

History of Research Ethics

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

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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 (Special) 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.,
82, Mark Lane Street, London, W., price 2/- per Single Bottle, 2s 6 half-
dozen, 41/- 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 20th 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

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Kefauver-Harris Amendments to FDA

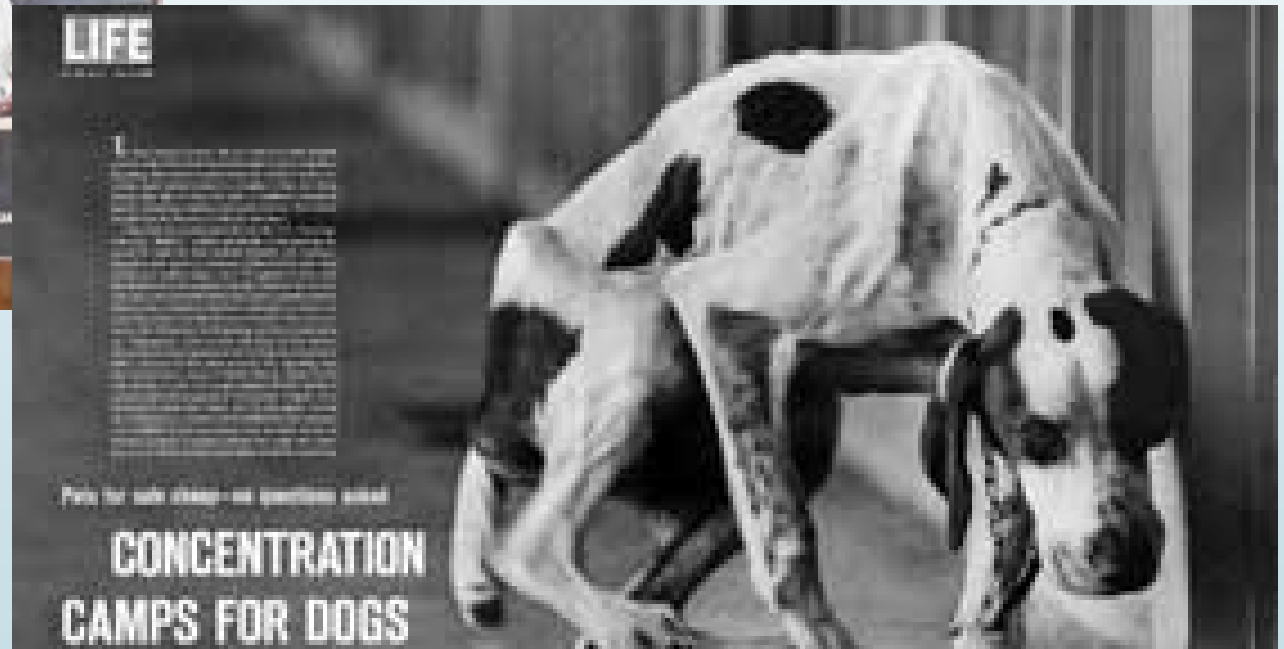
Drug makers must establish the effectiveness of drug products before they go on the market, and afterwards report any serious side effects.

Requires clinical studies conducted by qualified experts.

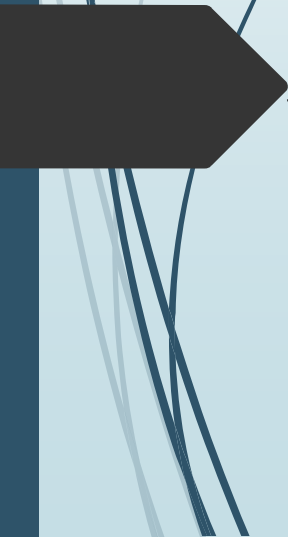
Requires informed consent by study subjects



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,

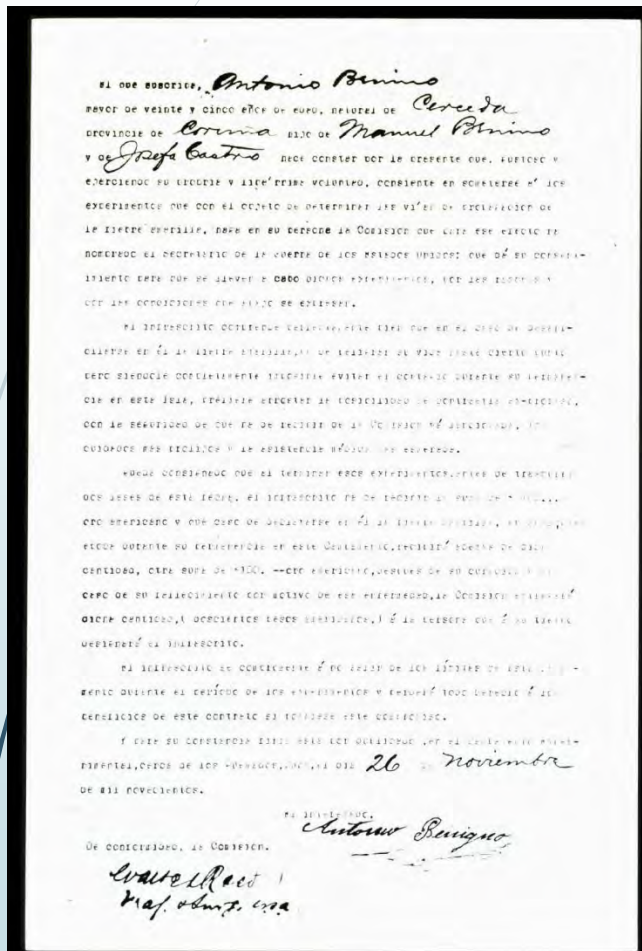
children under the age of 21,

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

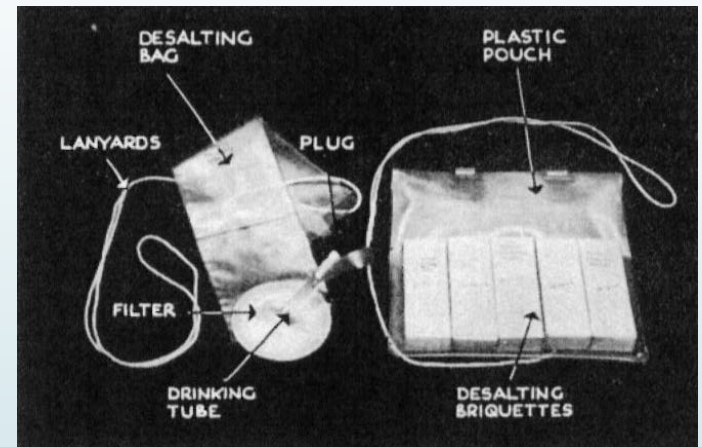
Prevention and treatment of infectious diseases

malaria

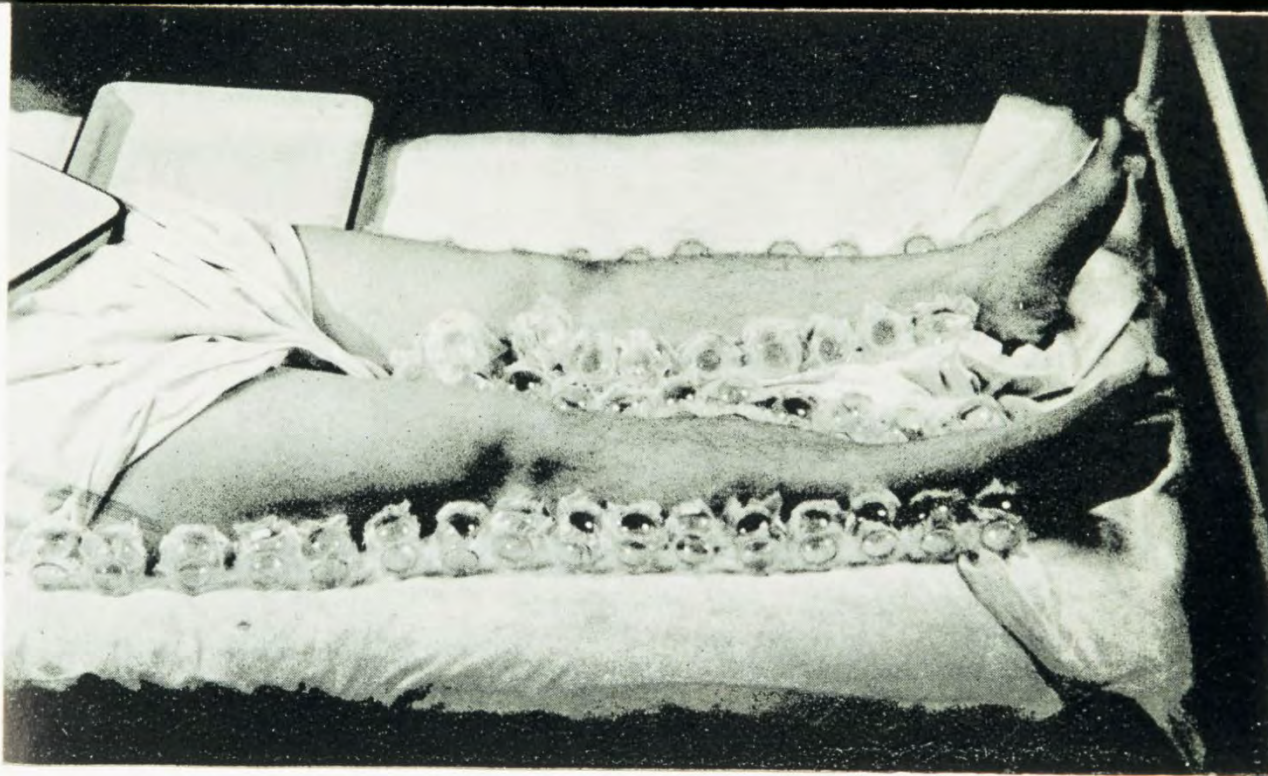
gonorrhea

hepatitis

De-salting sea water



Malaria research



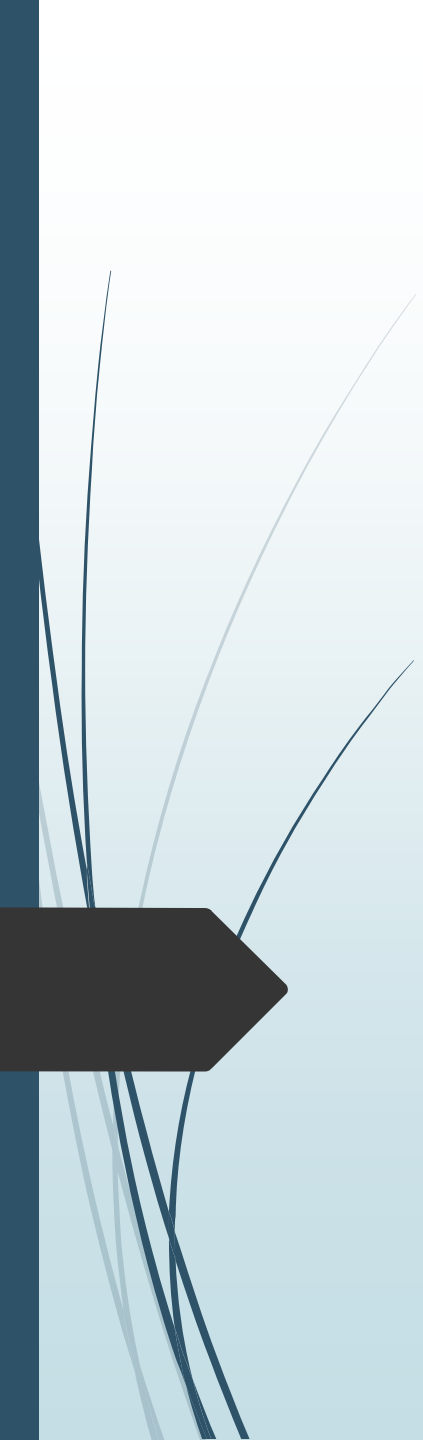
U. S. Public Health Service

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



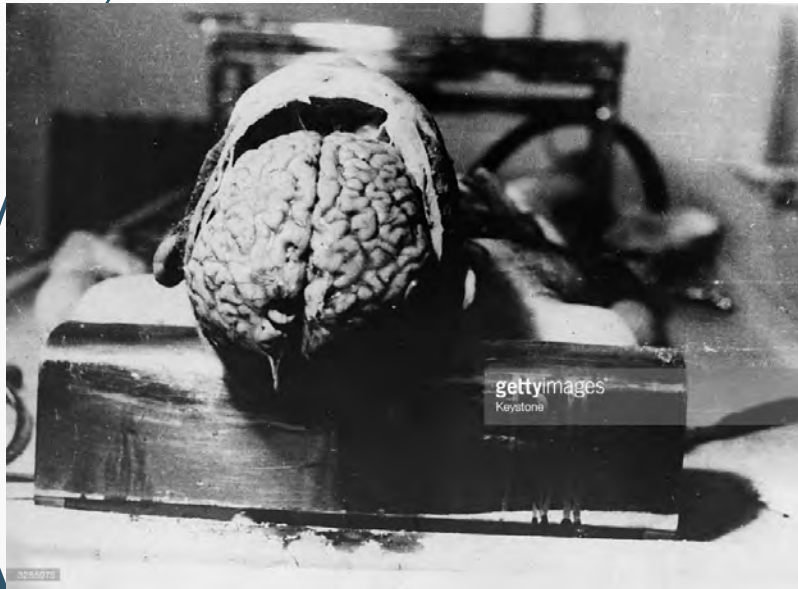
Nazi researchers use
concentration camp
inmates as subjects

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



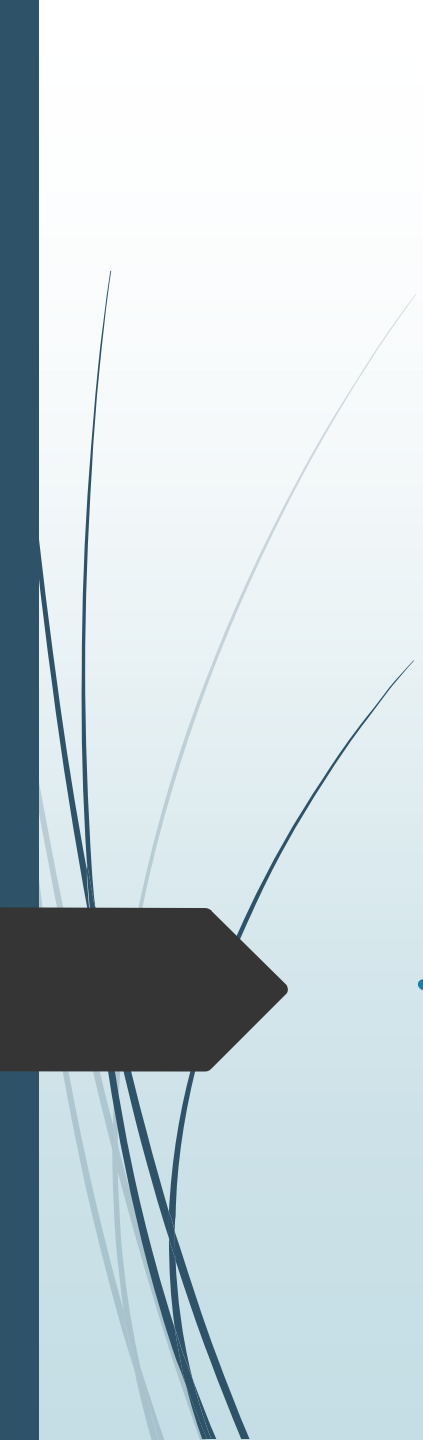
- disfigured leg of a survivor from Ravensbrueck,
- scars resulted from incisions made by medical personnel that were purposely infected with bacteria, dirt, and slivers of glass.

United States v. Karl Brandt et al

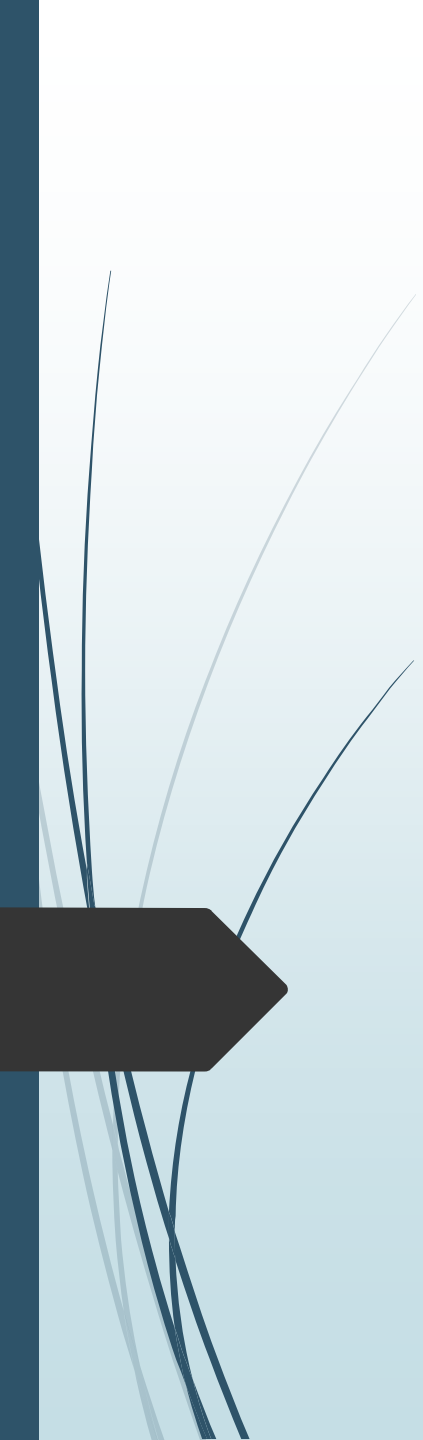


Nuremberg Doctors Trial
Prosecution of 23 Nazi medical personnel





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 Marvin 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.
People should know that
of

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

PRISON MALARIA

Convicts expose themselves to disease so doctors can study it

THE UNITED STATES GOVERNMENT PRINTING OFFICE: 1945

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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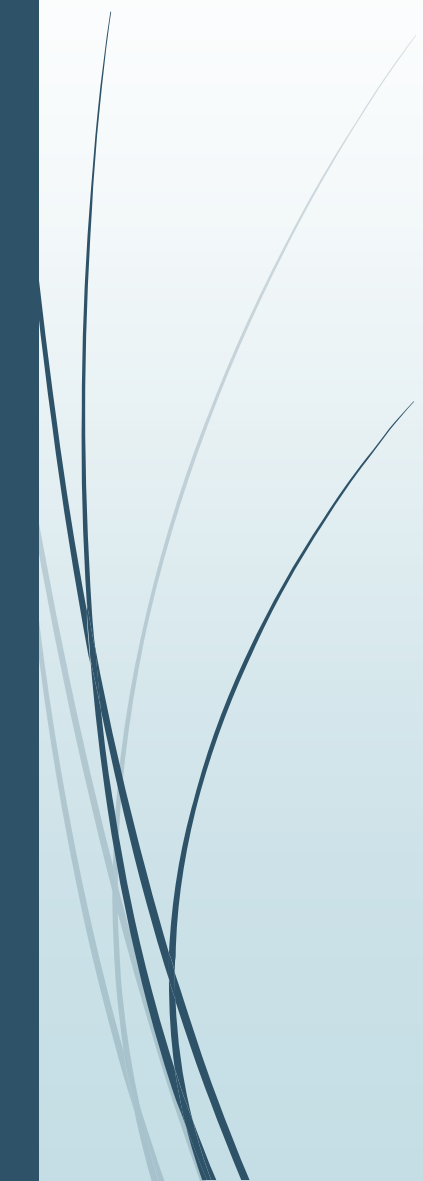
On the one hand Nuremberg Code known to American medical researchers

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



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



3/25/52

NVI

TI

Death of a Volunteer

March, 1952

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.



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

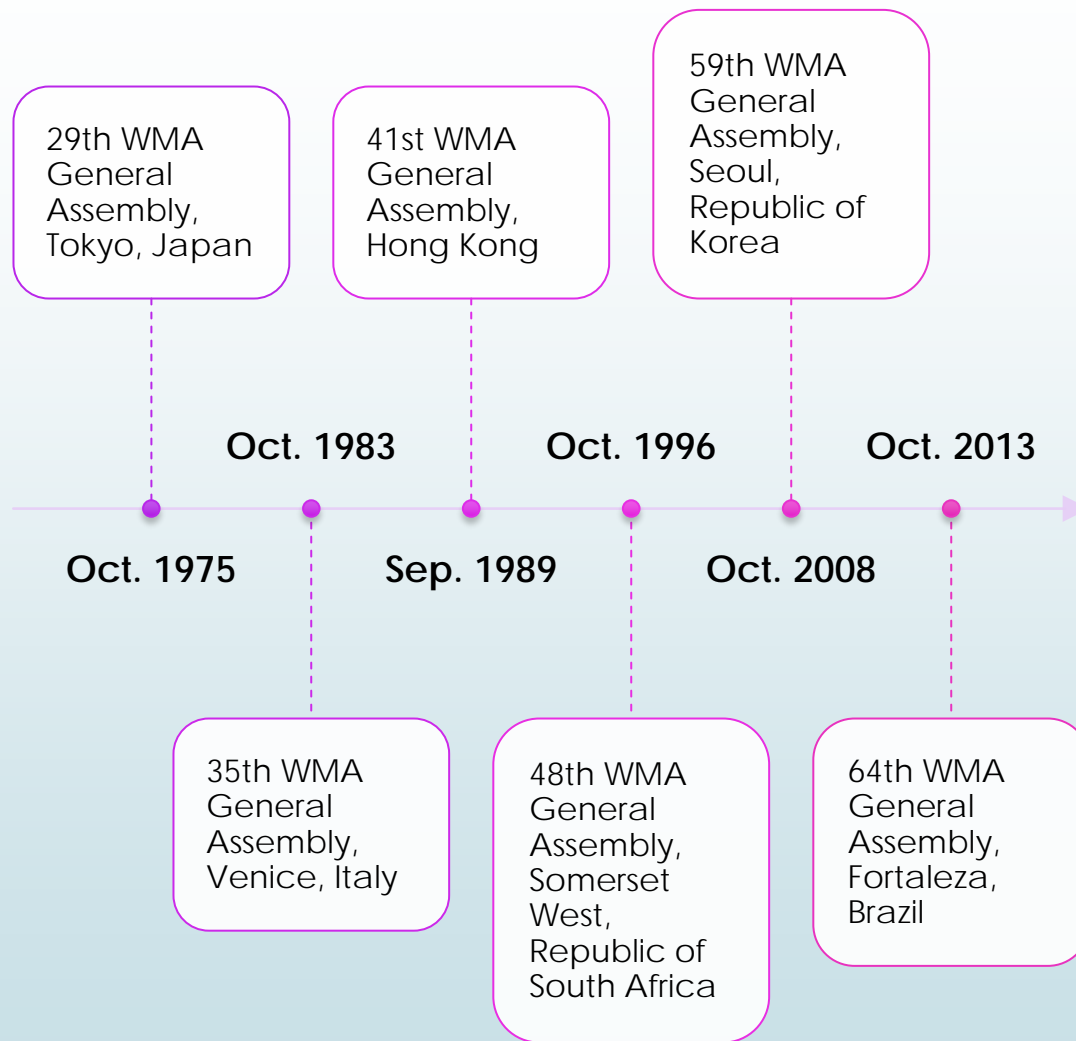
Recommendations Guiding Doctors in Clinical Research

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

Volume 274

JUNE 16, 1966

Number 24

Reprinted from pages 1354-1360.

SPECIAL ARTICLE

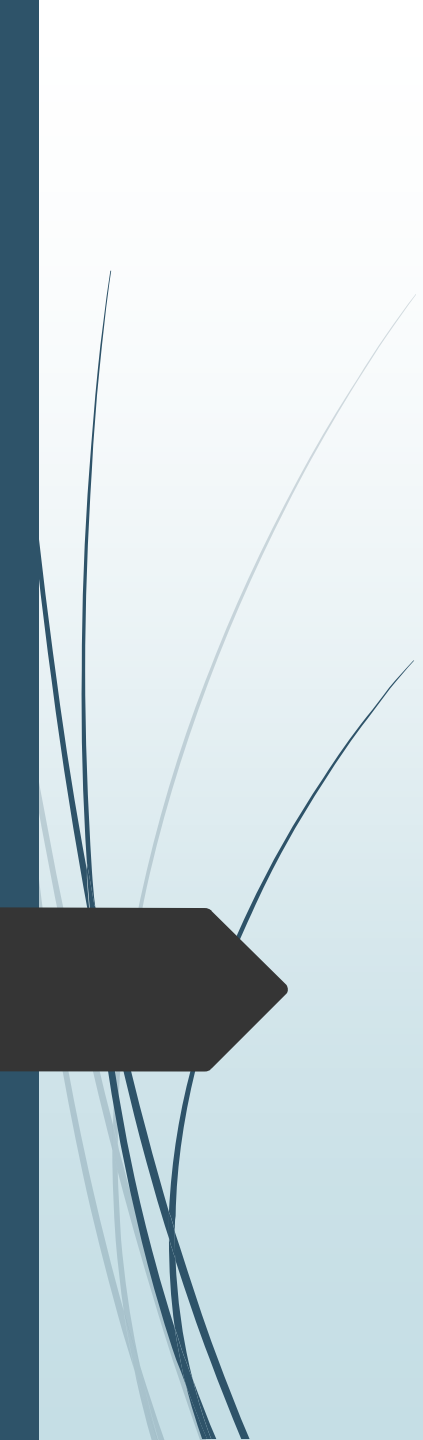
ETHICS AND CLINICAL RESEARCH*

HENRY K. BEECHER, M.D.†

BOSTON

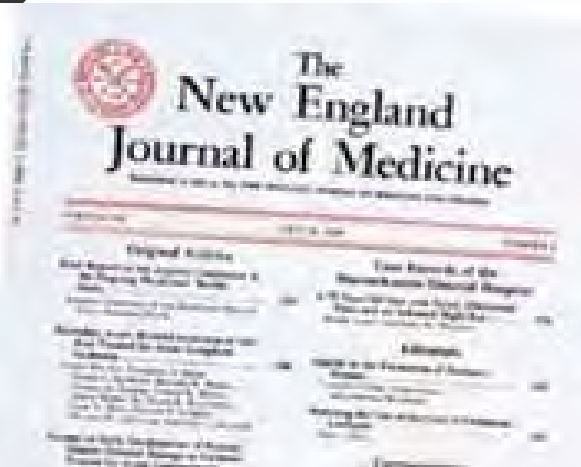
HUMAN experimentation since World War II has created some difficult problems with the increasing employment of patients as experimental

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

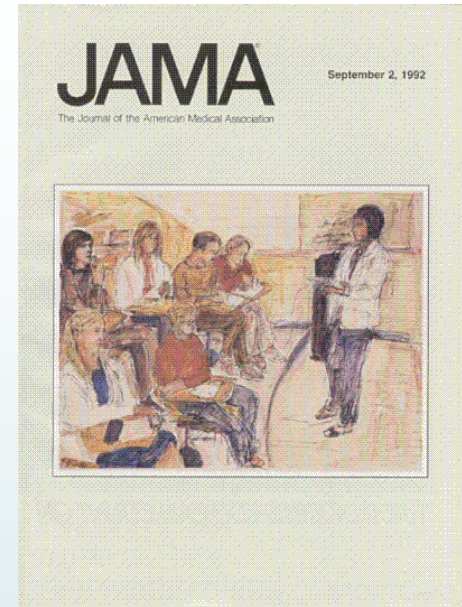


22 examples of “questionable” research practices

Not from fringe BUT from mainstream
researchers and institutions



5




2



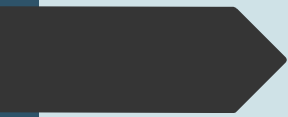
5



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

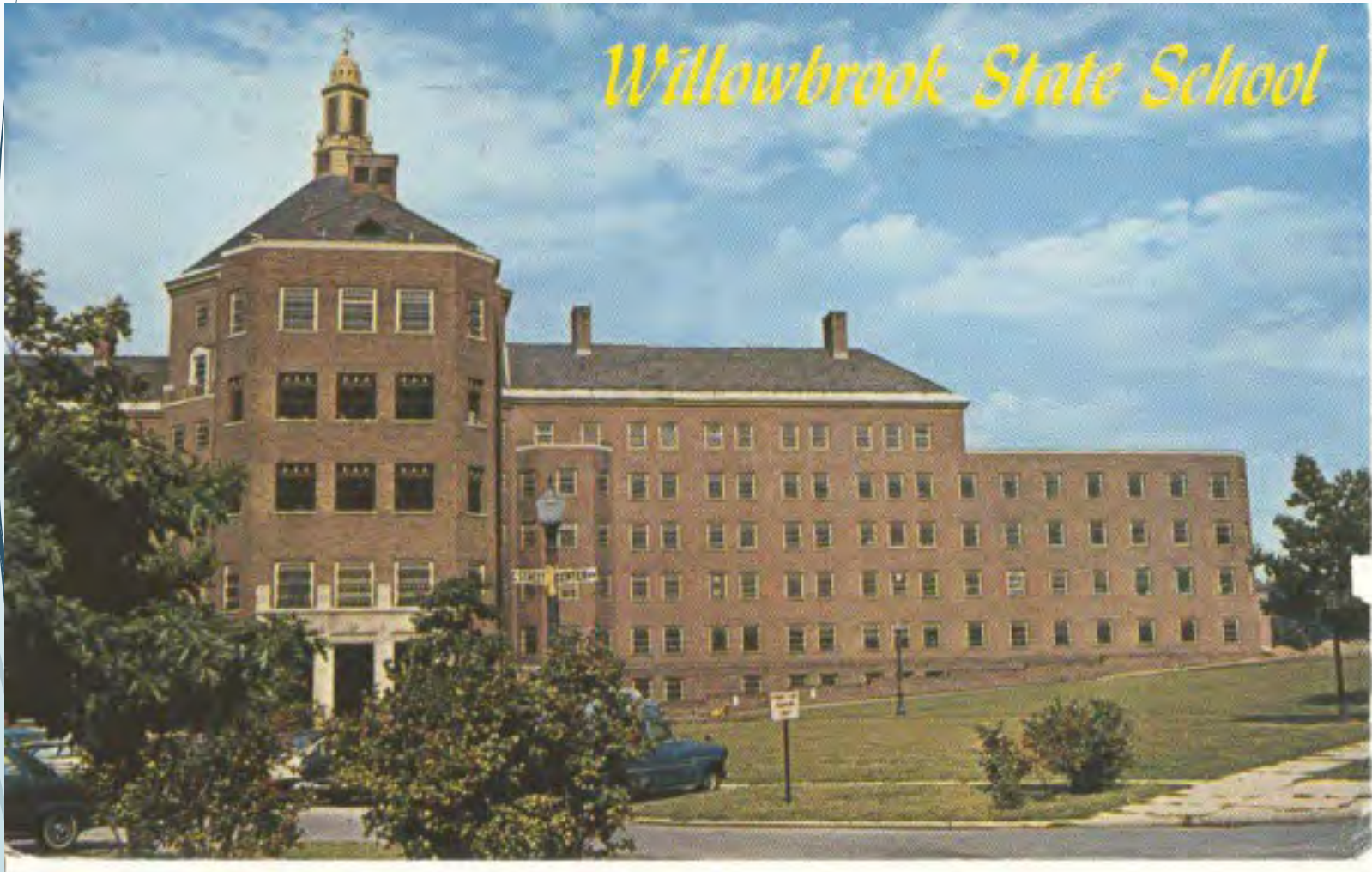
alcoholics

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

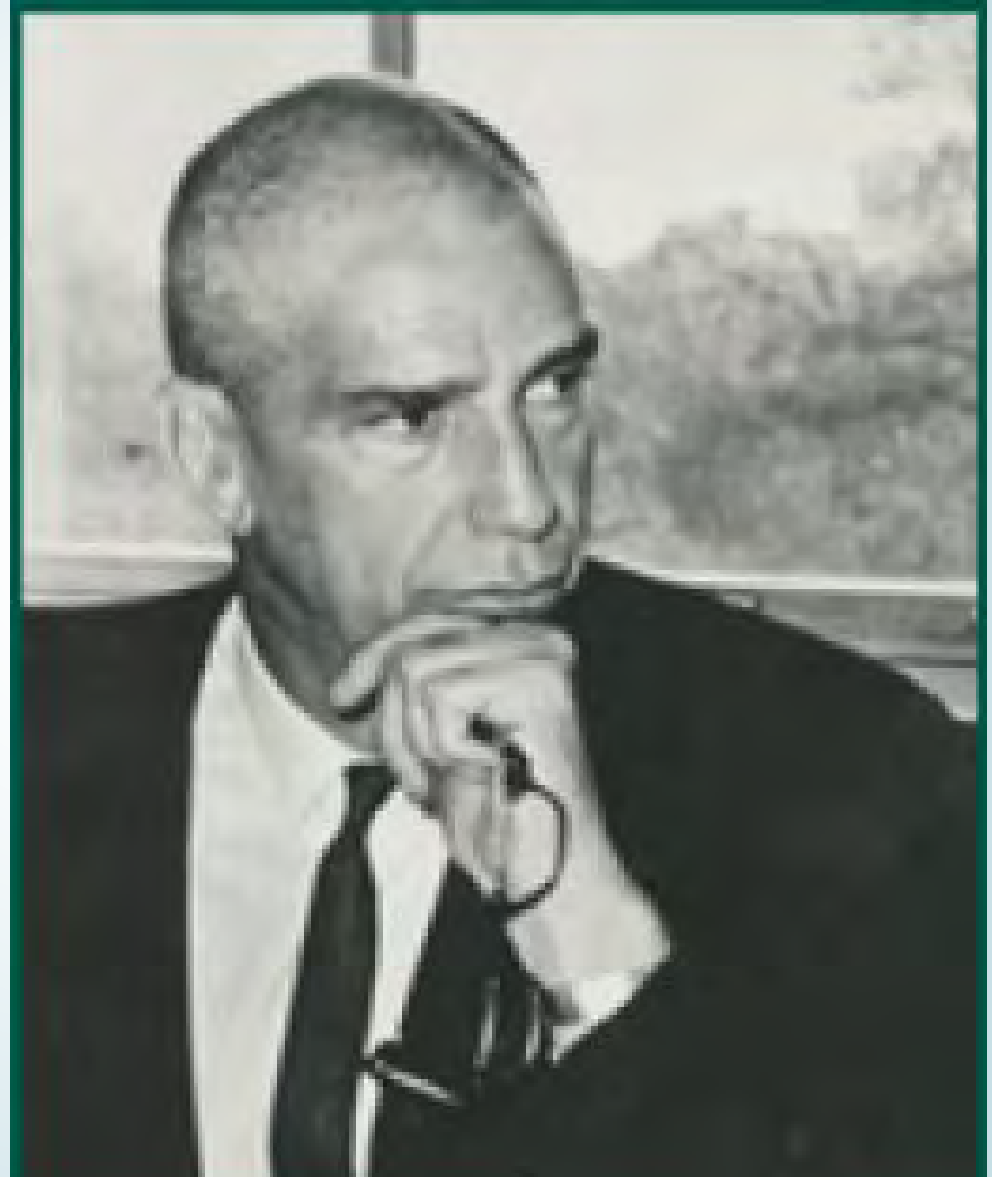
Injections of live cancer
cells into elderly patients
without consent

"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



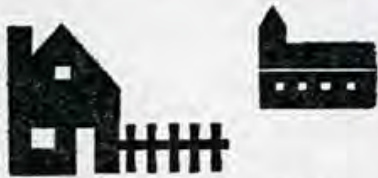
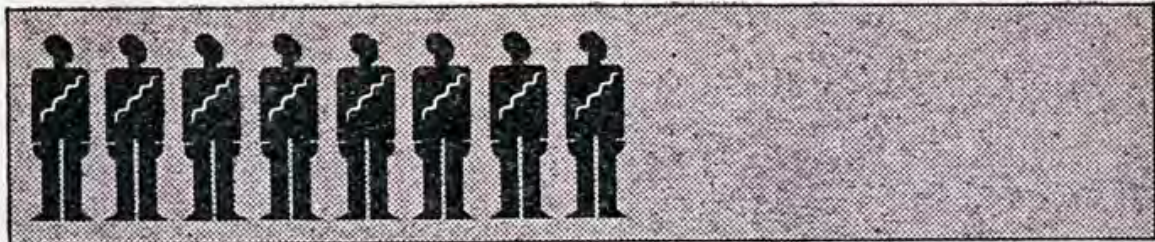
INCIDENCE OF SYPHILIS AMONG NEGROES



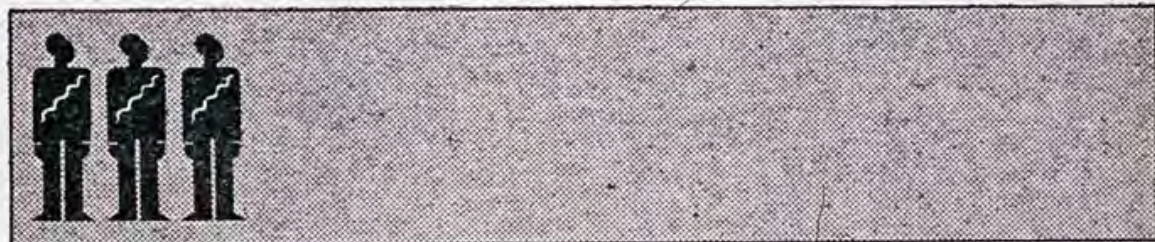
MACON COUNTY, ALA.



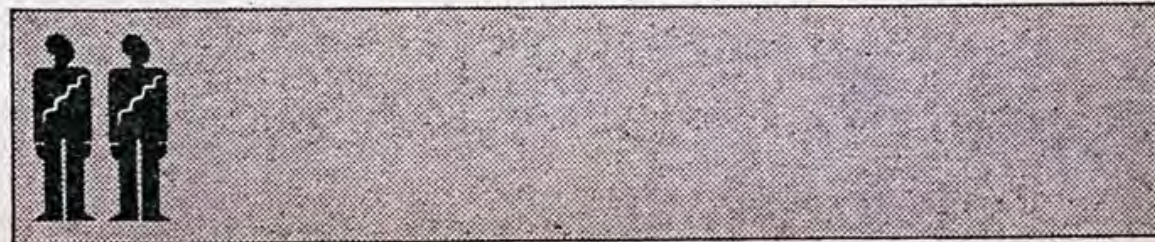
BOLIVAR COUNTY, MISS.




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



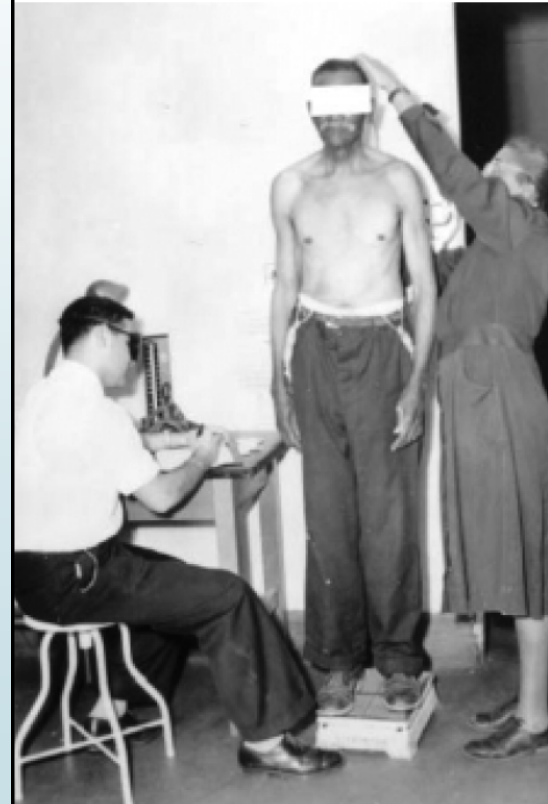
Nurse Rivers

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

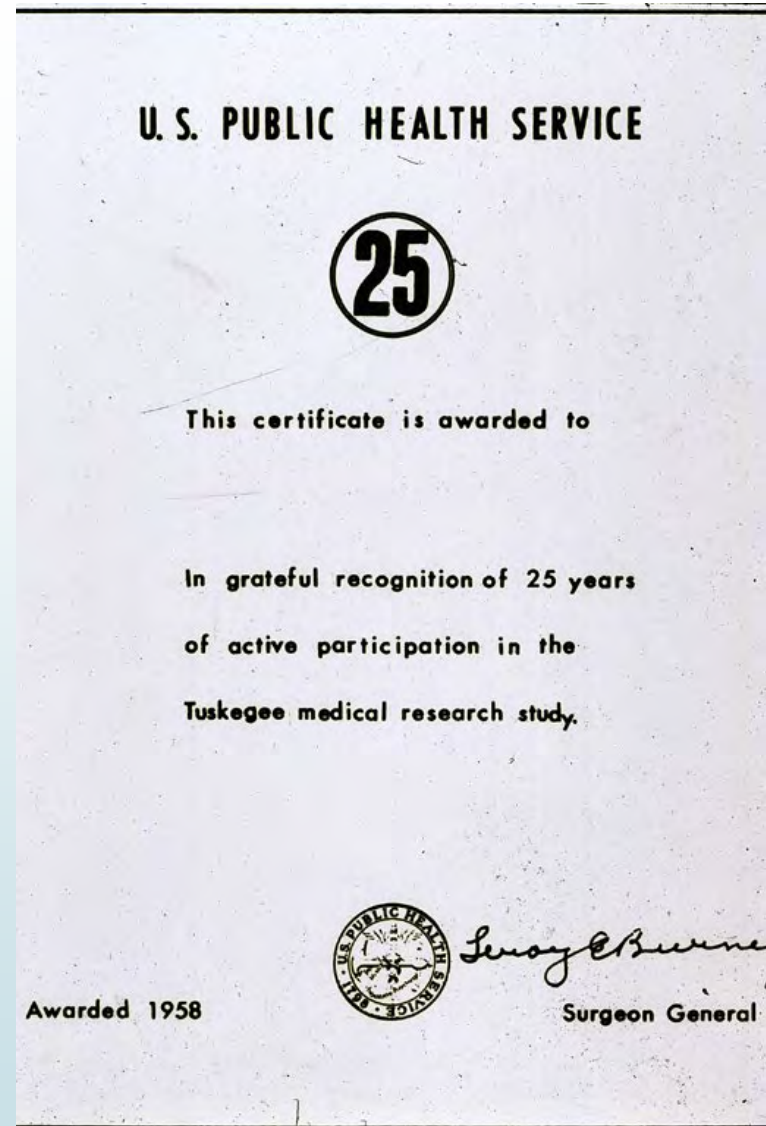
“for the first time, men in the study identified as “volunteers with social incentives”

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





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

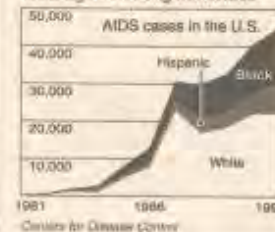
how AIDS got started, there are ways to stop it. Campaign officials reasoned that few blacks would believe government denials anyway. But surely black leaders and public figures with high credibility, such as Magic Johnson, the basketball star, could do much to discredit the pernicious and dispiriting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

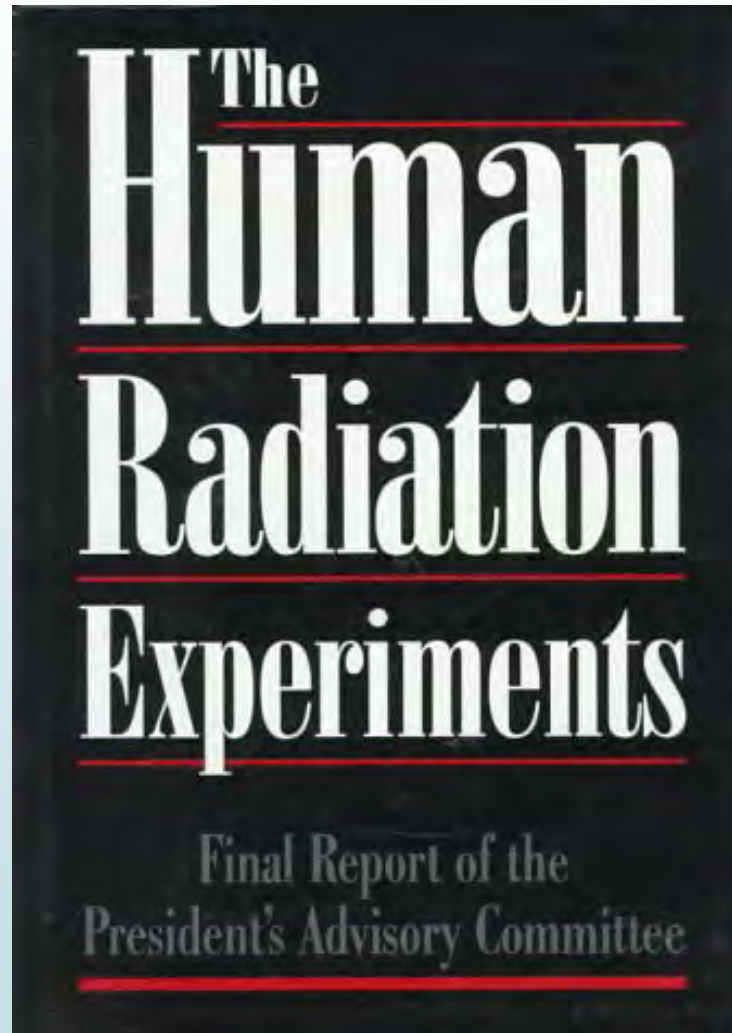
A rising toll among minorities



Centers for Disease Control



Presidential apology 1995

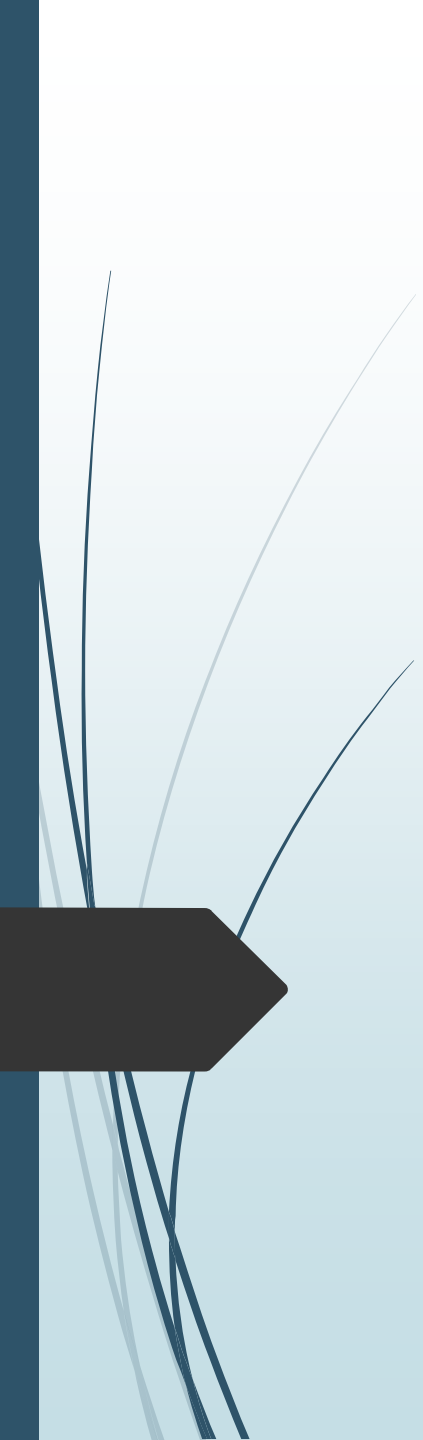


White House Apology for the Syphilis Study,





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 8:48 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

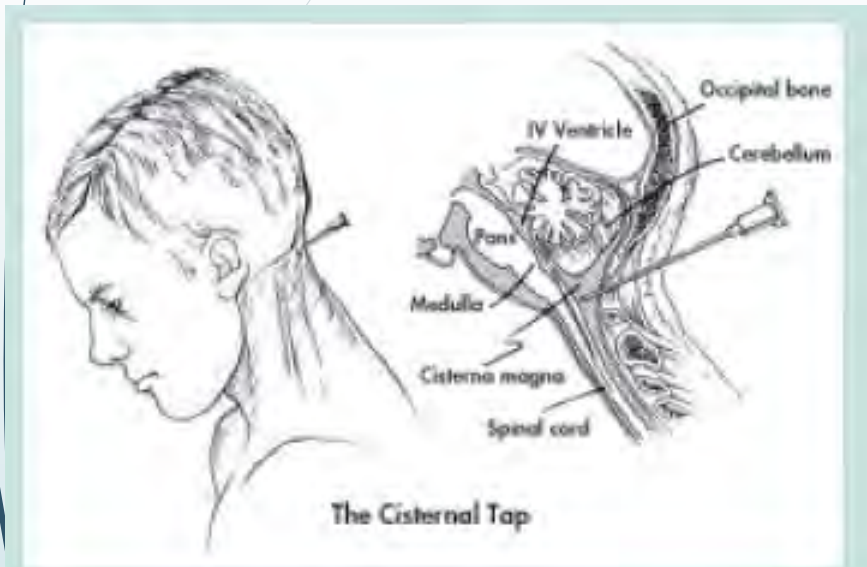


Diagram of a cisternal puncture.
From Alexander G. Reeves, M.D. and Rand S. Swenson,
M.D., Ph.D., "Disorders of the Nervous System"

- ▶ 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."

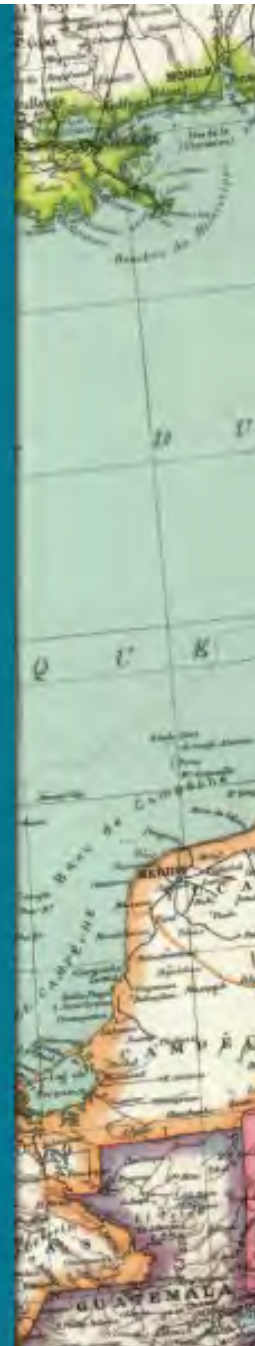
Surgeon General Thomas Parran, 1948



“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