



Biodefense Issues in Technology Transfer

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Biodefense Issues

- **Anthrax-tainted Letters**
- **Sarin Nerve Gas**
- **Senate Office Building Scare**
- **Global Threats of Chemical /Biological Material**

Results:

- **Cognizance**
- **Increase funding through Project Bioshield:**
 - **10-year \$6-billion program to develop and produce new vaccines and countermeasures against potential bioweapons**

Government's Role

- **U.S. Army –U.S. Army Medical Research Institute of Infectious Diseases**
 - **Walter Reed Army Institute of Research**
 - **Institute of Chemical Defense**
- **NIH**
 - **National Institute of Allergy and Infectious Diseases**
- **Homeland Security**
- **CDC**

USAMRMC

- **Headquartered at Fort Detrick, Frederick MD**
- **The R&D arm of the Army Medical Command**
- **Army's medical materiel developer**
- **Mission:**
 - **To provide medical materiel to sustain the health, well being and military readiness of U.S service men and women:**
 - **drugs**
 - **vaccines**
 - **devices**
 - **telemedicine**

MRMC Research Area Directorates

- **Infectious Diseases**
- **Combat Casualty Care**
- **Telemedicine**
- **Military Operational Medicine**
- **Medical Chemical and Biological Defense**
- **Congressionally Directed Medical Research Programs**

MRMC R&D Laboratories

- **Aeromedical Research Laboratory - Fort Rucker, AL**
- **Institute of Chemical Defense - Edgewood, MD**
- **Institute of Environmental Medicine - Natick, MA**
- **Institute of Infectious Diseases - Fort Detrick, MD**
- **Telemedicine and Advanced Telecommunications Research Center, Fort Detrick, MD**
- **Institute of Surgical Research - Fort Sam Houston, TX**
- **Walter Reed Army Institute of Research - Silver Spring, MD**

USAMRIID Biological Agents

Bacteria

Bacillus anthracis (anthrax)
Yersinia pestis (plague)
Francisella tularensis (tularemia)
Coxiella burnetii (Q Fever)
Brucella suis
Burkholderia pseudomallei (glanders)

Viruses

Variola virus (smallpox)
Monkeypoxvirus
Alphavirus encephalitides (VEE, WEE, EEE)
Ebola/Marburg (Viral Hemorrhagic Fevers)
Rift Valley Fever
Hantaviruses

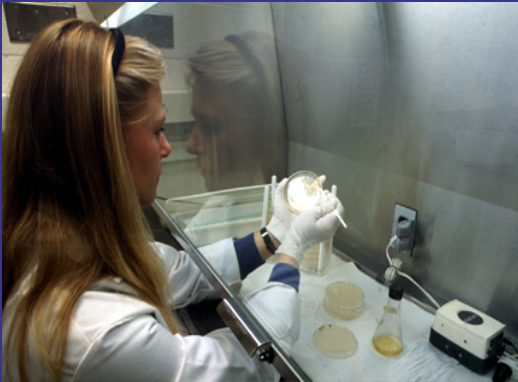
88 Biological Agents

39 Biological Select Agents and Toxins

Toxins

Botulinum neurotoxins
Other Clostridial toxins
Ricin toxin
Staphylococcal Enterotoxins
Marine toxins (tech watch)

USAMRIID's Unique Capabilities



Expert Bio Threat Knowledge



Containment Laboratory Operations



Medical Product R&D & GLP Studies



Clinical Studies

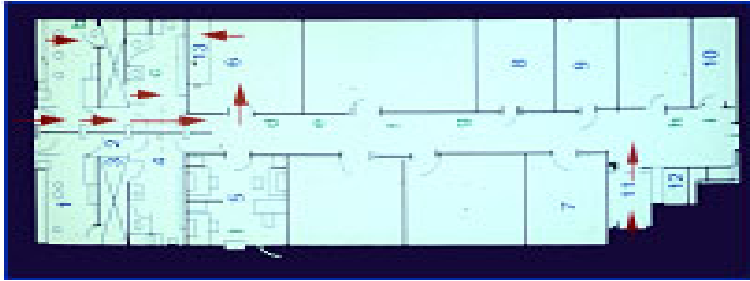


Training and Education



Rapid Response & SMART Teams

USAMRIID's Unique Facilities



- Largest collection of BSL 4
- Largest animal containment care facility
- Large Animal Care Facility (Farm)
- Unique *Center for Aerobiology*
- *Field Laboratory Training Center*
- World's Only BSL 4 Patient Care Suite

Limitations on Biodefense Research and Development in Private R&D

- **Unprofitable**
- **Mostly Based on Government Funding (especially small businesses)**
- **Limited Involvement of Big Pharmaceuticals**

Technology Transfer Issues in Biodefense

1. Materials

- Shipment and Receiving
- 42 CFR 73 (select agents)
- EA 101

2. Biosurety

- Inventory of Agents
- CDC Requirement- security risk assessment
- DoD Directive
- Army Regulations

Technology Transfer Issues in Biodefense

3. Personnel

- Citizenship
- Clearance
- National Agency Check

4. Export Control

- Guidelines Outlined by the Department of Commerce
- Export Control License
- CRADA Language/ CRADA Partners

Technology Transfer Issues in Biodefense

5. CRADA Partners

- **Funding: NIH/NIAID Grants**
- **Lack of Overhead Funding for Federal Agencies**
- **Lack of Grants Office**
- **Third Party Foundations**
- **3-way CRADAs**

Technology Transfer Issues in Biodefense

6. Licensees

- **High Risk Partners**
- **Small Biotech Companies**
- **No Track Record**
- **No Large Pharma**
- **Difficult Partnering Unless Have Guarantee of Government Funding**
- **Customer: US Government, State, Local Agencies, and Allies**

Technology Transfer Issues in Biodefense

7. Intellectual Property

- **Heightened Security**
 - **USPTO**
 - **Medical Inventions**

AUTHOR OF THE NEW YORK TIMES #1 BESTSELLER
THE HOT ZONE

RICHARD
PRESTON



THE
COBRA
EVENT

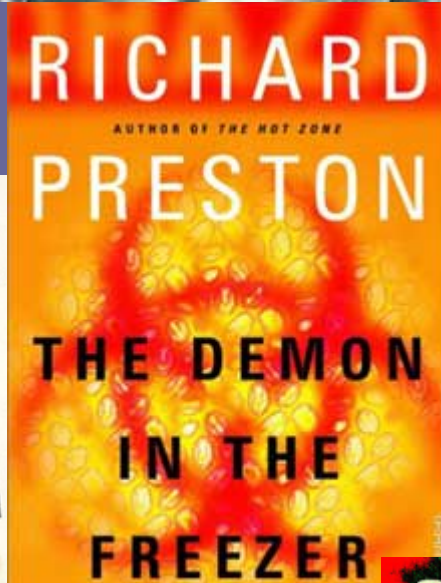
"THOROUGHLY FRIGHTENING." —*Newsweek*



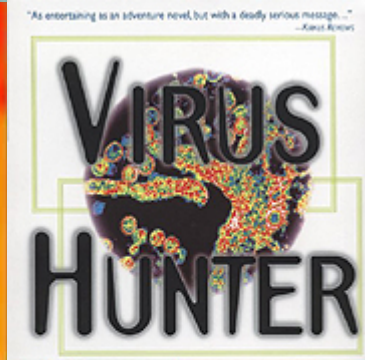
MEDICAL
INVESTIGATION

"As entertaining as an adventure novel, but with a deadly serious message..."
—*Kareem Abdul-Jabbar*

eloquent, gripping, and beautiful
...surses, and victims who lived
ring that harrowing nightmare."
—RICHARD PRESTON
R. OF THE HOT ZONE
CLOSE, M.D.
el of Its First Explosion
Doctor who was there



RICHARD
PRESTON
THE DEMON
IN THE
FREEZER

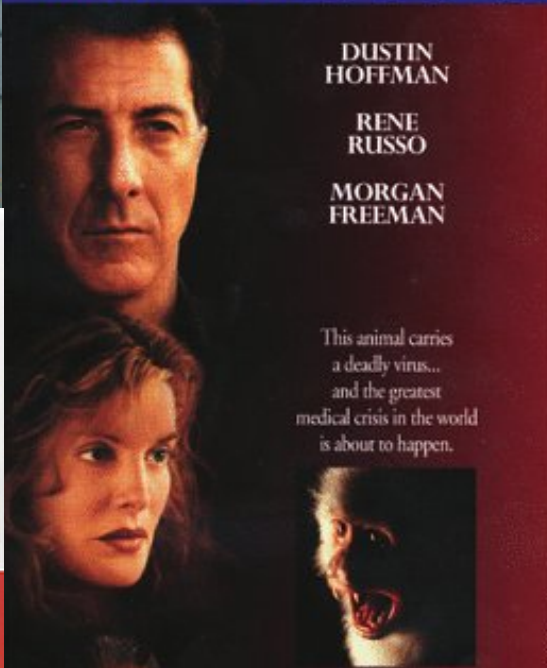


VIRUS
HUNTER



C.J. PETERS & MARK OLSCHAKER
COAUTHORS OF *Med Matters*

WARNER BROS. **HITS**



DUSTIN
HOFFMAN

RENE
RUSSO

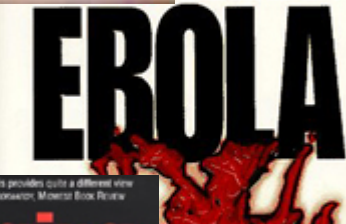
MORGAN
FREEMAN

This animal carries
a deadly virus...
and the greatest
medical crisis in the world
is about to happen.

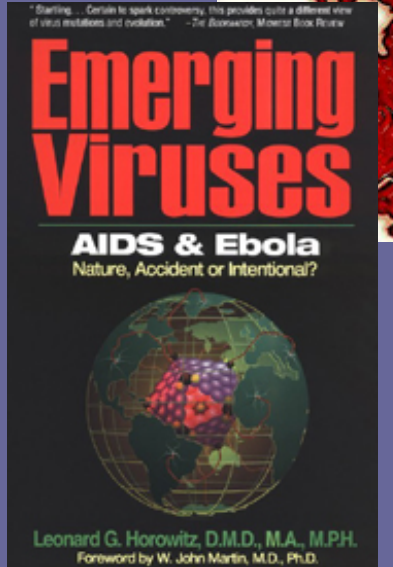


OUTBREAK

Try to remain calm.



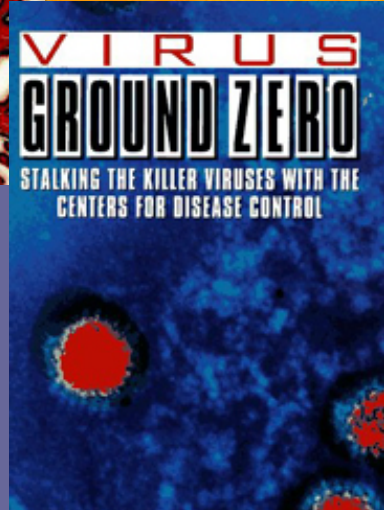
EBOLA



**Emerging
Viruses**

AIDS & Ebola
Nature, Accident or Intentional?

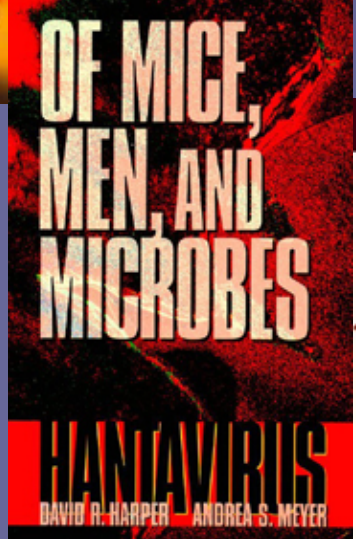
Leonard G. Horowitz, D.M.D., M.A., M.P.H.
Foreword by W. John Martin, M.D., Ph.D.



**VIRUS
GROUND ZERO**

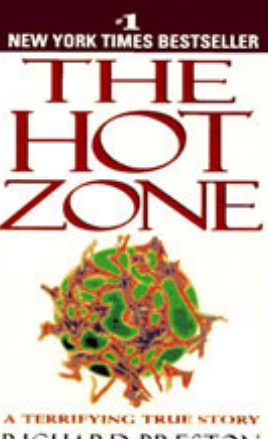
STALKING THE KILLER VIRUSES WITH THE
CENTERS FOR DISEASE CONTROL

ED REGIS



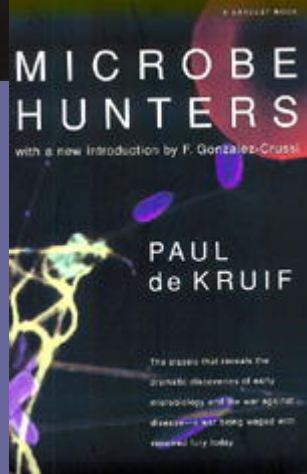
**OF MICE,
MEN, AND
MICROBES**

HANTAVIRUS
DAVID R. HARPER AND ANDREA S. MEYER



NEW YORK TIMES BESTSELLER
**THE
HOT
ZONE**

A TERRIFYING TRUE STORY
RICHARD PRESTON



**MICROBE
HUNTERS**
with a new Introduction by F. Gonzalez-Cruick

PAUL
de KRUIF

The gripping tale reveals the
dramatic discoveries of early
microbiology and the war against
disease... war being waged with
weapons far more deadly
than any today.