#### History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest

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OCTOBER 1, 2014

#### **Disclosure**

I have no relationships to disclose, and I will not discuss off label or investigational use products in my presentation

SUSAN E. LEDERER, PH.D.

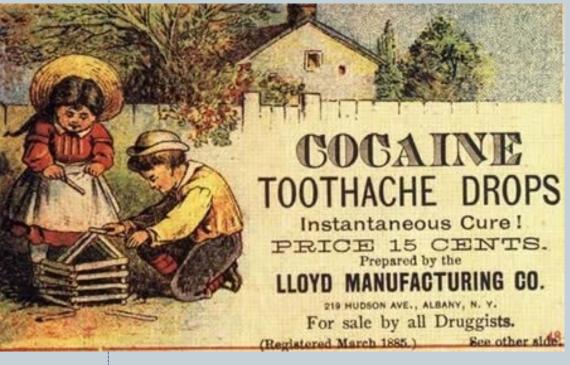


# U.S. LEGISLATION AS RESPONSE TO SCANDAL AND TRAGEDY

#### The Patent Medicine Evil in the Early 20th century



timer Street, London, W., price g. per Single fiettle, 22 6 helfdopen, 43 - dozen, and is sold by Chemists and Stores.



#### Safety of the food supply

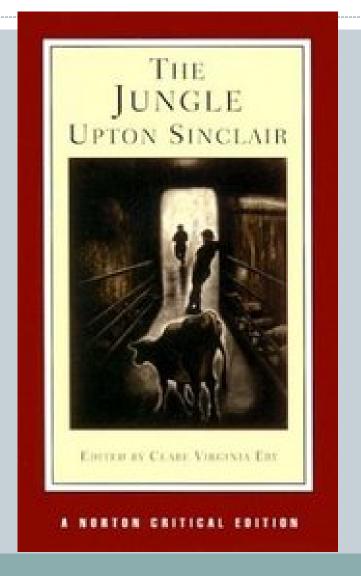




#### Food and Drug Act 1906



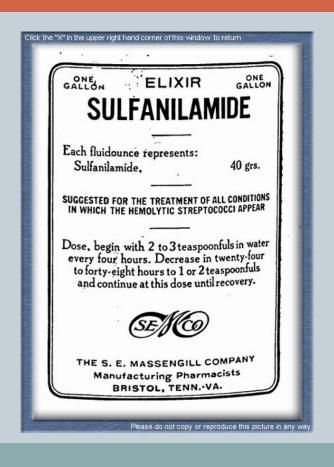




#### Elixir of Sulfanilamide tragedy 1937

#### 107 deaths





#### Diet and cosmetic dangers c. 1930s







#### Food, Drug and Cosmetic Act of 1938

 Drugs or cosmetics must be tested for toxicity before marketing

Adequate directions for use need to be on package

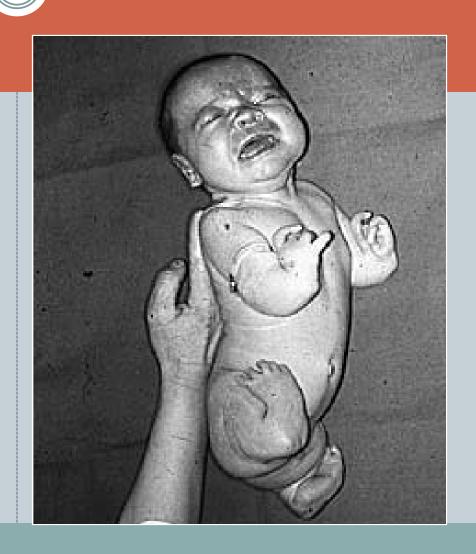
 Some drugs are designated "by prescription only"

#### **Thalidomide**

#### 1960-1961

83 children were born with unusual birth defects, not linked to thalidomide use.

a German scientist makes connections between thalidomide use and thousands of babies born with birth defects.



#### **Kefauver-Harris Amendments to FDA**

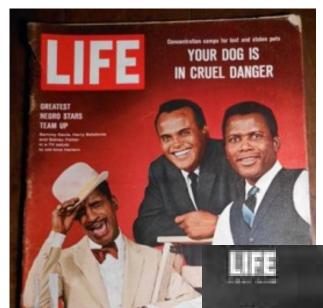
Drugmakers must establish the effectiveness of drug products before they go on the market, and afterwards report any serious side effects.

Requires clinical studies conducted by qualified experts.

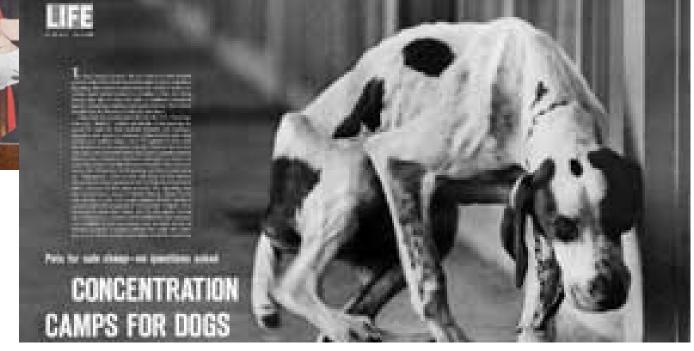
Requires informed consent by study subjects

## Animal Welfare Act,

1966



# LIFE MAGAZINE 1966



# WHY DO WE HAVE FEDERAL REGULATIONS FOR HUMAN EXPERIMENTATION?

### Scandals and tragedies prompt Congress to pass the National Research Act

1974

Both the history of human experimentation and history of controversy over human experimentation much older

#### United States Congress, 1900

considers Senate bill 3424, a law that

would require investigators to disclose in advance the purpose and procedures of any non-therapeutic experiment involving human beings.

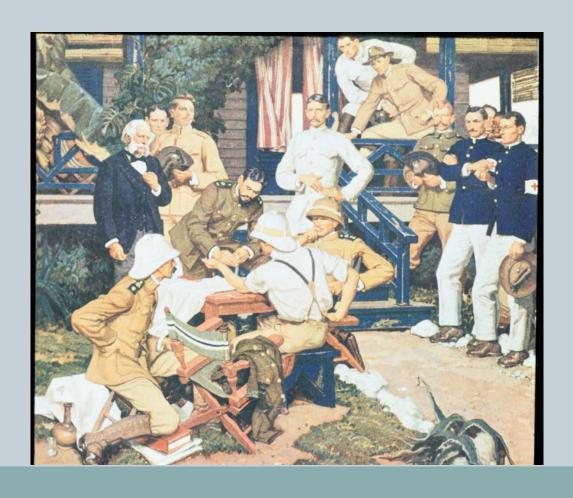
#### Senate bill 3424

calls for explicit ban on experiments using those persons deemed unable to consent, including

infants,

children under the age of 21, and pregnant women.

#### The Yellow Fever Board in Cuba, 1900



# Reed and his colleagues introduce written permission forms

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of the processing.

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available in both English and Spanish

#### The undersigned understands...

perfectly well that in case of the development of yellow fever in him, that he endangers his life to a certain extent but it being entirely impossible for him to avoid the infection during his stay in this island, he prefers to take the chance of contracting it intentionally in the belief that he will receive from the said Commission the greatest care and the most skillful medical service.

# Subjects receive \$100 in gold, \$200 if death occurs

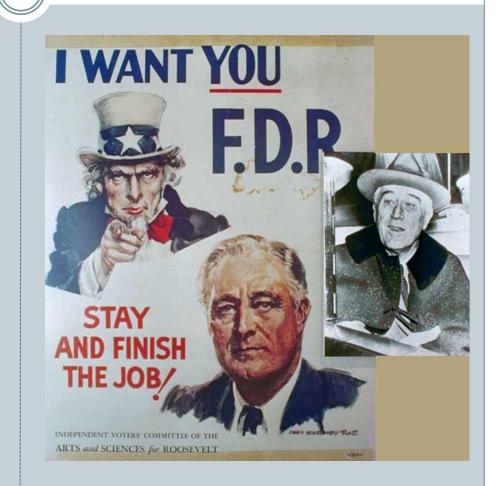


"A written consent was obtained from each one, so that our moral responsibility was to a certain extent lessened. Of course, only the healthiest specimens were experimented upon . . "

**Aristides Agramonte** 

#### World War II experimentation

- President Franklin Delano Roosevelt establishes the Office for Scientific Research and Development
- Committee on Medical Research
- Unprecedented federal funding for medical research



#### Research related to war effort

hypothermia effects of high altitude

de-salination studies

burns/wounds

blood substitutes

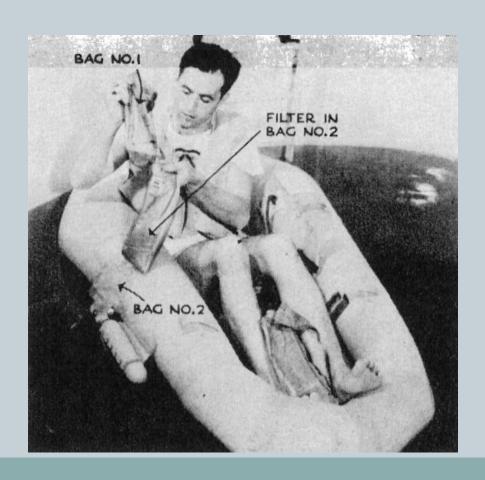
Prevention and treatment of infectious diseases

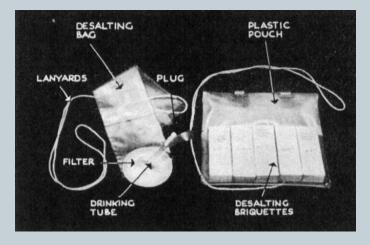
malaria

gonorrhea

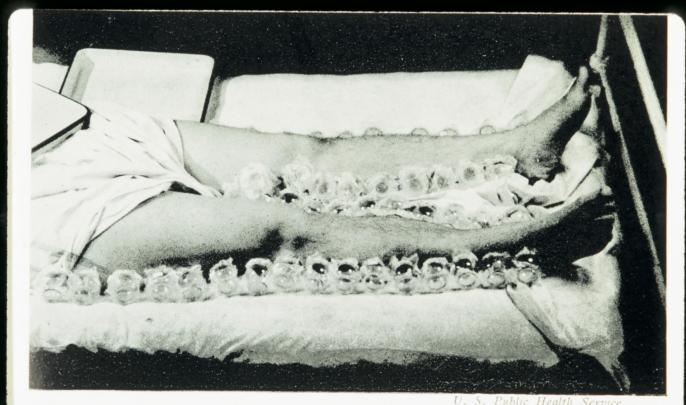
hepatitis

#### De-salting sea water





#### Malaria research



Malarial research: infecting mosquitoes by allowing them to bite an infected patient

#### Nazi war-time medical research agenda

hypothermia effects of high altitude de-salination studies burns/wounds blood substitutes vaccines and treatment malaria gonorrhea hepatitis

# Nazi research methods

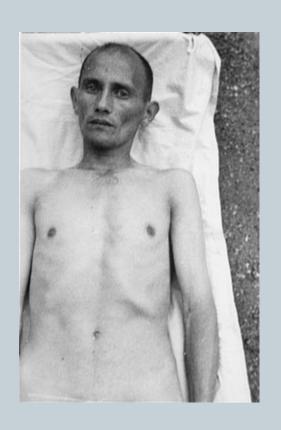
# Dachau Concentration Camp—effects of hypothermia



# Dachau Concentration Camp effects of high altitude



#### Sea water studies



• A Romani (Gypsy) victim of Nazi medical experiments to make seawater potable.



#### Seawater experiments, Dachau 1944

44 camp inmates ages 16-49) German, Czech, and Polish Roma.

"recruited" from Buchenwald and Auschwitz for a "clean up work detail"

promised extra rations and easier conditions

- Group 1 no water at all
- Group 2 fresh water
- Group 3 ordinary sea water
- Group 4 chemically filtered sea water,
- Group 5 sea water with a tomato extract to mask taste (but leaving high salt concentration).

# Rudi Taubmann's testimony at the Nuremberg Doctors' Trial

When test subjects
 refused to drink any more
 sea water, they were
 physically held down, and
 a red tube placed in their
 mouth in which sea water
 was added so that it went
 to the stomach

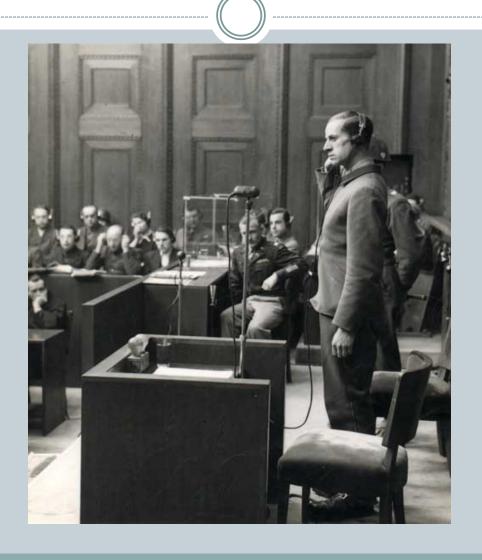
- Test subjects undergo:
  - Liver punctures
  - Spinal punctures

#### Studies of burns and wounds, 1942

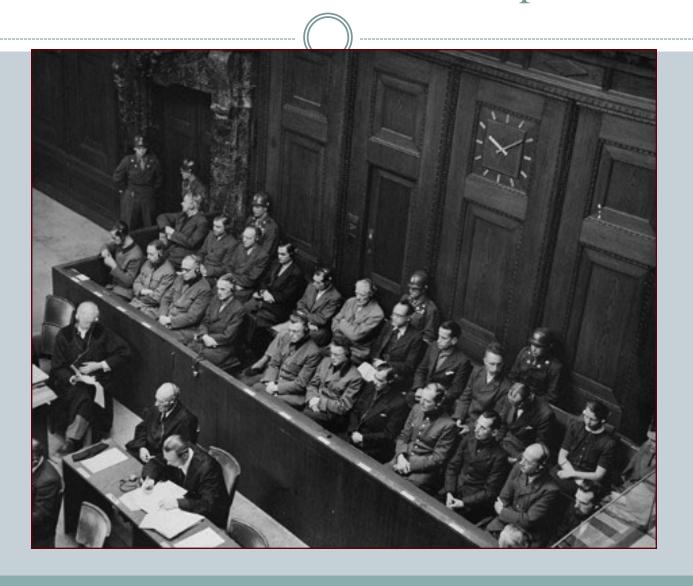


- disfigured leg of a survivor from Ravensbrueck,
- scars resulted from incisions made by medical personnel that were purposely infected with bacteria, dirt, and slivers of glass.

#### United States v. Karl Brandt et al



### Nuremberg Doctors Trial Prosecution of 23 Nazi medical personnel

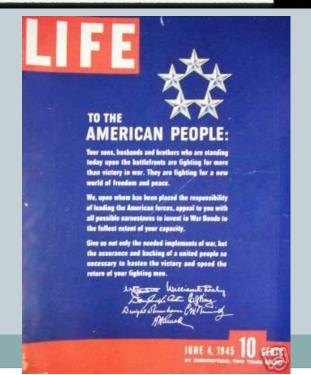


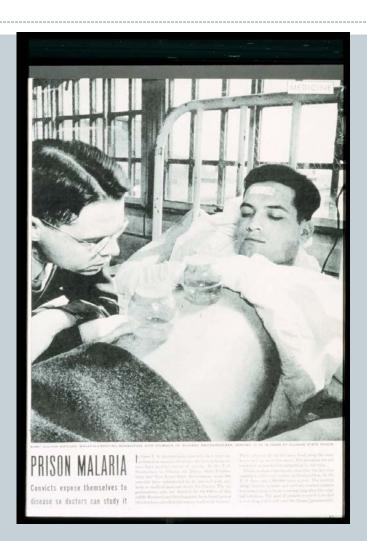
# Issue for the Tribunal: what standards to use to judge these experiments?

# Defense attorneys liken Nazi camp experiments to American prisoner research during wartime

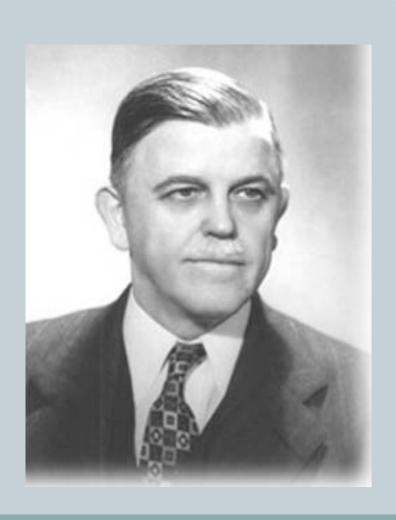


Malarial convicts contribute to knowledge of the disease





#### American researcher Andrew C. Ivy



- Sent by AMA in 1946 to Nuremberg as medical consultant to the American military tribunal in the Doctors' Trial.
- Self-experimenter in seawater studies, high altitude studies and experiments on volunteers for US Naval research

### Permissible Medical Experiments

# COMES TO BE KNOWN AS THE NUREMBERG CODE

### First principle

# CONSENT OF THE HUMAN SUBJECT IS ABSOLUTELY ESSENTIAL.

#### 9 additional principles

- Based on animal experimentation
- Must avoid all unnecessary suffering, injury
- No reason to think that death will result
- Risk should not exceed benefit
- Only scientifically qualified personnel

### Outcome of Doctors Trial

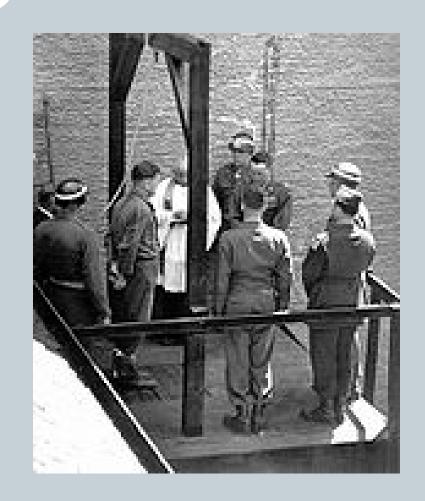
7 ACQUITTED, 7 RECEIVED DEATH SENTENCES, 9 RECEIVED PRISON SENTENCES RANGING FROM 10 YEARS TO LIFE IMPRISONMENT.

#### Karl Brandt sentenced to death

 Offers his body for experimentation

US Army rejects the offer

Executed at Landsberg
 Prison June 2, 1948



### The Nuremberg Code

### MEANING FOR AMERICAN MEDICAL RESEARCHERS?

### The Nuremberg Code

Published in Science in 1953

Part of a symposium about the limits and dilemmas posed by experimentation on human beings  Adopted by Secretary of Defense Charles Wilson in 1953 for the US armed forces

Classified as Top Secret

Implementation failure

# Would American investigators have met the Nuremberg Code?

NO.

## Many American researchers regarded the Code as unworkable

WOULD NOT ALLOW EXPERIMENTS ON CHILDREN, THOSE IN INSTITUTIONS, THE DYING, AND THE MENTALLY ILL.

#### In the 1950s Medical research in US

--associated with volunteers

- --traditions of self-experimentation
- --anticipated significant advances in medicine

#### Contaminated Blood Injection Kills Youth In Seattle Preservation Research Project

SEATTLE, March 24 (P)-An 18-year-old college honor student died yesterday of an injection of bacterially contaminated blood given during an experiment connected with war research on blood preservation by the University of Washington.

James Stanley Leedom, a freshman at Seattle University, was one of forty volunteers who participated in the project seeking better ways to preserve whole blood.

He died three days after the injection despite every effort to save his life.

Dr. Robert H. Williams, head of the University of Washington Department of Medicine, said the blood had become contaminated "by some phenomenon" after it had been refrigerated.

"The only way we can explain it," said Dr. Williams, "is that the bacteria was able to grow in some manner while the blood was at freezing temperature and not at body temperature."

ent A. Finch, Associate Professor shock and high fever, of Medicine in charge of hematol- The father, Stanley P. Leedom, ogy at the university, said they said he held no one at fault for would "gladly participate in the his son's death. same experiment tomorrow."

organism living on dead or decay- experiments." ing organic matter) that does not. The boy had planned to major grow at body temperature but in medicine.

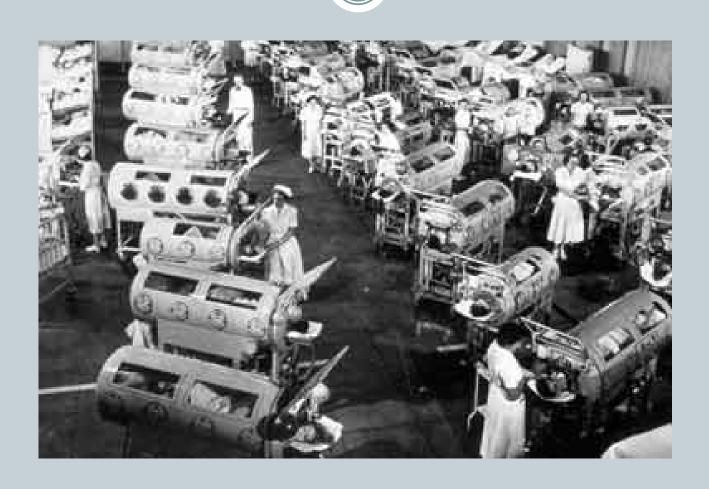


Associated Press Wirephoto James Stanley Leedom

Both Dr. Williams and Dr. Clem-thrives when chilled. It produces

"I don't blame anyone for this," They said the bacteria had not be said. "I just don't want this yet been identified, but they be-tragedy to deter in any way from lieved it to be a saprophyte (any the blood donor program or these

### Polio epidemic c. 1952







#### PARENTAL REQUEST FOR PARTICIPATION OF CHILD IN POLIOMYELITIS VACCINATION FIELD TRIAL

The National Foundation for Infantile Paralysis, Inc., in cooperation with state and local health, medical and educational authorities, is conducting a nation-wide field study of the effectiveness of a vaccine which may be protective against paralysis due to poliomyelitis. The vaccine consists of chemically killed poliomyelitis virus of all three known types. For purposes of this study, several thousand children will be given three injections of this vaccine into the arm over a period of several weeks; at least an equal number of unvaccinated children will be observed so that a comparison can be made between the two groups. The children in each group, those who are vaccinated and those who are not, are equally important to the study. In certain instances it will be necessary to test small samples of blood at intervals during the study to determine the amount of antibodies against poliomyelitis that are present.

I HEREBY REQUEST that my child,			<del></del>	, be vaccinated
if colored on atherwise he normitted to neutic	(first name)	(middle name)	(last name)	1
if selected, or otherwise be permitted to partic	ripate in the proce	edures described abo	ve without cost	to me.
Date	:	Signed		
	·			
	Relationship to	Child		
		(M	ust be parent or legal go	ardian)
School				
School		(Str	eet Address or Rural Lo	ocation)
Grade		W	7.4	8
		(City, Town	or Township)	(State)
				NFIP Form FT-1

### Efforts to create a workable code of ethics for human experimentation

- To protect human subjects
- To enable medical research to advance

 Undertaken by the World Medical Association and its committee on ethics

#### 1964

#### DECLARATION OF HELSINKI

Recommendations Guiding Doctors in Clinical Research

#### Declaration of Helsinki (1964)

- Distinguished clinical therapeutic research and nontherapeutic biomedical research.
- Clinical therapeutic research is justified if it improves the well being of the patient.
- Nonthereputic biomedical research is justified as long as the interest of society does not become more important than the concern for the well being of the patient.
- Permits proxy consent

#### Declaration of Helsinki Amended

- 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, Republic of South Africa, October 1996
- 59th WMA General Assembly, Seoul, Republic of Korea, October 2008
- 64th WMA General Assembly, Fortaleza, Brazil, October 2013

# Return to US and response to scandal and tragedy

#### By the 1960s no longer faith in medical researchers

## Henry Beecher's bombshell

Revelation of apparent abuses of human subjects, especially the Tuskegee Syphilis Study

#### HENRY K. BEECHER, M.D.



Professor of Anesthesia Research at Harvard Medical School

Convener of the Harvard Ad Hoc Brain Death Committee

## The New England Journal of Medicine

Copyright, 1966 by the Massachusetts Medical Society

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JUNE 16, 1966

Number 24

Reprinted from pages 1354-1360.

#### SPECIAL ARTICLE

#### ETHICS AND CLINICAL RESEARCH\*

HENRY K. BEECHER, M.D.†

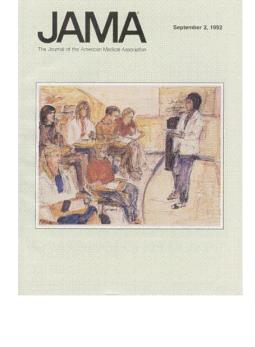
**BOSTON** 

HUMAN experimentation since World War II has created some difficult problems with the increasing employment of patients as experimental

Experimentation in man takes place in several areas: in self-experimentation; in patient volunteers and normal subjects in thereby and in the different

# 22 examples of "questionable" research practices

#### NOT FROM FRINGE BUT FROM MAINSTREAM RESEARCHERS AND INSTITUTIONS







Prevention of Infectory Embearditis. Caribities From the American Houst Association follows: In Caribities From the American Houri Association filteraturi. Association filteraturi. The Caribina Caribina Caribina, Caribina,

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Cover picarer. Localization of trepomodulin (grown) and a-settinit (rod) in candisensposts industed from a nontramagnic control (righ) and prosposoulin coverage-prosing transagesis (CDT) meass (pight). Control exh holes little or on overlay (solids)s) between trapermodulin and a-settinis tabels in control cells, but the abundant yellow signal in TOT cells indicates aberrant colocalization of trepomodulin with a-settinis. See that article by Sessions et al., pp. 31-61.

#### Why HENRY K. BEECHER?



Christian faith?

anesthesia?

experience with human subjects research?

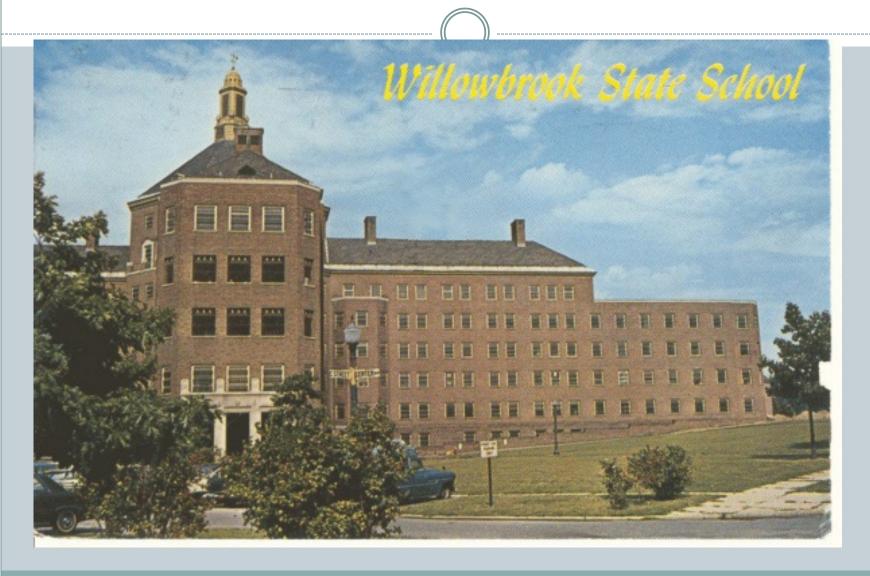
# Beecher concerned about new researchers who fail to understand their responsibilities

## BEECHER CONCERN WITH VULNERABLE RESEARCH SUBJECTS

# Who were the research subjects in Beecher's 22 examples?

"mentally defective" children mentally retarded and delinquent children the very elderly soldiers in the armed forces charity patients the terminally ill alcoholics children and newborns patients at the NIH Clinical Center

### Example 16



#### Willowbrook studies

Newly admitted children (whose parents give consent) are given intramuscular injections of hepatitis or "milkshakes" with hepatitis





Dr. Saul Krugman et al begin studies to acquire information about the natural history of hepatitis and work toward vaccine Krugman continued to defend the studies but issues persisted about informed consent, coercion, and study design (withholding gamma globulin)



SAUL KRUGMAN, M.D.

## Example 17



Funded by USPHS and American Cancer Society

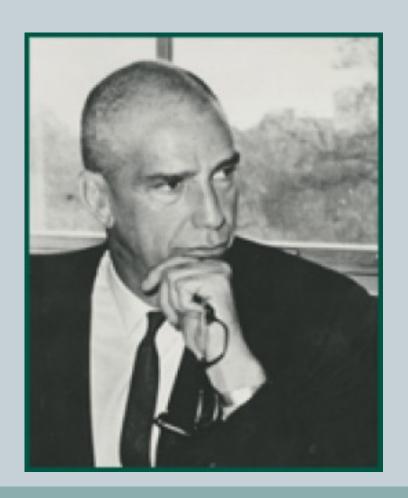
Injections of live cancer cells into elderly patients without consent

"did not wish to stir up any unnecessary anxieties in the patients" who had "phobia and ignorance" about cancer.

## Chester Southam, M.D.



Injecting prisoners at OSU



### Revelation of the Tuskegee Syphilis Study July 25, 1972

## The New York Times

#### Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,



## Study begins in 1932



(Courtesy National Archives)

## PHS Surgeon General Thomas Parran,



Shadow on the Land

Head of PHS, 1936-1948

#### INCIDENCE OF SYPHILIS AMONG NEGROES













ALBEMARLE COUNTY, VA.





Each symbol represents 3% of all Negroes studied

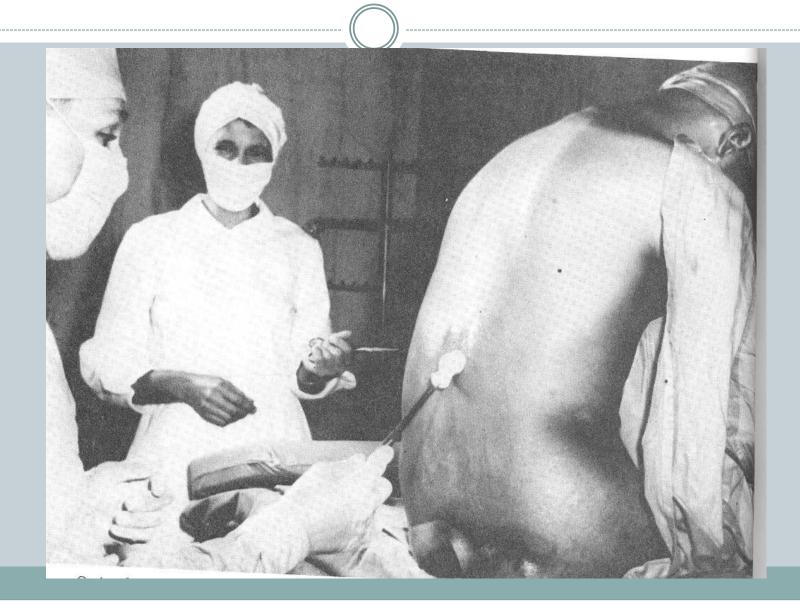
PICTORIAL STATISTICS, INC

## From treatment to "a study in nature"



Dr. Raymond
Vonderlehr offers
Negro men "last chance
for special free
treatment" for their
"bad blood"

## Lumbar puncture (to obtain spinal fluid for diagnosis)



### World War II

•PHS asks Tuskegee draft board to exempt the men in the study from the draft

They serve in another war

### **Nurse Eunice Rivers**



## Nurse Rivers

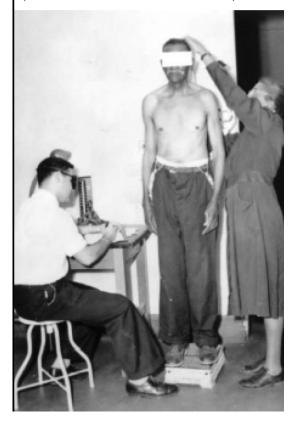


obtains permission for autopsy

easier when a burial stipend of \$50 is provided

only one refusal in 140 requests

Figure 3. An unaltered view. Nurse Eunice Rivers measures a participant in the TSUS. Dr. Stanley Schuman records the data. The photograph was taken in the TVAH in February 1952. (National Archives, CDC, East Point, GA)



## 1954

## FOR THE FIRST TIME, MENINTHE STUDY IDENTIFIED AS "VOLUNTEERS WITH SOCIAL INCENTIVES"

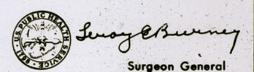
#### U. S. PUBLIC HEALTH SERVICE



This certificate is awarded to

In grateful recognition of 25 years
of active participation in the
Tuskegee medical research study.

Awarded 1958

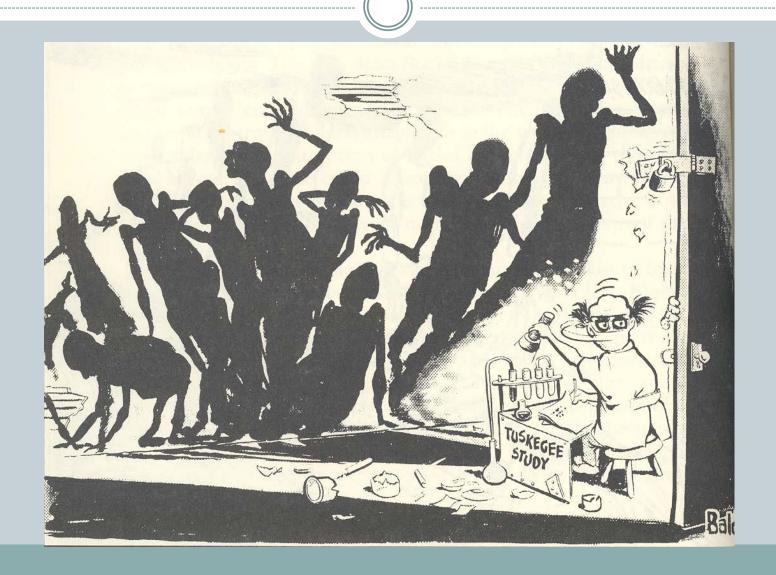


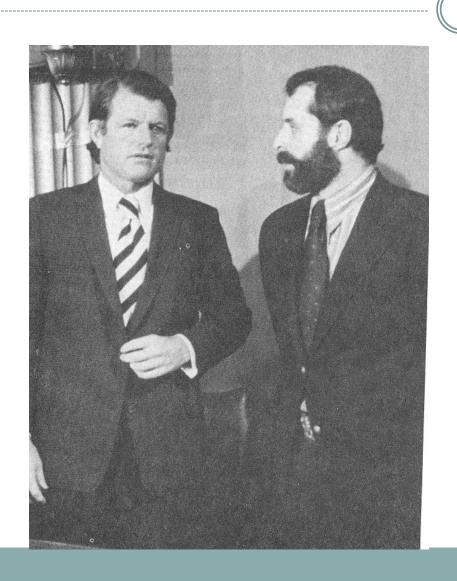
#### 1969

- --CDC convenes a blue-ribbon panel to determine whether Tuskegee study should continue
- --the only physician not familiar with the Study argues that the experiment should end and the men receive treatment

-- the Study continues until 1972

## Study Revealed July 25, 1972





- Senator Ted Kennedy holds hearings on human experimentation including the TSS
- Legislation passed1974
- National Research Act

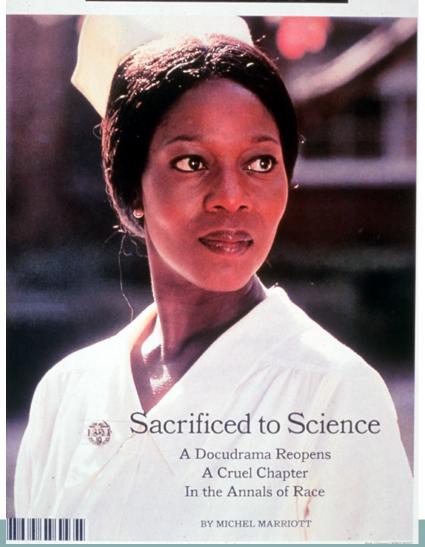
## 1974 National Research Act

creation of a National Commission to study the moral issues posed by human experimentation

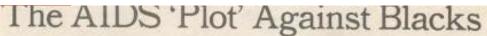
new federal regulations for IRBs and written informed consent

## **Television**

FEBRUARY 16-22



# Persistent stories about the deliberate infection of the men in Tuskegee with syphilis



Bizarre as it may seem to most people, many black Americans believe that AIDS and the health measures used against it are part of a conspiracy to wipe out the black race.

A survey of black church members in 1990 found that an astonishing 35 percent believed AIDS was a form of genocide. A New York Times/WCBS-TV News poll in 1990 found that 1 black in 10 believes the AIDS virus was "deliberately created in a laboratory in order to infect black people" and

an additional 2 in 10 thought that might be so. A Gallup/Newsweek poll in March produced similar results.

Even some dedicated black health workers engaged in the fight against AIDS decline to disavow these fears. Testifying before the National Commission on AIDS, one said that "until proven otherwise" she considered AIDS a man-made disease.

Worse yet, the treatments and preventives against AIDS have become suspect. Some blacks believe that AZT, the harsh drug used to combat the disease, is a plot to poison them.

... that campaigns urging use of condoms, the best way to prevent sexual transmission, are a scheme to reduce the number of black babies ... that distributing clean needles to slow transmission among addicts is a plot to encourage drug abuse.

At its most destructive, the paranoia causes many blacks to avoid medical treatment. Unless black and Hispanic leaders play a more vigorous role in countering the fears and mistrust, it will become ever harder to slow the epidemic.

The task is urgent because the disease is now spreading most rapidly among minorities. Last year, for the first time, the number of AIDS cases reported for minorities exceeded the number for whites. Most worrisome for the future, blacks account for a majority of AIDS cases in women and children. "AIDS in future generations may be primarily a disease of black people," the New York Department of Health warned last month.

Yet the response to this growing crisis has been sluggish. Financially pressed minority organizations and local governments have little energy for fighting AIDS, especially given the stigma attached to its main victims, homosexuals and drug addicts. But whether financing for minority AIDS programs has lagged behind white programs, as some black leaders charge, is not clear. Federal and state funds to minority AIDS organizations have gone up and the Government's central programs, like counsel-

ing and testing services, have huge minority caseloads.

No programs, even if well financed, will succeed without a change in attitudes. Thus it is welcome news that the New York State Health Department, with the help of black politicians and community leaders, has started a media campaign to encourage blacks to mobilize against AIDS.

The campaign rightly stresses that AZT and condoms are not plots against blacks. But it refuses to counteract the paranoia about AIDS as genocide, saying only that no matter

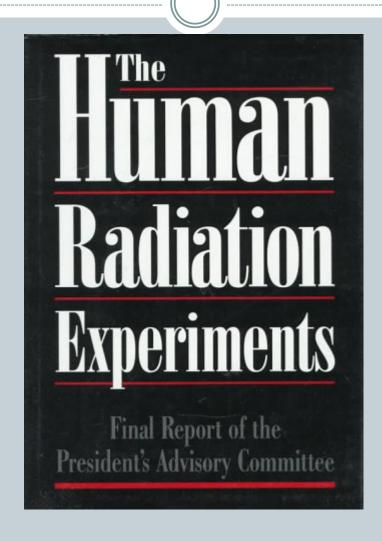
how AIDS got started, there are ways to stop it. Campaign officials reasoned that few blacks would believe government denials anyway. But surely black leaders and public figures with high credibility, such as Magic Johnson, the basketball star, could do much to discredit the pernicious and dispiriting rumors.

Meanwhile, Federal, state and local health officials need a far better assessment of the flow of AIDS money into minority communities and stronger programs to fight the disease there. Costly drug treatment ought to be provided to all who seek it, an investment that would yield dividends far beyond slowing the spread of AIDS. And more vigorous outreach programs might persuade more individuals to avoid risky behavior.

As white Americans, shaken by the riots in Los Angeles, search for ways to help afflicted and distrustful minorities, there's no wiser way to start than AIDS. A failure to treat and prevent AIDS among minorities: That would be the true genocide.



## Presidential apology 1995



## White House Apology for the Syphilis Study,





White House apology ceremony, 16 May 1997. Participants and survivors of the study (first row): Herman Shaw, Fred Simmons, Charles Pollard, Frederick Moss, Carter Howard. White House officials (back row): U.S. Surgeon General David Satcher, President William J. Clinton, Vice-President Albert Gore.

## Revelations of scandal and tragedy continue

#### 2010

 President Obama and Secretary of State Hillary Rodham Clinton apologize to people of Guatemala for studies conducted in 1946-1948



## US Infected Thousands of Guatemalans With STDs

Earlier reports said hundreds were victims

Sep 2, 2011 8:46 AM CDT

#### John Cutler, STD studies



John C. Cutler From the National Library of Medicine

 Using prostitutes infected with syphilis and gonorrhea to deliberately infect Guatemalan soldiers and prisoners

 Infecting prisoners manually with STDS

### Guatemala, 1946-48



 Infecting inmates of mental hospital with STDS



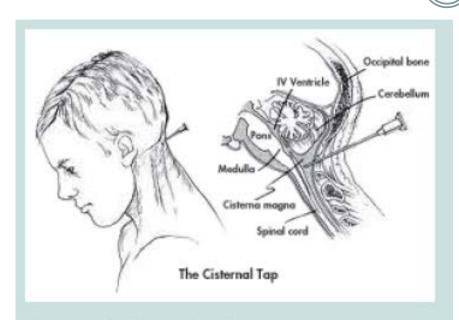
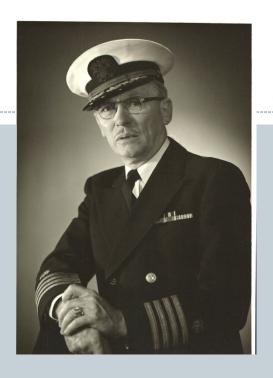


Diagram of a cisternal puncture. From Alexander G. Reeves, M.D. and Rand S. Swenson, M.D., Ph.D., "Disorders of the Nervous System"

- experiments in Guatemala that eventually expose 1,308 prisoners, soldiers and patients at a psychiatric hospital to STDs.
- The US team also takes blood from 1,384 orphans and other children to assess STD diagnostic tests.





I saw Doctor Parran on Friday and he wanted to know if I had had a chance to visit your project. Since the answer was yes, he asked me to tell him about it and I did so to the best of my ability. He was familiar with all the arrangements and wanted to be brought up to date on what progress had been made. As you well know, he is very much interested in the project and a merry twinkle came into his eye when he said, "You know, we couldn't do such an experiment in this country."



"ETHICALLY IMPOSSIBLE" STD Research in Guatemala from 1946 to 1948

Presidential Commission for the Study of Bioethical Issues

# Ongoing challenge to protect human subjects and advance medical knowledge