



# **Bi terrorism: Changing Priorities in Medical Training and Research**

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# **Bioterrorism is Biowarfare and vice versa**

Contagion and its terrorizing effect has been a part of wars and epidemics throughout history

- ⇒ A clear and present danger of Bioterrorism in the United States was no longer theoretical after 2001
- ⇒ These events required a major national response, a new federal agency DHS was created and secure systems for Biodefense R&D & communication were designed

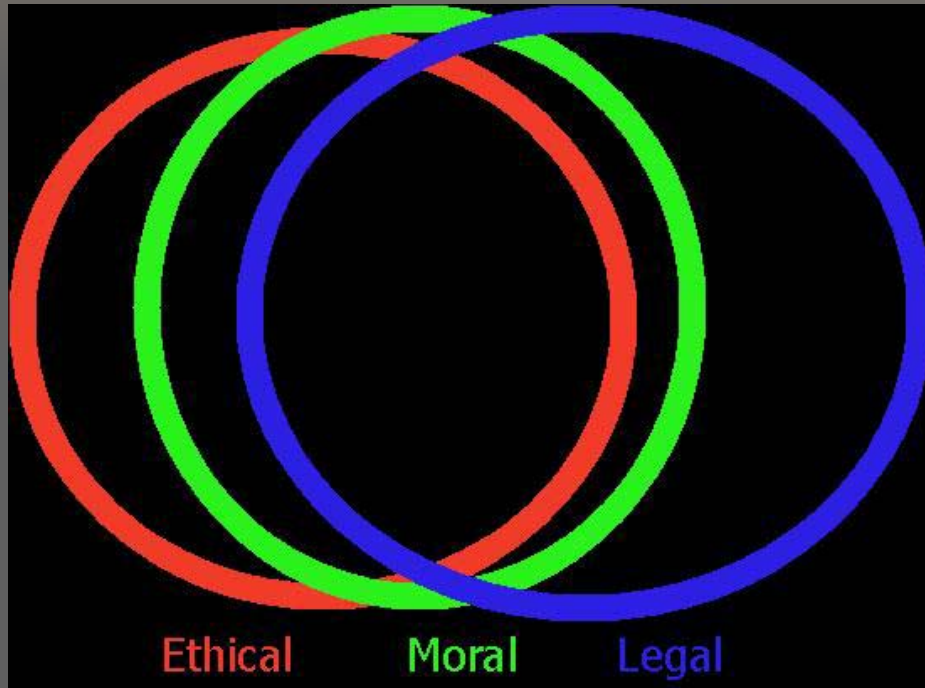
# Medical Ethics After 9/11/2001: Does it require Rethinking?

- ⇒ The US Health Care System Has Not Faced Threats of Bioterrorism or Major Epidemics since before WW I I
- ⇒ The Military has been preparing for **protecting troops** against BioWarfare since 1943 but it was assumed that it would happen “**over there**” and not inside the US
- ⇒ We must all adjust to the possibility that there may not be **time** to follow our present laws, regulations and ways of doing medical research and development when “pipeline” drugs, vaccines and devices are needed in **responding to national bioterror emergencies**

# Ethical Analysis vs Rules & Laws

- ⇒ Common Rule Regulates Research
  - It is based on Ethical Principles but codified as **Rules**
  - Conflict occurs when Rules block solutions determined by results of Ethical Analysis that differ from the Rule
- ⇒ FDA Regulates Product
  - FD&CA **Law** FDA regulations control development, labeling, marketing and use of drugs devices and biologicals
  - FDA defines use of product labeled IND/IDE as **Research** irrespective of intended use
- ⇒ Nuremberg Code provides **principles** that may be applied in Ethical Analyses for Biodefense Research

# What Is Ethical?



- ⇒ “Ethical” does not equal moral
- ⇒ “Ethical” does not equal legal

- ⇒ “Ethical” is not good or bad
- ⇒ “Ethical” does not convert bad to good, *i.e. it is not “Spin” or “Parsing”*
- ⇒ What is “Ethical” may be effected by circumstances
- ⇒ “Ethical” is determined by fact finding and logical analysis using commonly held values and principles

# Recipe for Ethical Analysis:

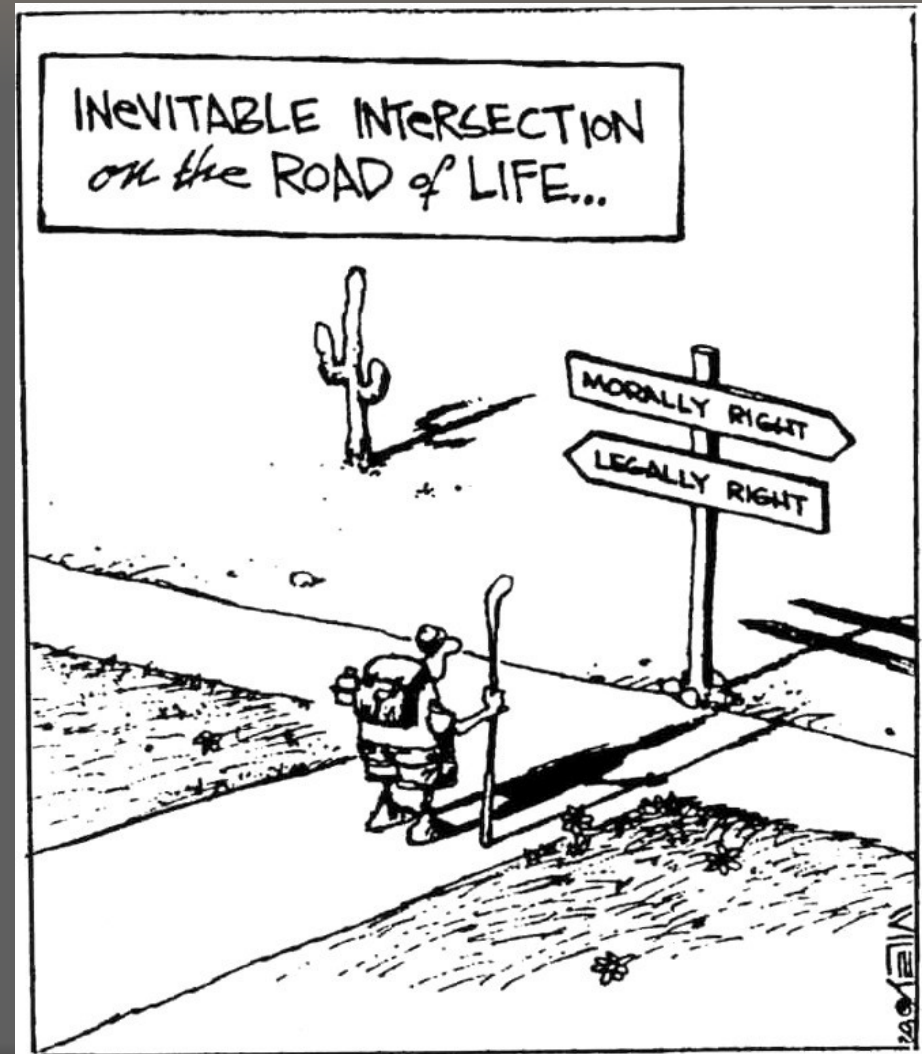
- ⇒ Identify **intention(s)**
- ⇒ Determine **actions** to achieve intention(s)
- ⇒ What are possible **consequences** of the intention or of taking specific actions
- ⇒ Determine which intentions/actions give greatest benefit and result in least harm
- ⇒ The **context, cultural values** and limits to available **choices** effect final determination

# A National Biodefense Program Produces an Ethical Dichotomy:

- ⇒ The context, cultural values and limits to available choices effect what actions ethical analyses may decide.
- ⇒ Respect the rights and welfare of subjects who participate in research designed to discover, validate and gain FDA marketing approval for products to be used in prevention and treatment of possible bioterrorism casualties.
- ⇒ Urgent need to use unapproved products reasonably thought to be beneficial for protection from - or immediate treatment of bioterrorism when there is an emergency and no approved alternatives are available.

# Moral Dilemma: Comply with FDA law vs Intent to Benefit in BW Emergency

- ⇒ 1962 Amendments to the FD&C Act that required proof of efficacy of drugs and vaccines against BW created a moral dilemma.
- ⇒ Risk killing subjects in a valid clinical trial, versus
- ⇒ withholding potentially life saving drugs or vaccines because they lacked substantial evidence of human clinical efficacy.







**IND SMART Team  
Iraq Reality**

# Legislation Needed to Overcome Obstacles of IND format in Biodefense

- ⇒ The “investigational” label and structured research format interferes with subject acceptance of products because of **perception of experiment** when treatment is intended.
- ⇒ Difficulties meeting IND/GCP regulatory requirements may cause DoD to deviate from FDA requirements or fail to successfully accomplish force health protection.
- ⇒ Seek “**streamlined IND**” from FDA for rapid licensure of advanced products with utility or potential utility.
- ⇒ Emergency use of key FDA-unapproved drugs is possible for “pipeline” products via **Project BioShield**.

# Project BioShield : Benefits

- ⇒ CDC, HHS & DoD may use HHS Project BioShield procedures if legislation is approved
  - Passed: **H.R. 2122—Project Bioshield Act of 2003**
  - Pending: **S. 15 Project BioShield Act of 2003 and the Biodefense Improvement and Treatment for America Act**
- ⇒ This legislation resolves the dilemma and the dichotomy that is associated with widespread use of FDA-unapproved products in civilians for national biodefense or in soldiers facing war hazards

# Project Bioshield

## Purpose:

- ➔ To accelerate the process of research, development, purchase, and availability of effective countermeasures against agents of bioterror or biowarfare

# Project Bioshield

## Three-pronged program:

1. Establish secure funding source for purchase of critical biomedical countermeasures
2. Increase authorities and flexibility for NIH / NIAID to expedite research and development of critical biomedical countermeasures
3. Establish an FDA Emergency Use Authorization for critical biomedical countermeasures

# Project Bioshield

1. Establish secure funding for purchase of critical biomedical countermeasures
  - ⇒ Permanent and Indefinite Appropriations to DHS
  - ⇒ Funding of specific countermeasures prioritized based on threat assessment
  - ⇒ Funding available for other countermeasures once production of licensable products is judged feasible

# Project Bioshield

## 1. Establish secure funding... (cont'd)

- ⇒ Appropriation can only be used when the President has approved a joint request from Secretaries of HDS and HHS
- ⇒ HHS is the procuring authority, however
- ⇒ Appropriation can only be used to purchase countermeasures for which there is no significant commercial market other than homeland security

# **Project Bioshield - ( NIH / NIAID )**

## **2. Increase authorities & flexibility to expedite R&D of critical biomedical countermeasures**

- ⇒ Bolster authorities for acquisition, construction, and renovation of facilities
- ⇒ Streamline procurement authority
- ⇒ Expedite review of grants, contracts and cooperative agreements
- ⇒ Expedite professional and personal services contracts
- ⇒ Provide flexibility with regard to personnel authority



# Project Bioshield ( DHS, DOD & HHS )

## 3. Establish FDA Emergency Use Authorization for critical biomedical countermeasures

- ⇒ Upon **threat determination** by Secretary of DHS, DOD or HHS, the HHS Secretary can issue an order that allows **emergency use** of an unapproved (IND or Off-label) drug or biologic (*subject to HHS conditions\**)
- ⇒ If HHS Secretary finds there is **reason to believe**:
  - that the product is effective,
  - that the benefits outweigh the risks, and
  - that there is no adequate alternative

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who may administer & to whom, consent requirements, labeling and record keeping

# **Bioterrorism: Changing Priorities in Medical Training and Research**

- ⇒ Translation of biosafety, biosurety, security and bioethical practices from a closed military environment to open university campuses will involve training
- ⇒ Providing for worker safety in high hazard containment may produce ethical dilemmas with regard to voluntary use of IND products for prophylaxis and treatment
- ⇒ Involvement of the larger academic community in developing bioterrorism countermeasures will hasten the rate of new accomplishments and also will speed important technological spin offs into the public sector

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