Defending the Rights of All Americans

Advancing Resuscitation Research for the Nation

Presented by

Paul E. Pepe, MD, MPH, FCCM, FACEP

Professor of Surgery, Medicine, Public Health

& Riggs Family Chair in Emergency Medicine

University of Texas Southwestern Medical Center and the Parkland Health and Hospital System

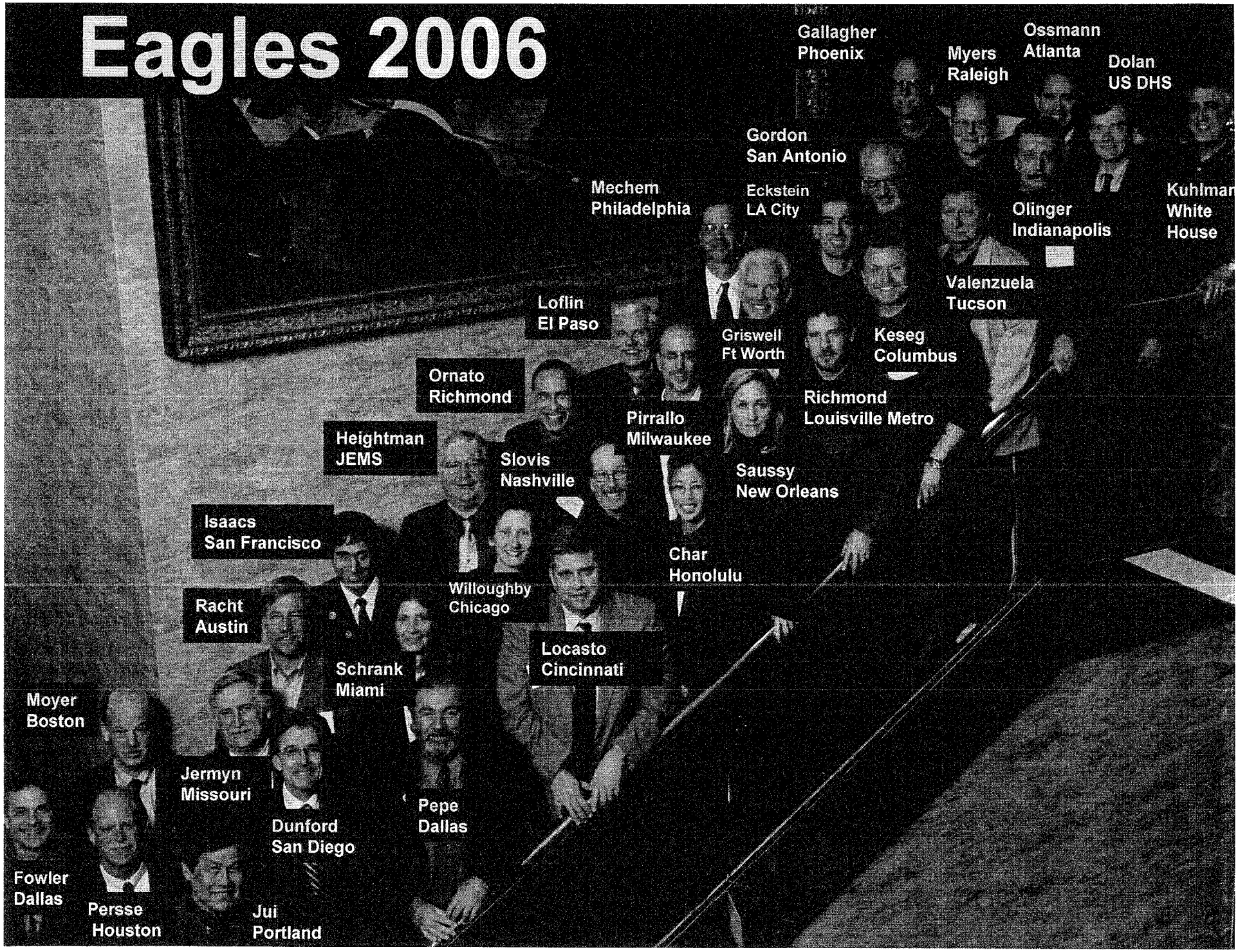
Director, City of Dallas Medical Emergency Medical Services for Public Safety, Public Health and Homeland Security

DALLAS, U.S.A.

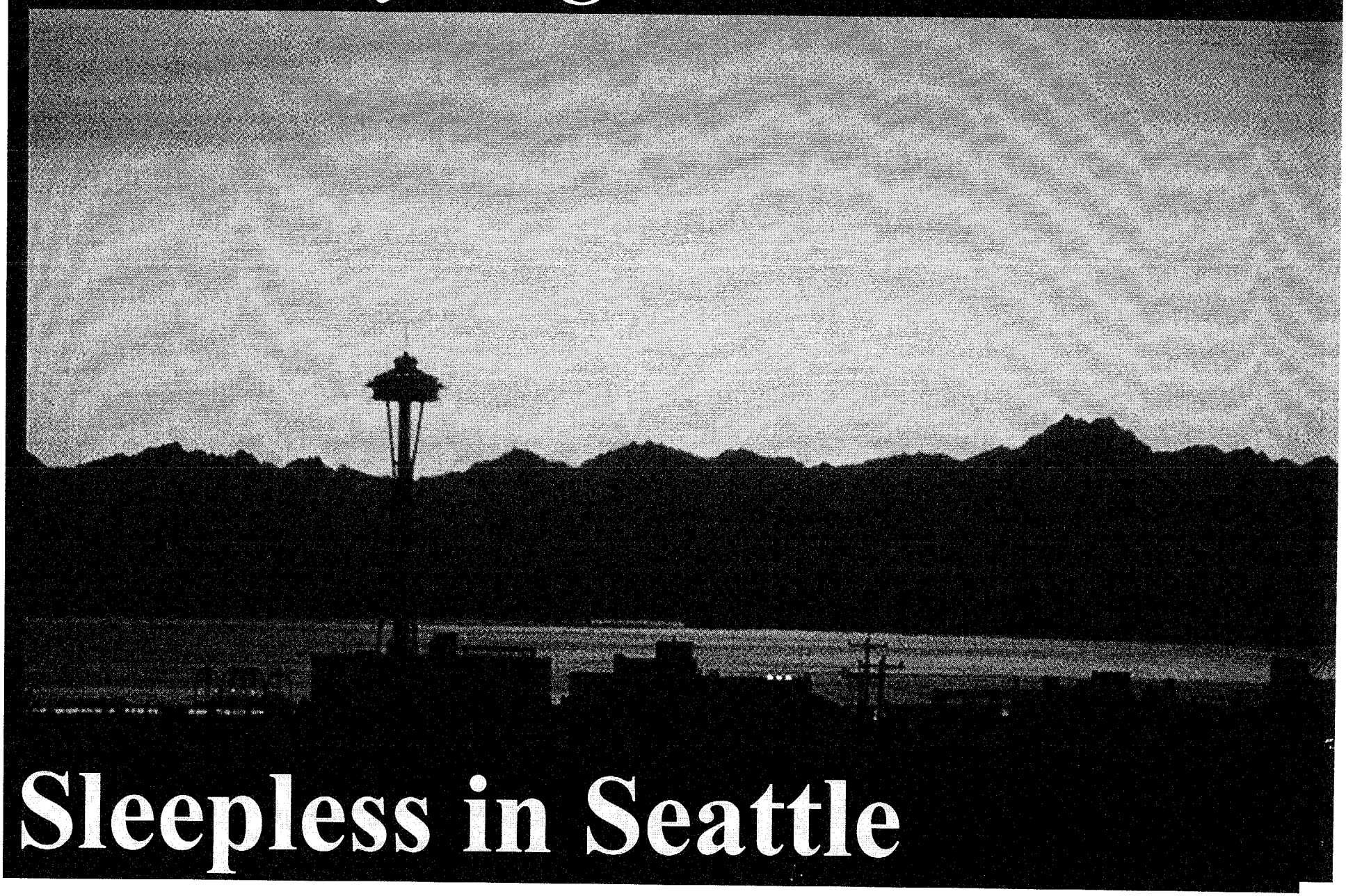
Representing....

U.S. Metropolitan 9-1-1 EMS System Medical Directors Consortium

a.k.a. "the Eagles" Coalition


Eagles 2006
Gallagher
Phoenix
Myers
Raleigh
Ossmann
Atlanta
Dolan
US DHS
Gordon
San Antonio
Mechem
Philadelphia
Eckstein
LA City
Olinger
Indianapolis
Kuhlman
White
House
Valenzuela
Tucson
Loflin
El Paso
Griswell
Ft Worth
Keseg
Columbus
Ornato
Richmond
Richmond
Louisville Metro
Pirrallo
Milwaukee
Heightman
JEMS
Slovis
Nashville
Saussy
New Orleans
Isaacs
San Francisco
Char
Honolulu
Willoughby
Chicago
Racht
Austin
Locasto
Cincinnati
Schrank
Miami
Moyer
Boston
Jermyn
Missouri
Pepe
Dallas
Dunford
San Diego
Fowler
Dallas
Persse
Houston
Jui
Portland

Our Story Begins...



Sleepless in Seattle

Even More Sleepless in Houston !

Now in Dallas and Part of the NIH ROC ...

The U.S. National Institutes of Health
Resuscitation Outcomes Consortium

National Heart, Lung, and Blood Institute

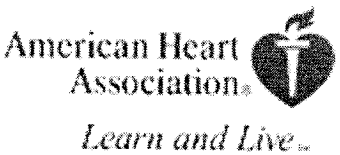
National Institute for Neurological Disorders and Stroke

Canadian Institutes of Health Research

U.S. Department of Defense

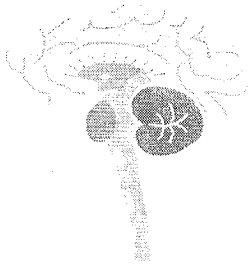
Defence Research and Development Canada

American Heart Association



Heart and Stroke Foundation of Canada

Cognitive Roadmap



At the end of this session, you should understand that…

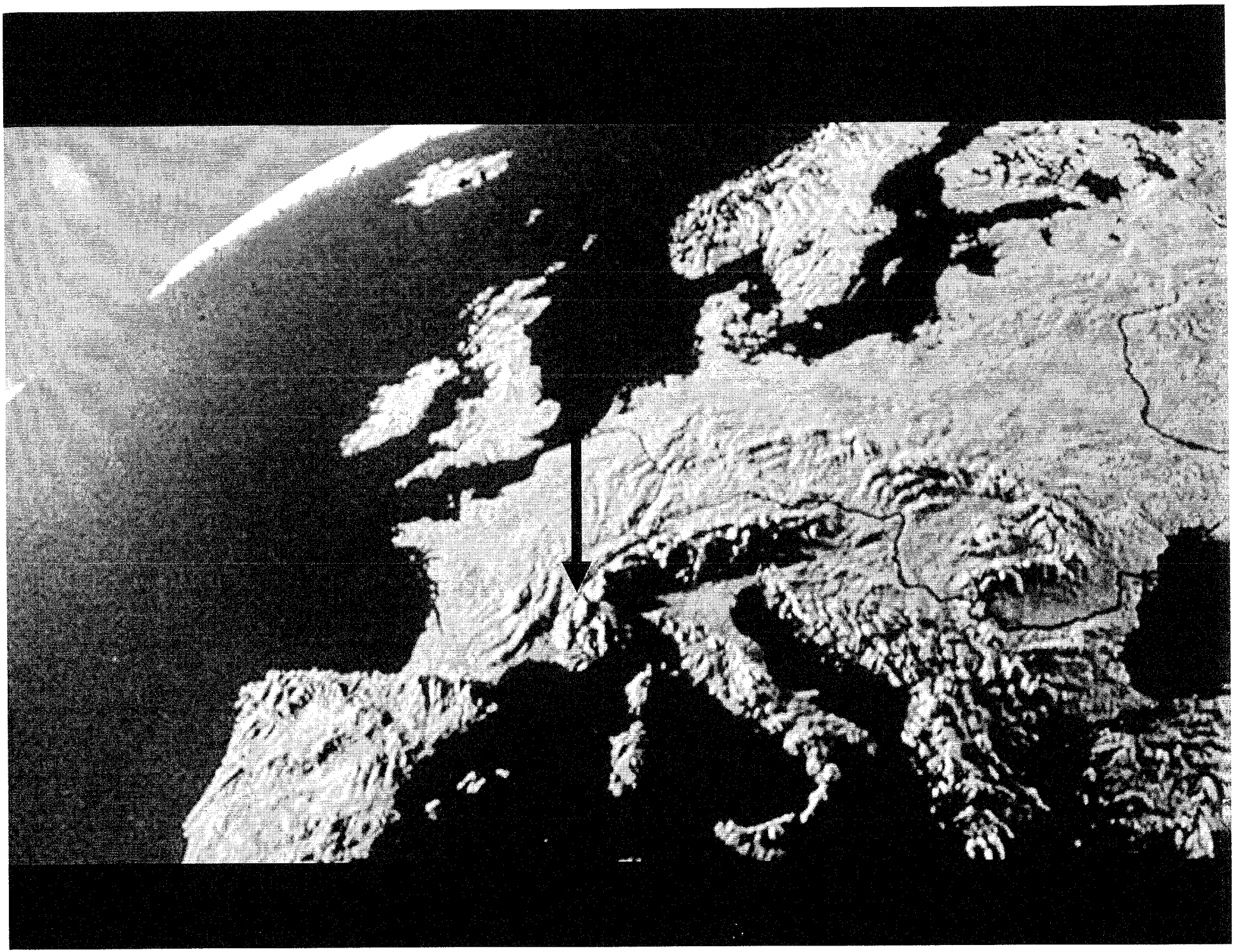
- **Exception to Consent Concept is Absolutely Crucial for Americans**
- **Many Currently-Accepted Treatment Plans are Empiric and May Even Be Harmful**
- **Even FDA-Approved Interventions Have Not Been Confirmed as Life-Saving**
- **Millions of American Families Denied their Right to the Most Advanced Care;**
- **Hundreds of Thousands Have Needlessly Lost Their Lives as a Result of Inaction**

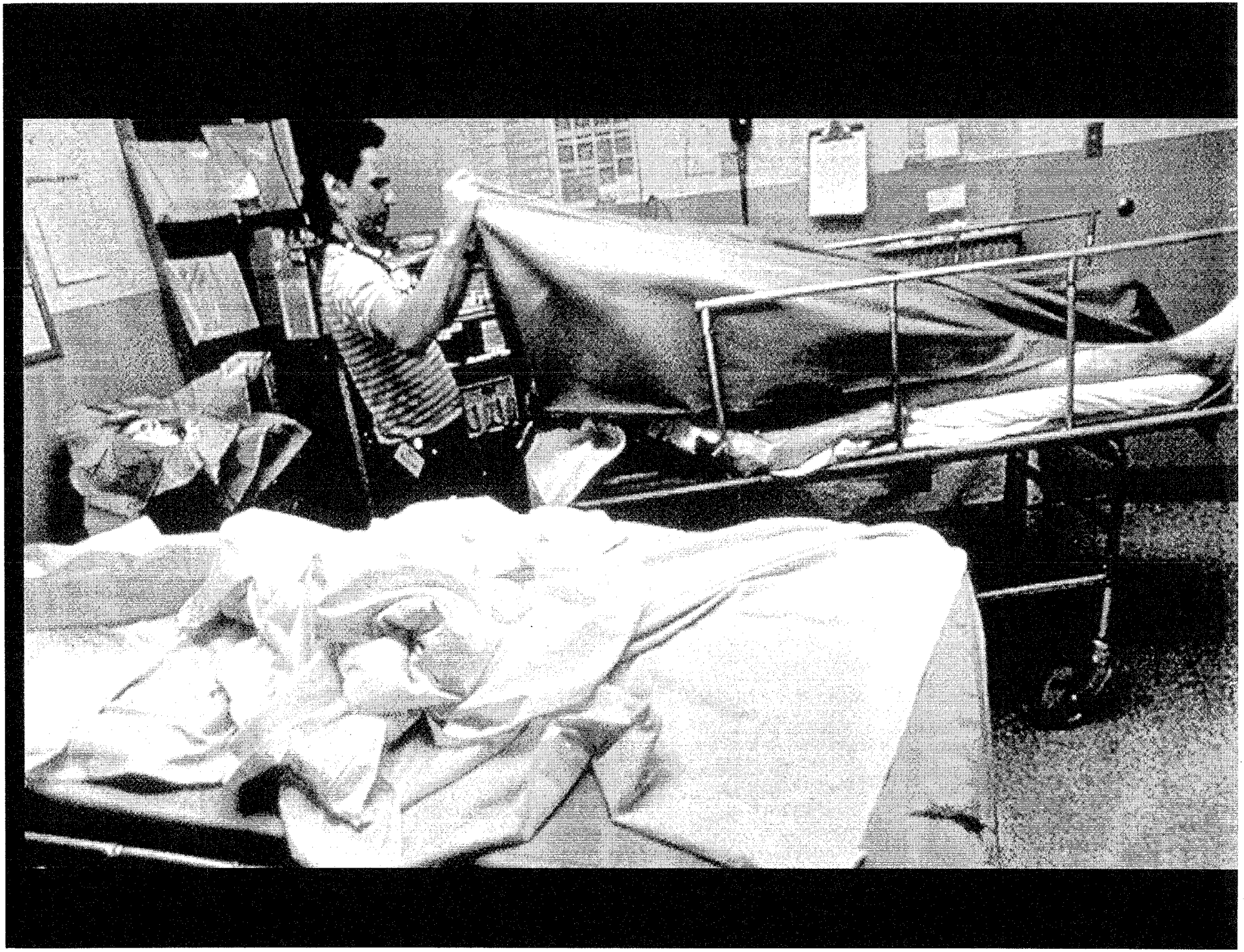
Cognitive Roadmap

(cont.)

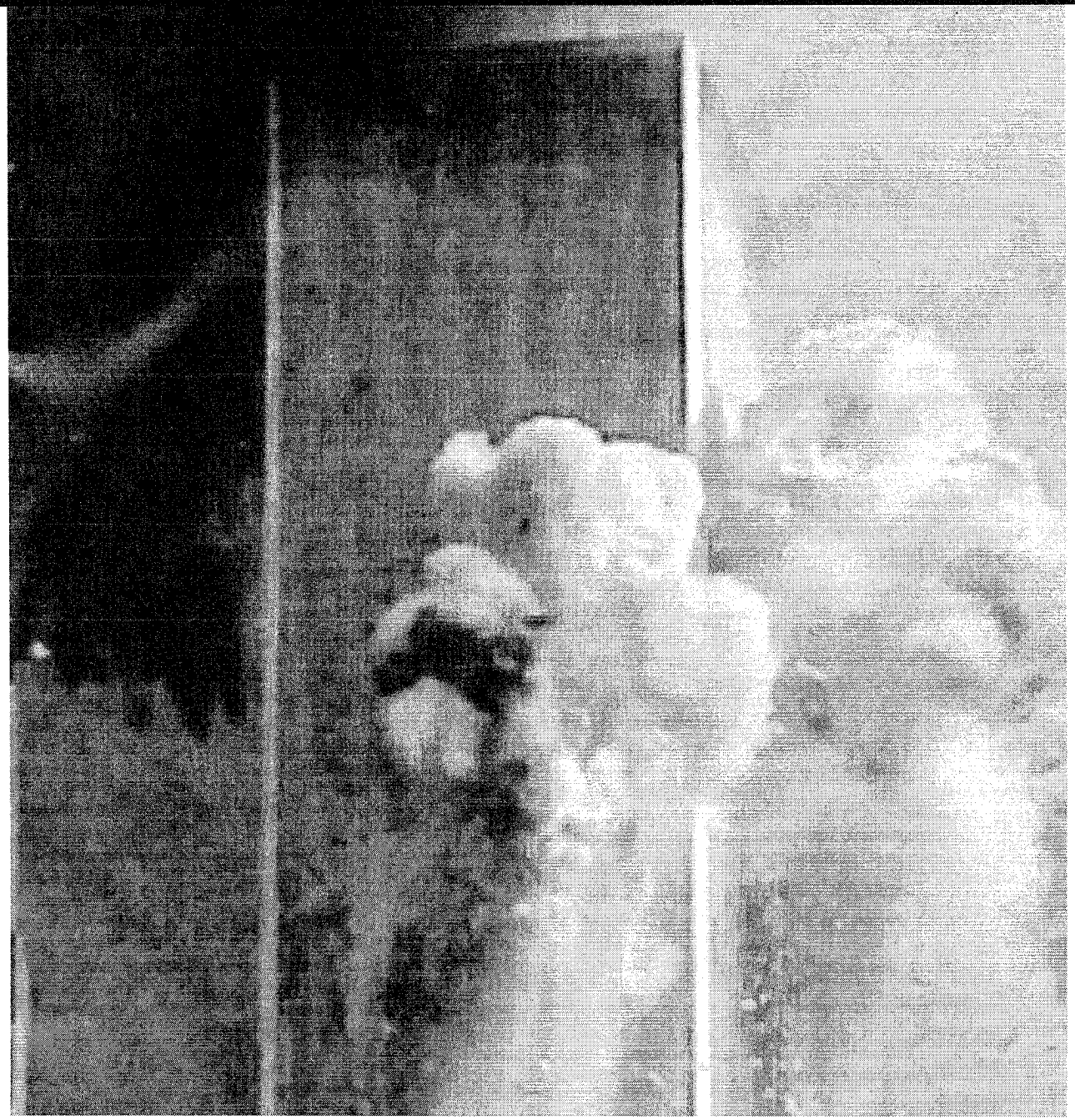
- Community Consultation Concept is Sound, But Has Certain Limitations
- Funding Has to be Provided
- The Need to Re-Focus on Key Targets
- The Need to Adopt a New Perspective as Stewards of the Public Trust

Why Exception to Informed Consent is Crucial to Americans and Our Future Generations





…and There's Also the Risk of Terrorist Events

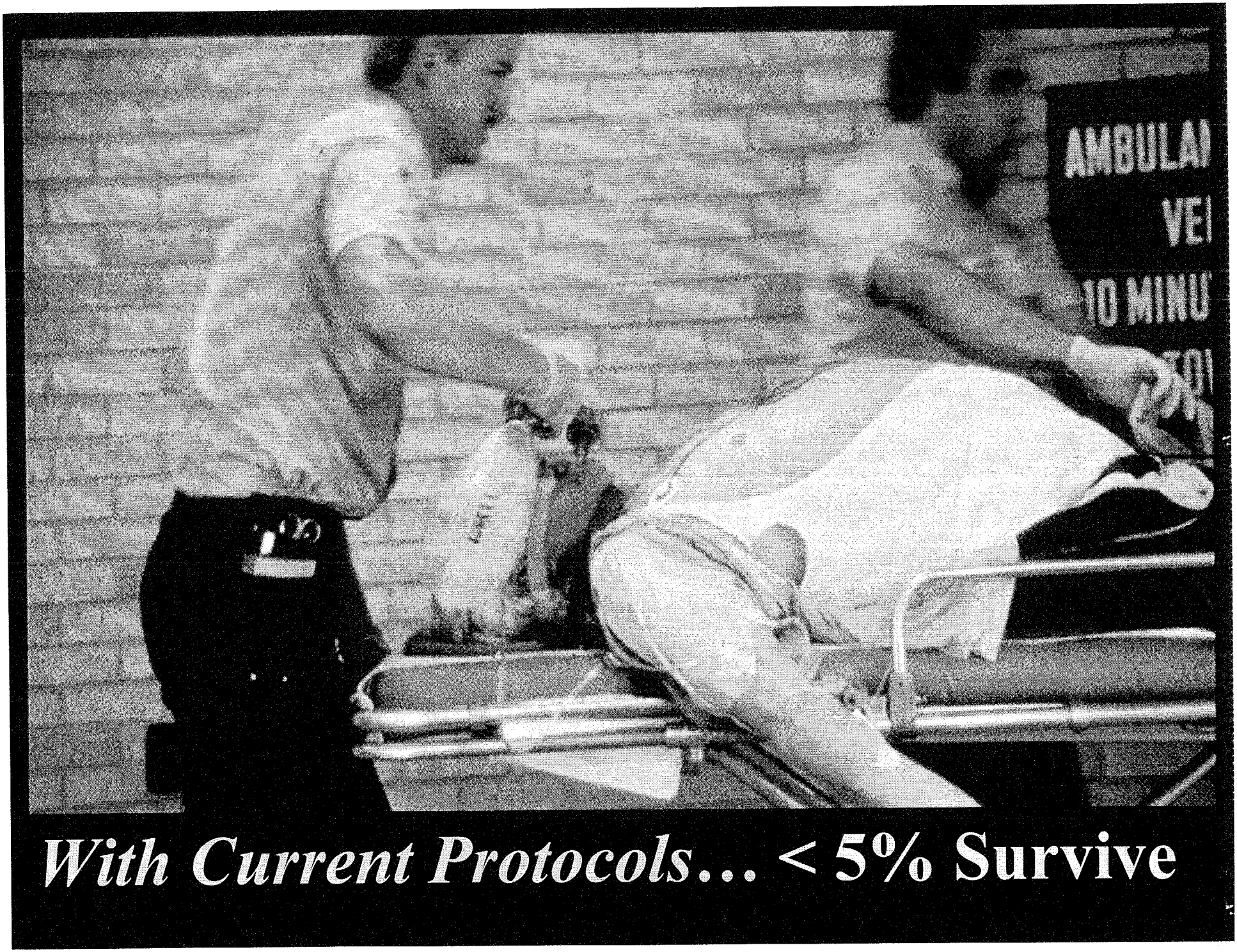


London Bombings July 2005

Likewise ...

Sudden Out-of-Hospital Cardiac Arrest

... Due to Ventricular Fibrillation



With Current Protocols… < 5% Survive

But ...

The Life-saving Potential is Tremendous

Automated External Defibrillator (AED) Studies

(e.g., the Chicago Airport Study)

Chicago Airport

1st Year of Study of Public AED Deployment

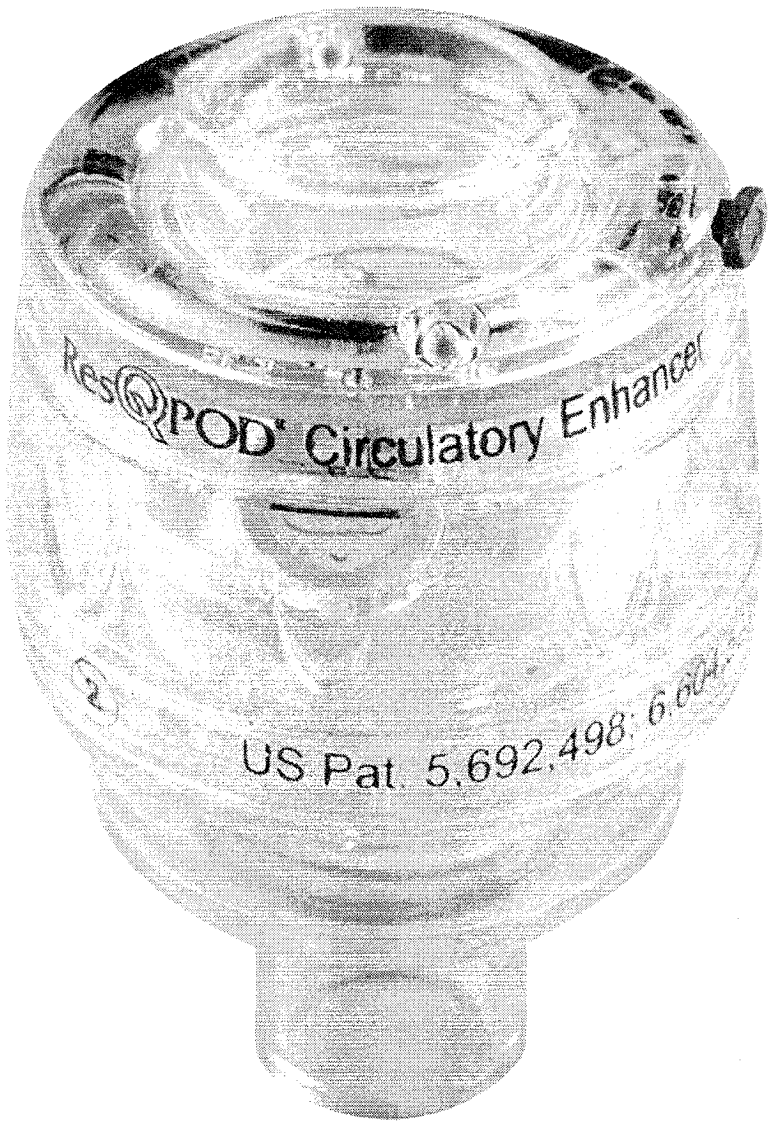
Of the 9 VF Cases in the Terminal Concourses and Ticket Counters...

- ***100% Were Saved***
- ***Most Waking Before EMS Arrived***
- ***Spared Precious ICU Resources ($$)***
- ***6 Rescuers Never Trained on AEDs***

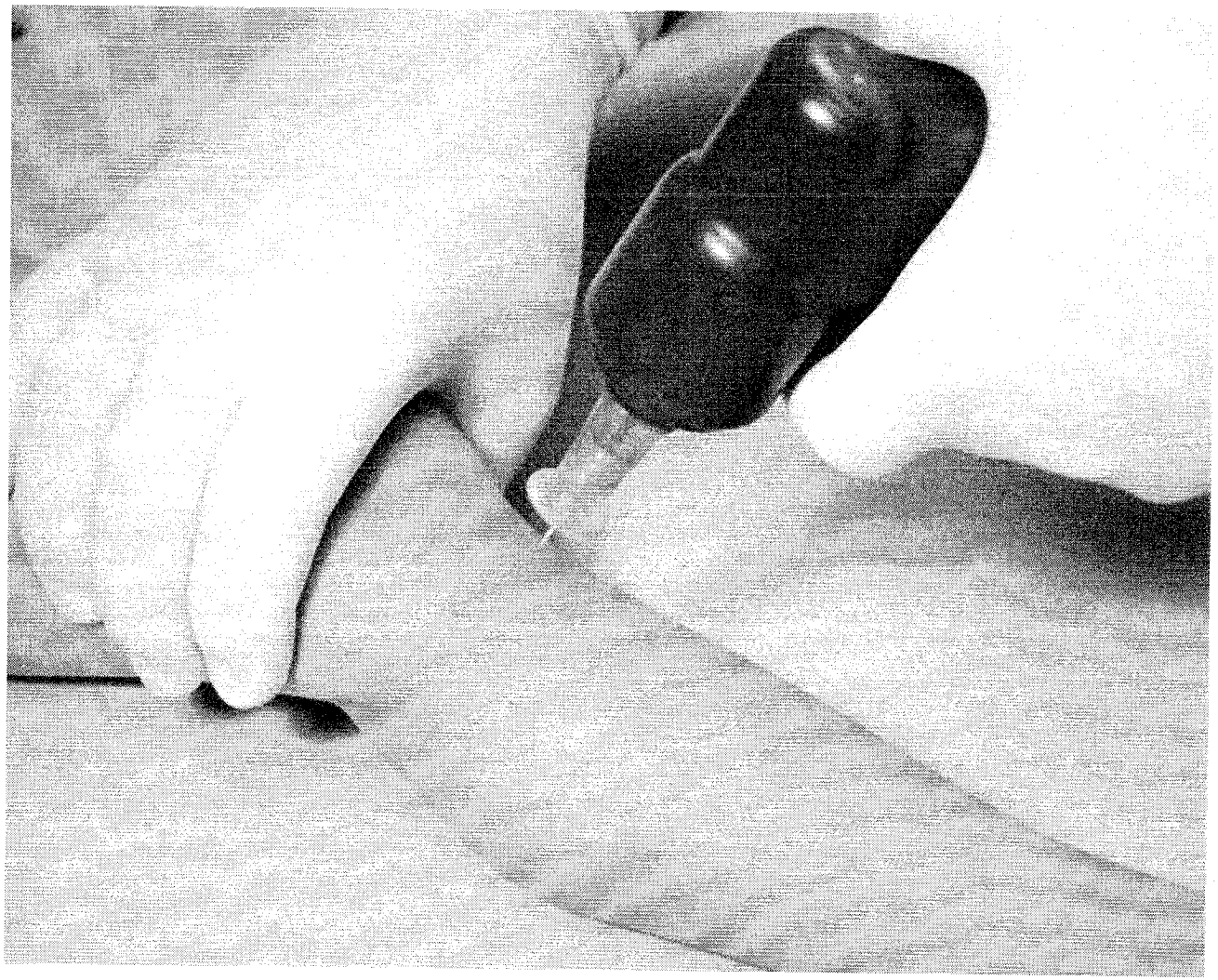
Nevertheless ...

- **AEDs Not Usually Available**
- **Many Cardiac Arrests Unwitnessed**
- **Many Arrests Not "Shockable"**
- **Life-Saving Devices Still Unvalidated**
- **Even Those "FDA-Approved"**

Impedance Threshold Device



EZ-IO (intraosseous infusion)



The Problems...

- **Even FDA-Approved Interventions Have Not Been Confirmed as Life-Saving**
- **Many Currently-Accepted Treatment Plans are Empiric and May Even Be Harmful**
- **Hundreds of Thousands of Americans Have Lost Their Lives as a Result of Inaction**

Widely-Accepted Standards of Care....

...Such as IV Fluid Resuscitation

No Clear Advantage Demonstrated ...

The New England
Journal of Medicine

©Copyright, 1994 by the Massachusetts Medical Society

Volume 331 OCTOBER 27, 1994 Number 17

IMMEDIATE VERSUS DELAYED FLUID RESUSCITATION FOR HYPOTENSIVE PATIENTS WITH PENETRATING TORSO INJURIES

WILLIAM H. BICKELL, M.D., MATTHEW J. WALL, JR., M.D., PAUL E. PEPE, M.D., R. RUSSELL MARTIN, M.D., VICTORIA F. GINGER, M.S.N., MARY K. ALLEN, B.A., AND KENNETH L. MATTOX, M.D.

Abstract *Background.* Fluid resuscitation may be detrimental when given before bleeding is controlled in patients with trauma. The purpose of this study was to determine the effects of delaying fluid resuscitation until the time of operative intervention in hypotensive patients with

Results. Among the 289 patients who received delayed fluid resuscitation, 203 (70 percent) survived and were discharged from the hospital, as compared with 193 of the 309 patients (62 percent) who received immediate fluid resuscitation ($P = 0.04$). The mean estimated intra-

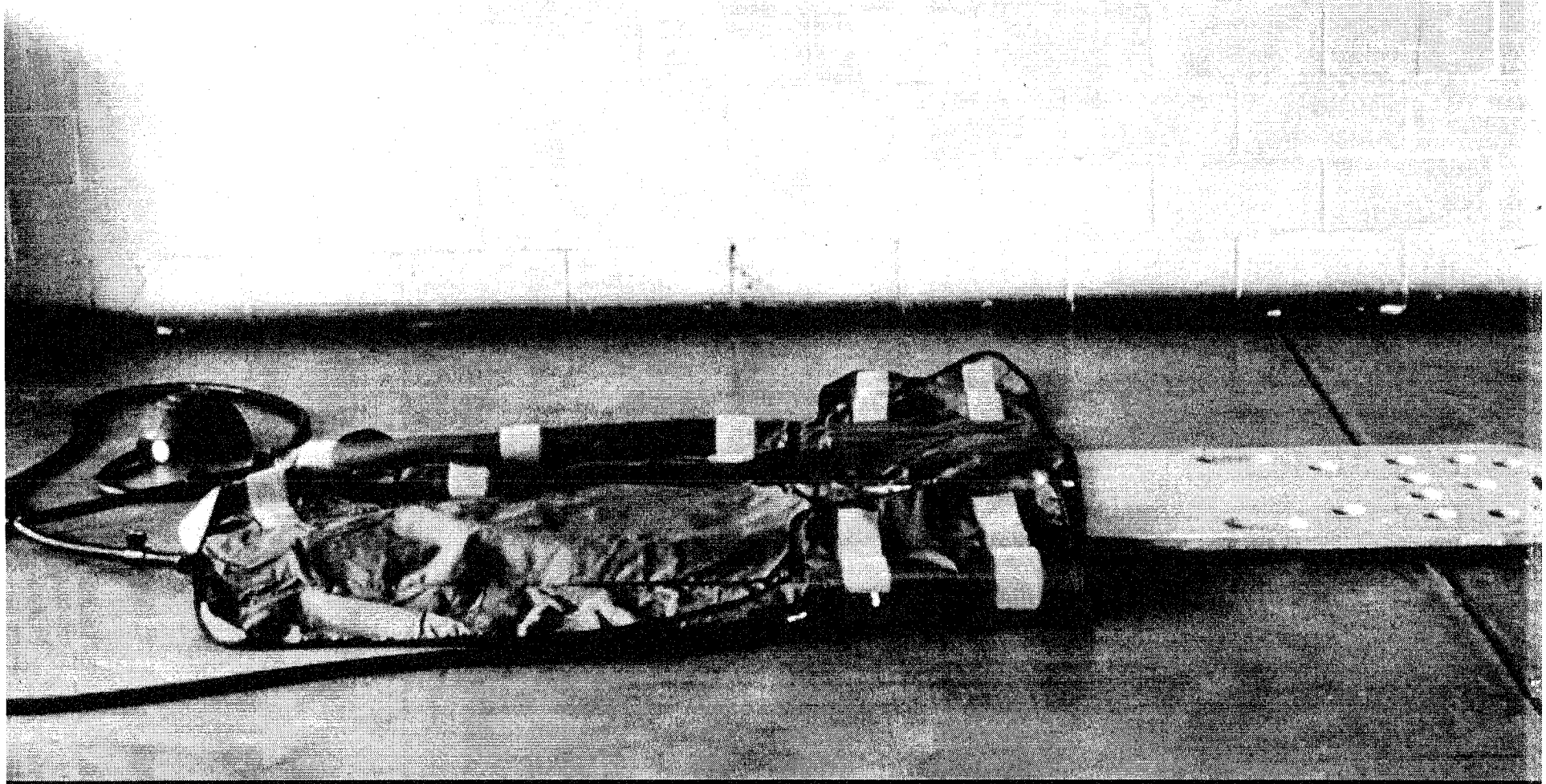
....And Possibly Harmful in Cases of Uncontrolled Hemorrhage

RESEARCH

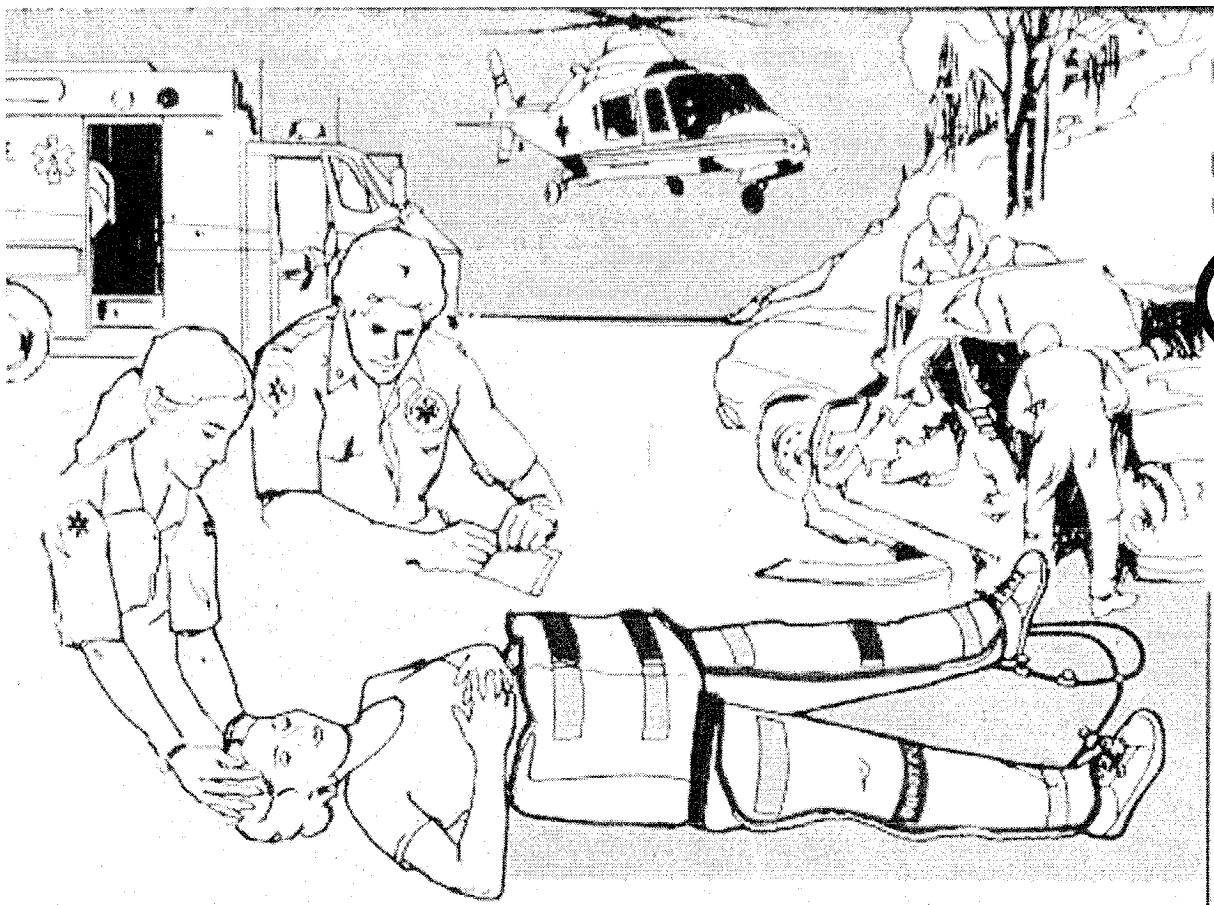
= “RE - SEARCH”

More Impressively ...

Medical Anti-Shock Trousers (MAST)...



...Required in Two-Thirds of the States



MAST®

(MEDICAL ANTI-SHOCK TROUSERS)

CONTROL SHOCK... SAVE LIVES

The MAST® (Medical Anti-Shock Trousers) can:

- Control or Reverse Shock
- Provide Rapid Autotransfusion
- Check Trauma

MAST® (developed by the David Clark Company, Inc.) is the first, the original Medical Anti-Shock Trouser:

- Fast...Applied in 60 Seconds

MAST® is used in:

- Accidents, Trauma, Surgery, In Patient and ICU
- Emergency Rooms

Also available: the Toddler-mast will fit a toddler within the ages of two to four years, and Pedi-mast will fit children in a size range between 46"-58" in height

mast® III-A

FEATURES:

- Automatic Relief Valves
- Removable Air Chambers
- Field Maintainable

mast® III-AT
TRANSPARENT

FEATURES: Same as MAST® III-A and AM
PLUS:

- Facilitates Examination Allows You To...
- Observe the Injury
- Monitor Skin Condition
- Easy Access to Femoral Artery

mast® III-AM
MODULAR

FEATURES: Same as MAST® III-A
PLUS:

- Easy Access to Femoral Artery

Patent No. 3933150 & Patent Pending

MAST® is the Registered Trademark of the:

David Clark COMPA
INCORPORA

360 Franklin Street, Worcester, MA 01

Improved Outcomes

- **Baseline Survival of 50%**
- **MAST Group Had 69%**
- **Control Group Had 78%**

Survival Advantages of Being in the Study Outweighed the Study Outcome Differences!

Improved Outcomes

- Closer Scrutiny of Care Given
- Reinforcement of Standardized Performance and Procedures
- Improved Survival for Both Control and Study Groups

Tens of Thousands of Lives Saved from Such Methodical Work

...A Matter of Public Trust

Actually, Most Members of the Public…

…Not Aware of Day-to-Day Protocols

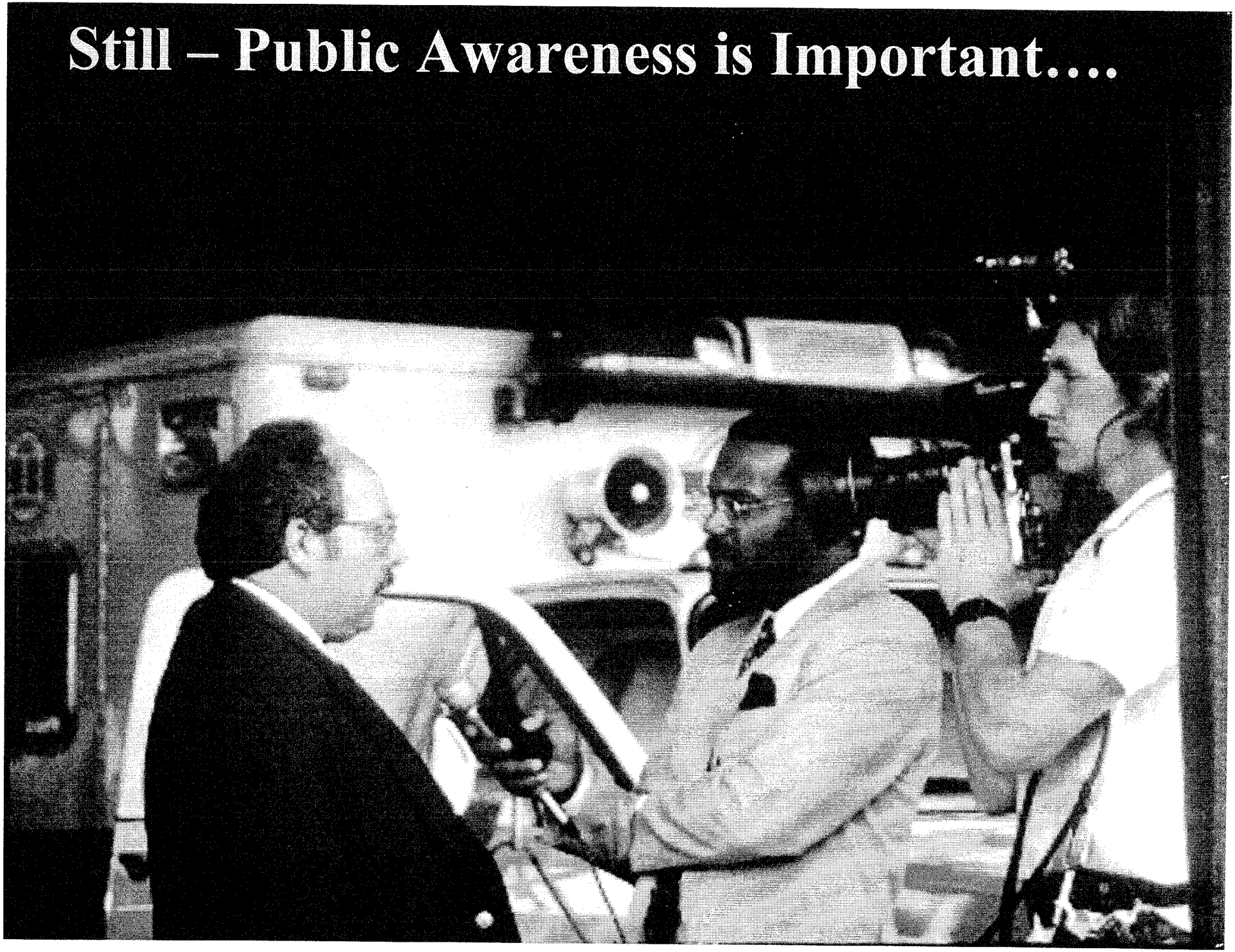
Concept of Implied Consent....

...Meeting Public Expectations

Scientific Protocols More Straightforward

Standardized Approach Known Ahead of Time

Still – Public Awareness is Important....



Community Consultaton...

Community Consultation

- **Community Consultation Concept is Sound, But Current Rules Cause Limitations**
- **Need to Re-Focus on Certain Key Targets**
- **Need Prospective Relationships with Media, Politicians, Health Officials & Physicians**
- **Also, Inspirational, Empowerment of EMS Personnel and Medical Community**

$$$ is an Issue

(so what's new !! ?)

Community Consultation

- **Q # 1 – IRB *Interpretation* of Current Rules May Lead to Unachievable and Unnecessary Disclosure**
- **Q # 6 – Need to Emphasize that Minorities and Other Underserved Groups Benefit the Most from this Work**
- **Q # 7 – Should Focus on Mass Media in All Languages and Use Their Internet Links and Maintain Updates**
- **Q # 7 – Should Focus on Other Public Advocates Such as Elected Officials**

Q # 8

Can Persons Opt out of Day-to –Day Trauma Care or Vaccinations and Other Public Health Protocols ?

Community Consultation

(Comments Cont.)

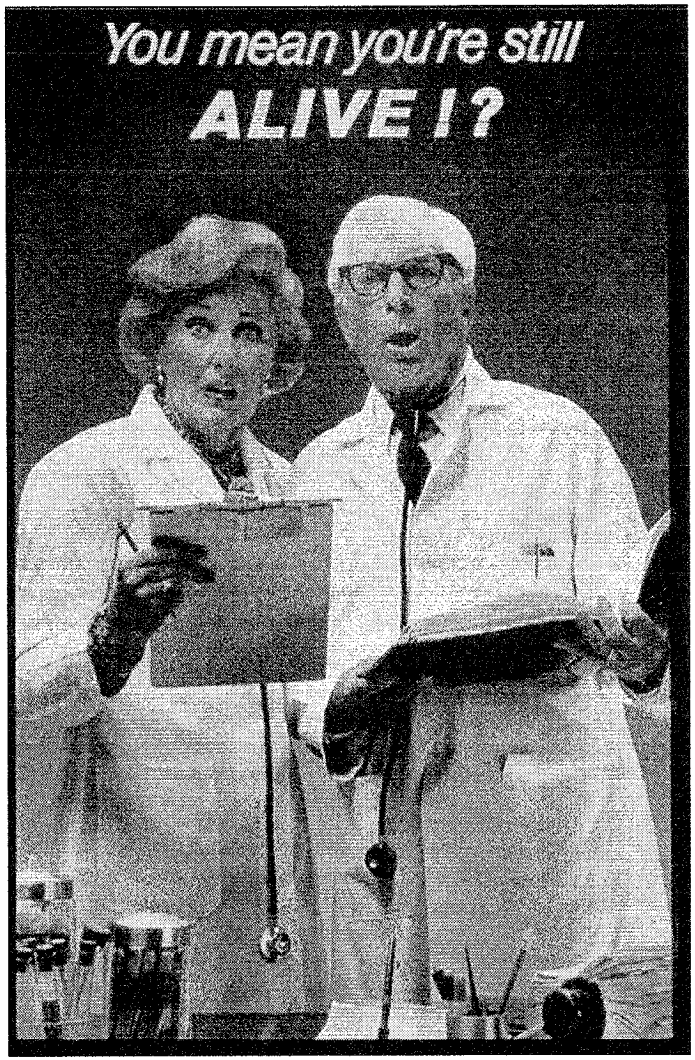
- **Q # 18 – A Community Consultation Committee be Established Including News Directors / News Managers, Elected and Health Officials, Medical Society Representatives, Care Providers and Host of Others That Have All Been Briefed**

- **Q # 18 – Meeting Location Should Be Neutral and Media Announcements Should Be Done Through the Medical Community Teamed with Various Stakeholders and "Persons on the Street"**

In Summary...

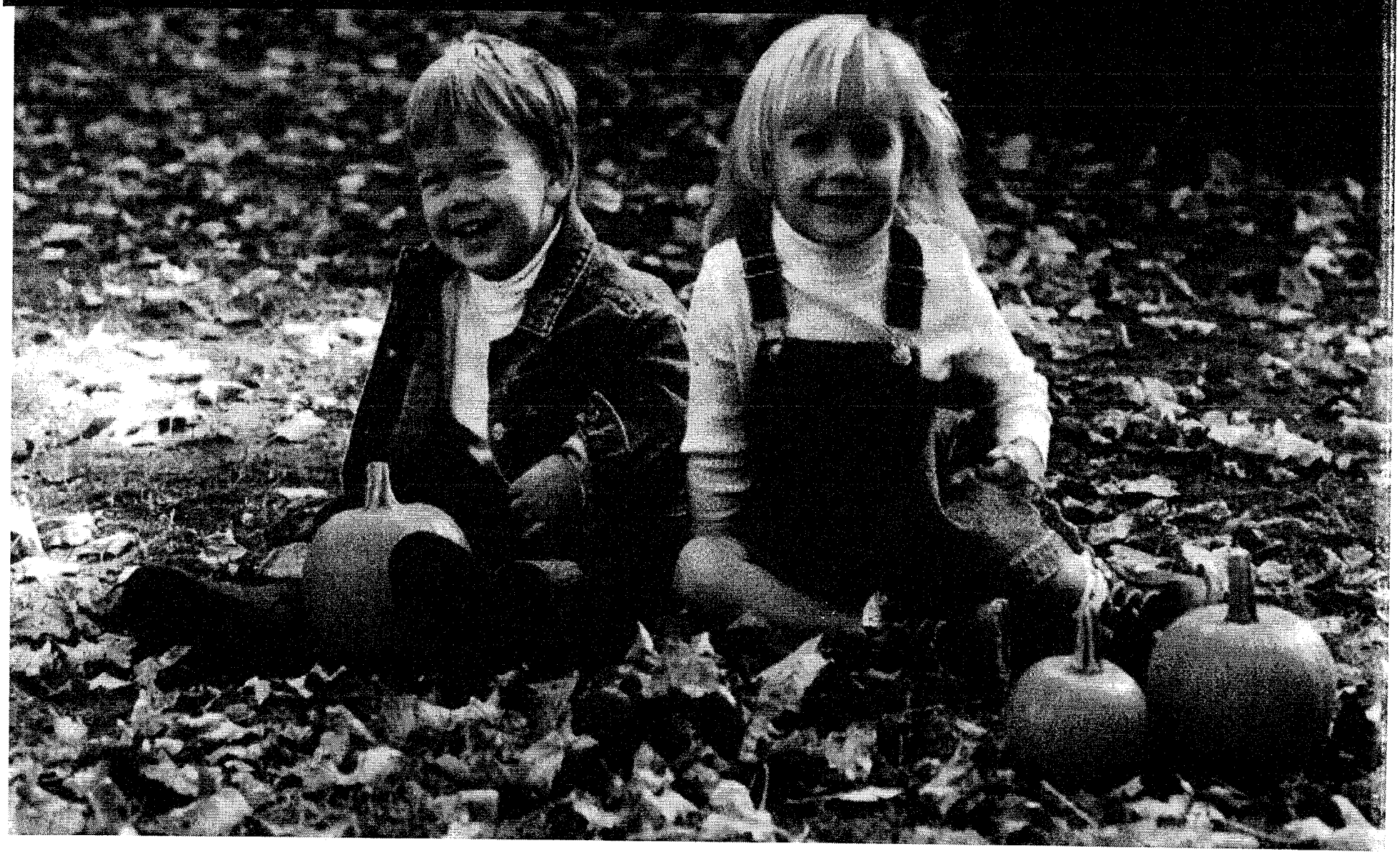
Current Rules More Than Adequate and Can Be Simplified

Resuscitation Research Should Be Facilitated…



On the Road to the 22nd Century...

We'll Make Life Better for Future Generations ....

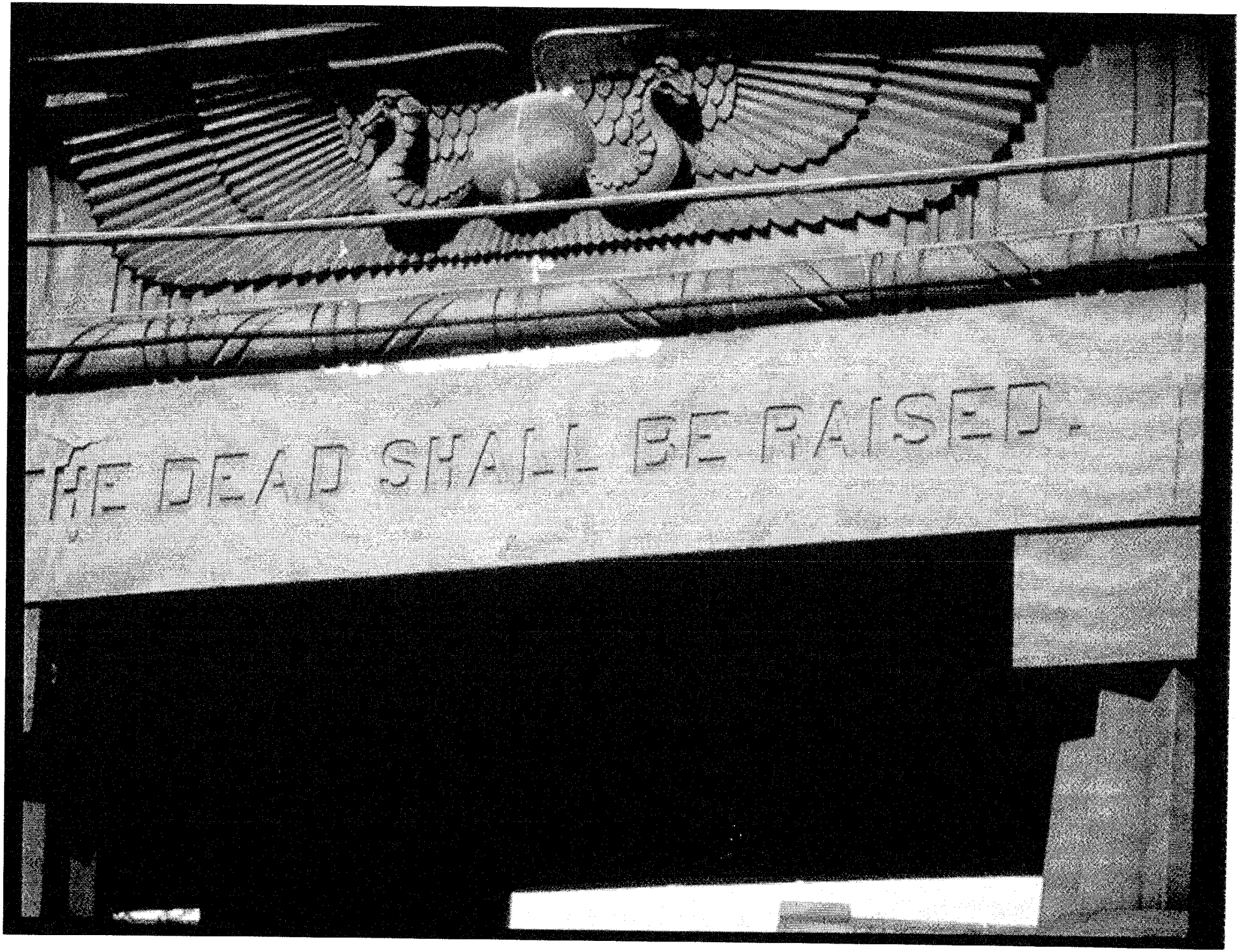


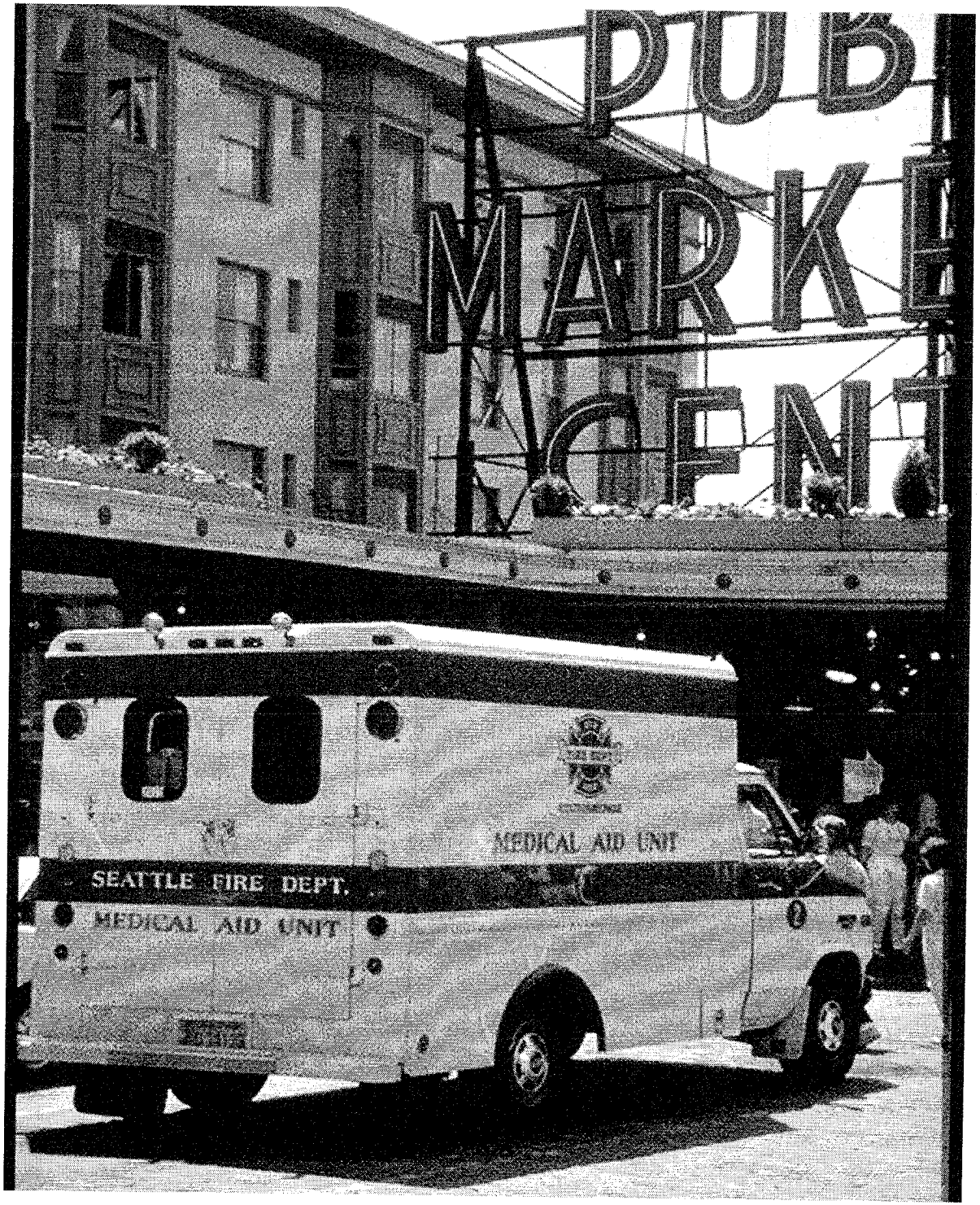
That's "Thanks a Million" -- *After Indirects*

THE END

Sen. Charles Grassley

(R – Iowa)

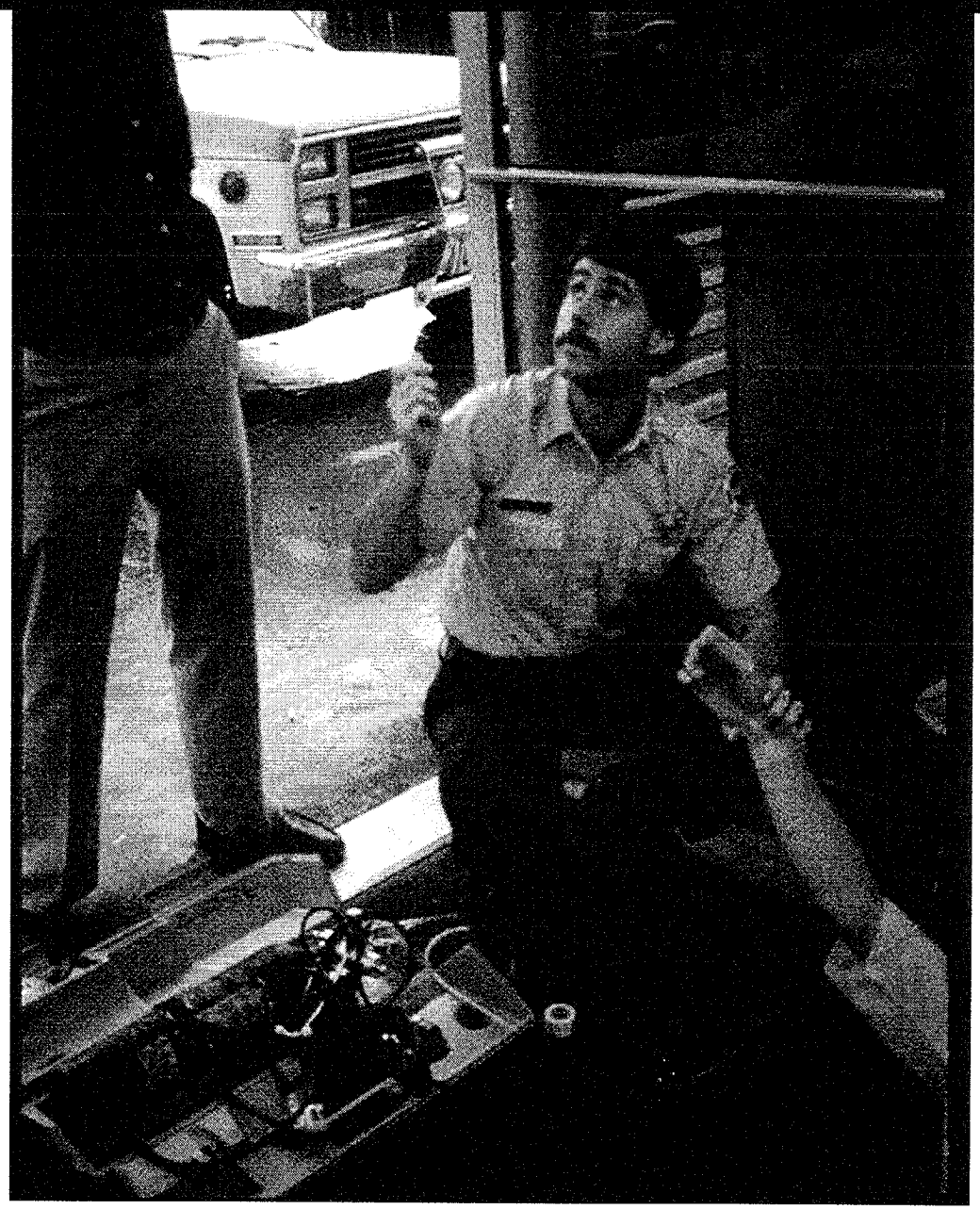

THE DEAD SHALL BE RAISED.


PUB
MARKE
MEDICAL AID UNIT
SEATTLE FIRE DEPT.
MEDICAL AID UNIT

Can Out-of-Hospital Resuscitation Research Really be Done?

- *Uncontrolled Setting*
- *Paramedics Not "Scientists"*
- *Difficulties with Consent and Data Collection*

Well, In Fact...



EMS Personnel

- Paramilitary in Nature
- Protocols Meticulously Followed
- Limited Scope of Practice
- Experienced at Resuscitations
- Better Compliance

The New England
Journal of Medicine

©Copyright, 1994, by the Massachusetts Medical Society

Volume 331 OCTOBER 27, 1994 Number 17

IMMEDIATE VERSUS DELAYED FLUID RESUSCITATION FOR HYPOTENSIVE PATIENTS WITH PENETRATING TORSO INJURIES

William H. Bickell, M.D., Matthew J. Wall, Jr., M.D., Paul E. Pepe, M.D., R. Russell Martin, M.D., Victoria F. Ginger, M.S.N., Mary K. Allen, B.A., and Kenneth L. Mattox, M.D.

Abstract *Background.* Fluid resuscitation may be detrimental when given before bleeding is controlled in patients with trauma. The purpose of this study was to determine the effects of delaying fluid resuscitation until the time of operative intervention in hypotensive patients with penetrating injuries to the torso.

Methods. We conducted a prospective trial comparing immediate and delayed fluid resuscitation in 598 adults with penetrating torso injuries who presented with a prehospital systolic blood pressure <90 mm Hg. The study setting was a city with a single centralized system of prehospital emergency care and a single receiving facility for patients with major trauma. Patients assigned to the immediate-resuscitation group received standard fluid re-

Results. Among the 289 patients who received delayed fluid resuscitation, 203 (70 percent) survived and were discharged from the hospital, as compared with 193 of the 309 patients (62 percent) who received immediate fluid resuscitation ($P = 0.04$). The mean estimated intraoperative blood loss was similar in the two groups. Among the 238 patients in the delayed-resuscitation group who survived to the postoperative period, 55 (23 percent) had one or more complications (adult respiratory distress syndrome, sepsis syndrome, acute renal failure, coagulopathy, wound infection, and pneumonia), as compared with 69 of the 227 patients (30 percent) in the immediate-resuscitation group ($P = 0.08$). The duration of hospitalization was shorter in the delayed-resuscitation group.

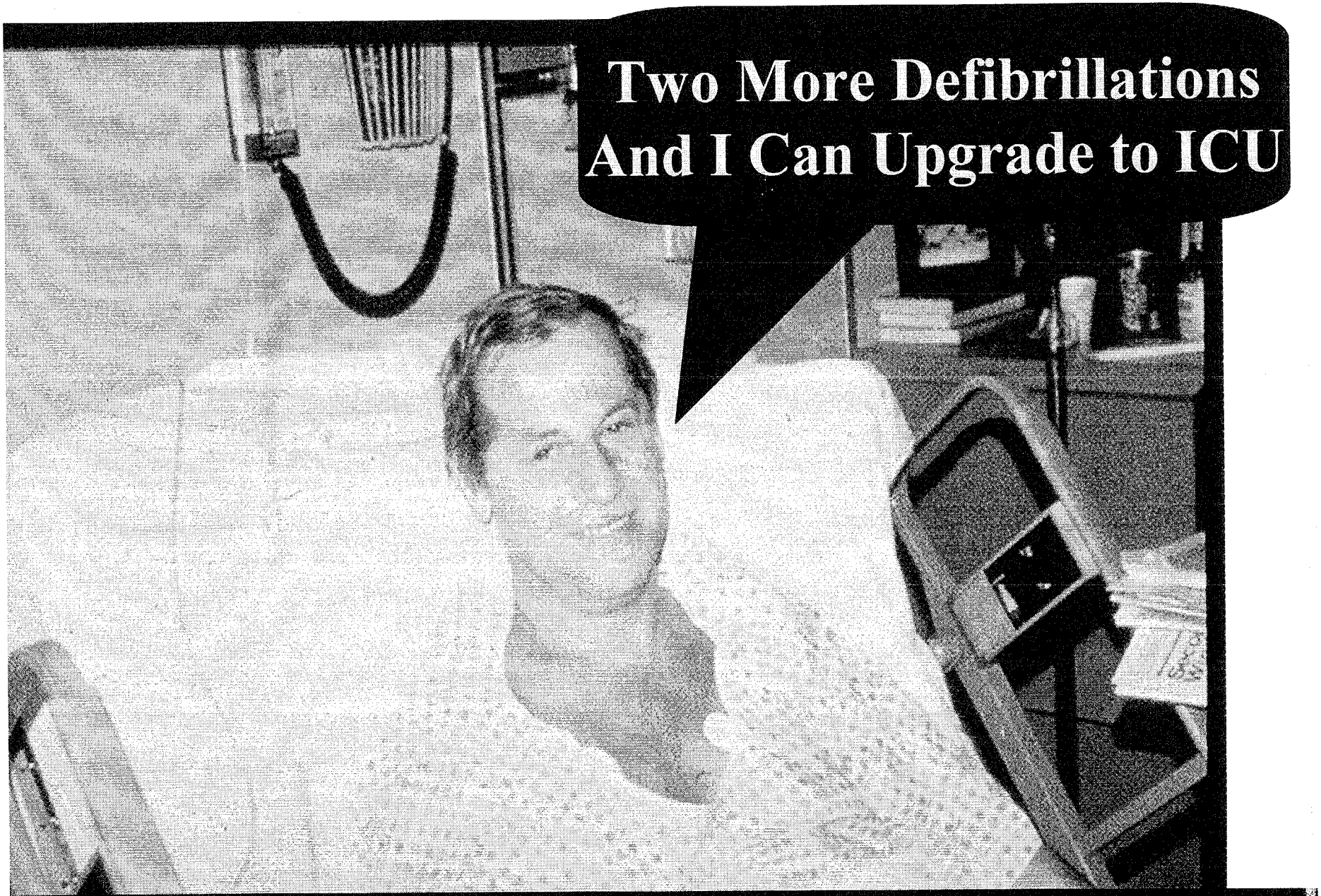
Better Study Design

- **Larger Numbers (entire population)**
- **Faster Study Completion**
- **Stronger Statistical Power**
- **Can Better Examine Subgroups**
- ***However: Multiple Facilities***

Emergency
Trauma Center
Ben Taub
General Hospital

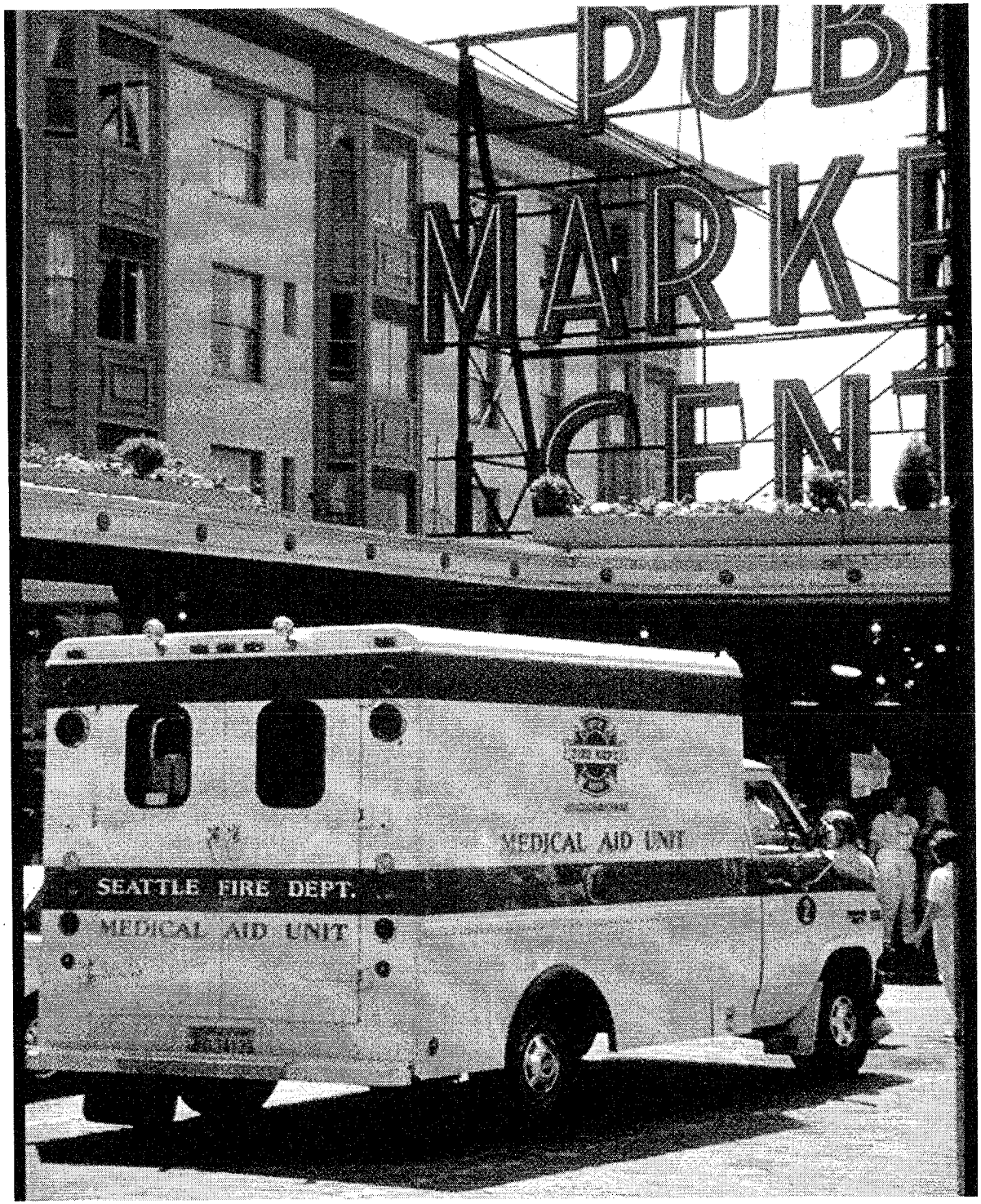
Achieved Study Endpoint...

Before EMS Crews Arrived !!



Frequent Flyers' View of the World...

Factors Associated With Success...


PUB
MARKE
MEDICAL AID UNIT
SEATTLE FIRE DEPT.
MEDICAL AID UNIT

Texas Medical
Center
NEXT RIGHT

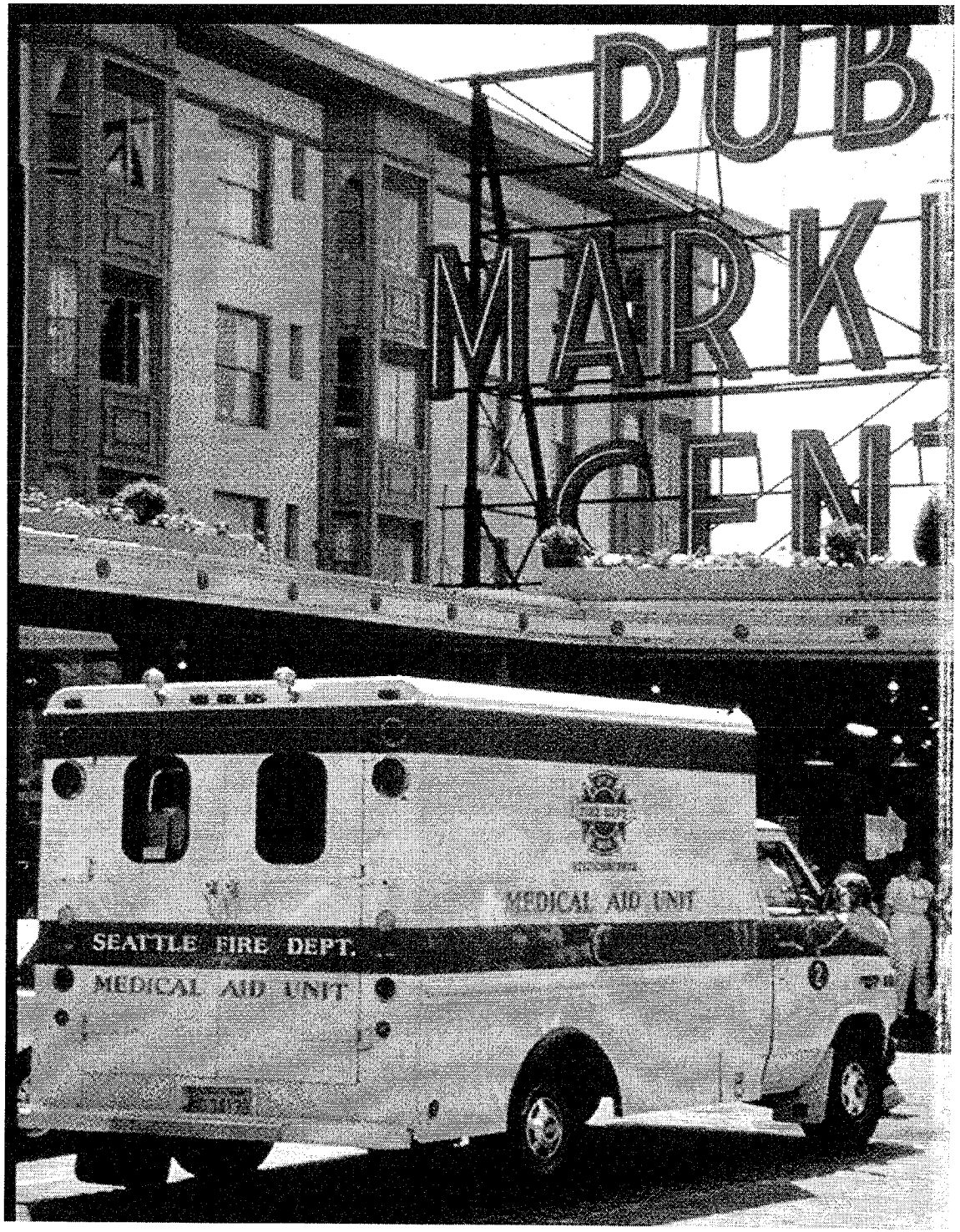
Also -- It's Personalities....

Not Principles That Move the Age

Factors Associated With Success

- **Involve Personnel in Design**
- **Meet Regularly Afterwards**
- **Make it *Their* Project**
- **Use a Supervisor System**

Still there are Other Caveats...

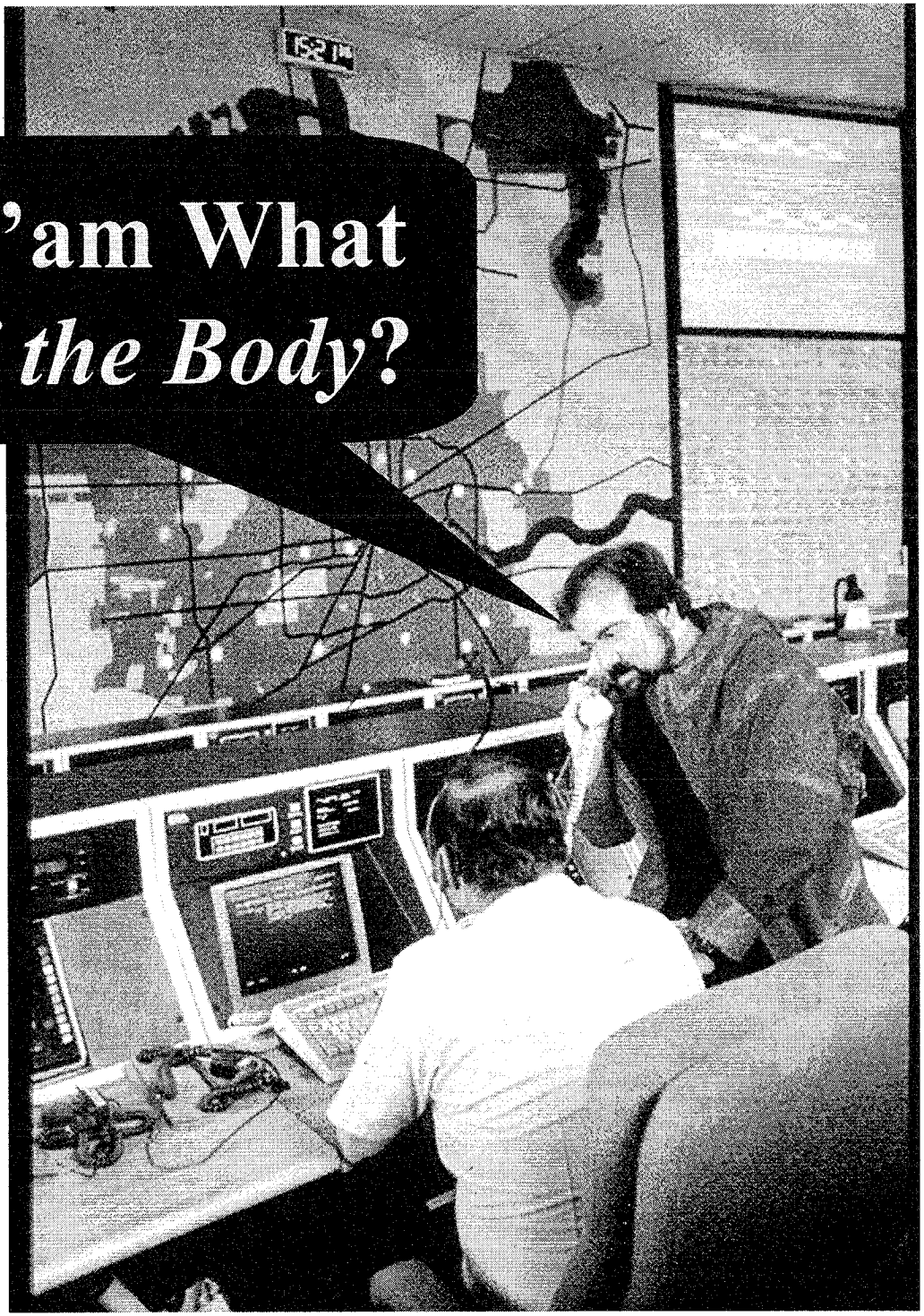


System Infrastructure

- **Already Has Good Outcomes**
  (1% vs 2% Meaningless)
- **Especially for Subgroup Analysis**
  (drugs, other interventions)
- **Highly-Skilled Personnel**
  (tiered ALS / BLS systems)

System Design Can Affect Outcome

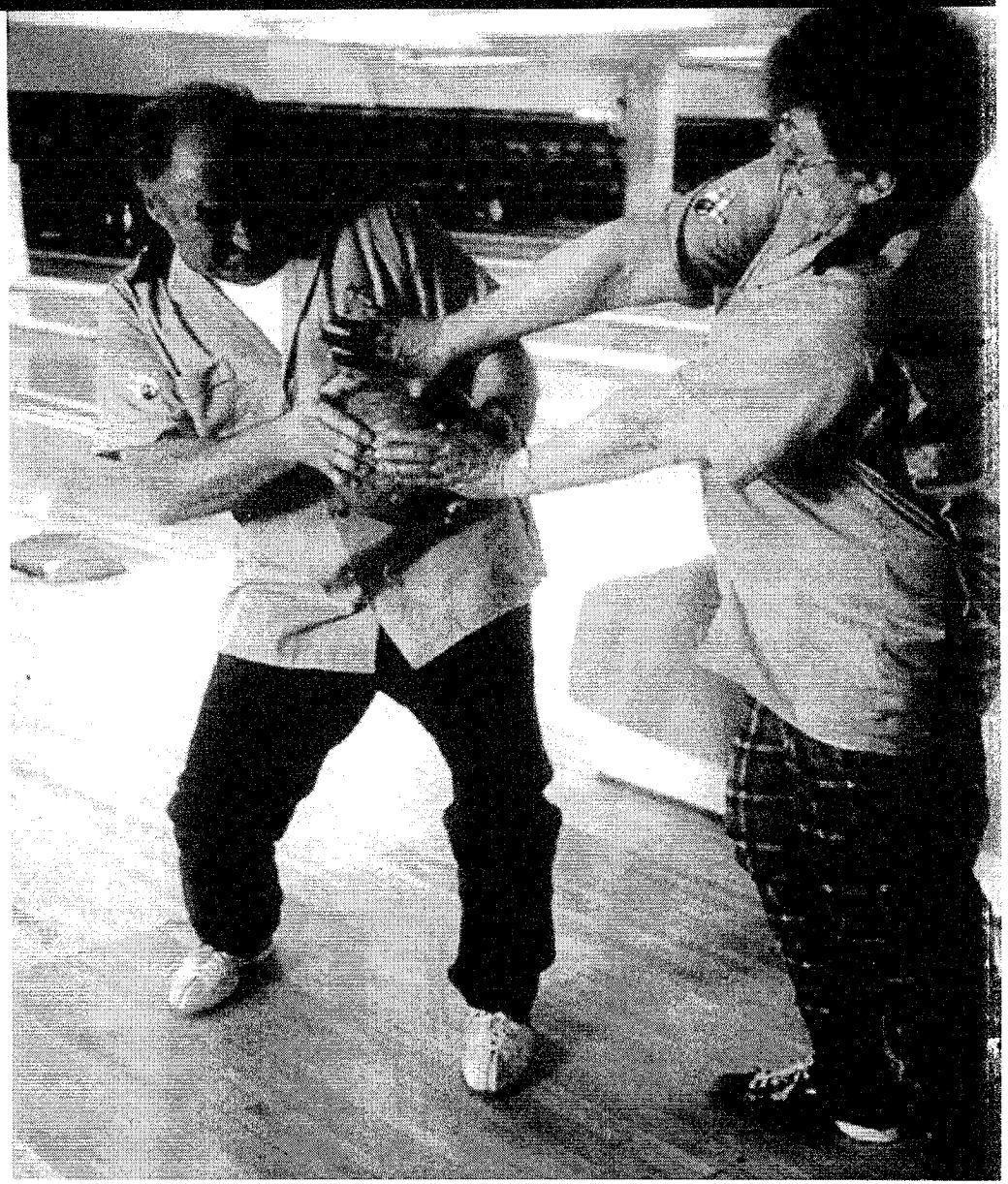
No, Ma'am What Part of *the Body*?



Obstacles

- **Institutional Review Boards**
- **Unions & EMS Administrators**
- **Hospitals (Access to Outcome Data)**
- **Media/Politicians**
- **The Loose Cannons**

Overcoming Obstacles

- **Avoid Special Data Forms**
- **Join Medical Staff *of All Hospitals***
- **Commit to Support the System**
- **Create Positive Reinforcement**

Consenting Adults...