TEACHING THE LESSONS THAT DEADLY MEDICINE TAUGHT US

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Masters Programs in College of Medicine
Designed for M.D. and Ph.D. prepared candidates
3 tracks

- MS CR with Mentored Research
  - 2-4 year curriculum
- MS CRM 32 Credits
  - 1 yr. curriculum
- MS CRM Executive 32 Credits Distance Learning
  - 1 yr. curriculum plus 6 on-site weekends
ETHICS AND PROPER CONDUCT OF RESEARCH
Modern Chronology

Nuremberg Code - 1946
Declaration of Helsinki
• 1964 - 2008
Belmont Report - 1978
Clinical Trial Volunteers’ Bill of Rights - 2002
HELSINKI EVOLVES

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington, DC, USA, October 2002
(Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo, Japan, October 2004
(Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, Korea, October 2008
A Transformative Opportunity

Deadly Medicine, Creating the Master Race
at the WW II Museum in
New Orleans July 25 to October 15, 2012
Produced by: US Holocaust Memorial Museum;
Presented by: National WW II Museum;
Sponsored by: Tulane University

A. Emphasis on Eugenics and Social Darwinism morphing into Racism
B. “Good Scientists” committing atrocities in pursuit of “good” Science
C. “Bad Scientists” seizing ‘opportunity’ to do bad science
D. Adoption of ‘advances’ wrongly discovered
COURSE DISCUSSION:
Rationale for Regulatory Oversight
And Proper Conduct of Human Research

Our Violations between 1946 and present:
Tuskegee
Nicaragua
Willowbrook
Milgram
Humphrey
ETC...

Thus we have recruited internal and external overseers for Clinical Research
CLASS DISCUSSION QUESTIONS

To What did the Nuremberg Principles Respond?

By whom were they articulated?
  When?
  Did they REFLECT American Values,
  or did they DRIVE American Values?

What was the Helsinki Code? Why has it evolved?
  What were the subsequent legal foundations
  of Bioethics in Medical Research today?
CLASS DISCUSSION QUESTIONS, Cont.

Compare and contrast Joseph Mengele and Gerhard Rose

What differences were there between whimsical, ideological, opportunistic experiments and military sponsored research during the Nazi era?
Discuss how good, well trained people could perform Unspeakable Atrocities in the name of Science?

Is it ethical to use scientific data obtained unethically and immorally? Provide examples.
POINTS RAISED by STUDENTS

A. Is Deception of study subjects ever warranted?
   i. From the Milgram’s study of Teacher’s stress
   ii. Krugman’s description of his hepatitis research at Willowbrook to parents

B. Of the ethical principles, can one override others?

C. Does “greater good” matter?

D. Justification for Phase I Clinical Trials – carefully done
   (No Therapeutic Benefit Intended)

E. Science cannot (should not) self-regulate – needs oversight
Protocol Development: Practical Application

- Revisit Nuremberg, Helsinki, Belmont, Bill of Rights
- Apply biostatistics, epidemiology, business
- Stress the relationship between good science and
  - Autonomy
  - Beneficence
  - Utility
  - Justice
  - Protection
  - PI Responsibility
TOPICS OF (RE)CURRENT INTEREST

- How do we deal with “ill-begotten knowledge”?
- How do we guard against future lapses?
CURRENT EVENTS
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- Wall Street Journal, Saturday, December 1, 2012 page 1!
  - The Hubertus Strughold Award For Outstanding Work in Aviation Medicine of the Space Medicine Association

- Wall Street Journal, Friday, September 6, 2013 Book-Review Section, Page 1!
  - Stanley Milgram’s Shock Experiments “Behind the Shock Machine” by Gina Perry
(RE)CURRENT INTEREST

- We don’t know how to deal with the innovators who worked under the Nazi culture
- We have learned to live with the innovations:
  - *Life jackets* and *space travel* to name only 2
- How?
ETHICAL CHALLENGES NOW AND IN THE FUTURE - THAT WE CAN ENVISION

A. “Justice”: Equal access to clinical trials – Implications for health care delivery systems – NSABP P1 13,000 women, 1% African American

B. “Beneficence”
   i. Phase I Clinical Trials – children and elderly
   ii. Claims on Data (Identification of significant genetic risk on study of bio-banked tissue)
   iii. Evidence based medical decision making
      i. Selection of references (X Up-to-Date)
OVERIDING QUESTIONS

- What are VALUES?
- How do we achieve them?
- Are they Immutable?
- Are “codes” enough?
- To whom do we delegate oversight?
  - IRB
  - Compliance Officer
  - Internal Audit
  - External Audit
  - Peer Review - PARTICIPATE
ETHICAL CHALLENGES THAT WE CANNOT ENVISION

A.
B.
C.
D.
E.
F.
G.
MAINTAIN VIGILANCE

- Act consistent with our “values”
- Teach consistent with our values
- Accept oversight – provide oversight
- Technology will complicate our ethical lives
- ACCEPT IT!
What keeps me up at night? Worry that we will lose the communal shame for the atrocities committed in the name of research and public policy.

Ken Jacobson,
Deputy Director,
Anti-defamation League
New Orleans, December 2, 2012
THANK YOU