasonable steps to procure

191. *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 473, 474 (3rd Cir. 1994).

192. *Id.*

193. Helen Klusek Hamilton, ed, *Procedures: The Nurse’s Reference Library*, NURSING 85 BOOKS, 1985 at 474.

Endotracheal Intubation is the oral or nasal insertion of a flexible, cuffed tube through the larynx into the trachea. Performed by a doctor, anesthetist, respiratory therapist, or specially trained nurse, it provides short-term ventilation, usually for 48 to 72 hours, when supplemental oxygen is needed. It’s used most frequently in emergency situations, such as respiratory arrest or obstruction; in pulmonary edema when a ventilator is indicated; and in the operating room just before surgery. The patient may be conscious during intubation. *Id.*

194. *Lundy*, 34 F. 3d at 474.

195. *Id.*

196. *Id.* at 473-74 (citing N.J. Stat., Ann. §2A:62A-1(West 2000)).

197. *Id.* at 474 (citing N.J.S.A. 2A:62A-1).

appropriate medical care.”¹⁹⁸

By analogy we can surmise that having an AED on-site is like having an intubation tube available in the *Lundy* case. The duty to render aid means to render basic first aid and take reasonable steps to get medical care.

Section 324 of the Restatement (Second) of Torts provides:

one who, being under no duty to do so, takes charge of another who is helpless adequately to aid or protect himself is subject to liability to the other for any bodily harm caused to him by a) the failure of the actor to exercise reasonable care to secure the safety of the other while within the actor's charge, or b) the actor's discontinuing his aid or protection, if by so doing he leaves the other in a worse position than when the actor took charge of him.¹⁹⁹

The Restatement was altered by New Jersey's Good Samaritan Act which provides that “anyone who in good faith renders emergency aid at the scene of an . . . emergency to the victim . . . shall not be liable for any civil damages as a result of acts or omissions by such person in rendering the emergency care.”²⁰⁰ Despite Good Samaritan laws, companies still cite fears that allowing their employees to operate AEDs may expose them to lawsuits if victims die. Pursuing even well intended policies, that might expose companies to the possibility of expensive lawsuits, makes managers and business owners very nervous. Assessing potential liability through a comparison to divergent industries does not help to quiet these fears. Both acquirers and users of AEDs look forward to federal legislation to provide relief. Until federal legislation is on the books, companies such as Ratheon in Virginia, may purchase AEDs but feel they must limit their use to pre-trained or pre-screened employees. According to company policy, out of Ratheon's four hundred employees, Scott Kalis, an environmental health and safety manager, is the only person who can use the AED.²⁰¹

The Cardiac Survival Act would limit the liability of both users and acquirers of AEDs.²⁰² Any person who maintains, tests or provides training on AEDs would be immune from civil liability, as would any physician who provides required medical oversight.²⁰³ The owners of the

198. *Id.* at 474.

199. Restatement (Second) Torts §324.

200. *Lundy*, 34 F.3d at 480.

201. See Davis, *supra* note 52.

202. Cardiac Survival Act of 2000, S. 1488, 106th Cong. (2000).

203. See *id.* at §4.

devices are also immune from liability if they have notified local emergency response personnel where AEDs were most recently placed within a reasonable time, and if they have been maintained properly. Users must be employees or agents within the class of persons expected to use the device during emergencies and these individuals must have received reasonable instruction in the use of AEDs through an approved course.²⁰⁴

B. *AEDs in the Workplace*

This Comment focuses on three particular industries that have already had significant experience with AED use by employees, who are not necessarily highly trained medical professionals. Health and fitness facilities have to contend with special circumstances such as significant risk of SCA due to the vigorous activities performed by patrons. Airlines have special considerations due to the inaccessibility to EMS while in flight. Casinos combine aspects of each; stress which may be more emotional than physical and crowds slowing the approach of swift EMS responses are combined with the consumption of alcohol. This section examines some cases arising in each industry and the issues that acquirers must contend with in deciding whether or not to promote workplace access to AEDs.

1. *Health and Fitness Facilities*

If laws are changed and AEDs are made more widely available, health and fitness facility owners believe that the standard of emergency response care in their facilities will undoubtedly move toward requiring the use of AEDs.²⁰⁵ Owners of fitness facilities make their decision about whether or not to purchase AEDs by balancing ethical and liability arguments. Some point to industry guidelines, which currently do not list them as required equipment.²⁰⁶ Others insist on providing state-of-the-art

204. *Id.*

205. *See* Herbert, *supra* note 9.

206. *See id.* The recently adopted standards of the American Heart Association and American College of Sports Medicine in their Scientific Statement, *Recommendations for Cardiovascular Screening, Staffing and Emergency Policies for Health/Fitness Facilities*, (1998) (which does not require the presence of a defibrillator as part of an emergency response plan for supervised cardiac rehabilitation programs.) *see also* *Guidelines for Clinical Exercise Testing Laboratories: A Statement for Health Care Professionals from the American Heart Association*, *see also* AHA, *GUIDELINES FOR CARDIAC REHABILITATION PROGRAMS*, (2d ed. 1995). While the second edition of ACSM's

medical equipment for their client's protection. A hotly debated issue in fitness trade journals is whether defibrillators are part of the standard of emergency response care owed to health and fitness facility patrons.²⁰⁷ Some industry leaders predict that new studies may eventually raise the standard of care for health and fitness facilities "seeking to uphold their duties and obligations."²⁰⁸ The Elmhurst, a facility in Illinois, has reportedly begun using an AED and provides training and instructional programs every four months, acquiring the device in order to provide the highest quality of service to its members.²⁰⁹

An Arizona court case, *Mandel v. Canyon Ranch, Inc.*,²¹⁰ illustrates present concerns. The fifty-year-old decedent went to the defendant's facility on a spa package for several days in 1995, where he had a consultation with the medical staff for "an evaluation of his health and physical condition."²¹¹ "Ten minutes into a "wallyball" game, he collapsed due to an alleged cardiac arrest. CPR and other on-site care provided by guests and members of the staff did not resuscitate him."²¹² The plaintiff alleged that the staff did not use an AED or "any type of cardiac resuscitation equipment or cart" at the time of the emergency.²¹³ The plaintiff further alleged that Canyon Ranch personnel were negligent in their screening and evaluation of the situation and that they failed to monitor and bring the appropriate medical equipment to handle this medical emergency. Specifically, the negligence included but was not limited to, the failure to bring and utilize a heart defibrillator unit, which is kept on the premises for this type of situation.²¹⁴ The jury concluded that facilities like Canyon Ranch, whose primary role does not include providing medical or rehabilitative care, are not obligated to adhere to standards of emergency response care requiring defibrillators.²¹⁵ In this

HEALTH/FITNESS FACILITY STANDARDS AND GUIDELINES (Human Kinetics, Champaign, Illinois, 1997) recommends the availability of a stocked first aid kit to deal with emergencies, no requirement for having a defibrillator is specified. Likewise, the International Health Racquet and Sportsclub Association (IHRSA) has no such requirement in its standards for member institutions. *Id.*

207. *See id.*

208. *Id.*

209. *Id.*

210. *Mandel v. Canyon Ranch, Inc.*, No. 312777 Ariz. Sup. Ct., Pima County, (unpublished).

211. Herbert, *supra* note 9 (citing *Mandel*).

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*

case, current laws and regulations supported the defendant's position. However, the emerging trend in favor of placing AEDs in health and fitness facilities and allowing them to be operated by lay individuals may lead to modifications to club operation codes nationwide.²¹⁶

In the *Mandel* case, both experts who testified during the trial acknowledged utilizing defibrillators during other cardiac arrest situations in health and fitness facilities. They said that all six persons who were treated with defibrillators survived.²¹⁷ Two out of three deaths due to SCA occur outside of the hospital in homes, at work or in public places like airports and malls.²¹⁸ A health and fitness facility seems a likely place to expect AEDs to be utilized, due to the nature of the activities that take place there. Patron's expectations are also a factor that is taken into consideration by managers of such facilities.

2. *The Airline Industry*

There may be a higher duty of care for common carriers, which will not be addressed in depth in this Comment. Public policy considerations have generated tremendous support for enhanced medical care in-flight. Congress has acted to eliminate some major legal hurdles for airlines and individuals attempting to provide medical assistance during in-flight medical emergencies. Specifically, the Aviation Medical Assistance Act of 1998 (Aviation Act) limits liability for both the air carrier and qualified medical personnel aiding passengers in emergencies.²¹⁹ Industry analysts point to a combination of an aging population and advances in medical therapy, which allow increasing numbers of passengers with chronic medical conditions to fly, as factors prompting major carriers to accelerate the pace of AED installation absent government regulations.²²⁰

The idea of equipping planes with AEDs was initiated by Qantas in 1991 and other international carriers such as British Airways and Virgin Atlantic, have been using them for years as well.²²¹ American Airlines became the first U.S. carrier to install AEDs in July 1997.²²² Until

216. *See id.*

217. *Id.*

218. *Id.*

219. Julie A. Buffington, *Airlines, Defibrillators, and Enhanced Medical Kits: Filling A Void or Creating a Duty?*, 64 J. AIR L. & COM 497 (1999).

220. Jane Costello, *U.S. Airlines Step Up Emergency Medical Care*, WALL ST. J., Aug. 16, 1999.

221. *Id.*

222. *Id.* ("Current FAA on-board medical equipment requirements date back to 1986; A first-aid kit with bandages, scissors and smelling salts, which can be

mandatory requirements are in effect, an airline must consider the liability implications surrounding the decision to upgrade its services by adding AEDs to its in-flight medical kits.²²³ As with health and fitness facilities the question arises as to whether flight attendants may use AEDs if they are not “qualified medical personnel?” Airlines, too, need to weigh negligence and assumption of duty issues in much the same way as fitness facilities. By providing AEDs on planes, is the airline assuming a duty and increasing the standard of care as well as its liability? When one airline, or any major player in an industry, provides this increased level of service, has it effectively put all others on notice that they will need to follow the state of the art? Some commentators have urged an examination of product liability laws and federal preemption issues to determine the extent of an airline’s exposure in equipping its planes with defibrillators.²²⁴

More than a dozen airlines carry AEDs on all planes; American Airlines, reported eight “saves” out of seventeen uses in two years.²²⁵ The following case illustrates what industry leaders fear. In *Somes v. United Airlines, Inc.*,²²⁶ the survivor of a passenger who suffered cardiac arrest and died, while traveling aboard an interstate flight, brought a wrongful death suit against United for failing to equip its aircraft with certain medical equipment, including an AED. The Plaintiff alleged that her husband would have survived if the in-flight emergency medical kit had contained an AED.²²⁷ The court held that the airline did not provide “service” within the meaning of the Airline Deregulation Act (ADA) by carrying emergency medical equipment to treat in-flight medical emergencies unrelated to actual operation of aircraft, therefore federal law did not expressly preempt state common-law wrongful death claims.²²⁸ The court stated “[u]nder implied preemption principles, if the allegedly preempted action involves public health, welfare, or safety, matters which the states have traditionally regulated, congressional intent to supercede

opened by a flight attendant, and an emergency supply kit for use by a medical professional. Supplies include nitroglycerin pills, epinephrine, inhalers and other life-saving equipment. The only FAA-mandated change to the kits in the past 13 years has been the addition of latex gloves.”) *Id.*

223. *See id.*

224. *See Brown, supra* note 42.

225. *Id.*

226. *Somes v. United Airlines, Inc.*, 33 F. Supp. 2d 78 (D. Mass. 1999).

227. *Id.* at 78-79 (citing U.S.C.A. Const. Art. 6, cl 2: 49 U.S.C.A. §41713(b)(1).)

228. *See Id.* at 78 (citing U.S.C.A. Const. Art. 6, cl 2).

that action must be clear and manifest.”²²⁹ Courts have held that regulations governing in-flight emergency medical kits merely establish minimum requirements.²³⁰

Congressional debate on the “savings clause” at the time of the enactment of the ADA seems to show that Congress intended to preserve state law surrounding personal injury actions.²³¹ The Supreme Court has interpreted the reach of the ADA’s express preemption clause on two occasions, but has not directly addressed whether state tort actions are within the provision’s preemptive scope.²³² However the court nevertheless acknowledged that “some state actions may affect airline rates, routes, or services in too tenuous, remote, or peripheral a manner to have preemptive effect.”²³³

The Plaintiff, Mrs. *Somes* argued that the medical equipment airlines deploy in-flight could not reasonably be found within such a limited conception of services, thus Congress could not have intended to preempt her claim.²³⁴ The government’s argument was unpersuasive because it ignored the presumption against preemption. “*Somes*’ claim is a common-law based personal injury action, which concerns health and safety, an area traditionally regulated by the states pursuant to their police powers.”²³⁵ “Because the provision of emergency medical equipment is not inherent in the nature of an airline’s operations and is typically not a ‘bargained-for or anticipated’ service, it is not an airline

229. *Id.* at 78. (Citing Federal Aviation Act of 1958, §101 et seq. 49 App. U.S.C. §1301 et seq.) (1994 Ed.).

230. *Somes*, 33 F. Supp. at 81; see *Nader v. Allegheny Airlines, Inc.* 426 U.S. 290, 300 (1976) (holding that state tort action for fraudulent misrepresentation could “coexist” with the Federal Aviation Act as contemplated by the “savings clause”). However, since the ADA’s enactment, the courts have divided over the interrelationship between the ADA’s preemption clause and Congress’ retention of the “savings clause” with respect to state tort claims.

231. See *Somes*, 33 F. Supp. at 81. The Court first construed the provision in *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, (1992) (where plaintiffs sought to enforce state airline fare advertising guidelines) the Court held that “. . . state enforcement actions having a connection with or reference to airline rates, routes, or services’ are preempted. *Id.* at 384, (citing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983).

232. *Id.* at 81 (citing *Shaw*, 463 U.S. 85 at 100 n. 21, and *Morales*, 504 U.S. at 390.)

233. *Id.* at 82.

234. *Id.*

235. *Id.* at 83.

‘service’ under the Fifth Circuit’s definition.”²³⁶

Federal Aviation Administration (FAA) regulations relating to the contents of emergency medical kits alone do not bar an airline from carrying supplemental devices to protect its passengers. Neither do they preempt states from legislating additional requirements for those airlines.²³⁷ A requirement that airlines carry an AED does not implicate “air safety” as understood by Congress in its enactment of the Federal Aviation Act and it is therefore not preempted.²³⁸ United claimed that an airline complying with state common law duty requiring airlines to carry AEDs may simultaneously be violating a federal requirement because it had not yet secured FAA approval for enhancing its emergency medical kits.²³⁹ The court found that this argument was premature because enhancing emergency medical kits cannot be a conflict unless the FAA declines to approve them.²⁴⁰

In *Fischer v. Northwest Airlines*²⁴¹ the plaintiff’s medical expert testified that the presence of a defibrillator and an adequate airway²⁴² would have made resuscitation “very likely”. The airline moved for summary judgment, contending that absent negligence, proximate cause can only be established where the chances of survival were more than fifty percent and noting that the plaintiff’s own expert pointed out that the chances are only that good in a hospital coronary care unit.²⁴³ The court denied the airline’s motion, holding that it was the defendant’s burden to use her own medical expert to establish as a matter of fact, that the deceased’s likelihood of survival was twenty-five percent or less.²⁴⁴

Some passengers may make their choice of a carrier relying upon its AED policy to ensure personal safety. The fact that there are air travelers who fly an air carrier because of its defibrillator policy is proof that this particular type of reliance exists.²⁴⁵ However, the standard of

236. *Id.* at 86.

237. *See id.* at 87.

238. *Id.* at 87-88 (stating that the contents of emergency medical kits must be approved by FAA; *see* 14 C.F.R. pt. 121 app. A).

239. *See id.* at 88.

240. *See* Buffington, *supra* note 219, at 532.

241. *Fischer v. Northwest Airlines*, 1990 U.S. Dist. Lexis 111517.

242. *Id.* at 533.

243. *Id.*

244. *Id.*

245. Medical experts disagree, however, because establishment of an adequate airway rises to the level of intubation, which lay persons, or even flight attendants would not have the skills or duty to accomplish under any

care element has arisen in instances where reliance on the availability of equipment such as AEDs was not an issue. Most courts have sided with defendants in these cases. The legal standard of care only requires a person, or facility, to provide “reasonable care” in situations where there is a “reason to know” of a danger. Carriers must provide special care until further assistance is available. “In sum, case law indicates that airlines who adopt the use of defibrillators are not faced with any greater duty than the special relations duty which requires affirmative aid to a passenger in need of care until they can be cared for by others.”²⁴⁶ As expected, according to tort law, negligence after employees became aware of a passenger’s needs, will subject an airline to liability for failure to perform. This could create a fact issue in product liability cases where an AED fails to operate.²⁴⁷ The acquirer, administrator and user could also face far reaching law suits.

Voluntary assumption of a duty is discussed in the case of *Newsome v. Csevak*.²⁴⁸ Although not involving a duty of medical care, *Newsome* involves similar issues. The New York Supreme Court held that the defendant’s internal policy of sanding and salting the entrance to the parking lot and roads of the mall did not, in itself, create a basis for liability of the defendant to the plaintiff.²⁴⁹ The *Newsome* court states “this argument is meritless since there is no basis for the proposition that a party may be held liable for failing to follow a policy which is has adopted voluntarily, and without legal obligation, especially when there is no showing of detrimental reliance by the plaintiff on the defendant’s following that policy.”²⁵⁰ This still raises the question of travelers making their choice of airlines based upon AED policy. If a case comes before a court, the burden of proving that the passenger relied on the availability and use of an AED would fall on the plaintiff.

In another case discussing airline liability, *Tandon v. United Airlines*,²⁵¹ the estate of a passenger who suffered a fatal heart attack during an international flight sued the carrier, alleging negligent failure to provide oxygen and other medical supplies to treat the passenger. The airline successfully moved to dismiss claims for nonpecuniary damages under the

circumstances.

246. See Buffington, *supra* note 219, at 533.

247. *Id.* at 534.

248. *Newsome v. Csevak*, 130 A.D.2d. 637 (N.Y. App. Div. 1987).

249. *Id.*

250. *Id.*

251. *Tandon v. United Airlines*, 968 F. Supp. 940 (1997).

Death on the High Seas Act (DOHSA).²⁵² The court granted the motion, holding that DOHSA precluded claims for loss-of-society, anguish or grief of survivors, decedent's pain and suffering, and punitive damages.²⁵³ In addition to DOHSA, plaintiffs have sought to employ the Warsaw Convention and Montreal Agreement (a federally approved private agreement among airlines) to impose absolute liability on airlines for injuries proximately caused by the risks inherent in air travel.²⁵⁴ Courts have held that "liability under Article 17 of the Warsaw Convention arises only if a passenger's injury is caused by an unexpected or unusual event or happening that is external to the passenger, and not where the injury results from the passenger's own internal reaction to the usual, normal and expected operation of the aircraft."²⁵⁵

In its Report accompanying The Cardiac Arrest Survival Act of 2000, the House states that the Act "does not create any new causes of action and does not impose any new regulations on the private sector, nor does the bill require AEDs be placed at any building or location. State laws are not superseded if the State has or enacts a statute or regulation providing immunity for the applicable persons."²⁵⁶

V. ETHICAL ISSUES SURROUNDING RESUSCITATION

The American College of Emergency Physicians states that "[i]f the patient's preferences regarding resuscitation are clear they must be respected. Patient preferences to refuse resuscitative efforts can be communicated by the patient's legal representative, a valid [do not attempt resuscitation] DNAR order, or an advance directive."²⁵⁷ Medically appropriate resuscitative measures should always be taken regardless of doubt about the validity of a directive or uncertainty about the wishes of the patient. Most writers on the subject agree that it is ethically permissible for health care providers to terminate treatment, when additional information is available, such as the lack of response to treatment or definitive information about the patient's or surrogate's

252. *Id.*

253. *Id.*

254. Buffington, *supra* note 219.

255. *Air France v. Saks*, 470 U.S. 392 (1985).

256. Committee on Commerce, U.S. House of Representatives, 106th Congress, Report to Accompany H.R. 2498: The Cardiac Arrest Survival Act of 2000, 106-634, May 2000.

257. *Ethical Issues For Resuscitation*, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, Policy Statement, at <http://www.acep.org/POLICY/po400133.htm> (last visited Oct. 18, 1999).

wishes.²⁵⁸

Depending on the state, and in some cases the county, first responders and all those who may have to decide whether or not to begin CPR or use an AED, (emergency physicians included) should familiarize themselves with applicable laws regarding living wills, durable powers of attorney for health care, prehospital advance directives, and health care proxies.²⁵⁹ Many health care providers also advocate creation of a national standard for these documents, which would make them visually recognizable and applicable in all jurisdictions.

A. *Presumed Consent to Treatment*

The current SCA survival rate in the U.S. is only five percent, largely because CPR and defibrillators are not used in time.²⁶⁰ CPR is like other emergency life-saving treatments, a procedure to which the patient is automatically presumed to consent in the absence of explicit prior decision to withhold consent. In its 1988 DNAR legislation, New York expounded that this principle stems from “the preciousness of life” theory combined with an unconscious patient’s incapacity to consent and the need to start CPR immediately if it is to have any chance of success.²⁶¹ Those who perform CPR cannot be convicted of assault and battery unless they are clearly aware that the patient has rejected the use of CPR in the case of cardiac arrest.²⁶² The same consent issues can be extrapolated with respect to AEDs.

The patient’s decision about CPR, therefore, is not one of consent but of withdrawal of presumed consent.²⁶³ The trend toward enabling patients to issue advance directives about their health care in the event they lose the ability to make decisions has led to, among other things, in the

258. *Id.*

259. *American Red Cross Leads the Fight Against Sudden Cardiac Arrest in the Workplace*, AMERICAN RED CROSS, at <http://www.redcross.org/news/inthenews/99/3-1-99.htm> (last visited Oct. 18, 1999) (stating “The interaction, which was an a priori hypothesis, described a relatively greater survival benefit for CPR before defibrillation as response intervals increased (and as the survival rate decreased), i.e. the adjusted odds ratio of the study was 0.8 for a 1-minute response interval, 2.1 for a 5-minute interval, and 6.8 for a 10-minute interval.”).

260. *See* Sorum, *supra* note 20, at 33.

261. *Id.*

262. *Id.*

263. *Id.* at 629.

Federal Patient Self-Determination Act.²⁶⁴ This Act, effective in December 1991, requires health care facilities to inform new patients about state regulations concerning their right to refuse treatment and to issue advance directives.²⁶⁵ Advance directives are dealt with on a daily basis in nursing homes and other elder care facilities. EMS representatives have difficulty dealing with these issues, even in this type of setting. Those difficulties are compounded when SCA occurs in public places, where the victim's history may not be known and a layperson may be the first person to render assistance.

B. Implications of "Do Not Attempt Resuscitation" Directives

Experts agree that every EMS system should have a definitive and comprehensive policy for dealing with out-of-hospital "Do Not Attempt Resuscitation" (DNAR) directives. EMS personnel need to know what to do before they are confronted with a DNAR, as do lay rescuers, thus, information regarding this policy must be widely disseminated among the public, prehospital personnel, and the medical community.²⁶⁶ A comprehensive DNAR policy must state whether prehospital personnel should honor a DNAR directive when the family member, the patient's designee, or the patient's responsible physician expresses a wish to initiate resuscitative efforts.²⁶⁷

Prehospital personnel should always initiate resuscitative efforts on a victim of cardiopulmonary arrest unless obvious signs of irreversible death are found, valid DNAR documentation is produced at the scene, or the patient's physician takes direct responsibility for withholding resuscitative efforts.²⁶⁸ With the increase in state legislation regarding advance directives, they are being used by more than just the old or dying. Increasing numbers of persons who are not terminally ill are designating DNAR wishes through living wills or advanced directives documents

264. *Id.* (citing the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508 " 4206, 4751, 104 Stat. 1388 (codified in scattered sections at 42 U.S.C., primarily 1396(a)).

265. "Do Not Attempt Resuscitation" Directives in the Out-of-Hospital Setting: Policy Statement, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, at [http://www.aecp.org/POLICY/po400165 .htm](http://www.aecp.org/POLICY/po400165.htm) (last visited Oct. 18, 1999).

266. *Id.*

267. *Id.*

268. "Do Not Attempt Resuscitation" Orders in the Out-of-Hospital Setting, Policy Resource and Education Paper, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, at [http://www.aecp.org/ POLICY/pr400165.htm](http://www.aecp.org/POLICY/pr400165.htm) (last visited Oct. 18, 1999).

when such mechanisms have been established by state legislation.²⁶⁹ This complicates the response of EMS technicians and lay users of AEDs who may be confronted with some of the same situations. This is especially true as more lay people are educated about public access defibrillation, CPR and AED use, and emphasis must be placed on learning to deal with DNARs.

While efforts have focused on the development of DNAR policies in the inpatient setting, such efforts for the patient who does not wish to be resuscitated out of the hospital have not been adequately addressed.²⁷⁰ There is always the option of ignoring the DNAR order if the patient is able to express a wish to be resuscitated prior to cardiopulmonary arrest or when the prehospital personnel have any doubts as to the authenticity of the DNAR order.²⁷¹ The American College of Emergency Physicians states that:

A comprehensive DNAR policy should . . . reiterate the need for a presumption in favor of resuscitation when patients wishes are not known; define the conditions under which a DNAR order can be considered; define which patient is competent to agree to a DNAR order and establish a mechanism for determining a surrogate when the patient is not competent to reach such a decision; establish that the decision not to attempt resuscitation must be an informed decision made by the patient or his surrogate; . . . identify the clinical procedures that are to be withheld in the execution of a DNAR order; . . . define the procedure for revocation of DNAR order; [and finally] establish immunity for health care providers who carry out DNAR order in good faith.²⁷²

A good DNAR policy should, at a minimum, include an educational program for patients, their families and the medical community regarding the appropriate use of EMS systems in the treatment of terminal medical conditions.²⁷³ A comprehensive DNAR policy should also address proper organ donor procedures.²⁷⁴ The next step would be to educate potential lay users of AEDs about how to handle resuscitation decisions when faced with DNAR directives.

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.*

273. *Id.*

274. *Nonbeneficial "Futile" Emergency Medical Interventions*, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, Policy Statement, at <http://www.aecp.org/POLICY/PO400198.htm> (last visited Oct. 18, 1999.)

C. *Nonbeneficial or Futile Emergency Medical Interventions*

Determinations about whether or not to use an AED in an emergency situation can be complicated by the age or wishes of the victim. Unless a bystander has a reason to know about a DNAR the victims' wishes may not be followed. Laypersons are not in a position to judge if using an AED will be futile. Health care professionals have policies to help them make such decisions. "The American College of Emergency Physicians believes that emergency physicians and other emergency health care professionals have a duty to provide appropriate evaluation and treatment for every patient who presents to the emergency department."²⁷⁵ "Physicians are under no ethical obligation to render treatments that they judge have no realistic likelihood of medical benefit to the patient."²⁷⁶ Personal decisions about acceptance of nonbeneficial treatment are commonly made near the end of one's life. Emergency physicians regularly encounter patients in cardiac arrest who have no realistic likelihood of survival and in such circumstances, they should consider discontinuing resuscitative efforts, in both the prehospital and hospital settings.²⁷⁷ These determinations cannot be made easily by the lay person, who has only had minimal training on the proper use of an AED.

CONCLUSIONS

AEDs must be recognized as essential components of available emergency medical equipment in public settings. Since their introduction, they have established a track record for successfully aiding victims of SCA. Programs, such as Chicago's airports emphasis on high visibility and easy access to AEDs, and similar programs being introduced in casinos, health and fitness facilities and on-board airlines serve as examples to corporate America of the importance of AEDs in the future of EMS and resuscitation. Increasingly, corporations, government agencies, sports stadiums, golf courses, hotels, and restaurants are choosing to make AEDs part of their emergency response to aid victims who collapse from SCA. Some insurance companies are now offering discounts on commercial premiums for organizations with AEDs available on site. For example, Prudential offers grants for these vital purchases.²⁷⁸ To date, more than forty-six states have some type of AED

275. *Id.*

276. *Id.*

277. *See* Heightman, *supra* note 10.

278. *See* Searcy, *supra* note 67.

legislation.²⁷⁹ More protection comes from the new federal legislation. In addition, manufacturers have indemnification programs available for purchasers.²⁸⁰ Physio-Control is willing to indemnify anybody who buys its devices and joins others in the industry in promoting the idea that it may be more hazardous not to have an AED.²⁸¹

The goal of public access defibrillation is to create a climate that would make reaching for a portable defibrillator as legally risk-free and as reflexive as breaking the glass on a fire extinguisher case.²⁸² Political infighting aside, every community should equip and train as many first responders as possible to use an AED. Critics complain of a “bandwagon approach” to medicine in America; they say that “if something is neat and works and does great stuff, it ought to be promoted without regard to the costs or the trade offs.”²⁸³ They believe those trade offs are police and firefighters who shy away from performing CPR or using AEDs because of the additional training, liability or political considerations.²⁸⁴ Paramedics are leery about the police infringing on their duties, adding to the conflicts over whether the general public should use them and whether widespread distribution is worth the cost. Although many insurance companies favor employers acquiring AEDs, some are making it a major issue. Some insurance companies have refused coverage for heart patients who would like to purchase them for home use or corporations who consider supplying them for employees. For example, a Palm Springs synagogue reconsidered purchasing one because its insurer would not provide liability coverage.²⁸⁵

H.R. 2498, The Cardiac Arrest Survival Act, was signed by President Clinton on November 13, 2000.²⁸⁶ According to the Committee Report it “encourages the Federal Government to be a role model for the private sector . . . and to publish in the Federal Register its recommendations for appropriate training courses, maintenance and testing of AEDs, training

279. *AED Legislation in the U.S.*, available at <http://www.padl.org/html/legislation/law-us.htm>.

280. See Searcy, *supra* note 67.

281. See Fritz, *supra* note 57, at A15.

282. *Id.*

283. *Id.*

284. *Id.* at A14 (“Police in Muncie, Indiana refused to take part in a defibrillator experiment because of liability worries until an off duty officer had a heart attack and was saved by a sheriff’s deputy who was carrying one.”)

285. *Id.*

286. *Bill Summary & Status for the 106th Congress*, available at <http://.thomas.loc.gov/cgi-bin/bdquery/z?d106:SN014488:@@L&summ2=m>.

for AED use, and coordination with local EMS. . .²⁸⁷ Hopefully citizens will take the opportunity provided to learn as much as possible about AEDs and rely upon the Good Samaritan protections from liability in civil suits for good faith users to put this technology to its best use. The AHA has proposed model state legislation, which has been adopted in some form by twenty states, while others have revised Good Samaritan laws to encourage bystander rescue efforts with AEDs. Still more has to be done in terms of public media campaigns and implementation of this recent federal legislation. Perhaps this will occur when AEDs are placed prominently in federal buildings.

Technology is making AEDs more affordable and user friendly, and significantly reducing associated maintenance. Three to five thousand dollars is a large amount to spend on a device that may never be used, but it is indeed a small price for saving a life. Studies have shown that immediate defibrillation and CPR, as part of the chain of cardiac survival, are the most important factors in a victim's chances for survival of a sudden cardiac arrest. It has been demonstrated that AED users need not be highly trained medical professionals. Basic training in CPR and the use of an AED can keep a patient alive until fully trained hospital or EMS personnel can take over and follow up with advanced cardiac life support. Legal concern about liability of lay users, acquirers or medical directors of public access programs can be further addressed through some of the progressive legislation already under consideration in several fora, or modeled upon the Cardiac Arrest Survival Act recently passed by Congress.

Despite their success rates, AEDs have not caught the public's attention. The media must cover the efforts of organizations such as Second Chance America and PADL and publicize AED success stories and legislative efforts to make public access defibrillation a reality in the near future. Scientists are proceeding with the next generation of even more user-friendly defibrillators, including inexpensive disposable devices and lightweight models that can be worn like a vest; others would automatically dial 911.²⁸⁸ It is time for laws and public acceptance to catch up with technology and for political conflicts to give way to saving lives. In these litigious times, fears of liability will accompany widespread lay use of AEDs. However, responsible state legislation can help alleviate the potential for lawsuits by providing Good Samaritan protections for acquirers and users of this lifesaving technology.

287. See Committee Report, *supra* note 256 at 5.

288. *Id.*