

Legal Aspects of Public Access Defibrillation

Paul S. Weinberg, J.D.
Weinberg & Garber, P.C.
71 King Street
Northampton, MA 01060
(413) 582-6886
www.w-g-law.com

Common interest, different roles

“Just as epidemiology moved from *ad hoc* to being an academic subject, to being used in public health practice, so we see the same thing happening with the law in public health... It became my awakening when I saw how long we in public health had been working on tobacco, and then the lawyers got involved and overnight, it all changed. And I began asking students, ‘What else should we be asking the lawyers to do?’”

William H. Foege, MD, MPH; “Redefining Public Health,” *The Journal of Law, Medicine & Ethics*

Common interest, different roles

M.D.s

J.D.s

- Development of new technology
- Body of information (includes studies, etc.)

- Common law
- Lobbying/politics

What you (as a physician) can do

- Act as a medical director for a public access defibrillation program
- Be involved in lobbying activities relating to public access defibrillation
- Educate, Educate, Educate

Medical directors



Medical Professional's Key Duties

- Providing medical leadership and expertise
- Serving as an advocate and possibly a spokesperson for the program
- Identifying and reviewing local and state AED regulations
- Assisting in coordinating the program with local EMS
- Helping develop program procedures, such as the following:
 - Internal Medical Emergency Response Plan (MERP)
 - Training plan for targeted responders
 - Maintenance plan for the AEDs
 - Quality review and improvement plan for the AED program
 - Internal communication plan

Ensuring Program Quality

The physician or other medical professional supervising the program also guards the program's quality. He or she should

- Help develop the emergency response procedure for the facility
- Advise about the proper location of AEDs
- Advise about how responders should be notified of an emergency
- Conduct a review each time the AED is used. The main purpose of the review is to give responders positive feedback and practical suggestions for improvement. Talking to rescuers about their feelings following the emergency is important. The review allows problems in the program to be quickly spotted and fixed.

Source: American Heart Association's Automated External Defibrillation Implementation Guide

How One Industry Combats AED Legislation: Lies, Damned Lies, and Other Tales my Lobbyist Told Me



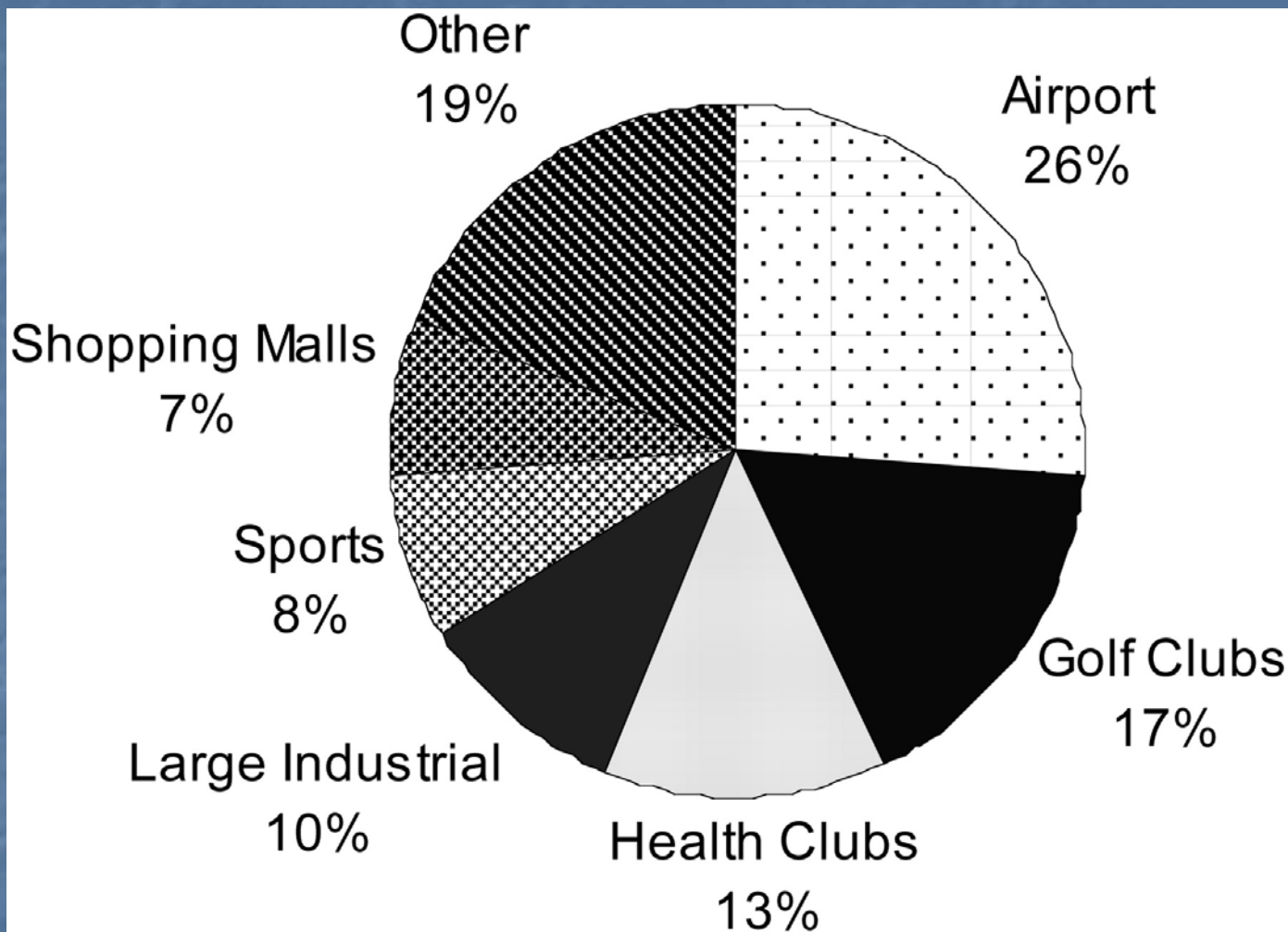
The FDA requires a prescription from a physician to purchase an AED... Some health clubs may be unable to secure physician authorizations and many physicians will be unwilling to accept the liability that accompanies such prescriptions

Survival rates for AED use by lay responders in the PAD trials show that PAD doesn't work as well as advocates claim in the "real world"

Few health clubs meet the American Heart Association's criteria for AED placement – a reasonable probability of one sudden cardiac arrest every five years

Since 85% of all sudden cardiac arrests occur at home, the risk of a cardiac arrest occurring in a commercial health club is small (one occurrence in every 1.5 million episodes of vigorous exercise). Since most people do not exercise at levels that can be classified as vigorous, there is no pressing need to place AEDs in health clubs

Public locations with high incidence of SCA in Seattle and King County, Washington, 1990 to 1994 (n=134)



Hazinski, M. F. et al. *Circulation* 2005;111:3336-3340

Operating an AED when the victim has been in or the incident occurred near a swimming pool can be dangerous and possibly inadvertently shock the responder.

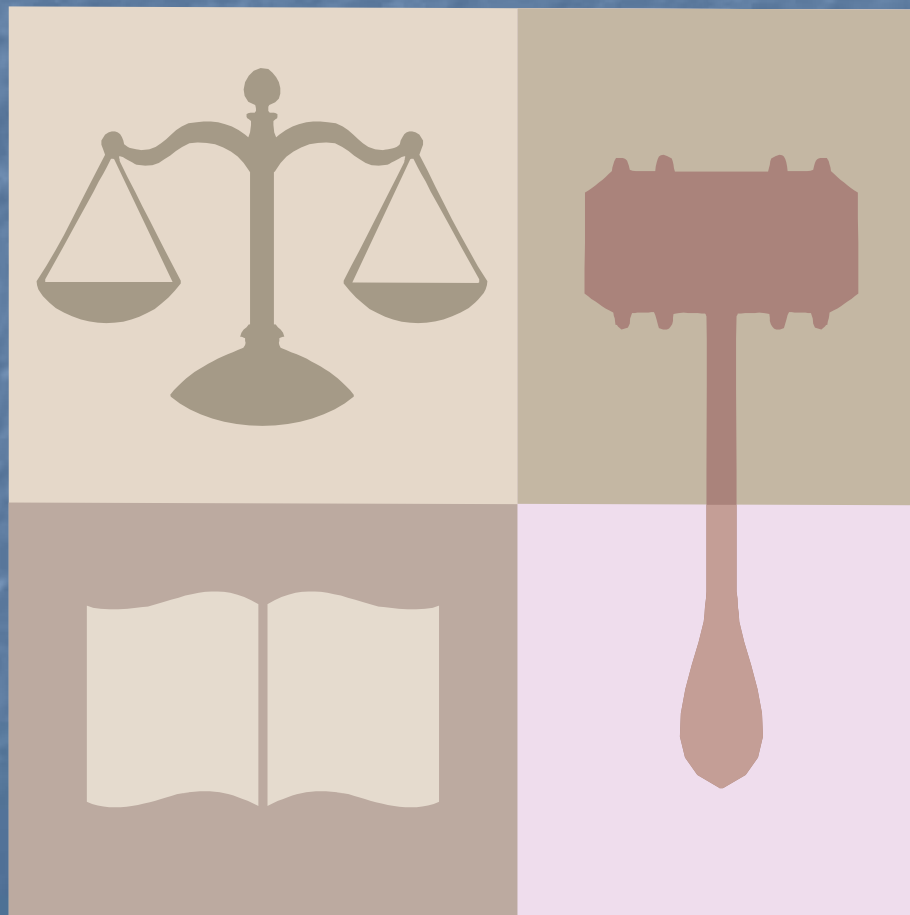
AEDs are not appropriate treatment for heart attacks, as opposed to sudden cardiac arrest. Medical professionals must administer medication or other life-saving procedures, and sometimes surgery is necessary to unblock the blood vessel to ensure adequate blood flow to the heart. Health clubs are recreational facilities, not medical facilities

Many health clubs are located near firehouses or ambulance dispatch centers, and some are located near hospitals. The emergency response time when an incident occurs at these clubs is well within the recommended time frame for cardiac emergencies; therefore, this legislation would be both costly and unnecessary. The public would be better served by legislation requiring every police vehicle, ambulance, and fire engine to be equipped with a portable AED, rather than passing this governmental mandate out to private health clubs.

Health club employees might choose to not use an AED (due to panic, fear of hurting the individual, or other reasons). Health clubs should have complete immunity for the non-use of an AED if one is installed.

It is unrealistic and unfair to expect health clubs to purchase equipment and train staff in less than a year. A grace period of at least a year is more realistic and obtainable

Common Law 101



Functions of Common Law

- Regulatory - enforcing “reasonable” behavior through lawsuits
- Defining circumstances where use is reasonable



Principles of Negligence

- **Duty**
- **Breach of duty**
- **Which causes**
- **Injuries**

WHO'S RESPONSIBLE FOR ME WHEN I FLY?

In a word, us. That's why United Airlines is initiating training programs for all of our employees. We will empower them to solve problems and make the decisions that will help make your flying experience a better one. This is going to be a different United Airlines. An even more professional United Airlines. Compared to the rest of the airline industry, we're heading in a different direction.



Our employees are being trained to help minimize the hassles of travel.



With your Premier Card you'll get dedicated check-ins, best seats available and increased levels of service.



United is upgrading its fleet with more of the planes our customers prefer to fly.

Duty

- Duty to act “reasonably” in light of circumstances
- Industry standard is not dispositive

Industry does not set standard of care

"It is any final answer that the business had not yet generally adopted [the technology]? [A] whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests....

Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."

The *T.J. Hooper* case (1932), Justice Learned Hand

Liability Issues Surrounding Public Access Defibrillation



Possible Litigation From Use of an AED


- Improper use
- Failure to use
- Defective equipment

Liability and Good Samaritan Laws



AED Legislation by State

- By 2000, all 50 states had enacted some form of “Good Samaritan” law to cover laypersons and others involved in PAD.
- Protection by state laws has not been universally afforded to medical directors and trainers

AEDHELP.COM
BIPHASIC.COM
PHYSIO-CONTROL.COM

SCA	AEDs	Implementation	LIFEPAK AEDs	Saving More Lives	Everything Else
Overview	What steps do I take?	What about liability?	Legislation Summaries	Documents to Download	

■ **AED Legislation by State**

Choose a state from the drop-down or by clicking on the map:

Download all [Legislation Summaries](#) (414 KB)



Cardiac Arrest Survival Act (HR2498) (Nov 2000)

- Provides federal immunity
- Preempts contrary state law for AED users, acquirers & doctors if:
 - EMS provider is notified of the AED's location
 - the AED is appropriately maintained
 - appropriate training is provided

No Immunity For:

- Gross negligence or willful or wanton misconduct
- Licensed or certified health professional who used [AED] while acting within scope of license or certification, and within scope of employment or agency

Volunteers

As a volunteer responder:

- The Federal Volunteer Protection Act of 1997; and
- Most states;

Provide immunity, except for:

- Gross negligence
- Willful misconduct

AED Manufacturers

- Most AED manufacturers provide broad indemnification to all participants in a PAD program, including medical directors

Airline AED Litigation: A Microcosm of the Stages in the Adoption of an Important Health and Safety Device



4 Stages of Acceptance of Health & Safety Technology

1. Voices in the wilderness – early adopters
2. Overcoming resistance
3. Reformers, reporters, legislators and lawyers
4. General Acceptance

The Cry in the Wilderness

- 1
 - Benefits come into public view
 - Details of how to adopt are lacking
 - Little hard data available
 - Adoption on small scale
 - Technology is relatively expensive

Resistance

2

- Adoption resisted as technology improves
- Obstacles:
 - institutional inertia
 - problems with evolving technology
 - cost concerns
 - fear of liability
- Extremely promising early returns
- Widespread knowledge

Reformers, Reporters, Legislators & Lawyers

3

- Technology more effective, uniform & better understood
- Less expensive
- Benefits established and proven
- Device adopted on larger scale by high-profile users
- Legislative assistance enacted

General Acceptance

4

- Technology ubiquitous & unquestioned
- Universally adopted where appropriate
- Often required by law

The United Airlines Example



1975

Doctors at New York's St. Vincent's Hospital and several other centers across the country are currently testing a new lightweight defibrillator...

Newsweek, Sept. 22, 1975

Sept 1988

Dr. Jeremy Ruskin wrote in *New England Journal of Medicine* about AEDs

“Automatic external defibrillators were developed in the late 1970s, and their refinement over the past decade represents an important technological advance....

Several semi-automatic or advisory units (devices that analyze the cardiac rhythm but do not automatically deliver a shock) are currently available for use outside the hospital by minimally trained personnel....

The time required to analyze the rhythm, charge, and deliver a shock if criteria for arrhythmia are met ranges from 10 to 30 seconds.”

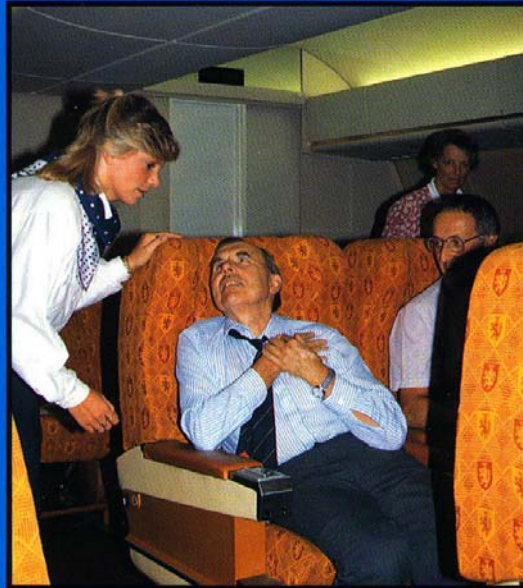
Sept 1988

Dr. Jeremy Ruskin wrote in *New England Journal of Medicine* about AEDs

“Because of its relative simplicity and ease of operation and the fact that it obviates the need for skilled recognition of arrhythmia, the automatic external defibrillator requires far less time and expense for both initial training and skill maintenance. All these factors support the use of this device by a wide range of trained and supervised emergency personnel, including police, firefighters, ambulance operators, and appropriate workers in factories, office buildings, and public places such as airports and stadiums.”

1991

AIRLINE MEDICAL MANUAL



PETER CHAPMAN



Chapman and Hall Medical

In-flight Deaths During Commercial Air Travel

How Big Is the Problem?

Richard D. Cummings, MD, MPH, MSc; Peter J. C. Chapman, MS, DPH; Douglas A. Chamberlain, MD; Jessica A. Schaubert, BA; Paul E. Litwin, MS

Do passenger deaths occur during commercial air travel? If so, how often and from what causes? We reviewed information reported to the International Air Transport Association on in-flight deaths that occurred during commercial air travel for the eight years between 1977 and 1984. Of the 120 airlines in the International Air Transport Association, 82 carriers reported deaths during those eight years. A total of 577 in-flight deaths were recorded, for a reported average of 72 deaths per year. Deaths occurred at average rates of 0.31 per million passengers, 125 per billion passenger-kilometers, and 25.1 per million departures. The majority of those who died were men (85%, 382/577) and middle-aged (mean age, 53.8 years). Most of the individuals (77%, 386/515) reported no health problems prior to travel. Physicians aboard the aircraft offered medical assistance for 43% (247/577) of the deaths. More than half of the deaths (56%, 320/577) seemed to be related to cardiac problems. Sudden unexpected cardiac death was the cause of death in 63% (253/399) of the apparently healthy people and seems to be the major cause of death during air travel. These observations support the initiation of programs to train cabin personnel in the skills of basic cardiopulmonary resuscitation and in the use of automatic external defibrillators.

(JAMA 1986;255:1335-1338)

BACKYARD, the airfield of the world transport hundreds of millions of passengers.¹ Regardless of their prior physical or mental conditions, the

passengers are expected to survive the flight.

From the Center for the Evaluation of Emergency Medical Services, Division of Emergency Medical Services, New York County Department of Public Health (Dr Cummings, Ms Schaubert, and Dr Chamberlain) and the Department of Medicine, University of Washington (Dr Chapman); the State Medical Director's Office, Oregon Department of Health, Oregon (Dr Chamberlain); and the Department of Cardiology, Royal Brompton Hospital, London, England (Dr Chamberlain).

The authors wish to thank the following individuals for their assistance in the collection of data: Dr Robert A. G. Harrison, Director of the International Air Transport Association.

Reprint requests: Center for the Evaluation of Emergency Medical Services, 110 West 12th St, Box 500, Seattle, WA 98101 (Dr Cummings).

overwhelming majority of these air travelers complete their flights safely. With so many people in the air, however, deaths during air travel can be expected on the basis of their numbers alone.² In addition, some passengers who board the airplane in ill health may die when they experience deterioration in their conditions.³

Although anecdotal accounts of in-flight deaths appear regularly in lectures to the editor,^{4,5} objective information about this problem is rare. Published estimates of in-flight deaths are often unrefined statements,^{6,7} ie, unpublished surveys from individual airlines,^{8,9} or are unreported statements that such deaths rarely occur.^{10,11}

Lack of accurate data about the true frequency and nature of in-flight medical emergencies hampered the recent US debate about airline emergency kits.^{12,13} In a compromise arrangement, the Federal Aviation Administration (FAA) mandated that effective Aug 1, 1984, all commercial common carriers must maintain a specific medical aid kit¹⁴ that is separate from their regular first aid boxes. These kits contain only three injectable medications (diazepam, epinephrine, and diltiazem hydrochloride), one sublingual medication (nitroglycerin), a stethoscope and a sphygmomanometer, and three sizes of oropharyngeal airways. The medical aid kits do not contain cardiac defibrillators, endotracheal intubation equipment, or parenteral analgesic, sedatives, or antiarrhythmics. The new FAA regulations also require that the airlines gather information about all in-flight emergencies that require use of the new kit or about unscheduled landings that occur for medical emergencies or in-flight deaths. These records will be reviewed after two years to determine if the contents of the medical kit should be modified.

A paradox to these regulations is that they obligate the airlines to supply equipment and medications but do not require the personnel to know how to operate the equipment or administer the medications.¹⁵ To perform these actions, the airlines remain dependent on "good luck" health professionals who are asked to come forward in the event of an in-flight emergency. From the perspective of the physician, an

United's Response

6. The high frequency of apparent sudden cardiac arrest as the major cause of death among air travelers suggests that the medical aid kits now required by the FAA would not be particularly useful during in-flight resuscitation attempts.

CPR^x

7. The preponderance of sudden cardiac death among apparently healthy people as the major cause of death dur-

BS

ing air travel provides strong support for programs to train cabin personnel in the skills of basic cardiopulmonary resuscitation and in the use of automatic external defibrillators.

“BS”



United's cost benefit analysis

- better to enter
- calculations not correct
- HT. reference
- pol. factors used + it's
- better overall

72 deaths/yr
 $\times .69$ — no prev. health problems

50 unexpected deaths/yr
 $\times .63$ — unexp. cause

31 unexpected deaths/yr.
 $\times .109$ (70% of deaths = early U.S.)

2

$\times .95$ (74 don't receive hospitalization) — insurance 450%

1.95

$\times .43$ (MS occurrence)

0.9

31 average all fib

\$4300/copy
3600 U.S.
 7000 antibodies
 net. —
 rising costs —

400,000

United responds to Cummins' article

In-flight Medical Emergencies

One Year of Experience With the Enhanced Medical Kit

Joseph J. Cotter, MD; James T. O'Leary; Gary M. Kohn, MD; Eugene C. Henkle, MD; Robert H. Rogers, MD

Recent regulations require commercial US airlines to carry an enhanced medical kit. We reviewed its use on United Airlines during the initial year of the regulations. We also surveyed passengers who came ashore during flight and health care providers who used the kit. The medical kit was used 362 times on 351 flights (once in every 1000 flights or one use for every 160 000 air travelers). Health care providers indicated that the kit was useful in more than 80% of emergencies and was occasionally lifesaving. In the emergencies in which the kit was used, 70% fell into one of seven major diagnostic groupings, including syncope/near syncope (24%), cardiac chest pain (14%), arrhythmias/dizziness/irregularity of breath (15%), and allergic reactions (9%). With 450 million domestic air travelers per year, we would expect 3000 in-flight medical emergencies annually, and conclude that the enhanced medical kit is beneficial and propose small modifications that would be improved by the addition of a bronchodilator for inhalation

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THE MEDICAL care of passengers who become ill during flight has been a concern since the early days of commercial aviation.¹⁻⁴ Although there have been many changes in both aviation medicine and aviation operations during the last 50 years, the medical supplies carried aboard aircraft have, until recently, remained constant.⁵ On August 1, 1989, the Federal Aviation Administration, after several years of debate and "regulations," mandated new regulations requiring additional medical supplies on enhanced medical kits aboard all US aircraft capable of carrying 10 or more passengers.⁶ The success of this kit was listed in Table 1.

Much of the debate over the new regulations centered on conflicting estimates of the incidence and nature of in-flight medical emergencies. Although these incidents are sporadic and highly publicized, exact information concerning such events is essential for aviation.⁷ What little is available has been well summarized by Eisenberg.⁸ Re-

garding the inadequacy of the available information, the new regulations also required basic data collection concerning kit use during the first 2 years. We collected additional information beyond that required by the regulations. Our goals were to try to define better both the extent and frequency of in-flight illness and to assess the utility of the new medical kit in actual use. Information was obtained both on the time of kit use and by subsequent follow-up questionnaires to both those passengers who became ill ("recipients") and those health care professionals who provided "ground ambulance" care.

METHODS

Each United Airlines enhanced medical kit contains all the items listed in Table 1, plus a medical record form and a free mask for mouth-to-mouth ventilation. In the event of an in-flight medical emergency, United Airlines procedures call for initial assessment by the cabin crew. If indicated, an announcement is then made over the cabin address system, requesting medical assistance. Health care providers are seated for some form of identification before being allowed to use the kit. Neopristin tablets are permitted to use the kit at the captain's discretion. All providers are asked to fill out the medical record form (Fig 1). All medical record forms were forwarded to use of our I.C.R.U. in

Seattle, Wash, and placed in a separate folder. Backup data were provided by both passengers and crew reports. For a 1-year period, attempts were made to identify and locate all recipients and all health care providers. Each identified individual was mailed a questionnaire. If there was no response, the mailing was repeated two additional times before a final attempt at telephone contact was made. Table 1 lists categories of data accepted by questionnaire concerning such cases. Additional information on aircraft type, dimensions, and seating was also available to us.

All questionnaire responses were entered into a database. Whenever possible, the most specific medical diagnosis was used in the final analysis. In those instances where no diagnostic information was available, the most specific symptoms or signs were reported. Subsequently, symptoms and diagnoses were grouped into major categories, including cardiovascular, infectious/digestive/pulmonary, respiratory, and other. All data were then categorized by gender and age.

To ensure that response bias was minimal, we compared our response data with those collected at the emergency department of Washington Hospital, Chicago, Ill, which were obtained over the same period. This institution receives all passengers transported from Chicago's O'Hare International Airport and maintains a separate log of these events.

We also assessed in-flight emergencies from an aviation perspective. United Airlines operated seven major types of aircraft during the study period: the Boeing B-737, B-747, B-757, and B-767; the McDonnell Douglas D11-8 and DC-14; and the Lockheed L-1011. It flew these aircraft a combined total of 1.46 million hours; 186 man-years. These types vary in capacity by a factor of 4, from the smallest, B-737, to the largest B-747. They vary considerably in the length of cross-country flight, from a few hundred miles to several thousand miles. In-

From the University of Illinois College of Medicine at Chicago (Dr Cotter and Dr Henkle), Medical College of Virginia Health Center (Dr Kohn), and the University of Chicago (Dr Rogers). Received for publication July 15, 1993. Accepted for publication October 15, 1993. Reprint requests: Dr Cotter, University of Illinois College of Medicine, 600 S. E. Tenth St., Chicago, Ill 60607. © 1994 American Medical Association. All rights reserved. 0885-0666/94/1105-0515\$05.00/0

"We recognize that our data have several limitations, all of which would cause an underestimate of the actual rates of illness..."

Table 6.—Death Rates*

	United Airlines	International Air Transport Association	Ratio
Deaths per million seat-miles	7.25	25.1	0.29
Per billion passengers	91	310	0.29
Per billion passenger-miles	73	200	0.36

*Comparison of death rates on United Airlines and International Air Transport Association flights. The ratio is the United Airlines rate divided by the International Air Transport Association rate.

quently a β -adrenergic blocker.

Chest pain and myocardial ischemia represent the most controversial area of in-flight medical care. Clearly, many individuals feel strongly that all commercial aircraft should provide advanced medical facilities for defibrillation, monitoring, and airway management.^{18,19} Indeed, on an individual basis, if a passenger suffers an acute cardiac event, and if there are qualified providers of advanced cardiac life support in attendance, advanced medical supplies would clearly be helpful. In a more conventional risk-benefit assessment, using our incidence data, we believe that the cost per life saved would be very high and that the data do not justify placement of defibrillators and other advanced medical equipment on aircraft. Table 6 compares our death incidence data with those of the International Air Transport Association reported by Cummins et al.,²⁰ who reached an opposite conclusion. Our rates are significantly lower, although they are parallel in all categories. The differences in death rates may be related to differences between air travelers on domestic and international flights. None of our recipients were known to be ill prior to flight, while 20% of the deaths reported by the International Air Transport Association oc-

curred among individuals with known illness, many of whom were being transported as aeromedical patients.

The "shortness of breath" category represents an area in which we believe augmentation of the medical kit might be useful. Many providers suggested the addition of an inhaled β -adrenergic agonist, for use in asthma and other situations of airway obstruction. Many providers were hesitant to use the parenteral epinephrine, and would prefer an inhaler. We concur with these suggestions and think that this addition would improve the medical kit.

Finally, it must be noted that travelers who are allergic to peanuts on the ground are also allergic to them in the air. Nonetheless, several individuals with known food allergies consumed these foods in flight, with resulting severe reactions. Epinephrine was con-

cluded in our medical kit. In our study, we did not underestimate the actual rates of illness: (1) We looked only at those emergencies that come to the attention of the crew and did not look for any minor illness. It is possible that there were serious illnesses that did not come to anyone's attention. Pulmonary embol-

ism, which has been associated with long-distance air travel, frequently manifests itself long after the flight.²¹ We suspect that the decreased incidence of medical problems on shorter-distance flights may be the result of passengers—who realize they will soon be on the ground—not calling attention to themselves. (2) There may have been instances in which no health care provider was available or the enhanced medical kit was not used and no data were generated. (3) Our study reports the use on one major air carrier. Although this contributed to consistency in data collection, there may be unrecognized differences between air carrier operations and passenger populations. (4) We intentionally did not seek data on ethanol intake. Although ethanol seems to be a contributing factor to many in-flight medical emergencies, we felt that seeking data on it might inhibit individual responses.

Recognizing these limitations, we feel that our data justify a conclusion that the current rate of serious in-flight medical emergencies remains low. Health care providers who have used the new enhanced medical kit indicate that it is a significant improvement over previous medical kits and we believe that its implementation and continued use are justified. Although we do not concur with recent suggestions^{22,23} that multiple other medications should be added, we do conclude that the enhanced medical kit could be further improved with the addition of a bronchodilator for inhalation.

We thank David C. Meyers, MD, director of emergency services, Resurrection Hospital, Chicago, Ill, for his cooperation.

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“Clearly, many individuals feel strongly that all commercial aircraft should provide...for defibrillation, monitoring, and airway management... Indeed, on an individual basis, if a passenger suffers an acute cardiac event, and if there are qualified providers of advanced cardiac life support in attendance, advanced medical supplies would clearly be helpful. In a more conventional risk-benefit assessment, using our incidence data, we believe that the cost per life saved would be very high and that the data do not justify placement of defibrillators and other advanced medical equipment on aircraft.”

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Finally, it must be noted that travelers who are allergic to peanuts on the ground are also allergic to them in the air. Nonetheless, several individuals with known food allergies consumed these foods in flight, with resulting severe reactions. Epinephrine was considered to be lifesaving in this situation by several providers.

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1991

Small Foreign Carriers Begin to Deploy AEDs

- Qantas



- Virgin Atlantic



Dec 1994

EXHIBIT NO. 20
10-11-99
R.C. STEWART

~~Background Information:~~ For purposes of this discussion, data from 1993 were used, since a full year's data were available from the data base maintained in SEAMD of medical kit usage, as well as in the data base maintained by the company on flight diversions.

"ENHANCED SUPPORT OF IN-FLIGHT MEDICAL EMERGENCIES

The question has been posed as to whether or not there are possible changes or enhancements that could be made to the United Airlines Medical Department response and support to in-flight medical emergencies which would be feasible and clinically *and/or financially advantageous*. This paper is an effort to *address this question.*"

others provide details of the status of a passenger," while of oxygen bottles used, and other details. Another difficulty is the relatively poor correlation between the two data bases. Only 13 of the 21 diversions reported in the medical kit data base appear in the operations diversions reports, also. Of the 37 cases reported in the operations reports where MDs were on board and the problem was serious enough to result in diversion, one would expect the medical kit would have been used in most cases, if only for the stethoscope and sphygmomanometer and to review what medications were available. However, medical kit use reports were submitted in only 13 of these instances.

007975

UAL operations personnel reported that they use an average cost figure for flight diversions of \$2,000.00 per diversion. Based on this figure and the reported 57 diversions due to passenger illness, the total cost for such diversions in 1993 was an estimated \$114,000. This figure appears to be on the conservative side, but is the only figure currently available to me.

Possible Alternatives/Enhancements: There are several possibilities to be considered. These include no change to present equipment/procedures, improving awareness/utilization of current support provisions, enhancing current support with improved communications capabilities/resource data base information, contract out primary ground-based medical consultation support, contract out back-up consultation for in-house primary medical support, purchase risk management/managed care assessment methodology (protocols/decision trees), or provide enhanced on-board equipment (IV capability, automatic defibrillator, ventilatory assist devices, etc.) Combinations of two or more of the above could also be considered.

Discussion: It must first be recognized that the limitations of the available data make discussion and analysis on a scientific basis extremely tenuous, if not impossible. Making no change at all does not appear desirable if there is any feasible possibility of reducing the 21 (or 57) diversions and 7 in-flight deaths reported. Available risk management/assessment systems do not appear likely to provide much benefit. They are mostly designed for use by non-physician screeners to determine if emergent care is or is not warranted, are designed to be used in conversation with the prospective patient directly, and are generally predicated on the availability of emergent care, if that decision is reached. From the standpoint of clinical outcomes improvement, a [redacted] offer some potential.

Improving in-house resource data base does not appear feasible. The cost of gathering such resource data for all areas served by UAL and keeping it current would be significant. Making it available to the various on-call physicians, in various locations, would be

"The available data, though admittedly not complete, would seem to indicate that the majority of the in-flight deaths were cardiac related. Since none of these patients were in cardiac arrest at the time of boarding, there is a reasonable possibility that these situations were witnessed events or detected very soon after onset. In such circumstances, the availability of a good ventilatory support, early defibrillation, and ACLS medication support might well make a difference.

From a financial feasibility point of view, however, this approach is difficult to support. To put such equipment on a fleet of over 500 aircraft would cost, conservatively, over \$2,000,000. The expense and operational difficulty of maintaining such equipment would be very considerable, and the liability exposure, if the equipment was not used, was not used properly, or failed to perform properly in even a single case, would be very high."

3. Provide improved communications for on-call physician support by providing paging cellular telephone capability to each Medical Department location. This, combined with recommendation #1, has potential for improved support service for in-flight medical emergencies. This would be cost-neutral if only one unnecessary flight diversion per year were prevented. This would not require any capital investment and could be terminated after 1-2 years if found to be not cost-effective.

4.

These approaches should be informally monitored and periodically reviewed by the Medical Department for potential future usefulness. These approaches could also be reviewed if recommendation #2 were implemented.

5. Recommend a short on-site visit be made to MedAire, Inc.'s MedLink operations center in Phoenix by myself and/or Dr. Kohn and/or Dr. Brady. The purpose of such a visit would be to gain first-hand knowledge of their capabilities for future reference.

W. Michael Waring

W. Michael Waring, M.D.
SEAMD

December 29, 1994

Addendum: An additional possibility for improving communications would be to make some arrangements for use of Airfone services to contact the UAL doctor on call, so that doctor to doctor, doctor to patient, or doctor to other on-scene attendant would be possible. (April 5, 1995)

"I do NOT recommend outsourcing medical support services or providing on-board ACLS/defibrillator equipment, primarily because of the relatively high costs involved. Based on available data, it appears these costly alternatives would produce relatively low measurable yields in terms of costs or improved clinical outcomes."

- At the Air Transport Association, the airline industry's trade association, United's medical director chaired medical panel from 1991 to 1996
- Late Feb 1995, a fellow medical director inquired about inviting Dr. Roger White to address the panel
- The invitation was never extended



Air Transport Association

FAX COVER SHEET

To: [United's Medical Director]

Fax Number: (708) 952-6298

From: Ron Welding
Air Transport Association
1301 Pennsylvania Avenue, NW
Suite 1100
Washington, D.C. 20004
(202) 626-4012 (Voice)
(202) 626-4149 (Fax)

Date: February 28, 1995

Pages: 2 (Including the Cover Sheet)

Bob Orford wants to invite Dr. Roger White, one of the U.S. experts on defibrillator equipment, to the next ATA Medical Panel as he has interesting news about ventricular defibrillation which he feels may be of interest to our members. Would you want to invite him to the next Medical Panel meeting if Dr. White is agreeable to such a meeting? If so, when would be a good time to schedule it?

Also attached is a copy of a press release from "The Lancet" titled: "Shocking Truth About Airbuses" which I apologize for its poor quality but I think you will find interesting. This article almost triggered a CBS News segment on airline inflight medical equipment.

“Also attached is a copy of a press release from “The Lancet” titled: “*Shocking Truth About Airlines*” which I apologize for its poor quality but I think you will find interesting. **This article almost triggered a CBS News segment on airline inflight medical equipment.**”



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July 1995

"I've seen [AEDs] and I've got to tell you, as a physician I'm pretty intimidated by it.... It makes nice PR to say "We've got a defibrillator on board...."

United Airlines' medical director

Feb 1996

SurvivaLink

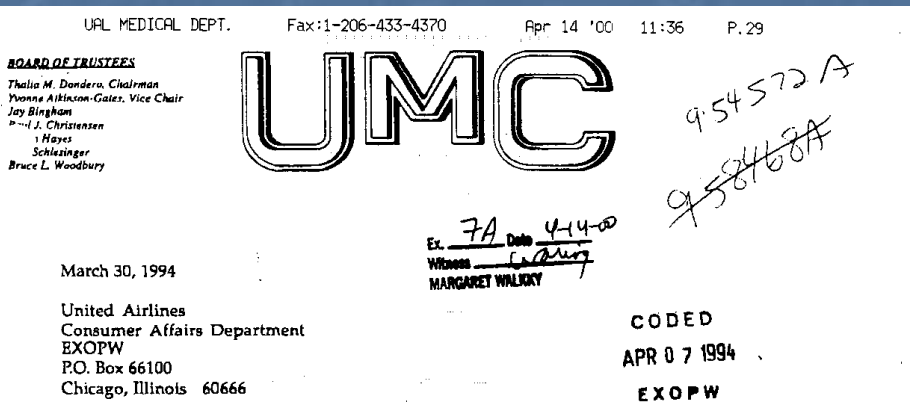


Stage 3 begins

**Reformers, Reporters,
Legislators & Lawyers**

United continued its opposition to AEDs

In April 1994, their assistant medical director received a letter from Dr. Steven Karch



“Perhaps more important, you would certainly save lives if you equipped your planes with automatic defibrillators; they are designed for use by the lay public, they are relatively inexpensive, and your flight crews could be trained to use them in under 4 hours. I’d be happy to help teach. So would other members of the community.”

March 30, 1994

United Airlines
Consumer Affairs Department
EXOPW
P.O. Box 66100
Chicago, Illinois 60666

Dear Sirs,

Having had the somewhat unique experience of managing two in-flight medical emergencies on UA flights within the last 6 months (November 21 Newark to Denver and March 23 Las Vegas-San Francisco), I feel I am becoming something of an expert on the matter. Based on my experience, I think you should give serious thought to revising your medical kit; it isn't very useful.

If you can carry a minimal kit, why not carry a complete kit - one containing IV lines, medications, and surgical instruments.

I know the standard reply: it costs money and the airlines are concerned about liability problems. Somebody needs to be concerned about the patient. I realize that many physicians have neither the training nor inclination to aggressively manage a medical emergency at 30,000 feet. But some of us do, and if I am prepared to take the risk in hope of saving someone, it seems to me you should be just as willing.

Sincerely, *SBK*
Steven B. Karch, M.D.
Associate Professor of Surgery

SBK:es

“You can't imagine anything more frustrating than being stranded with a sick patient who could be helped, if the proper supplies were available.”



Steven B. Karch, M.D.
University Medical Center
1800 W. Charleston Blvd.
Las Vegas, Nevada 89102

May 18, 1994

Ex. 7B Date 4-14-00
Witness MARGARET WALKER
MARGARET WALKER

Dear Dr. Karch:

Your recent letter has been referred to this office for a reply.


Thank you for your letter, your kind assistance with the medical emergencies onboard your recent flights, and for your comments and recommendations concerning the emergency medical kit onboard our aircraft. We very much appreciate them.

Regarding the kit contents, this has been the topic of other physician/nurse/user comments and recommendations in the past. The original selection of equipment and drugs was made by the Federal Aviation Administration after reviewing comments and recommendations from the American Medical Association's Commission on Emergency Medical Services as well as five other physician associations and two emergency nurse associations.

While the current contents of the kit may not be ideal, they may not satisfy all users, particularly those with a broad range of expertise in the use of emergency drugs and equipment, they do address the more common emergency conditions and are useful to a majority of traveling physicians.

Thank you again for your help and comments.

Sincerely,


W. Michael Waring, M.D.
Regional Flight Surgeon

WMW/sb

Seattle Tacoma International Airport, Seattle, Washington 98158

The assistant director issued a "canned" reply:

"As mentioned above, future changes in the emergency medical kits will undoubtedly be made on the basis of current usage surveys as well as input and suggestions like yours. The automatic defibrillator you suggested may well be considered by the F.A.A. and/or the airline in future revisions in the emergency medical equipment requirements."

Special Report

SUNDAY, JUNE 30, 1996

This Special Report replaces the Perspective section this week. It will return next week.



Illustration by Kevin Irby

Code Blue: Survival in the Sky

Each year an unknown number of U.S. airline passengers die of a crash or a fire, but because the medicines and equipment lives were not on board the plane. In fact, air travel in the U.S. now more likely to die of illness in flight than in a crash.

Cardiac arrest at 37,000 feet

A funeral service will be held today for Steven Paul Somes, vice president of State Street Research and Management in Boston. Mr. Somes died Wednesday of heart failure in Latter Day Saints Hospital in Salt Lake City while on a business trip. He was 37.

— OBITUARY IN THE BOSTON GLOBE

paramedic — as much medical firepower as could have been assembled by the average hospital emergency room — but not the cardiac

STEVEN SOMES wasn't on a business trip to Salt Lake City at the time of his death, nor did he die in a hospital there. At the moment his heart ceased to function, Steven Paul Somes, Phi Beta Kappa graduate of Bates College and MIT, avid sportsman and golfer, father of two young daughters, up and coming leader of the Boston financial community, was seven miles above the western slope of the Rocky Mountains, flat on his back on the floor of the first-class cabin of United Airlines Flight 37, surrounded by three physicians, a nurse and a

drugs or defibrillation equipment that might have reclaimed his life. The story of Steven Somes' death belies three of the U.S. aviation industry's fundamental convictions: that everyone who dies on an airplane is elderly or suffering from a terminal illness; that physicians who respond to in-flight medical emergencies are not likely to be well-versed in emergency medicine; and that it is always better to land an airplane than try to treat a seriously ill passenger in mid-flight.

■ STEVEN SOMES' FATAL FLIGHT, PAGE 2





September 24, 1996

Steven B. Karch, M.D.
P.O. Box 5139
Berkeley, California 94705

Ex. 8 Date 4-14-00
Witness Waring
MARGARET WALKKY

Dear Dr. Karch:

Your September 9, 1996 letter to Dr. Kohn was referred to me. First let me thank you for your willingness to assist fellow passengers and our crew members in the case of an inflight medical emergency. We appreciate your willingness to assist and your time and effort in letting us know of your concerns. We certainly hope your future travels in the Friendly Skies will be uneventful.

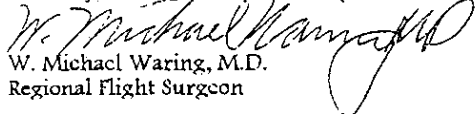
[REDACTED]

also a number of other questions and issues concerning training, etc., including what standards for training should be followed, since there are various standards/requirements for the use of AEDs in different states, etc. We are, as I said, evaluating these issues and concerns and Dr. Kohn currently has three members of his staff who are trained and practicing emergency medicine physicians reviewing our inflight medical emergencies data to determine if there are additions we should make to our supplies/equipment. We

[REDACTED]

The Emergency Medical Kits and equipment we carry aboard the aircraft meet the requirements specified by the Federal Aviation Administration (FAA.) Given the very highly competitive nature and cost constraints of the airline industry, it is unlikely that any company will make major changes in equipment carried, unless all carriers are required to make similar changes. You may wish to address your concerns also to the Office of Aviation Medicine, FAA, 800 Independence Avenue, S.W., Washington, D.C. 20591-0001.

Sincerely,


W. Michael Waring, M.D.
Regional Flight Surgeon

In Sept. 1996, Dr. Karch wrote again & got a different "canned" response

“With respect to Automatic External Defibrillators (AEDs), we are continuing to study developments and research in this area. Many of the studies showing benefit from AEDs are in settings where very rapid entry into ACLS or hospital level care follows defibrillation. This would generally not be the case in most airline operations.”

“We also closely monitor and participate in national and international medical and air transport professional groups for developments and recommendations in this area.”



UNITED AIRLINES

September 24, 1996

Steven B. Karch, M.D.
P.O. Box 5139
Berkeley, California 94705

Ex. 8 Date 4-14-96
Witness Waring
MARGARET WALKKY

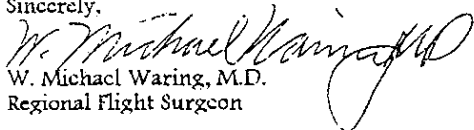
Dear Dr. Karch:

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With respect to Automatic External Defibrillators (AEDs), we are continuing to study developments and research in this area. Many of the studies showing benefit from AEDs are in settings where very rapid entry into ACLS or hospital level care follows defibrillation. This would generally not be the case in most airlines operations. There are also a number of other questions and issues concerning training, etc., including what standards for training should be followed, since there are various standards/requirements for the use of AEDs in different states, etc. We are, as I said, evaluating these issues and concerns and Dr. Kohn currently has three members of his staff who are trained and practicing emergency medicine physicians reviewing our inflight medical emergencies data to determine if there are additions we should make to our supplies/equipment. We also closely monitor and participate in national and international medical and air transport professional groups for developments and recommendations in this area.



You may wish to address your concerns also to the Office of Aviation Medicine, FAA, 800 Independence Avenue, S.W., Washington, D.C. 20591-0001.

Sincerely,

W. Michael Waring, M.D.
Regional Flight Surgeon

“The Emergency Medical Kits and equipment we carry aboard the aircraft meet the requirements specified by the Federal Aviation Administration (FAA). Given the very highly competitive nature and cost constraints of the airline industry, it is unlikely that any company will make major changes in equipment carried, unless all carriers are required to make similar changes.”

Nov 1996

- American Airlines announces it will deploy AEDs

Cost Savings v. Lives

“[D]on’t think of cost savings with this program....There [are] none. But if you want to save the lives of customers, this is what you need to do.”

*David McKenas, M.D., American Airlines’
corporate medical director*

United's Valentine to its Passengers

Feb. 14, 1998

"We've been looking at this for a number of years and decided there's very clearly medical value in it."

United's medical director

Feb. 14, 1998

"These devices aren't like in 'E.R.' where there's all these monitors and you stick paddles on someone and turn the 'juice' on. The only thing the flight attendant needs to do is to apply a couple of pads, stand back, and the machine's computer makes the decision from there."

United's medical director

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

January 30, 1998

CIVIL ACTION NO.

JAMIE E. SOMES, AS EXECUTRIX OF)
THE ESTATE OF STEVEN P. SOMES,)
Plaintiff)
)
vs.)
)
UNITED AIRLINES, INC.,)
Defendant)

COMPLAINT AND DEMAND FOR JURY TRIAL

PARTIES

1. The plaintiff, Jamie E. Somes, is a resident of Wellesley, Norfolk County, Massachusetts and is the Executrix of the Estate of her late husband, Steven Somes. She was appointed Executrix on February 22, 1996, by order of the Norfolk County Probate Court, Dedham, Massachusetts. She is duly qualified and authorized to bring this action.
2. United Airlines, Inc. ("United") is a Delaware corporation with a principal place of business in Elk Grove Township, Illinois. United is a common carrier of passengers for compensation.

March 4, 1999

“The decision to deploy [AEDs] across our entire fleet demonstrates our commitment to passenger safety and places United Airlines among an elite group of airlines dedicated to ensuring inflight passenger safety.”

United's medical director

"Even though the efficacy of the AED may not be as impressive as some advocates would have us believe, it does offer, under certain circumstances, a true life-saving measure."

Continental's Chief Flight Surgeon, June, 1999



*Senior A.M.C.
United States
United Kingdom
Australia*

*H.R. Conwell, M.A., M.D., ATTP
Civil Aviation Medicine*

*(409) 295-5222
2800 Lake Road
Huntsville, Texas USA 77340*

June 25, 1999

Captain C. D. McLean
Executive Vice President of Operations
Continental Airlines
Houston, Texas

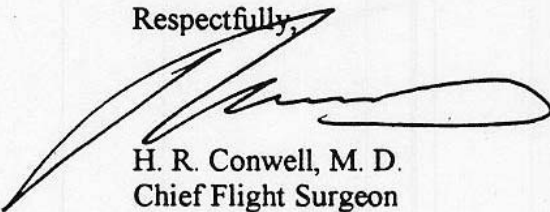
Dear Captain McLean:

Continental probably has enough information at this point to safely install Automatic External Defibrillators (AED) aboard our aircraft. There has been insufficient evidence to show the AED did not have a potential for injury to passengers requiring cardiac resuscitation aboard airliners.

Even though the efficacy of the AED may not be as impressive as some advocates would have us believe, it does offer, under certain circumstances, a true life-saving measure. CAL provides passengers with the highest level of personal safety and concern for their physical well being. An onboard AED might enhance that level of security.

Our medical service personnel will investigate each manufacturer of this product to assure we have the most reliable and advanced device available.

Respectfully,



H. R. Conwell, M. D.
Chief Flight Surgeon

hrc:mac

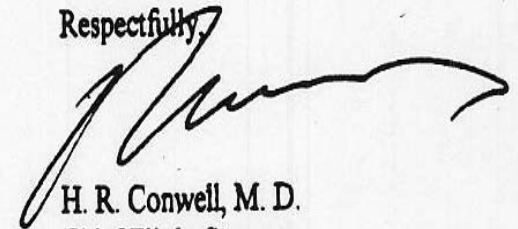
"There is total agreement in governmental agencies and airlines that this is a **cost ineffective operation....**"

Continental's Chief Flight Surgeon, Sept. 1999

During my visit with their marketing and sales personnel, Heartstream agreed to place, at no cost, their automatic external defibrillator (AED) in our corporate headquarters. They also are willing to make significant concessions in the usual and customary cost of their training syllabus. These accommodations amount to a package worth several thousand dollars.

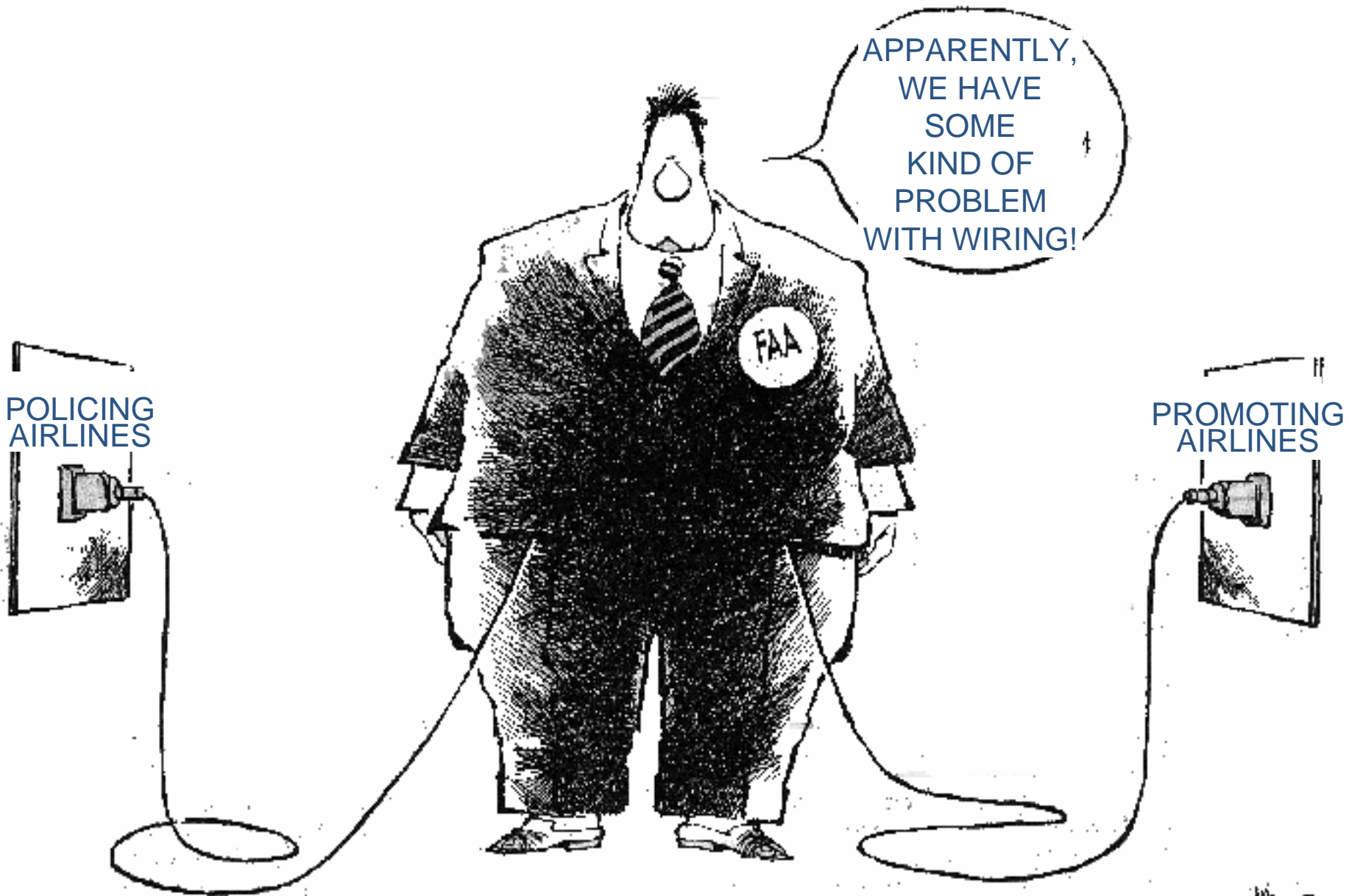
The Company is aware of my concerns regarding the precipitous manner and lack of solid information that could affect passengers' well being at the time this entire aircraft-based defibrillator program was initiated. There is total agreement in governmental agencies and airlines that this is a cost ineffective operation, so it is important we get the best quality and effective measures for our passengers on our first try. That means durable, reliable electronic equipment with ease of maintenance and flight crews who are not overwhelmed by the complexity of their training and will feel assured of their competency in the use of this device.

Respectfully,



H. R. Conwell, M. D.
Chief Flight Surgeon

cc: Jun Tsuruta
George Mason
Wendy Wade
✓ Connie Ridgeway
Pat Clayborne



Ben Bond

June 6, 2001: A New Man

“United always takes the extra step to provide customers and employees with added medical safety and service,” says [United’s medical director], who cites the airline’s leadership in installing [AEDs] and training flight attendants in their use...”

www.UAL.com, June 6, 2001

Resources

- AED legislation by state:
www.aedhelp.com/legal/legislation_states.cfm
- National Center for Early Defibrillation: www.early-defib.org
- The National Immunity/Good Samaritan Law Database and National EMS Info Exchange: www.naemt.org/nemsie/immunity.htm
- Safety Services Network: www.aedinfo.com
- National Conference of State Legislatures:
www.ncsl.org/programs/health/aed.htm
- Aufdeheide, Tom et al., "Community Lay Rescuer Automated External Defibrillation Programs..." *Circulation*; Jan 16, 2006
- England, Hannah et al., "The Automated External Defibrillator: Clinical Benefits and Legal Liability" *JAMA*; Feb 8, 2006: Vol. 295, No. 6