

# History of Research Ethics

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University of Wisconsin  
**SCHOOL OF MEDICINE  
AND PUBLIC HEALTH**



# Disclosure

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



Why do we have the  
rules for research that  
we have?

U.S. health policy as  
response to scandal and  
tragedy

# Early 20th century the Patent Medicine Evil

**MARIANI WINE**

MARIANI WINE Quality Restores  
**HEALTH, STRENGTH,  
ENERGY & VITALITY.**

MARIANI WINE  
FORTIFIED, STRENGTHENS,  
STIMULATES & REFRESHES  
THE BODY & BRAIN

HASTENS  
CONVALESCENCE  
especially after  
**INFLUENZA.**

His Holiness  
**THE POPE**

writes that he has fully appreciated the beneficial effects of this Tonic Wine and has forwarded to Mr. Mariani as a token of his gratitude a gold medal bearing his august effigy.



**MARIANI WINE**

Is delivered free to all parts of the United Kingdom by WILCOX & CO.,  
83, Mark Lane Street, London, W.; price 4/- per Single Bottle, 22/- half-  
dozen, 43/- dozen, and is sold by Chemists and Stores.



**COCAINE**  
**TOOTHACHE DROPS**

Instantaneous Cure!  
**PRICE 15 CENTS.**

Prepared by the  
**LLOYD MANUFACTURING CO.**

219 HUDSON AVE., ALBANY, N. Y.

For sale by all Druggists.

(Registered March 1885.) See other side.

# Early 20<sup>th</sup> century Unsafe food supply



# Food and Drug Act 1906



# Elixir of Sulfanilamide Tragedy 1937

Click the "X" in the upper right hand corner of this window to return


ONE GALLON ELIXIR ONE GALLON

## SULFANILAMIDE

Each fluidounce represents:  
Sulfanilamide, 40 grs.

SUGGESTED FOR THE TREATMENT OF ALL CONDITIONS  
IN WHICH THE HEMOLYTIC STREPTOCOCCI APPEAR

Dose, begin with 2 to 3 teaspoonfuls in water  
every four hours. Decrease in twenty-four  
to forty-eight hours to 1 or 2 teaspoonfuls  
and continue at this dose until recovery.



THE S. E. MASSENGILL COMPANY  
Manufacturing Pharmacists  
BRISTOL, TENN.-VA.

Please do not copy or reproduce this picture in any way.

## DRUG FATALITY CAUSE IS TRACED TO 'ELIXIR'

### A.M.A. Chemists Say Diethylene Glycol Added to Sulfanilamide Killed 13

CHICAGO, Oct. 19 (AP).—Dr. Morris Fishbein, editor of the Journal of the American Medical Association, said tonight that laboratory experiments made it quite evident that the diethylene glycol, not the sulfanilamide of an "elixir of sulfanilamide" was responsible for the deaths of thirteen persons using the



107 DEATHS  
ATTRIBUTED TO  
ELIXIR OF  
SULFANILAMIDE

DISSOLVED IN  
DIETHYLENE  
GLYCOL

Massengill fined \$15,000

**VICTIM OF 'BOTTLED DEATH'**

**Bravely Takes Hated 'M...ine,' Dies**



**JO ANNE**

Bottles like the one shown here contained a mixture which brought high hopes to physicians throughout the country. But the hopes turned to shocked despair when some patients who had been treated with the new elixir of sulfanilamide began to die. First Ohio victim of the "bottled death" was 6-year-old Jo Anne Cramer of Ghent, who died here Oct. 17.



# Diet and cosmetic dangers c. 1930s



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# Food, Drug and Cosmetic Act of 1938

Drugs or cosmetics must be tested for toxicity before marketing.

Adequate directions for use needed to be on package

Some drugs are designated “by prescription only”



# Thalidomide

1960-1961

83 children born with unusual birth defects,

a German scientist connects prenatal thalidomide use and thousands of babies born with birth defects.



# Kefauver-Harris Amendments to FDA

Frances Kelsey,  
FDA



FDA can  
demand  
scientific  
data to  
determine  
the drug  
works



# Kefauver-Harris Amendments to FDA

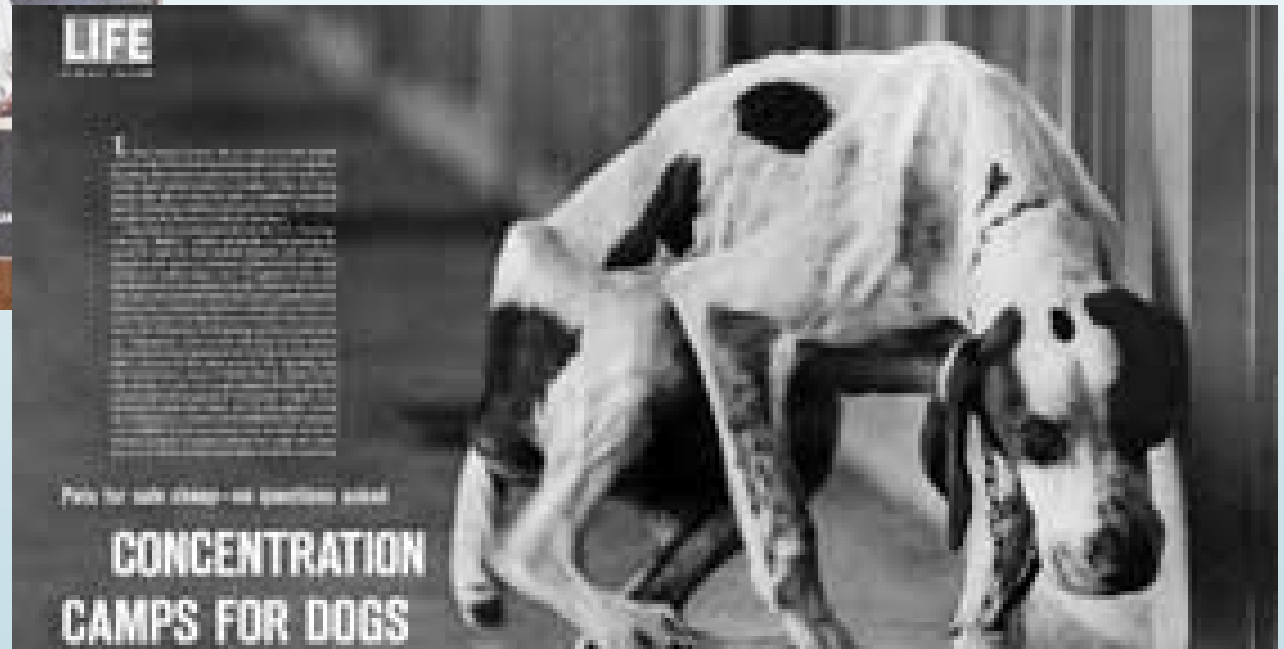
Drug makers must establish the effectiveness of drug products before they go on the market, and afterwards report any serious side effects.

Requires clinical studies conducted by qualified experts.

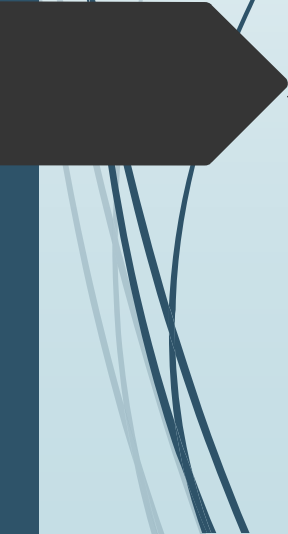
Requires informed consent by study subjects



# LIFE MAGAZINE 1966



# Animal Welfare Act, 1966



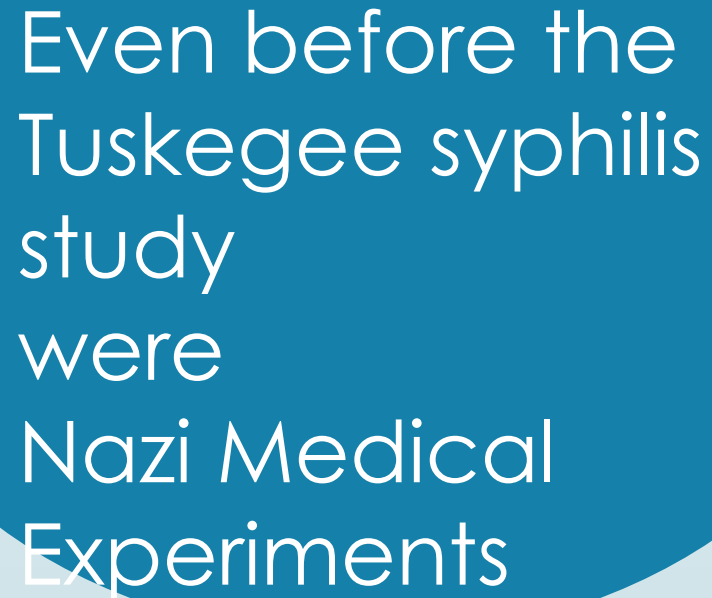

After six decades of agitation, the photoessay in Life prompted more mail to Congress than the Vietnam War and led to legislation (later amended).






# National Research Act 1974





Even before the  
Tuskegee syphilis  
study  
were  
Nazi Medical  
Experiments



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

# United States Congress, 1900

Proposed legislation

Senate bill 3424,

a law that would have

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



# Senate bill 3424

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



including

infants,

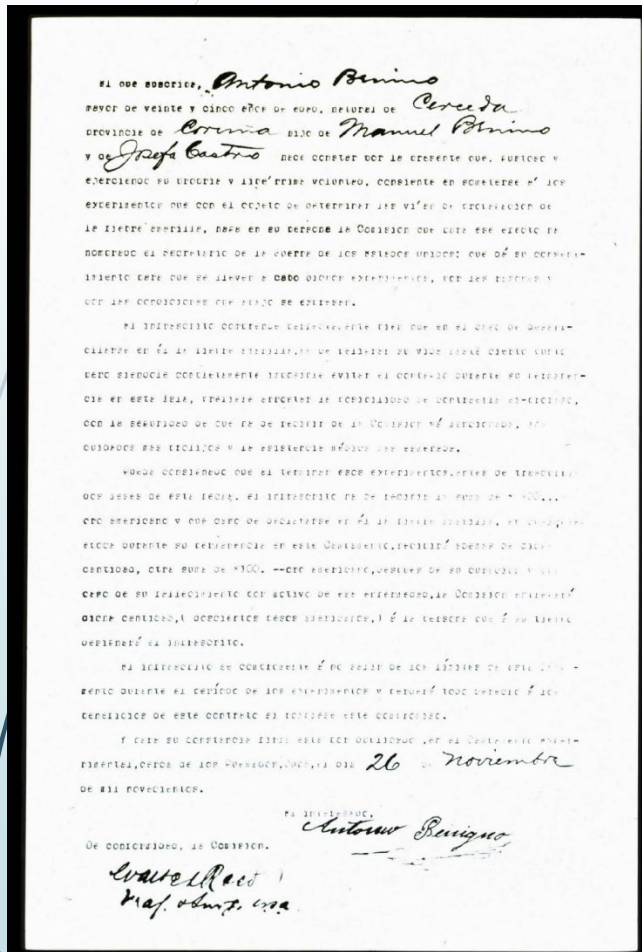
children under the age of 21,

and pregnant women.

# U.S. Army Yellow Fever Board in Cuba, 1900



# Reed and his colleagues introduce written permission forms



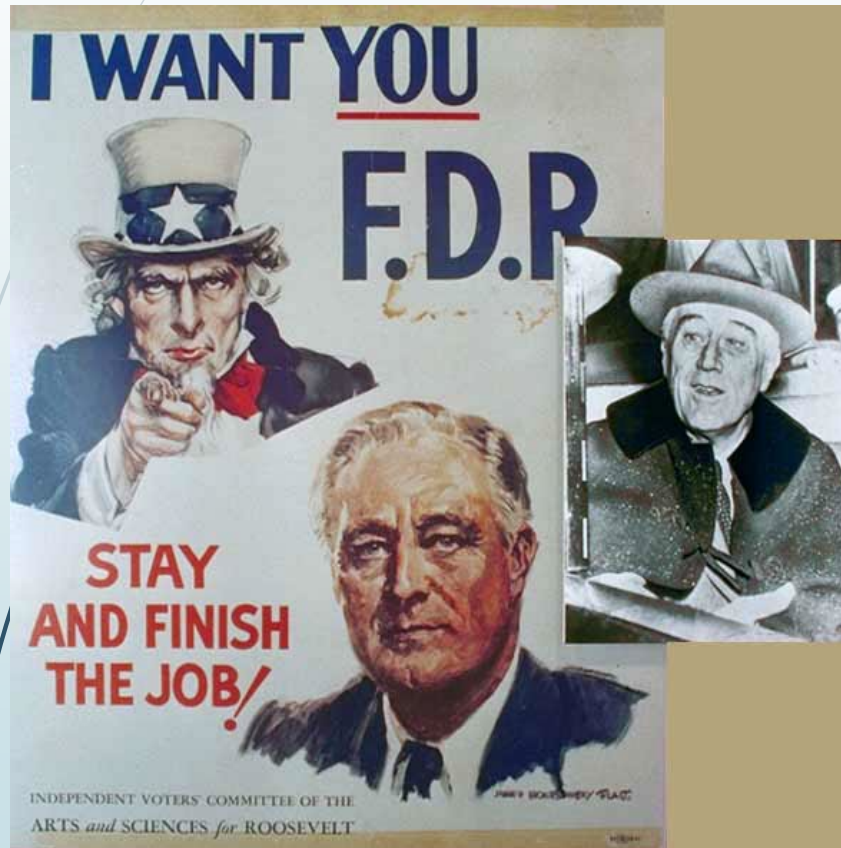
available in both  
English and Spanish

warns of danger to  
life in experiments  
with mosquitos and  
infected material  
promises good  
medical care  
compensation

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



# World War II



- ▶ President Roosevelt's Office for Scientific Research and Development (1941)
- ▶ Unprecedented federal funding for medical research related to war effort



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# Military Medical Research agenda

hypothermia

effects of high altitude

de-salination studies

burns/wounds

blood substitutes

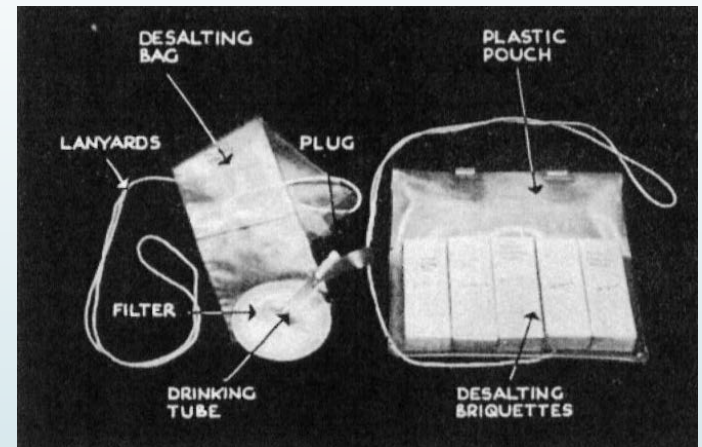
Prevention and treatment of infectious diseases

malaria

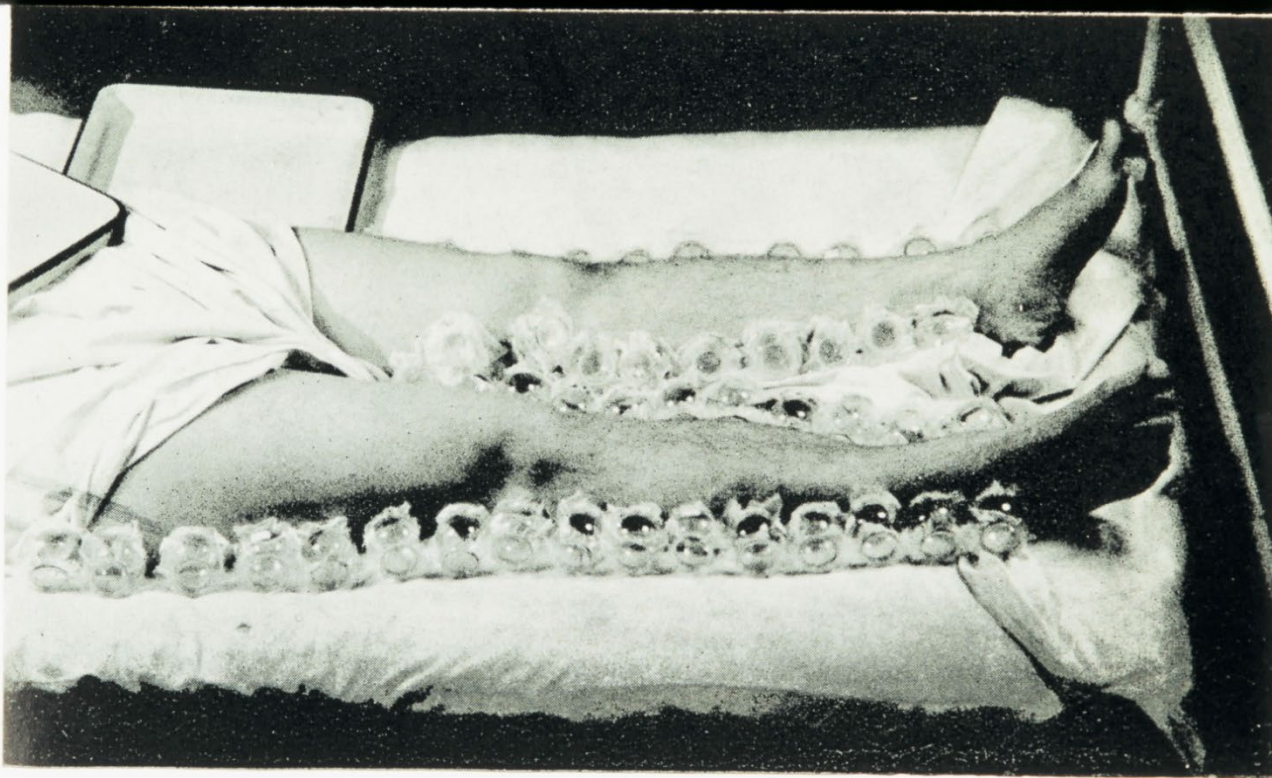
gonorrhea

hepatitis

# De-salting sea water



# Malaria research



*U. S. Public Health Service*

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

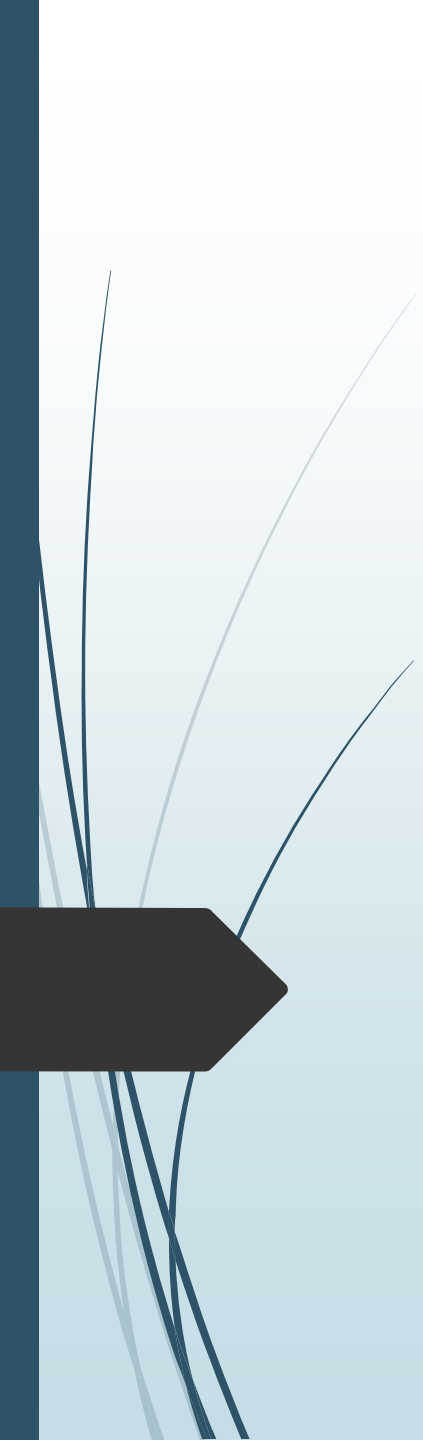
blood substitutes

vaccines and treatment

malaria

gonorrhoea

hepatitis



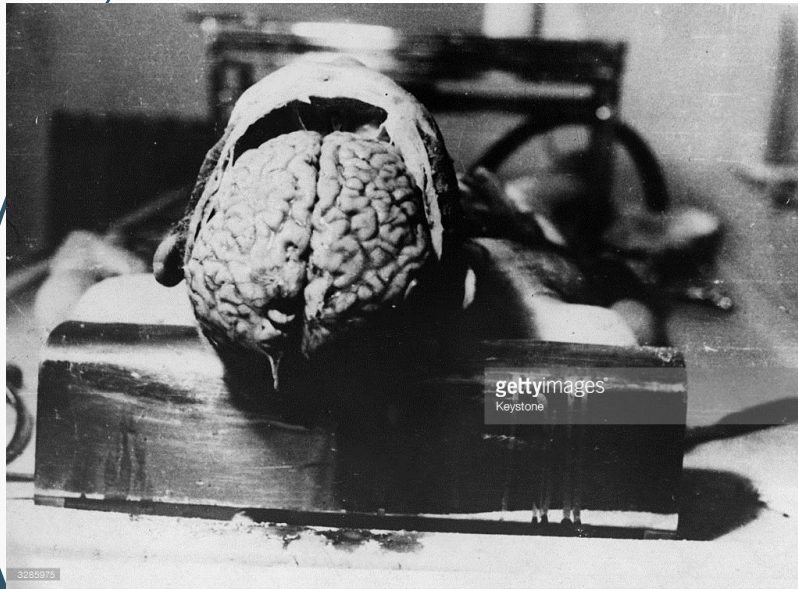
Nazi researchers use  
concentration camp  
inmates as subjects

# Dachau Concentration Camp— studying effects of hypothermia and rewarming c. 1942



## Dachau Concentration Camp studies of effects of high altitude

- ▶ Death as an endpoint in order to study post-mortem changes in brain



# Sea water studies

- ▶ A Roma 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”

- 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

- Brutal treatment of subjects when unable to comply with regime
- Test subjects undergo:
  - Liver punctures
  - Spinal punctures

# Studies of burns and wounds, 1942



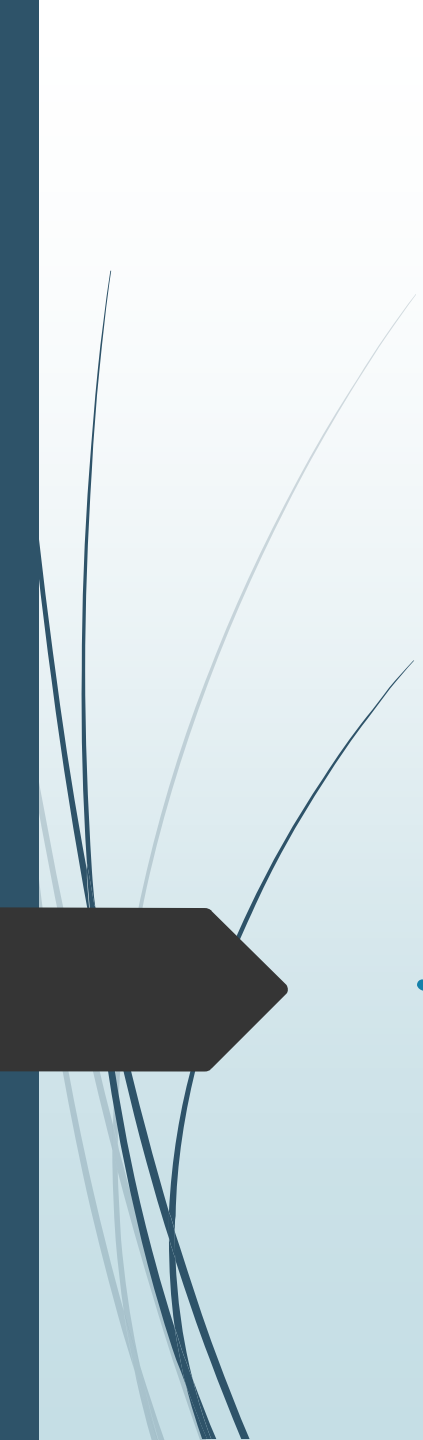
- disfigured leg of a survivor from Ravensbrueck,
- scars resulted from incisions made by medical personnel that were purposely infected with bacteria, dirt, and slivers of glass.

# 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



Life Photo by Myron Davis

Malarial convicts contribute to knowledge of the disease

**LIFE**

**TO THE AMERICAN PEOPLE:**

Your sons, husbands and brothers who are standing today upon the battlefronts are fighting for more than victory in war. They are fighting for a new world of freedom and peace.

We, upon whom has been placed the responsibility of leading the American forces, appeal to you with all possible earnestness to invest in War Bonds to the fullest extent of your capacity.

Give us not only the needed implements of war, but the assurance and backing of a united people so necessary to hasten the victory and speed the return of your fighting men.

*William F. Buckley Jr.*  
*Do it for the fighting*  
*A simple thing to do, but*  
*of great importance*  
*W. F. Buckley Jr.*

**JUNE 4, 1945 10 CENTS**  
 BY SUBSCRIPTION, TWO YEARS \$1.00

MEDICINE

**PRISON MALARIA**

Convicts expose themselves to disease so doctors can study it

THEY COLLECT MALARIAL PARASITES FROM CONVICTS OF SEVERAL PRISONS, SERVING TO 10 YEARS AT ILLINOIS STATE PRISON.

John C. W. malarial convicts who have been imprisoned in various of nearly 400 prisons and penitentiaries in Illinois, the Illinois State Penitentiary, the State Reformatory for Women and the State Reformatory for Men. The convicts have volunteered to be infected with malarial parasites so that they can study the disease. The convicts, who are divided by the type of their offense, are kept in separate, well-ventilated cells. Research on the convicts has been going on for several years. The convicts are kept in their cells for several days before they are infected with malarial parasites. The convicts are kept in their cells for several days before they are infected with malarial parasites. The convicts are kept in their cells for several days before they are infected with malarial parasites.



# 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

. The voluntary consent of the human subject is absolutely essential.

# 9 additional principles include

Based on prior 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.

Many had sentences reduced.

# 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

What did it mean to American  
medical researchers?

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# On the one hand Nuremberg Code known to American medical researchers

In 1953 the journal  
Science published the  
Code and a symposium  
about the Code and its  
implications for research

- ▶ 1953  
Secretary of Defense  
Charles Wilson requires  
code for research in the  
US armed forces
- ▶ Classified as Top Secret



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# On the other hand

- ▶ The Code seen as necessary for "barbarians" like Nazis
- ▶ Americans already careful about safety and welfare of their subjects



Would American investigators  
have met the Nuremberg  
Code?

No.

## In the 1950s Medical research in US

--associated with volunteers

--traditions of self-experimentation

--anticipated significant advances in  
medicine



# Death of a Volunteer

March, 1952

3/25/52

NYT

TI

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

SEATTLE, March 24 (AP)—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."

Both Dr. Williams and Dr. Clement A. Finch, Associate Professor of Medicine in charge of hematology at the university, said they would "gladly participate in the



Associated Press Wirephoto

James Stanley Leedom

thrives when chilled. It produces shock and high fever.

The father, Stanley P. Leedom, said he held no one at fault for his son's death.

# 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, \_\_\_\_\_, be vaccinated  
(first name) (middle name) (last name)  
if selected, or otherwise be permitted to participate in the procedures described above without cost to me.

Date \_\_\_\_\_

Signed \_\_\_\_\_

Relationship to Child \_\_\_\_\_  
(Must be parent or legal guardian)

School \_\_\_\_\_

\_\_\_\_\_  
(Street Address or Rural Location)

Grade \_\_\_\_\_

\_\_\_\_\_  
(City, Town or Township)


\_\_\_\_\_  
(State)



# Many American researchers regarded the Code as unworkable

would not allow experiments on children, those in institutions, the dying, and the mentally ill.



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# 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

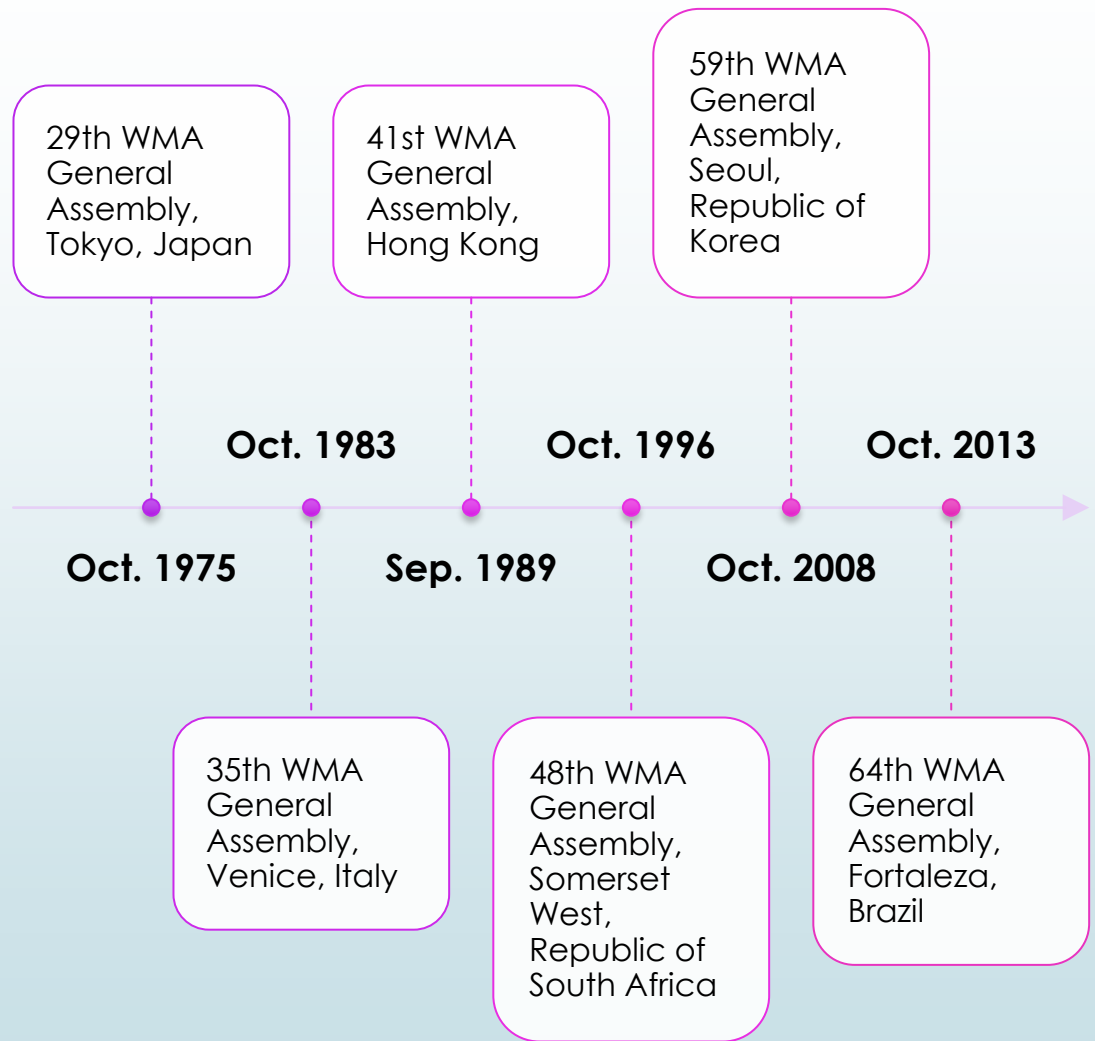
Recommendations Guiding Doctors in Clinical Research

# 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.
- ▶ Non-therapeutic 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





# Return to US and response to scandal and tragedy



By the 1960s  
no longer faith in medical  
researchers

Dr. 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



1966

# The New England Journal of Medicine

Copyright, 1966 by the Massachusetts Medical Society

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Volume 274

JUNE 16, 1966

Number 24

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*Reprinted from pages 1354-1360.*

## **SPECIAL ARTICLE**

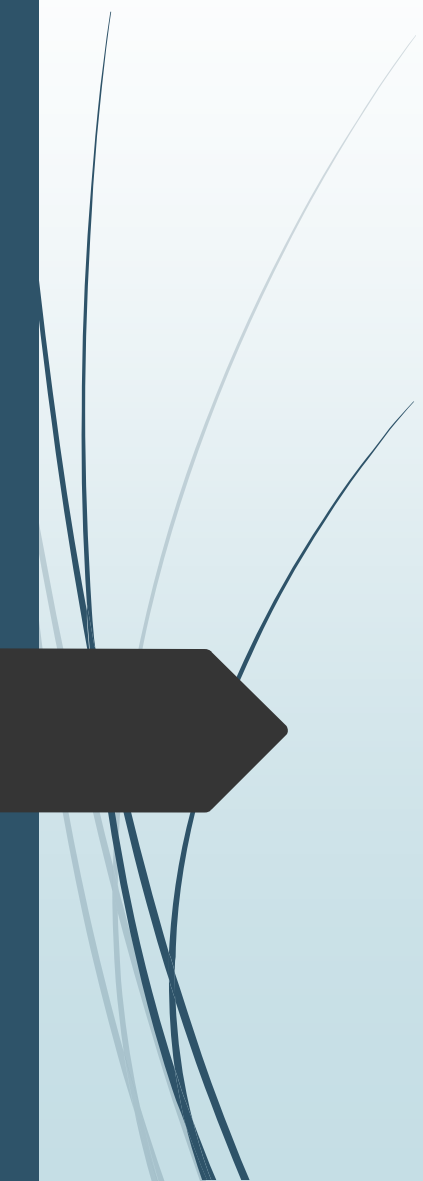
### **ETHICS AND CLINICAL RESEARCH\***

HENRY K. BEECHER, M.D.†

BOSTON

**H**UMAN experimentation since World War II has created some difficult problems with the increasing employment of patients as experimental subjects. Experimentation in man takes place in several areas: in self-experimentation; in patient volunteers and normal subjects; in therapy; and in the different



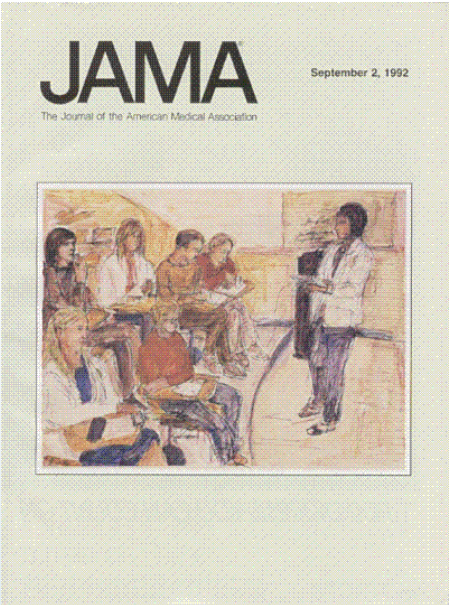


# 22 examples of “questionable” research practices

Not from fringe BUT from mainstream  
researchers and institutions



5




2



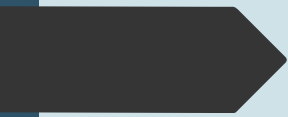
5



2



Beecher concerned  
about young  
researchers who fail  
to understand their  
responsibilities



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

“mentally defective” children

“mentally retarded” people and  
“juvenile delinquents”

the very elderly

soldiers in the armed forces

charity patients

the terminally ill

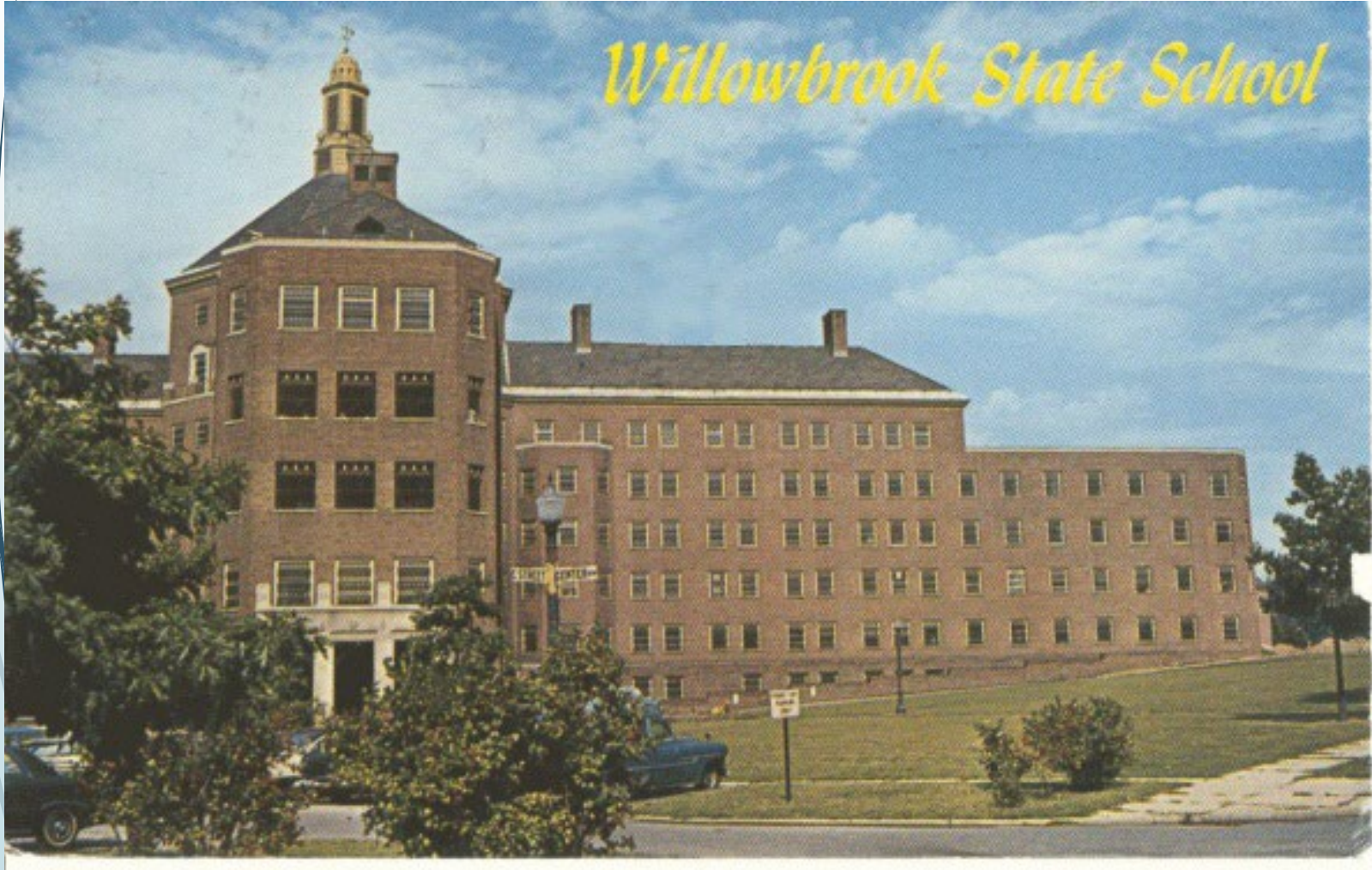
alcoholics

children and newborns

patients at the NIH Clinical Center

# Example 16

*Willowbrook State School*



# Willowbrook: an institution for “mentally defective children”

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

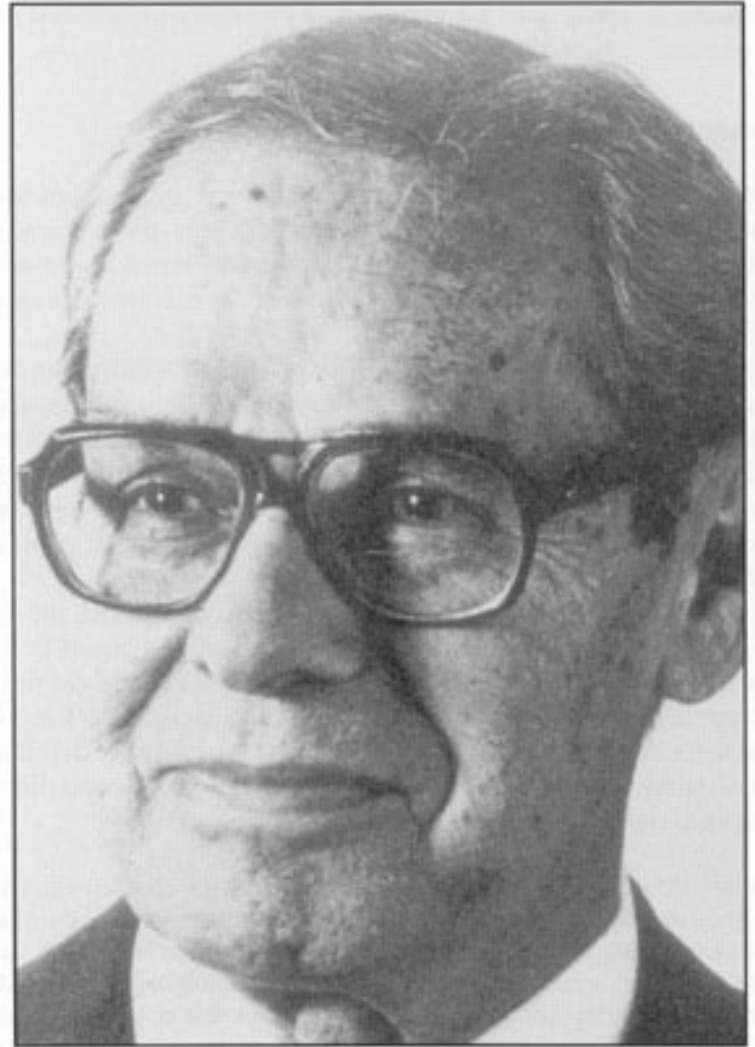


- ▶ Dr. Saul Krugman et al begin studies to acquire information about the natural history of hepatitis and work toward vaccine



Krugman continued to defend the studies but

issues persist about informed consent, coercion, and study design (withholding gamma globulin)



**SAUL KRUGMAN, M.D.**



## Example 17

# Jewish Chronic Disease Hospital case

Funded by USPHS and  
American Cancer  
Society

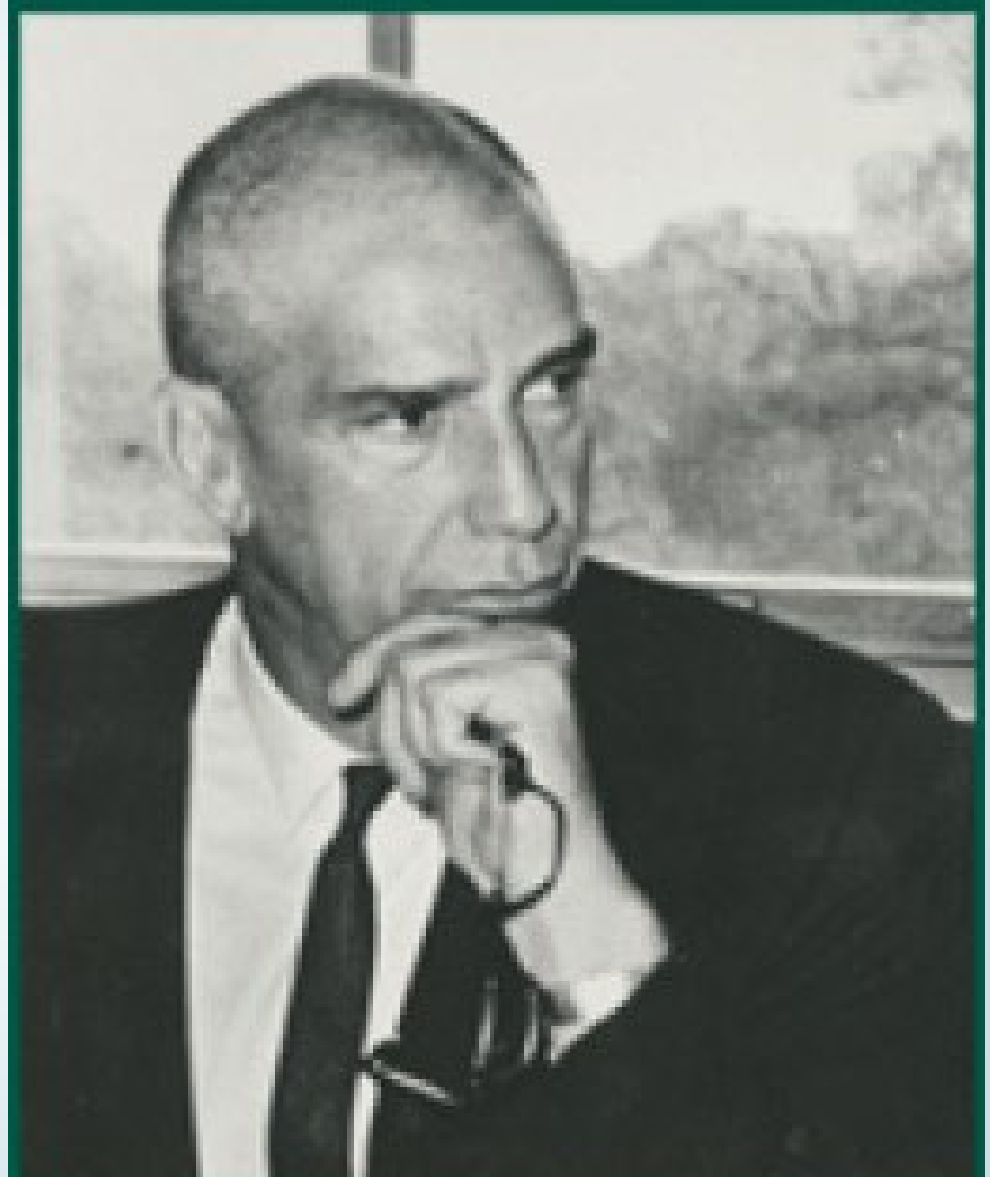
Injections of live cancer  
cells into elderly patients  
without consent

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

## Chester Southam, M.D.

risks and nonetheless eager to take part in it. "I would not have hesitated," Southam said, "if it would have served a useful purpose. But," he continued, "to me it seemed like false heroism, like the old question whether the General should march behind or in front of his troops. I do not regard myself as indispensable—if I were not doing this work someone else would be—and I did not regard the experiment as dangerous. But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk."

Science, 1964



# 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)

# Public Health Service Surgeon General Thomas Parran,

*Shadow on the  
Land*

Head of PHS, 1936-  
1948



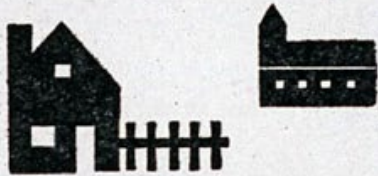
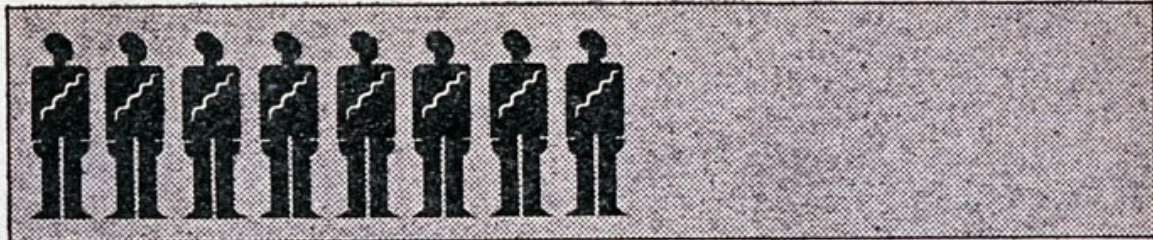
# INCIDENCE OF SYPHILIS AMONG NEGROES



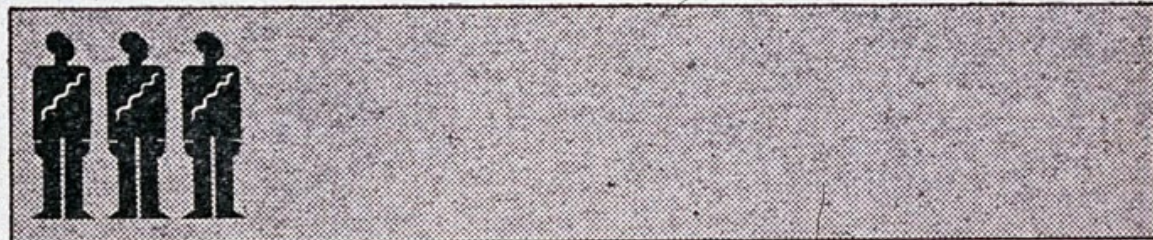
MACON COUNTY, ALA.



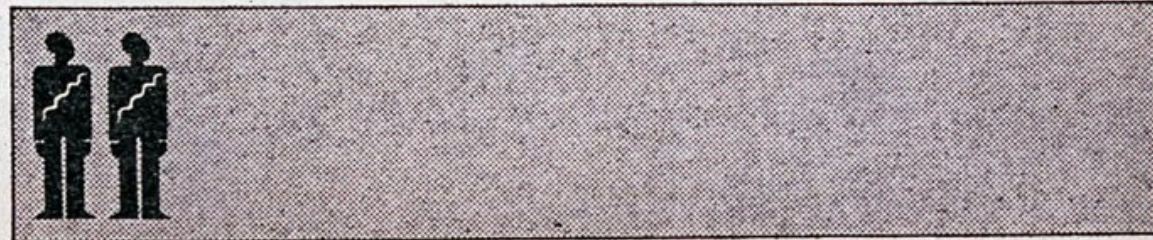
BOLIVAR COUNTY, MISS.




ALBEMARLE COUNTY, VA.



MEHARRY UNIVERSITY, TENN.



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



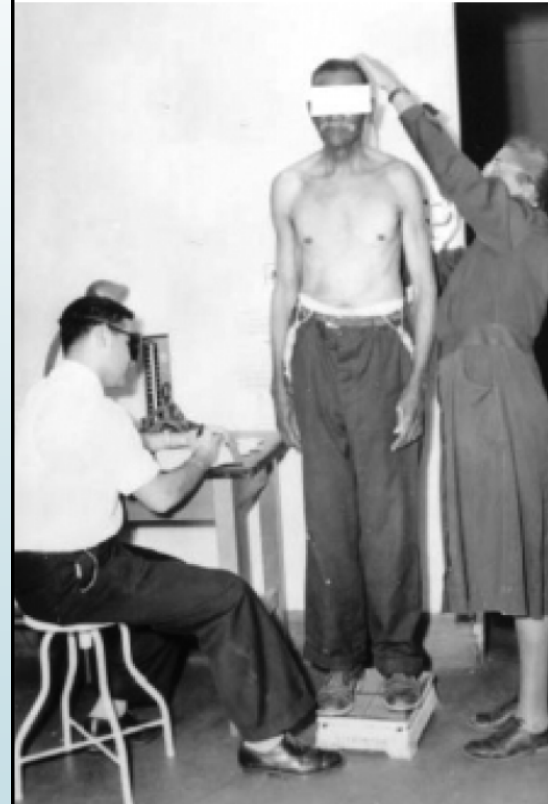
# Nurse Rivers

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, men in the study identified as “volunteers with social incentives”

1957-1958

Efforts to keep up morale in study subjects

Each man in the study receives a dollar for every year of their participation

\$25

U. S. PUBLIC HEALTH SERVICE

25

This certificate is awarded to

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



Awarded 1958

*LeRoy C. Burne*

Surgeon General



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 passed 1974
- ▶ National Research Act



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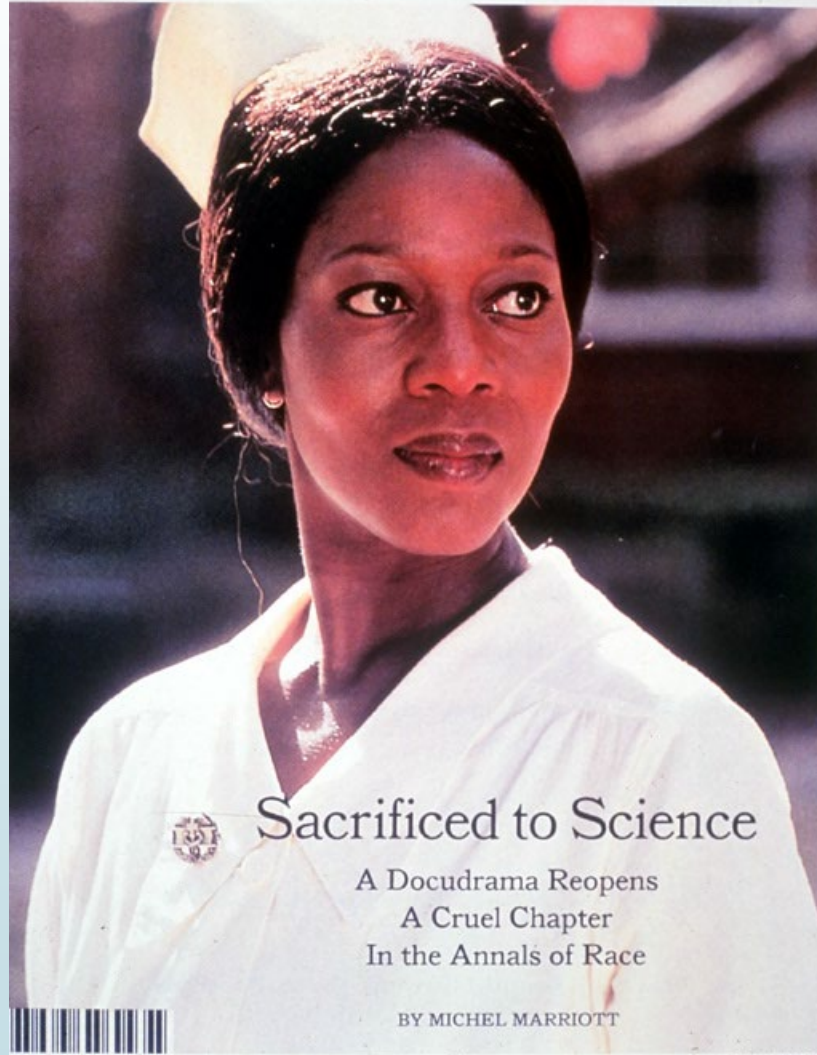
# 1974 National Research Act

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



## Sacrificed to Science

A Docudrama Reopens  
A Cruel Chapter  
In the Annals of Race

BY MICHEL MARRIOTT





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

c. 1992

Impact on willingness of African Americans to participate in AIDS research and treatment

## The AIDS 'Plot' Against Blacks

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 counseling 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

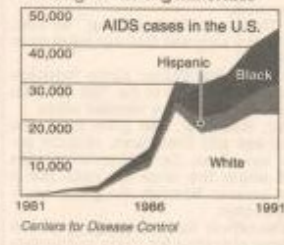
how AIDS got started, there are ways to stop it. Campaign officials reasoned that few blacks would believe government denials anyway. But surely black leaders and public figures with high credibility, such as Magic Johnson, the basketball star, could do much to discredit the pernicious and dispiriting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

### The Plague Spreads

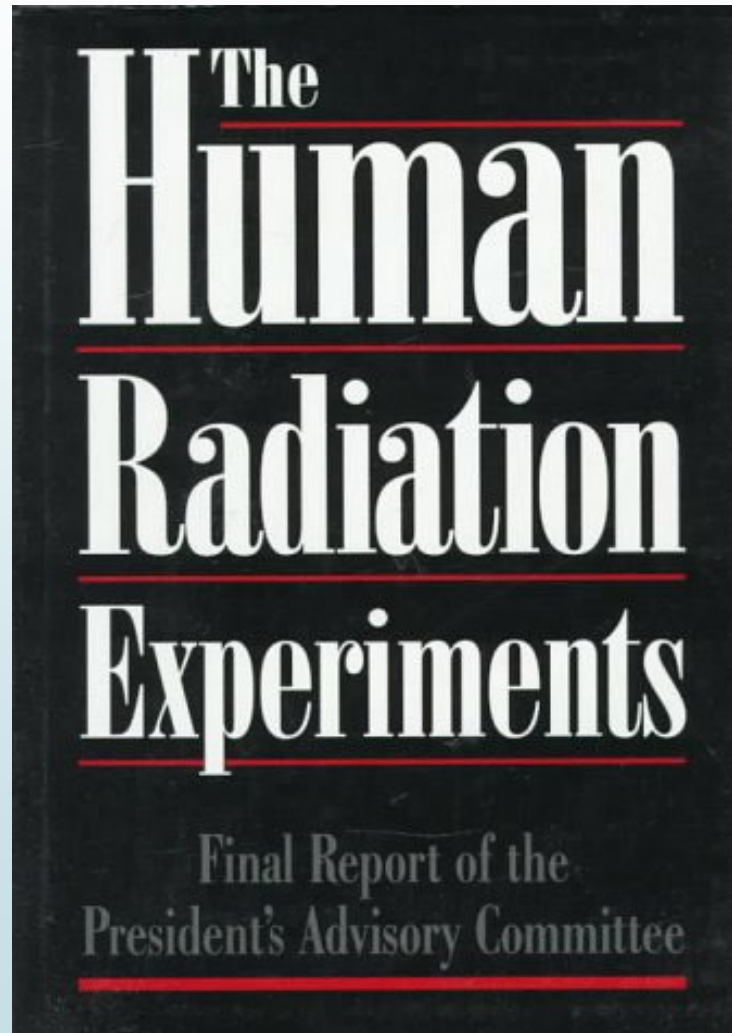
A rising toll among minorities



Centers for Disease Control



# 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*

- ▶ Uses sex-workers infected with syphilis and gonorrhea to deliberately infect Guatemalan soldiers and prisoners
- ▶ Infected prisoners manually with STDs

# Guatemala, 1946-48



- ▶ Infecting inmates of mental hospital with STDS



# PHS STD studies in Guatemala

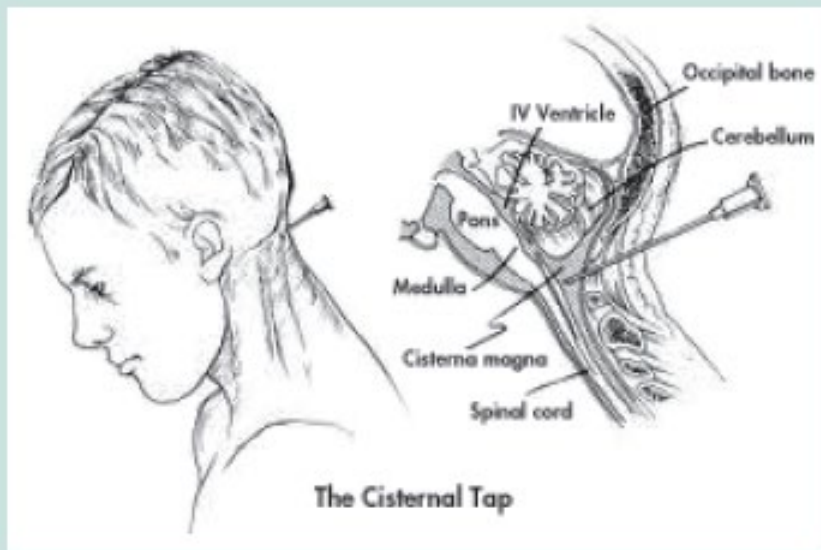


Diagram of a cisternal puncture.  
From Alexander G. Reeves, M.D. and Rand S. Swenson,  
M.D., Ph.D., "Disorders of the Nervous System"

- ▶ eventually infect 1,308 prisoners, soldiers and patients at a psychiatric hospital with STDs.
- ▶ Evidence that 80% or more recent penicillin as treatment
- ▶ The US team also takes blood from 1,384 orphans and other children to assess STD diagnostic tests.

# Guatemalan Studies never published

- ▶ Cutler kept records of the studies in his papers
- ▶ Included photographs of the “subjects”
- ▶ Correspondence between researchers and PHS, physicians at other institutions



“You know, we couldn’t do such an experiment in our country.”

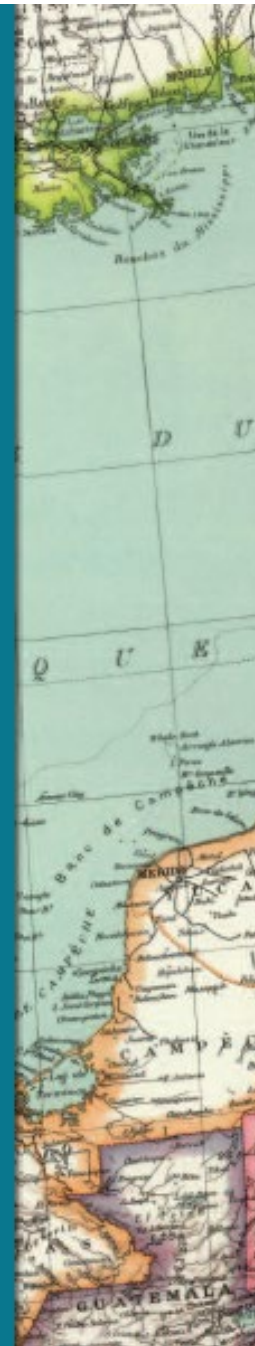
Surgeon General Thomas Parran, 1948



“ETHICALLY IMPOSSIBLE”  
STD Research in Guatemala  
from 1946 to 1948

Presidential Commission  
*for the Study of Bioethical Issues*

September 2011





Ongoing challenges  
to protect human  
subjects and  
advance medical  
knowledge