Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

Dear Medical Device Classification Officer:

I am writing as a healthcare professional to encourage you to reclassify Automatic External Defibrillators (AEDs) from Class III to Class II, as a medical device. I understand that this reclassification will allow AEDs to reach the American market more quickly, but with reasonable safeguards for pre-marketing testing and assurance that they will function properly. My own interests in AEDs stem from my involvement for the last 15 years under the American Heart Association, and the National Heart Lung and Blood Institute auspices in the development, testing of AEDs for public use (see CV and papers). I was President of the American Heart Association in 1990. I chaired a taskforce of the American Heart Association that championed covering AEDs by the Good Samaritan Laws, and allowing advancement of AEDs through the FDA Regulatory System as "prescription device" to be placed in the hands of non-professionals for use during cardiac arrest. References to papers published by the task force include:


I have had no personal revenue, grant support or other financial relationship including stock ownership with any AED manufacturers.

As well, I have been involved as a member of the steering committee and as a liaison officer in the development, conduct and creation of the Public Access Defibrillation study which was recently reported as initial results at the meeting of the American College of Cardiology in March. This study documented that with non-physician, non-professional lay volunteers, the presence of AEDs in public places can result in twice the survival rate compared to sites where AEDs are not present (and CPR is instructed). These results along with the results in airports, casinos and other places where individuals are trained to have a duty to respond show a very dramatic benefit of these devices. It is certainly my belief and the belief of many health professionals that these devices over the next several years will be broadly distributed in public buildings, as well as in many homes and residences where there are patients with cardiac disease. I do believe that the FDA re-classifying these devices would be of help to the industry and to the straightforward development of better and easier to use devices as new resuscitation science and clinical trial results indicate.

I support reclassification of AEDs to Class II based on a review and knowledge of the record of error-free operations of these devices, the literature, my clinical experience and safeguards currently in place to address potential risk. The record is nearly serious risk-free for their use. I am convinced by my knowledge and experience that risk and adverse events are rare and minimal compared to the clinical benefit they provide.

Thank you for the opportunity to share my views.

Sincerely,

Myron L. Weisfeldt, M.D.
William Osler Professor of Medicine

Enclosure: Curriculum Vitae of Myron L. Weisfeldt, M.D.
Curriculum Vitae
The Johns Hopkins University School of Medicine

Signature: Myron L. Weisfeldt, M.D.
Date 01/08/04

DEMOGRAPHIC INFORMATION

Current Appointments:
- William Osler Professor of Medicine
- Director, Department of Medicine, Johns Hopkins University School of Medicine
- Physician-in-Chief, Johns Hopkins Hospital
- Director of Medicine, Johns Hopkins Medicine

Personal Data:
Office Information: Johns Hopkins University School of Medicine
Department of Medicine
1830 E. Monument Street, Room 9026
Baltimore, MD 21287
Phone: 410-955-6642
Fax: 410-614-8510
e-mail: mlw5@jhu.edu

Home Information:

Date of Birth: April 25, 1940
Married:
Children:

Education and Training:
- 1954-1958 Whitefish Bay High School
  Milwaukee, Wisconsin
1958-1960 Northwestern University  
   Evanston, Illinois

1960-1962 Johns Hopkins University, Baltimore, MD  
   B. A. (Accelerated Program)

1962-1965 Johns Hopkins Medical School, Baltimore, MD  
   M. D.

1963-1964 Post-Sophomore Fellow  
   Laboratory of Cardiovascular Physiology  
   (Dr. Stanley Sarnoff)  
   National Institutes of Health  
   Bethesda, MD

1965-1967 Intern & Assistant Resident in Medicine  
   Columbia Presbyterian Medical Center, New York, NY

1967-1969 Clinical Associate  
   U. S. Public Health Service  
   National Institutes of Health  
   Gerontology Research Center  
   Baltimore, MD

1969-1970 Senior Assistant Resident in Medicine  
   Massachusetts General Hospital  
   Boston, MA

1970-1972 Clinical & Research Fellow in Cardiology  
   Massachusetts General Hospital  
   Boston, MA

**Professional Experience:**

1972-1975 Assistant Professor of Medicine  
   Johns Hopkins University School of Medicine  
   Baltimore, MD

1972-1991 Director, Peter Belfer Laboratory for  
   Myocardial Research  
   Johns Hopkins University School of Medicine  
   Baltimore, MD
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<th>Year(s)</th>
<th>Position</th>
<th>Institution/Department</th>
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<td>1972-1977</td>
<td>Assistant Physician</td>
<td>Johns Hopkins Hospital</td>
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<td>Baltimore, MD</td>
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<td>1972-1977</td>
<td>Guest Investigator</td>
<td>National Institutes of Aging</td>
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<td>National Institute of Child Health &amp; Human Development</td>
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<td>1974-1975</td>
<td>Established Investigator</td>
<td>American Heart Association</td>
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<tr>
<td>1977-1991</td>
<td>Active Staff Physician</td>
<td>Johns Hopkins Hospital</td>
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<td>Baltimore, MD</td>
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<tr>
<td>1975-1978</td>
<td>Associate Professor of Medicine</td>
<td>Johns Hopkins University School of Medicine</td>
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<td>Baltimore, MD</td>
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<tr>
<td>1975-1991</td>
<td>Director, Cardiology Division</td>
<td>Johns Hopkins University School of Medicine</td>
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<tr>
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<td>Baltimore, MD</td>
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<tr>
<td>1976-1991</td>
<td>Member, Principal Staff</td>
<td>The Johns Hopkins Applied Physics Laboratory</td>
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<tr>
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<td>Laurel, MD</td>
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<tr>
<td>1977-1991</td>
<td>Director, Ischemic Heart Disease</td>
<td>Specialized Center of Research (SCOR)</td>
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<tr>
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<td>National Heart, Lung, and Blood Institute</td>
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<td>1978-1991</td>
<td>Professor of Medicine</td>
<td>Johns Hopkins University School of Medicine</td>
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<tr>
<td>1979-1991</td>
<td>Robert L. Levy Professor of Cardiology</td>
<td>Johns Hopkins University School of Medicine</td>
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<tr>
<td>1991-2001</td>
<td>Samuel Bard Professor of Medicine</td>
<td>Chair, Department of Medicine</td>
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<td>Columbia University - College of Physicians &amp; Surgeons</td>
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<td>Director, Medical Service</td>
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<td>Columbia-Presbyterian Campus</td>
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<tr>
<td></td>
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<td>New York Presbyterian Hospital</td>
</tr>
</tbody>
</table>
RESEARCH ACTIVITIES:

Publications:


**Books, Sections, Reviews, Editorials and Other**


Inventions, Patents, Copyrights (pending, awarded):

Patents:

09/09/83 Patent #4397306 - "Integrated system for cardiopulmonary resuscitation and circulation support." Weisfeldt ML, Tsitlik JE, Chandra NC.


Extramural Sponsorship/Major Grant Support

1973-1991 Ischemic Heart Disease (SCOR) Grant National Heart, Lung, and Blood Institute
1977-1991 Principal Investigator
Funded to 1995
1975-1991 Institutional National Heart, Lung, and Blood Institute Training Grant
Principal Investigator
Funded to 1996
1993-1997 Markey Foundation; Principal Investigator: "Career Tracks Toward Excellence in Basic Research." $2.0 million MD/Ph.D. post doctoral training grant.

EDUCATIONAL ACTIVITIES
Editorial Board Appointments:

1975-1981  *Journal of Molecular and Cellular Cardiology*
            *(Journal of Clinical Investigation)*
1987-1989  *Journal of Molecular and Cellular Cardiology*
1978-1981  *Circulation*
1981-1983  *American Journal of Cardiology*
1982-1984  *Journal of Cardiovascular Ultrasonography*
1983-1993  *Circulation*
1993-       *Circulation*, Consulting Editor
1985-1994  *Circulation Research*
1987-1992  *Journal of American College of Cardiology*
1990-1992  Editorial Advisory Board: *Internal Medicine News*
1991-       *American Journal of Geriatric Cardiology*

**CLINICAL ACTIVITIES**

**Certification:** United States:
- Maryland - 1965
- Massachusetts - 1970
- New York - 1991

**ORGANIZATIONAL ACTIVITIES**

Institutional Administrative Appointments (committees, dates):

**Johns Hopkins Medical School Committees:**

1975-1991  Executive Committee, Department of Medicine
1978-1980  Promotions Committee, Department of Medicine
1979-1985  Member, Professorial Promotions Committee
1981-1985  Chairman, Professorial Promotions Committee
1990-1991  Member, Advisory Board

**Johns Hopkins Applied Physics Laboratory:**

1981-1991  Chairman, Frank T. McClure Fellowship Program
Columbia-Presbyterian Medical Center Appointments:

1991-2001  Medical Board of Presbyterian Hospital
1998-2001  Executive Committee of the Medical Board
1994-2001  Voting Member, Faculty Council of the Faculty of Medicine
1994-2001  President, Columbia-Presbyterian Physicians Network (CPPN)
1996-1997  Acting co-CEO and President of Columbia-Cornell Care, LLC and MSO, Inc.
1996-2000  Vice Chair, Policy Board of Columbia-Cornell Care, LLC and MSO, Inc.

National Institutes of Health:

1979-1983  Research Review Committee - Cardiovascular Program Project
          National Heart, Lung and Blood Institute
1986-1990  Cardiology Advisory Board
          National Heart, Lung and Blood Institute
1987-1990  Chairman, Cardiology Advisory Board
          National Heart, Lung and Blood Institute
1994-1995  Chairman, Parent Committee on the Heart Disease SCOR
          National Heart, Lung and Blood Institute
1994-1998  Member, Board of Scientific Counselors, National Institute on Aging
1998-2000  Advisory Committee to NIH Director on Intramural Program, NHLBI
1999-2003  Member, National Advisory Council, National Institute on Aging
2000      Vice-Chairman, GPRA Assessment Working Group of the Advisory Committee to the Director, National Institutes of Health
2000      Co-Chair PULSE Working Group and Workshop on Resuscitation Research
2001      Chairman, GPRA Assessment Working Group of the Advisory Committee to the Director, National Institutes of Health

Institute of Medicine:

1996      Elected member
2001      Committee on Stem Cell Research and the Promise of Regenerative Medicine
American Heart Association:

1989-1990  President, AHA (National)
1976-1979  Member-at-Large, Executive Committee
           Council on Basic Science
1982-1985  Member-at-Large, Executive Committee
           Council on Basic Science
1977-1985  Member, Board of Directors, Maryland
           Chapter and/or Affiliate
1978-1980  Representative, Basic Science Council to Program Committee,
           Scientific Sessions
1982-1985  Chairman, Katz Prize Committee, Basic Science Council
1984-1987  Member-at-Large, Board of Directors, Steering Committee
1988-1989  President-Elect, AHA (National)
1992       Award of Merit recipient
1993-1995  Chairman, International Program Committee
1993-1997  Chairman, Task Force on External Cardiac Defibrillation
1995-1996  Chairman, Conflict of Interest Review Committee
1998       Gold Heart Award, American Heart Association
2001       Task Force on Automatic External Defibrillators

Foundation Appointments:

           Planning Committee, "Conference on Challenges to Medical
           Education" New York 1993 and "Conference on the Financing of
           Medical Education in the Era of Health Reform" Bermuda, 1994

1994       New York Academy of Sciences, New York
           Conference Planning Committee, "Excellence and the Future of
           Health Care, Public Health, and Biomedical Science"

           Chairman, Grants Monitoring Program,
Professional Societies (membership, committees, dates, role):

1962  Phi Beta Kappa
1965  Alpha Omega Alpha
1969  American Society for Clinical Research
1972  Gerontological Society
1974  American Physiological Society
1975  Cardiac Muscle Society
1975  American Heart Association
1977  Basic Science Council
1989  Circulation Council
1989  Clinical Cardiology
1977  International Society for Heart Research
1977  Fellow, American College of Cardiology
1977  Association of University Cardiologists
1977  American Society for Clinical Investigation
1982  Interurban Clinical Club
1988  Association of American Physicians
1989-1992 Member, Academic/Scientific - Technion's
      International Board of Governors Haifa, Israel
1991  Fellow, American Association for Advancement of Science
1992  Fellow, New York Academy of Medicine
1992  New York Cardiological Society, Inc. Board of Directors
1992  Association of Professors of Medicine
1993-1994 New York Cardiological Society, Inc., Chairman, Program Committee
1994-1996 Member of the New York State Council on Graduate Medical Education
1994  Fellow, The New York Academy of Sciences
1995  Fellow, American College of Physicians
Consultantships (organization/agency, date, role):

1993- Cambridge Heart, Inc., Boston, MA., Scientific Advisory Board
1999-2001 KBL Ventures Fund Scientific Advisory Board
1999- CHF Solutions (Intelicardia, Inc.), Chairman, Scientific Advisory Board
2000 Paramount Venture Fund
2000- Institute Of Medicine, Committee on Stem Cell Research
2001 MPM Capital Investment in Healthcare Innovation

RECOGNITION

Awards:

2003 Diversity Recognition Award

Visiting Professorships and Lectureships

1979 Pennsylvania State University, Hershey, PA
University of Texas Southwestern at Dallas, Dallas, TX
Case Western Reserve, Cleveland, OH
Guest Faculty Spring Cardiovascular Symposium
Duke University, Durham, NC

1980 University of Chicago, Chicago, IL
Queens University, Kingston, Ontario, Canada
John R. Sampson Visiting Professorship
University of California, San Francisco, CA
Vanderbilt University, Nashville, TN

1981 University of Pennsylvania, Philadelphia, PA
University of Connecticut, Hartford, CT
Albert Einstein College of Medicine, Bronx, NY
Cornell University, New York, NY
Case Western Reserve, Cleveland, OH
1982
· University of Alabama, Birmingham, AL
  University of Kansas, Kansas City, KS
  University of Iowa, Iowa City, IA

  University of Michigan, Ann Arbor, MI
  Canadian Heart Foundation Lectureship

1983
  Harvard University (Beth Israel Hospital), Boston, MA
  Understein Memorial Lecture, George Washington University
  John Kent Lewis Lectureship, Stanford University, Stanford, CA
  Texas College of Osteopathic Medicine, Ft. Worth, TX

1984
  University of Chicago, Chicago, IL
  Boston University, Boston, MA
  Keynote Speaker: Japanese Circulation Society, Japan
  State University of New York at Stony Brook

1985
  University of Alabama at Birmingham
  Kirsh Memorial Lecturer: Sinai Hospital of Baltimore
  Plenary Address: World Congress of Critical Care Medicine
  Jerusalem, Israel

1986
  American Federation for Clinical Research - Frontiers of
  Science Lectureship - "Reperfusion and Reperfusion Injury"
  Washington, D.C.
  Xth World Congress of Cardiology - Geriatric Cardiology
  Washington, D.C.
  American Heart Association - State of the Art Lecture
  "Role of Free Radicals and Inflammatory Mediators"
  Dallas, TX
  American Heart Association - Plenary Lecture -
  "New Concepts of CPR" Dallas, TX

1987
  J. Gerald Mudd Lecture - St Louis University
  Medical School, St. Louis, MO
  Neuton Stern Visiting Professor - University of Tennessee
  College of Medicine, Memphis, TN
  Teaching Fellowships - Rochester General Hospital Association
  Rochester, NY
  Visiting Scientist - Polish People's Republic - Instytut of
  Kardiologii - Warsaw - Sponsored by National Institutes of Health
  14th Annual Arvilla Berger Lecture - The New York Cardiological
  Society - NY
1988  Lawrence H. Green Lecture - Brigham & Women's Hospital, Boston, MA
       Hamilton Southworth Lecture - College of Physicians & Surgeons, Columbia University, New York, NY

1989  Hans Hecht Lecturer - University of Chicago
       Duke Heart Center Lecturer - Duke University, Durham, NC
       Invited Speaker - Interamerican Congress of Cardiology, Rio de Janeiro, Brazil

1990  First Robert Neely Lecturer - Weis Research Institute
       Louis Sudler Lectureship in Cardiology - Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL

1991  John S. Lawrence Visiting Professor of Medicine, UCLA
       Borun Visiting Professor and Lecturer - UCLA
       Second Calabresi Lectureship - Yale University School of Medicine

1992  Keynote Speaker - National CPR Standards Conference, American Heart Assn
       First Nahum J. Winer Lecture in Cardiovascular Disease. New York Academy of Medicine, New York

1993  R.T. Hall Lecturer, 41st Annual Scientific meeting, The Cardiac Society of Australia & New Zealand, Christchurch, New Zealand
       First Myron Belfer Lecturer, Johns Hopkins Medical School, Baltimore, MD

1994  State University of New York Health Science Center at Brooklyn, Brooklyn, NY
       Visiting Professor of Medicine, Massachusetts General Hospital, Boston, MA
       Sixth Lawrence Hicks Memorial Lecture, Northwestern University Medical School, Chicago, IL
       James V. Warren Memorial Lecturer and Visiting Professor, Ohio State Univ., Columbus, OH
       32nd Hugo Roesler Memorial Lecture, Temple University School of Medicine, Philadelphia, PA
       Sixth Annual Thomas E. O'Brien M.D. Memorial Lecture Award for Excellence in Medicine, Fairfax, VA
       Keynote speaker AHA Conference on Public Access Defibrillation, American Heart Association, Washington, DC
<table>
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<tr>
<th>Year</th>
<th>Institution Details</th>
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</table>
| 1995 | University of Iowa, Iowa City, IO  
Brown University, Providence, Rhode Island  
Medical College of Virginia, Richmond, VA |
| 1996 | Riven Visiting Professor, Vanderbilt University, Nashville, TN  
University of Texas at Houston, TX |
| 1997 | Ross Kyger Jr., M.D. Visiting Professor, University of Pennsylvania |
| 1998 | Emory University School of Medicine, Visiting Professor of Cardiology  
University of Pennsylvania, Visiting Professor  
University of Wisconsin, Malcomb Rodgers lecturer  
American College of Legal Medicine, Keynote Speaker |
| 1999 | Ohio State University, Visiting Professor |
| 2000 | University of Maryland, Visiting Professor  
Albert Einstein Medical Center, Grand Rounds Speaker  
Columbia University Deans Distinguished Lectureship in the Clinical Sciences |
| 2001 | University of Minnesota, Jay Cohen Lecturer  
Dickenson Richards Lecture, American Heart Association Scientific Sessions  
Case Western Reserve University, Visiting Professor |
| 2002 | St. Agnes Health Care, Grand Rounds Speaker  
University of Maryland, Visiting Professor  
Sinai Hospital of Baltimore, Grand Rounds Speaker  
University of Maryland, Grand Rounds Speaker  
Robert Wood Johnson Medical School, Grand Rounds Speaker |
| 2003 | Montefiore Medical Center, Grand Rounds Speaker  
Mercy Medical Center, Grand Rounds Speaker |