

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Vanessa Gamble to Dr. John C. Fletcher [partial] (1 page)	05/23/1996	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10454

FOLDER TITLE:

Tuskegee Apology [2]

2014-0046-S

rc1385

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Questions and Answers

Tuskegee

Q1. What was the purpose of the Study? What was its official title? How long was it conducted?

A1. The U.S. Public Health Service Syphilis Study was officially called "Untreated Syphilis in the Negro Male" and was conducted in Macon County, Alabama. It began in 1932 as a study of untreated syphilis in approximately 400 African-American men who were at least 25 years of age and had syphilis for 5 years or longer. A year later a control group of approximately 200 African-American men without syphilis was added to the study. The study was undertaken to compare the course of untreated syphilis in black men with the results of an Oslo study on untreated syphilis in whites which began in 1890 and was reported in 1929. The study in Alabama was funded by the U.S. Public Health Service. The study was stopped in 1972.

BACKGROUND: The Tuskegee Syphilis Study was supposed to last 6-12 months with the purpose of documenting the course of disease and using that information to obtain funding for treatment. After a year, it was decided to continue the study until the men died. The study was stopped in 1972 after a news story about the study caused public outcry. Left untreated syphilis remains in the body and can damage the internal organs including the brain, nerves, eyes, heart, blood vessels, liver, bones, and joints.

Q2. Why was it conducted in Tuskegee?

A2. In 1926, the U.S. Public Health Service conducted surveys of the prevalence of syphilis in Macon County, Alabama, which was one of several sites surveyed in the United States. The prevalence of syphilis among African-Americans was particularly high and many people remained untreated.

BACKGROUND: In 1930, the Macon County Syphilis Control Demonstration Project began; this project provided treatment which was a combination of neoarsphenamine and mercury. This project was funded by the Rosenwald Fund. About 1400 patients were enrolled in the project; none of them received the full course of treatment because funding ended. In 1932 the Tuskegee Syphilis Study was started. The study was

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undertaken to document the course of untreated syphilis with the original intention that the information could be used to obtain funding for treatment. Later, the purpose of the study shifted to document the natural history of the disease in the African-American male.

Q3. Why is the President issuing an apology for the Study now? Is this apology politically motivated?

A3. The President is issuing an apology in an effort to redress the wrongs of the past. He is apologizing now because it is the opinion of many that the legacy of the Study continues to have an adverse effect on the health of African-Americans. The Study continues to figure prominently in discussions of the difficulties experienced by the African-American population in obtaining access to medical care, being forthright with their physicians, participating in clinical trials, donating organs, and accepting advice from public health officials regarding prevention of diseases.

Q4. What was the Public Health Service's involvement? Who planned and implemented the Study?

A4. The U.S. Public Health Service funded the Tuskegee Syphilis Study and was responsible for the design and implementation of the study. Throughout the 40 years many physicians, who were members of the U.S. Public Health Service, were involved in the study, including designing the study, examining patients, analyzing results from the study, and publishing findings.

Q5. How many people were recruited into this Study?

A5. The total number of men enrolled in the study is not clear. It is generally accepted that about six hundred (600) African-American men were initially enrolled in the study, approximately 400 African-American men who had syphilis and 200 who did not.

BACKGROUND: Researchers told the men that they were being treated for "bad blood", a local term used at the time to describe several ailments, including syphilis. In exchange for taking part in the study, the men received free medical exams, free meals and burial insurance, but no treatment for syphilis. Although originally planned for months, the study actually went on for 40 years.

Q6. What has been done to compensate Study participants and their

descendants? Who is eligible for the compensation program?

- A6. The Tuskegee Health Benefit Program is a comprehensive health benefit program that pays for all necessary medical services not covered by other insurance programs. In addition to Study participants, the program is also available to wives, widows, and offspring who may have been infected with syphilis as a result of withholding treatment for Study participants. The program is currently administered by the National Center for HIV, STD, and TB Prevention within the Centers for Disease Control and Prevention.

BACKGROUND: On March 3, 1973, the Secretary of the Department of Health, Education, and Welfare (HEW), Dr. Casper Weinberger, directed the Public Health Service to provide study participants with necessary medical care. Men and their families were offered comprehensive health assessments and lifetime medical services.

In addition, on July 23, 1973, Mr. Fred D. Gray filed a class action lawsuit on behalf of the Study participants against the United States government and others. The action, Pollard v. United States, U.S. District Court for the Middle District of Alabama, Northern Division, did not go to trial. Instead, on August 28, 1975, the parties entered into a Stipulation of Settlement that was ultimately approved by the court. A cash payment was provided of \$37,500 to every living man with syphilis who was alive on July 23, 1973; \$15,000 to the heirs of each of the deceased men with syphilis; \$16,000 to every living member from the group of controls who was alive on July 23, 1973; and \$5,000 to the heirs of each of the deceased controls.

- Q7. How much money was spent to fund the Study? How much money has been allocated for the Tuskegee Health Benefit Program?
- A7. Records are not available that outline the cost of the Study. During the most recent fiscal year (1995), expenditures for the Tuskegee Health Benefit Program totaled \$2,789,715. *
- Q8. What procedures have been put in place to ensure that studies such as Tuskegee does not happen again?
- A8. In 1974 the National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Also in 1974, Federal Regulations were developed creating institutional review boards (IRBs) that review and approve research involving human subjects. A critical part of the IRB

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review is examining the informed consent process and informed consent form which describes the purpose of the study and details the risks and benefits to subjects who choose to participate, among other things. In addition, every institution which receives Federal funds to conduct research on human subjects must provide an assurance that it will adhere to Federal regulations governing research on human subjects. In October 1995, the President established the National Bioethics Advisory Commission to review all current regulations, policies, and procedures with respect to human research to make sure these high standards are being met.

BACKGROUND: The activities of local IRBs are among the many steps in place to ensure that a study such as the U.S. Public Health Service Tuskegee Syphilis Study does not happen again.

Q9. Where are the records stored and how can they be requested for review?

A9. The Tuskegee Syphilis Study records are stored at the National Archives Southeastern Branch located in East Point, Georgia. These records were transferred to the ownership of the National Archives, in accordance with Federal records management regulations, for safekeeping. The medical records, which contain personal medical information, are closed to the public until the year 2030. However, the administrative records are open for the public review.

Q10. How long was the Study continued after it was determined that syphilis could successfully be treated with penicillin? Why was the Study halted?

A10. Penicillin became known as an effective therapy for syphilis in the mid-1940's and became the standard of care for treatment of the early stages of syphilis in 1947 and for the late stages of syphilis in the early 1950s. The study ended in 1972 following a review of the study by the Tuskegee Syphilis Study Ad Hoc Advisory Panel who found the study to be unethical and recommended that it be terminated.

Q11. Was this Study considered ethical at the time it was conceived?

A11. This question is complex because the ethics of the study must be judged on two different dimensions. First, the men with syphilis were untreated, and secondly, the men were never informed about the purpose, risks and

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benefits of the study, nor did they consent to participate in the study.

Regarding the issue of treatment, in retrospect, the Study may appear to have met ethical standards of the day at its outset, when treatments were of uncertain efficacy and often associated with serious adverse reactions.

Regarding the second issue, the Study was never ethical because the men were never informed about the study, never asked to provide informed consent to their participation in the Study, and were misled about the purposes of the study.

BACKGROUND: Most current consent documents include explicit information stating that should new information or treatment become available, participants will be notified and offered treatment. Such issues are also considered during the annual ethical review process now required for each new research protocol. It is not unusual for current studies to be halted because effective treatment has become available.

Q12. Who made the decision, once penicillin became the standard of care for syphilis, not to notify Study participants about the availability of this treatment? Why was this decision made?

A12. In 1943, Dr. John Mahoney reported the first cures of primary and secondary syphilis with penicillin. When this drug became the standard treatment regimen for syphilis in 1947. The question arose concerning the advisability of treating those in the Study group. A decision was made by PHS at that time not to recommend treatment because: (1) no data were available on the efficacy of penicillin treatment in the late stage of syphilis; and (2) short- or long-term side effects of treating late stage syphilis with penicillin had not been documented. The decision at the time was made that the possible risks to the patients from treatment outweighed their risks from the disease. Later, in the 1950s, the recommendation was changed, reflecting that penicillin was an effective treatment for the late stages of syphilis.

Also, there was a desire to complete the Study because the data that were available on the long-term effects of untreated syphilis were considered potentially flawed in that they came from a study that lacked controls and included limited autopsy results.

Q13. Why do rates of syphilis continue to be the highest among African-Americans in the South?

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A13. It is not entirely clear why the rates of syphilis are highest among African-Americans in the South. Multiple factors are probably involved. Certain populations in the United States, especially economically disadvantaged African-Americans in some urban settings and in the rural South, have many interrelated and competing problems including poor access to quality medical care and substance abuse. These problems are often compounded by lack of knowledge about the symptoms, consequences, and prevention of syphilis and, in some communities, by social or religious norms that limit education about syphilis or other sexually transmitted diseases (STDs).

In some communities, the legacy of mistrust left by the Tuskegee Study also is probably a contributing factor. However, these high syphilis rates and the resulting increased risk of HIV infection and high rates of syphilis in newborns can be eliminated. The country, overall, is now at historically low rates of infectious syphilis. Most communities in the United States, including almost 70% of counties, have already eliminated this infection. Approximately 50 percent of infectious cases of syphilis are now concentrated in less than 1.5% of counties.

Q14. What evidence exists that the Tuskegee experience continues to discourage minority populations, especially African-Americans from accessing health care, participating in clinical research, or has had an adverse impact on their trust in government health officials?

A14. It may never be possible to document fully the impact of the Tuskegee Syphilis Study on minority populations. Health care behaviors, decisions to participate in clinical research, and attitudes toward government health officials are all shaped by many factors that are difficult to evaluate. Furthermore, in some families and communities, the Study in Tuskegee may no longer be named explicitly as a problem, but, instead has been incorporated as the foundation for a range of conspiracy theories or generalized mistrust of "the government."

BACKGROUND: The evidence that is available includes a study conducted by a researcher at the University of Alabama Health Studies at Tuscaloosa, African-Americans in general reported less interest in participating in health promotion and research because of their knowledge of the Study. African-American males in particular reported a high degree of resistance because of knowledge of the Study. In addition, many other scholars have collected evidence to support the same or similar conclusions.

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Q15. What was the involvement of the Tuskegee Institute in the Study?

A15. The Institute was aware of the Study and was consulted during the Study period regarding one or more areas.

Q16. We understand that there is a group called the Tuskegee Legacy Committee which made some recommendations regarding actions that should be taken to heal the wounds left by the Study. Did the President accept all of the recommendations of that group? If not, why?

A16. One of the principal recommendations of that Committee was that President Clinton publicly apologize to the living participants, their families and to the Tuskegee community. Also the committee recommended the establishment of a center at Tuskegee University to preserve the national memory of the study and transform its legacy.

BACKGROUND: Last year during a conference at Tuskegee sponsored by the U.S. Department of Health and Human Services on minority participation in research, the Tuskegee Study Legacy Commission was created to help all of us move beyond the negative legacy of the PHS Tuskegee Syphilis Study. The purpose of the Legacy Committee was to transform the legacy of minority mistrust of the health and medical establishment into positive efforts to close the health gap between blacks and whites.

Q17. Is it really likely that a study begun more than 60 years ago and stopped nearly 25 years ago continues to have an impact today?

A17. Yes. The Study continues to be discussed by the mass media, academicians, and "the public" as an example of how certain minority groups (in this case, African-American men) can be exploited for seemingly "good" reasons, such as medical research. Obviously, other factors such as segregation, discrimination, and hate crimes against African-Americans, have also contributed to the mistrust some African-Americans have of the establishment, including our health care systems, but the Study itself continues to figure prominently in discussions of the difficulties experienced by the African-American population in obtaining access to medical care, being forthright with their physicians, participating in clinical trials, donating organs, and accepting advice from public health officials regarding prevention of diseases such as AIDS.

Q18. Is syphilis an important health problem for the United States today?

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A18. Syphilis is a serious, chronic infectious disease. It causes ulcers that allow the AIDS virus to be transmitted much more efficiently between people. The bacteria that cause syphilis can cross the placenta to kill the fetus or cause permanent neurologic damage in the baby. Recent studies suggest that heterosexual HIV transmission in the United States still largely follows the geography of the syphilis epidemic of the late 1980s and early 1990s. In addition, in American cities with syphilis outbreaks, there is a continuing high but usually under-reported impact on infant health. For example, in one Texas city undergoing a syphilis outbreak, nearly 2% of all deliveries to African-American women resulted in congenital syphilis, with the known associated fetal and neonatal mortality, morbidity, and high cost of in-hospital treatment.

Q19. What can we do about syphilis today?

A19. Today, syphilis is a disease that is inexpensive to diagnose and easy to cure. It has been eliminated from several industrialized countries and is now at such low levels and so locally distributed in the United States that it could be eliminated here, as well.

In 1997, we are approaching the lowest rate of syphilis ever reported in the United States. However, reported infectious syphilis rates are approximately 60 times higher among African-Americans than among white Americans, and syphilis is highly concentrated across the South. Syphilis elimination would eliminate both an important factor contributing to higher rates of HIV infection among African Americans and an unnecessary cause of fetal and infant mortality and disability.

Q20. How many of the original Study participants are going to Washington for the apology event?

A20. Five

Q21. Who is paying for the participants to attend the Washington apology event?

A21. CDC is paying the expenses (travel, lodging, food) for 39 people; including five original Study participants, family members of several Study participants, and escorts.

Q22. Why wasn't this event held in Tuskegee?

A22. It is significant that the apology is taking place at the White House, the

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highest center of authority in this country. Having the President issue the apology from the White House reaffirms our commitment to uphold the highest ethical standards in conducting research involving human subjects.

Q23. What are the costs of establishing a Center for Bioethics at Tuskegee University?

A23. The Department is prepared to award up to \$200,000 to Tuskegee University to support a planning grant. Tuskegee University will be asked to develop plans and a budget for the establishment of a Center for Bioethics in Research and Health Care. Plans for the Center will address the creation of a public museum at Tuskegee, Alabama, effort to provide public education regarding the Study and bioethics, a plan for providing technical assistance to produce educational materials for public and professional education, and a plan to develop partnerships with schools of medicine and public health to provide opportunities for students to receive training in bioethics.

Q24. How are we strengthening bioethics?

A24. Much has been done to ensure the protection of human subjects, such as passage in 1974 of the National Research Act which created the National commission for Protection of Human Subjects of Biomedical and Behavioral Research, the creation of the Office for Protection from Research Risks, the promulgation of regulations for the protection of human research subjects, and most recently, the creation of the President's National Bioethics Advisory Commission which is supported by the Department of Health and Human Services. As charged by the President, the commission serves as the central forum for discussion of ethical issues, and is reexamining current regulations, policies, and procedures to ensure that all possible safeguards are in place to protect all person who volunteer to participate in research studies.

To build on these efforts, we will undertake the following actions as outlined by the President: HHS will work with Tuskegee University to establish a Center for Bioethics in Research and Health Care at Tuskegee University; HHS will offer fellowship to promising students, with special outreach to attract minority students, to receive postgraduate training in bioethics, and will also develop a short-term ethics training program as a component of research fellowship programs; HHS will collaborate with other partners to develop materials for bioethics courses and related training materials to enable research institutions to strengthen their efforts in bioethics training as it relates to research; and HHS will develop and disseminate strategies to assist researchers in their outreach to

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communities—especially minority communities—to foster partnerships and enhance the involvement of minorities in research studies.

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WHITE HOUSE TUSKEGEE CEREMONY

DATE:	May 16, 1997
LOCATION:	East Room
TIME:	1:30 p.m.
FROM:	Maria Echaveste Ben Johnson

I. PURPOSE

You will meet with five of the remaining eight survivors of the Tuskegee syphilis experiment, recognize the injustice done to them, and issue a formal apology on behalf of the nation. Additionally, you will announce steps aimed at preventing experiments of this type from ever happening again.

II. BACKGROUND

In 1932, Federal, State, and local officials, began a long-term study of untreated syphilis in African-American males in Macon County, Alabama. The study was intended to justify a syphilis treatment program for African-Americans. Instead, it has become known as a case of medical research gone wrong. The project was scheduled to last for six months, but it continued for 40 years--even after penicillin became available to treat syphilis in the late 1940's. The study ended in 1972 when the New York Times ran a front-page story that led to a public outcry across the nation.

In 1973, Attorney Fred Gray filed a lawsuit on behalf of the participants and their heirs seeking redress. In 1974, the case was settled for \$9 million. Under the settlement, the U.S. Government provided Study participants and affected members of their families with comprehensive medical care for the rest of their lives.

Since 1974, all Federal studies using human subjects must be reviewed by Institutional Review Boards. In 1995, you created a National Bioethics Advisory Commission to review research regulations and procedures, and to provide all possible safeguards for research volunteers. Unfortunately, the Federal Government has never adequately expressed its responsibility in the Tuskegee Syphilis study. The Study continues to cast a shadow on the relationship between African Americans and the biomedical community. Many commentators believe that the government's failure to make such an acknowledgment has helped perpetuate feelings of widespread distrust among African-Americans toward health related initiatives.

Although you made the decision to host this ceremony several weeks ago, a press conference held by the survivors last month has heightened the attention on the event. You have received letters from the Congressional Black Caucus and a number of national organizations, requesting an apology to the victims of the study. Additionally, there has been a media frenzy and numerous editorials have been written to support an apology.

In addition to extending an apology on behalf of the nation, you will announce the signing of an executive order extending the charter of the National Bioethics Advisory Commission to October 1999. You will also announce four additional steps the Department of Human Services will take to insure we learn from the syphilis study. Hopefully these measures will rebuild trust, and protect human subjects in the future.

The Tuskegee survivors range in age from 85 years old to over 100 years old (see attached Bios). They left the Tuskegee area yesterday with an overwhelming send off from the community. A number of relatives of victims who are unable to attend the White House ceremony, are expected to watch via satellite at the Kellogg Center on the Tuskegee University campus. Acting Surgeon General Audrey Manley will be there to represent you. According to our contacts, the men and their families are some of your most loyal supporters. They are said to be very excited to be invited to the White House and are looking forward to concluding this terrible ordeal.

III. PARTICIPANTS

Pre-brief participants

Maria Echaveste

Kitty Higgins

Ben Johnson

Elizabeth Drye

David Satcher

Ann Lewis

Carolyn Curiel

Event Participants

Survivors, Wives and Widows of Survivors, Children and Grand Children of Survivors

Members of Congress

Representatives of National Black Associations and Organizations

Government Officials

IV. PRESS PLAN

Open Press

V. SEQUENCE OF EVENTS

- o Event briefing for YOU and THE VICE PRESIDENT in the Red Room
- o YOU and THE VICE PRESIDENT proceed to Blue Room and greet the Following guests:

Dr. David Satcher
Congresswoman Maxine Waters
Congressman Earl Hillard
Congressman Louis Stokes
Herman Shaw
Charlie Pollard
Howard Carter
Fred Simmons
Fred Moss
Ms. Gwendolyn Cox, Daughter of Sam Doner, Survivor
Mr. North R. Hendon, Grandson of Ernest Hendon, Survivor
Attorney Fred Gray (Counsel for survivors)

- o Survivors are announced into the East Room
- o YOU and THE VICE PRESIDENT are announced into the East Room
Accompanied by Dr. Satcher and Mr. Shaw.
- o THE VICE PRESIDENT makes remarks and introduces Dr. Satcher.
- o Dr. Satcher makes remarks and introduces Mr. Shaw.
- o Mr. Shaw makes remarks and introduces YOU.
- o YOU MAKE remarks and proceed to the Blue Room for receiving line.

**NOTE: The receiving line will flow from Red to Blue to Green.
Guests proceed to State Room for reception following receiving line.**

VI. REMARKS

To be provided by Speech writers

VII. ATTACHMENT

- 1) Biographic information on survivors

**SUGGESTED REMARKS FOR HERMAN SHAW
TUSKEEGEE STUDY EVENT, THE WHITE HOUSE
Friday, May 16, 1997**

On behalf of all the survivors who are here today, and those who could not be here, I want to thank President Clinton for bringing us to the White House -- to help us close a very tragic and painful chapter in our own lives, and in all of American history.

The basic injustice and unfairness of what happened as part of the Tuskegee Study has been well-documented. And as all of us know, the wounds that were inflicted cannot be undone. It saddens me especially to think of those who did not survive, and whose families will forever live with the knowledge that their deaths and suffering were preventable.

But this ceremony is important because the damage created by the Tuskegee Study runs much deeper than the wounds any of us may have suffered. It speaks not only to our personal treatment, but to our faith in government, and in the ability of medical science and inquiry to serve as a force for good. That is a legacy that must concern us long after the last of the Tuskegee Study survivors has passed.

In my opinion, it is never too late to work to restore that faith and trust. And so, a quarter century after the Tuskegee Study was finally ended, President Clinton's decision to gather us here -- to allow us to finally put this horrible episode behind us, as a nation -- is a most welcome decision.

President Clinton knows that for America to reach its fullest potential, we must truly be One America, black and white together -- trusting each other, caring for one another, and never, ever allowing the kind of atrocity that occurred in the Tuskegee Study.

Mr. President, words cannot express my gratitude to you for bringing us here today -- for doing your best to right this tragic wrong -- and for resolving that America should never again suffer such an episode. Because of your leadership, I am confident that we never will.

And so it is with the greatest admiration and respect that I introduce our President, Bill Clinton.

ROUTING & REQUEST

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UNIVERSITY OF
WISCONSIN-MADISON
MEDICAL SCHOOL

23 May 1996

Dr. John C. Fletcher
Director, Center of Biomedical Ethics
Cornfield Professor of Religious Studies
University of Virginia
Box 348 HSC
Charlottesville, VA 22908

Dear John:

Enclosed you will find a copy of the final report of the Tuskegee Legacy Committee. As you recall, the formation of this committee grew out of the January meeting sponsored by the Minority Health Professions Foundation, the Office of the Assistant Secretary for Health, and the CDC.

I am sorry for the delay in submitting the report to you. However,

(b)(6)
(b)(6) The report has been sent to the CDC and I will keep you informed about any developments. Finally, I want to thank you for your assistance in making this report possible.

Sincerely,

Vanessa

Vanessa Northington Gamble, M.D., Ph.D.
Associate Professor
History of Medicine and Family Medicine

Department of History of Medicine

1420 Medical Sciences Center 1300 University Avenue Madison, WI 53706-1532 608/262-1460 FAX 608/262-2527

Vanessa Northington Gamble, M.D., Ph.D.

REPORT OF THE TUSKEGEE
SYPHILIS STUDY
LEGACY COMMITTEE

FINAL REPORT .

VANESSA NORTHINGTON GAMBLE, MD, PhD, CHAIR
JOHN C. FLETCHER, PhD, CO-CHAIR

May 20, 1996

TUSKEGEE SYPHILIS STUDY LEGACY COMMITTEE¹

In 1932, the United States Public Health Service (USPHS) initiated the Tuskegee Syphilis Study to document the natural history of syphilis. The subjects of the investigation were 399 poor black sharecroppers from Macon County, Alabama, with latent syphilis and 201 men without the disease who served as controls. The physicians conducting the Study deceived the men, telling them they were being treated for "bad blood".² However, they deliberately denied treatment to the men with syphilis and went to extreme lengths to ensure that they would not receive any therapy from other sources. In exchange for their participation, the men received free meals, free medical examinations, and burial insurance.³

On 26 July 1972 a front-page headline in the New York Times read, "Syphilis Victims in U.S. Study Went Untreated for 40 Years."⁴ The accompanying article publicly revealed the details

¹ The Committee was established at a meeting at Tuskegee University, January 18-19, 1996. All communications with the Committee should be addressed to the Chair of the Committee, Vanessa Gamble, M.D., PhD, History of Medicine Department, 1300 University Ave., Madison, WI 53706 (608) 262-5319. FAX: (608) 262-2317; email: vngamble@facstaff.wisc.edu. A list of the Committee members is attached. The Committee wishes to thank Judith A. Houck for her assistance in the preparation of this report.

²The term "bad blood" encompassed several conditions including syphilis, anemia, and fatigue.

³For a complete history see Jones, James H, Bad Blood: The Tuskegee Syphilis Experiment, new and expanded ed., New York: Free Press, 1993.

⁴Jean Heller, "Syphilis Victims in the U.S. Study Went Untreated for 40 Years," New York Times, 26 July 1972: 1, 8. The story first broke the previous day in the Washington Star.

of the Tuskegee Syphilis Study - "the longest nontherapeutic experiment on human beings in medical history"⁵. In the almost twenty-five years since its disclosure, the Study has moved from a singular historical event to a powerful metaphor. It has come to symbolize racism in medicine, ethical misconduct in human research, paternalism by physicians, and government abuse of vulnerable people.

The Tuskegee Syphilis Study continues to cast its long shadow on the contemporary relationship between African Americans and the biomedical community. Several recent articles have argued that the Tuskegee Syphilis Study has predisposed many African Americans to distrust medical and public health authorities.⁶ The authors point to the Study as a significant factor in the low participation of African Americans in clinical trials and organ donation efforts and in the reluctance of many black people in seeking routine preventive care. As one AIDS educator put it, "so many African American people that I work with do not trust hospitals or any of the other community health care service providers because of that Tuskegee Experiment. It

⁵Jones, Bad Blood, 91.

⁶See for example, Asim, Jabari, "Black paranoia far-fetched? Maybe, but understandable," The Phoenix Gazette February 23, 1993 Op-Ed: A13; Karkabi, Barbara, "Blacks' health problems addressed," The Houston Chronicle April 10, 1994 Lifestyle: 3; "Knowledge, attitudes and behavior; conspiracy theories about HIV puts individuals at risk," AIDS Weekly, November 13, 1995.

is like ... if they did it then they will do it again."⁷

The Tuskegee Syphilis Study Legacy Committee is dedicated to preserving the memory of the Study while moving beyond it, transforming the legacy into renewed efforts to bridge the chasm between the health conditions of black and white Americans. To this end, the Committee is pursuing two inseparable goals:

1) to persuade President Clinton to publicly apologize for past government wrongdoing to the Study's living survivors, their families, and to the Tuskegee community, and 2) to develop a strategy to redress the damages caused by the Study and to transform its damaging legacy.

In his recent apology for the government's role in human radiation experiments (1944-1974), President William J. Clinton claimed that "the American people ... must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing," and that "when the government does wrong, we have a moral responsibility to admit it."⁸ President Clinton is not alone in his belief that an apology for past wrongs is "doing the right thing." Recently, the Southern Baptist Church apologized to all African Americans for its stand on slavery during the Civil War and the Prime Minister of Japan similarly apologized to the people of the United States for the attack on

⁷Thomas, Stephen B. and Quinn, Sandra Crouse, "The Tuskegee Syphilis Study, 1932-1972: Implications for HIV Education and AIDS Risk Programs in the Black Community," Am J of Pub Health. 1991; 81: 1503.

⁸President William J. Clinton, "In Acceptance of Human Radiation Final Report," Washington, DC, October 3, 1995.

Pearl Harbor.⁹

And yet, these apologies do not merely acknowledge wrongdoing: they act as a first step toward healing the wounds inflicted. President Clinton, for example, saw his apology as "laying the foundation stone for a new era"¹⁰ in trying to regain the trust of the country.

It is within this context of doing the right thing, redressing past injuries, and regaining trust that the Committee adamantly believes that a Presidential apology to the victims of Tuskegee is critical to heal the devastating wounds that remain from this shameful episode in the history of medical research.

1. A Presidential Apology for the Tuskegee Syphilis Study

a) Moral and physical harms to the community of Macon County

It is clear that the U.S. government scientists irreparably harmed hundreds of socially and economically vulnerable African-American men in Macon County, their family members, and their descendants by deliberately deceiving them and withholding from them state of the art treatment. When the Tuskegee Study began, the standard therapy for syphilis consisted of painful injections of arsenical compounds, supplemented by topical applications of mercury or bismuth ointments. Although this therapy was less

⁹See for example, Niebuhr, Gustav, "Baptist group votes to repent stand on slaves," New York Times 21 June, 1995: A2 and Watanabe, Teresa and David Holley, "Japan Premier offers apology for WWII role," Chicago Tribune 15 August, 1995: A10.

¹⁰Clinton, 3 October, 1995.

effective than penicillin would later prove to be, in the 1930s every major textbook on syphilis recommended it for the treatment of the disease. After penicillin became available, the researchers withheld its use as well. Published medical reports have estimated that between 28 and 100 men died as a result of their syphilis.¹¹ Due to a lax study protocol, we cannot be sure that all the men had latent syphilis. It is therefore entirely possible that the infected men passed syphilis to their sexual partners and to their children in utero.¹² Thus physical harm may not be limited just to the men enrolled in the Study. ✓

b) No public apology has ever been made

In the aftermath of a Health, Education and Welfare task force report, a Senate hearing, and an out of court legal settlement, the U.S. government provided economic compensation and continues to give free health benefits to the surviving subjects and their families. However, no public apology has ever been offered for the moral wrongdoing that occurred in the name of government medical research. No public official has ever stated clearly to the nation that the Tuskegee Syphilis Study was morally wrong from its inception, and no public official has ever apologized to the survivors and their families. Yet, an apology is sorely needed. The Committee believes that an apology from

¹¹Jones, Bad Blood, 2.

¹²Hammonds, Evelyn M, "Your silence will not protect you: Nurse Eunice Rivers and the Tuskegee Syphilis Study," in The Black Women's Health Book: Speaking for Ourselves ed. Evelyn C. White, 2nd ed., Seattle: Seal Press, 1994: 323-331.

the President could facilitate the healing of the victims and the nation.

c) The harmful legacy of the Study

The historical record makes plain that African American's distrust of the medical profession predates the revelations of the Tuskegee Syphilis Study and involves a myriad of other social and political factors. Nevertheless, the Study has become a powerful symbol for the fear of exploitation in research and the deprivation of adequate medical care that is widespread in the African-American community. Recent articles argue that Tuskegee has created a climate of suspicion that taints the relationship between many African Americans and the medical profession. The Tuskegee Study is offered as the reason why few blacks participate in research trials,¹³ why the need for transplant organs by African Americans widely surpasses the supply,¹⁴ and why African Americans often avoid medical treatment.¹⁵ It is also offered as an explanation as to why rumors about genocide persist in the African-American community, ranging from the notion that AIDS is a plot to exterminate black people to the idea that needle exchange programs fuel a drug epidemic that

¹³Gamble, Vanessa, "A Legacy of Distrust: African Americans and Medical Research," Am J of Preventive Medicine, November/December 1993: 35-38.

¹⁴"Fear Creates Lack of Donor Organs Among Blacks," Weekend Edition, National Public Radio, 13 March 1994.

¹⁵See for example, Voas, Sharon, "Aging black sick, scared; past abuses, tradition keep them from clinic," Pittsburgh Post-Gazette, August 27, 1995: B1.

disproportionately affects black neighborhoods.¹⁶ For many African Americans, the fact that the Tuskegee Study occurred at all proves that black life is not valued. The Committee believes that an apology combined with a strategy for addressing the damages of the Tuskegee legacy would begin the process of regaining the trust of people of color.

d) The harm done to the community and the University

Because the name of the Study points to Tuskegee Institute (now Tuskegee University) rather than the United States Public Health Service, it clouds the funding and responsibility for the Study. Although facilities and staff of the Tuskegee Institute were involved, primary direction came from the government under the auspices of the USPHS. The notoriety of the Study obscures the achievements of the Tuskegee Institute in improving the health care of African Americans. These achievements include initiating the National Negro Health Week, building the John A. Andrew Hospital, creating the John A. Andrew Clinical Society, establishing a nurse training school, and organizing a school for midwives.

¹⁶Bates, KG, "Is it Genocide?" Essence, September 1990: 76; Thomas, Stephen, and Quinn, Sandra, "Understanding the Attitudes of Black Americans," In Stryker, J. and Smith, MD, eds. Dimensions of HIV Preventions: Needle Exchange, Menlo Park: The Henry J. Kaiser Family Foundation; 1993: 99-128; Kirp, David and Bayer, Ronald, "Needles and Race," Atlantic. July 1993: 38-42.

The Apology: Context and Opportunity

The Committee urges President Clinton to apologize on behalf of the American government for the harms inflicted at Tuskegee. The apology should be directed to those most directly harmed: to the elderly survivors of the Study, to their families, and to the wider community of Tuskegee and its University. Also included within the apology should be all people of color whose lives reverberate with the consequences of the Study.

As the highest elected official of the United States, the President should offer the apology for the Study which was conducted under the auspices of the United States government. The significance of a presidential apology was recognized recently when the President apologized to those harmed by Cold War radiation experiments as a way to regain confidence of the American people. In the context of President Clinton's stated desire to bridge the racial divide, this apology provides the opportunity to begin to heal the racial wounds that persist in this country.

Given the ages of the living participants and the period of time since the Study was disclosed, we believe that the apology should be offered swiftly. There are only eleven survivors; a twelfth died as recently as March 3, 1996. We recommend that the government issue the apology from Tuskegee University, perhaps linked with an early meeting of the new National Bioethics Advisory Commission (NBEAC). Because the Tuskegee

Study is a starting point for all modern moral reflection on research ethics, a meeting of the NBEAC at Tuskegee in conjunction with a presidential apology would be an ideal new beginning.

2. Transforming the Legacy

Although a public apology is necessary to heal the wounds of Tuskegee, it alone would not be sufficient to assure the nation that research like the Tuskegee Syphilis Study will not be duplicated. Despite the significance of a Presidential apology, it must not be an isolated event. Consequently, the Committee also recommends the development of a mechanism to move beyond Tuskegee and to address the effects of its legacy. The Committee strongly urges the development of a professionally staffed Center at Tuskegee University, focused on preserving the national memory of the Study and transforming its legacy. ✓

Regret for past mistakes must be accompanied by a determination to prevent future wrongs. Until now for black Americans the legacy of the Tuskegee Syphilis Study has been a negative one - a symbol of their mistreatment within American society. The proposed Center could help transform the legacy of Tuskegee into a positive symbol for all Americans by demonstrating the importance of acknowledging past wrongs, rebuilding trust, and practicing ethical research.

The new Center's mission would be to preserve the national memory of the Syphilis Study for public education and scholarly ✓

research, and to analyze and disseminate findings on effective and ethically acceptable ways to address the profound mistrust that is the tragic and enduring legacy of this Study, especially among African Americans and other persons of color. (See Appendix 1.)

Although the Committee sees the creation of a Center as the most valuable attempt to redress the damages of Tuskegee, we envision several possible concurrent programs. These include:

- 1) a Minority Health Initiative, similar in scope to the newly established Women's Health Initiative;
- 2) training programs for health care providers to better understand the social and cultural issues of providing health care and of conducting research in communities of color;
- 3) a clearinghouse to help investigators conduct ethically responsible research.

The Committee recommends that funding for the Center must combine government and private funding. The announcement of a federal challenge grant would be very useful as a catalyst for future fundraising efforts.

It is undeniable that the Tuskegee Syphilis Study has adversely affected the attitudes that many African Americans hold toward the biomedical community and the United States government. But despite the long shadow that it casts, we now have an opportunity to challenge this legacy and create a more beneficial one.

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APPENDIX 1

Possible functions for a Tuskegee research center:

- a) to create and maintain a public museum in Tuskegee, Alabama, to preserve the memory of the Study and to provide a focal point for efforts to transform its negative legacy;
- b) to provide a place for scholars to examine the ethical, legal, and social significance of the Study and other issues in bioethics;
- c) to conduct public education on the Study and its legacy in schools, community organizations, and medical institutions;
- d) to aid in the production of audiovisual aids for public education that will place the Study within its broadest social and historical context and provide suggestions for transforming its past legacy;
- e) to assure the rigorous preservation of presently endangered documents and other records to further encourage studies of race, ethnicity, and medicine;
- f) to offer support for medical researchers seeking ways to conduct research in diverse populations that is both scientifically sound and ethically responsible.

APPENDIX 2

TUSKEGEE SYPHILIS STUDY LEGACY COMMITTEE

Ms. Myrtle Adams
Chairman, Macon County Health Care Authority
704 Patterson St.
Tuskegee, AL 36088

Ms. Patricia Clay
Administrator, Macon County Health Care Authority
PO Drawer 180
Tuskegee, AL 36088

Dr. James A. Ferguson
Dean, School of Veterinary Medicine
Patterson Hall
Tuskegee University
Tuskegee, AL 36088

Dr. John C. Fletcher, co-chair
Director, Center for Biomedical Ethics
Cornfield Professor of Religious Studies
University of Virginia
Box 348 HSC
Charlottesville, VA 22908

Dr. Vanessa Northington Gamble, chair
Associate Professor of History of Medicine and Family Medicine
University of Wisconsin Medical School
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Madison, WI 53706

Dr. Lee Green
Assistant Professor
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Tuscaloosa, AL 35487

Ms. Barbara Harrell
Director, Division of Minority Health
Alabama Department of Public Health
434 Monroe St.
Montgomery, AL, 36130-3017

Dr. Bill Jenkins
Epidemiologist
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS-E02
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Dr. James H. Jones
Professor of History
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Dr. Ralph Katz
Professor
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Community Health
School of Dental Medicine
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Collection and Services
Health Sciences Library, Box 234
University of Virginia Health Sciences Center
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Luella LaMer Professor for Women's Studies
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Atlanta, GA, 30333

Mr. Anthony Winn
Program Analyst
Minority Health Professions Foundation
20 Executive Park Drive, #2021
Atlanta, GA 30333

rec'd 2/18/97

Action: Science

Gabrie

Platz

Levinson

Ofe

WHITE HOUSE STAFFING MEMORANDUM

DATE: 2/18/97 ACTION/CONCURRENCE/COMMENT DUE BY: 2/20/97

SUBJECT: Tuskegee Study

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	McCURRY	☐	☒
BOWLES	☒	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☒	☐
PODESTA	☒	☐	RUFF	☒	☐
MATHEWS	☒	☐	SMITH	☒	☐
RAINES	☐	☐	REED	☒	☐
BAER	☒	☐	SOSNIK	☒	☐
ECHAVESTE	☒	☐	LEWIS	☒	☐
EMANUEL	☒	☐	YELLEN	☐	☐
GIBBONS	☒	☐	STREETT	☒	☐
HALE	☐	☐	SPERLING	☐	☐
HERMAN	☐	☐	HAWLEY	☒	☐
HIGGINS	☒	☐	WILLIAMS	☒	☐
HILLEY	☒	☐	RADD	☐	☐
KLAIN	☐	☐	<u>Verrier</u>	☒	☐
BERGER	☐	☐		☐	☐
LINDSEY	☐	☐		☐	☐

REMARKS:

RESPONSE:

Please advise. Note policy issue and scheduling request



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

97 FEB 10 11:03

FEB 13 1997

MEMORANDUM FOR THE PRESIDENT

ISSUE:

Whether to issue a Presidential message on the Government's responsibility for the Tuskegee Syphilis Study to the surviving participants, their families, and the African American community.

BACKGROUND:

In 1932, Federal, State, and local officials, working with the Tuskegee Institute, began a long-term study of untreated syphilis in African-American males in Macon County, Alabama. The Study was established after surveys revealed a high prevalence of syphilis, particularly in rural areas of the South, and a high rate of untreated syphilis in African-American men. The Study was intended to justify a syphilis treatment program for African-Americans. Instead, it has become known as a classic case of medical research gone wrong.

That is because researchers enrolled about 400 African-American men with non-infectious syphilis and about 200 men without syphilis (the latter group for control purposes) in the Study and told them they were being treated for "bad blood" -- a local term used to describe a number of conditions, including syphilis. Men with infectious, early stage syphilis were treated and excluded from the Study; however, those with late term, non-infectious syphilis received no treatment and none was available at the time the Study was begun. Researchers actually were observing the natural progression of untreated syphilis in their bodies.

The project was scheduled to last for only six months, but it continued for 40 years -- even after penicillin became recognized as the standard of care for treating syphilis by the late 1940s. The Study was not ended until 1972, when a front-page story in the New York Times led to a public outcry and the government convened an advisory panel that declared the Study to be "ethically unjustified."

The Federal Government has tried to mitigate the damage since the study was ended. In 1973, HEW Secretary Weinberger directed the Public Health Service to provide Study participants and certain members of their families with comprehensive medical care for the

rest of their lives. Also, in 1973, a class-action lawsuit was settled for \$9 million. And, beginning in 1974, regulations for review and approval of experiments on human subjects were instituted to ensure that studies such as Tuskegee do not happen again:

- Since 1974, we have better instituted in research on human beings the practice of obtaining their voluntary informed consent.
- Also since 1974, all Federal studies using human subjects must be reviewed by Institutional Review Boards (IRBs) that are diverse and sensitive to community attitudes.
- In 1995, you created a National Bioethics Advisory Commission to review regulations and procedures, and to provide all possible safeguards for research volunteers.
- A 1996 meeting sponsored by the Centers for Disease Control and Prevention and HHS led to the establishment of the Tuskegee Syphilis Study Legacy Committee, which studied ways to preserve the memory of the Study and to transform the legacy into renewed efforts to bridge the gap between the health conditions of African-Americans and white Americans.

Even so, the Federal Government has never adequately expressed its responsibility for failure to inform Study participants and their families when treatment became available. Many commentators believe that the government's failure to make such an acknowledgment has helped to perpetuate feelings of widespread distrust among African-Americans toward government health-related initiatives. For example, African-Americans are far less likely than any other ethnic group to receive influenza vaccines (33.1 percent in 1993, compared to 50.4 percent for the total population). Similar low participation rates among African-Americans also are evident in research trials, organ donation, accessing simple medical care, and accepting advice from public health officials regarding the prevention of diseases such as AIDS. Even though there are many complex reasons for these low participation rates, the Tuskegee Study is cited as one significant contributing reason.

CURRENT ACTIVITIES INVOLVING THE TUSKEGEE STUDY

The Tuskegee Syphilis Study Legacy Committee has urged you to make an apology, and has issued a number of recommendations that would help assure the nation that research like the Tuskegee Study would not be duplicated.

You received last week a letter from two members of the Congressional Black Caucus -- Representative Louis Stokes, the Chairman of the Congressional Black Caucus Health Braintrust, and Representative Maxine Waters, Chairwoman of the Caucus -- requesting that you issue a formal apology on behalf of the United States for the Tuskegee Study, similar to the apology you issued to the so-called "atomic veterans." They note that Black History Month would be "a most appropriate time" to issue such a statement.

Home Box Office has produced a movie about the Tuskegee Study, entitled "Miss Evers' Boys," that is expected to receive substantial attention throughout the month of February, which is National African American History Month. Between February 11 and February 18, public screenings of "Miss Evers Boys" will be held in seven cities across the country -- Washington, New York, New Orleans, Los Angeles, Atlanta, Stamford, and San Francisco. The screenings and ensuing panel discussions will be attended by prominent African-American officials, including United Negro College Fund President William H. Gray III, Charles Drew University President Reed Tuckson, Former HHS Secretary Louis Sullivan, Emory School of Public Health Dean James Curran, Atlanta Journal-Constitution Editor Cynthia Tucker, "Our Common Welfare" Director Fay Brown-Sperling, and CDC Director David Satcher M.D. After the public screenings have been held, HBO will air the movie nationally on February 22.

There are eight participants of the Tuskegee Study still surviving, as well as 23 wives or widows, 15 children and two grandchildren.

RECOMMENDATIONS:

I recommend that you issue a statement similar to the one you made to atomic veterans -- one made on behalf of leaders from another time and era. You could either issue this statement as a written statement, or preferably, you could deliver it in person at an event coordinated to address participants and their families as well as African-American leaders.

In doing so, you would send a positive message that could help shift perceptions within the African-American community about medical research. You could add to your statement an announcement of additional steps you will take to further protect all human participants in research studies. Those steps would be as follows:

- Have HHS work with academic institutions and schools of public health to expand bioethics training, paying particular attention to minority perspectives and the needs of minority communities.

- Have HHS offer fellowships to postgraduate students for training in bioethics, with the goal of creating a national cadre of individuals -- especially minorities -- who would serve as experts in the conduct of research involving human subjects and as future leaders in the field of bioethics.
- Extend for two years the charter of the National Bioethics Advisory Commission, which you created, and ask it to explore ways in which communities -- particularly minority communities -- can become more involved in the development, implementation, and analysis of medical research. (There are other reasons currently under consideration for extending the Charter for two additional years).

DECISIONS

- Issue a Presidential message on the Government's responsibility for the Tuskegee Study to the surviving participants, their families, and the African American community.

Approve _____ Disapprove _____ Other _____

- Additional steps could be taken with academic insitutions and schools of public health, researchers, and the National Bioethics Advisory Commission to further protect human participants in research studies:

- HHS would expand bioethics training that are diverse and sensitive to minority communities.
- HHS would offer fellowships to postgraduate students, including minorities, who would serve as experts in research involving human subjects and in the field of bioethics.
- Extend the charter of the National Bioethics Advisory Commission for two more years and ask it to explore ways to better involve minorities in the mechanics of medical rsearch.

Approve _____ Disapprove _____ Other _____



Donna E. Shalala

CHRONOLOGY

Public Health Service Syphilis Study in Tuskegee

- 1926: The United States Public Health Service (PHS) began a survey of syphilis in Macon County, Alabama, one of several survey sites in the United States.
- 1930: PHS began the Macon County Syphilis Control Demonstration Project with funding PHS received from the Julius Rosenwald Fund. Participants were treated with a combination of neoarsphenamine and mercury; however, none of the 1400 patients received the full course of treatment.
- 1932: The Rosenwald Fund terminated funding for the control demonstration project. PHS began and funded the Tuskegee Syphilis Study. This was a study of untreated syphilis in approximately 400 black men who were at least 25 years of age and had syphilis for 5 years or longer. There is no protocol which documents the original intent of the Study; however, in 1932, much was still unknown regarding the latent stages of syphilis, especially pertaining to its natural course. It appears that the Study was undertaken to compare the course of untreated syphilis in black men with the results of an Oslo study on untreated syphilis in whites. The study was supposed to last 6 - 12 months with the intention to document the course of disease and use that information to obtain funding for treatment. The Alabama Department of Health agreed to the Study with the stipulation that some treatment be provided. Tuskegee Institute and local white physicians in Macon County also agreed to the Study.
- 1933: PHS decided to continue the study until the men died and added a control group of approximately 200+ men without syphilis.
- 1947: Penicillin became widely available for the treatment of syphilis in its early stages.
- 1950: The therapeutic benefits of penicillin in treating the late stages of syphilis were documented in scientific reports.
- 1957: PHS transferred the Venereal Disease Division, of which the Study was a part, to the Communicable Disease Center (now Centers for Disease Control and Prevention [CDC]).
- 1972: News of the study was reported in the New York Times, Los Angeles Times, and Washington Star. PHS convened the Tuskegee Syphilis Study Ad Hoc Panel to investigate the Study. The Study was terminated by the Department

of Health, Education, and Welfare (HEW), now the Department of Health and Human Services (HHS).

- 1973: The Secretary of HEW directed PHS to provide necessary medical care. CDC contacted the men and their families and gave them information about the Study and offered them comprehensive health assessments and lifetime medical services. The Tuskegee Health Benefit Program was set up and administered by CDC. Attorney Fred Gray filed a class action lawsuit on behalf of the living Study participants and heirs of deceased participants.
- 1974: Congress appropriated funding for the Tuskegee Health Benefit Program. The National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. HEW promulgated Federal regulations requiring research organizations to establish institutional review boards (IRBs) to review and approve HEW-funded research involving human subjects.
- 1975: The class action suit was settled. HEW provided a cash payment of \$37,500 to every living man with syphilis who was alive on July 23, 1973; \$15,000 to the heirs of each of the deceased men with syphilis; \$16,000 to every member of the class of living controls who was alive on July 23, 1973; and \$5,000 to the heirs of each of the deceased controls.
- 1979 - The Belmont Report summarizing the basic ethical principles governing research involving humans was released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- 1991: Seventeen Federal agencies, including HHS, adopted the Federal regulations for the protection of human subjects (known as the Common Rule), extending human subjects protections, including IRB review, to 16 other Federal agencies and to Federally-funded research.
- 1996: The Tuskegee Syphilis Study Legacy Committee issued a report on May 20, 1996 recommending that "President Clinton publicly apologize for past government wrongdoing to the Study's living survivors, their families, and to the Tuskegee community," and that a strategy be developed "to redress the damages caused by the Study to transform its damaging legacy."

WHITE HOUSE TUSKEGEE CEREMONY

DATE: May 16, 1997
LOCATION: East Room
TIME: 1:30 p.m.
FROM: Maria Echaveste
Ben Johnson

I. PURPOSE

You will meet with five of the remaining eight survivors of the Tuskegee syphilis experiment, recognize the injustice done to them, and issue a formal apology on behalf of the nation. Additionally, you will announce steps aimed at preventing experiments of this type from ever happening again.

II. BACKGROUND

In 1932, Federal, State, and local officials, began a long-term study of untreated syphilis in African-American males in Macon County, Alabama. The study was intended to justify a syphilis treatment program for African-Americans. Instead, it has become known as a case of medical research gone wrong. The project was scheduled to last for six months, but it continued for 40 years--even after penicillin became available to treat syphilis in the late 1940's. The study ended in 1972 when the New York Times ran a front-page story that led to a public outcry across the nation.

In 1973, Attorney Fred Gray filed a lawsuit on behalf of the participants and their heirs seeking redress. In 1974, the case was settled for \$9 million. Under the settlement, the U.S. Government provided Study participants and affected members of their families with comprehensive medical care for the rest of their lives.

Since 1974, all Federal studies using human subjects must be reviewed by Institutional Review Boards. In 1995, you created a National Bioethics Advisory Commission to review research regulations and procedures, and to provide all possible safeguards for research volunteers. Unfortunately, the Federal Government has never adequately expressed its responsibility in the Tuskegee Syphilis study. The Study continues to cast a shadow on the relationship between African Americans and the biomedical community. Many commentators believe that the government's failure to make such an acknowledgment has helped perpetuate feelings of widespread distrust among African-Americans toward health related initiatives.

Although you made the decision to host this ceremony several weeks ago, a press conference held by the survivors last month has heightened the attention on the event. You have received letters from the Congressional Black Caucus and a number of national organizations, requesting an apology to the victims of the study. Additionally, there has been a media frenzy and numerous editorials have been written to support an apology.

In addition to extending an apology on behalf of the nation, you will announce the signing of an executive order extending the charter of the National Bioethics Advisory Commission to October 1999. You will also announce four additional steps the Department of Human Services will take to insure we learn from the syphilis study. Hopefully these measures will rebuild trust, and protect human subjects in the future.

The Tuskegee survivors range in age from 85 years old to over 100 years old (see attached Bios). They left the Tuskegee area yesterday with an overwhelming send off from the community. A number of relatives of victims who are unable to attend the White House ceremony, are expected to watch via satellite at the Kellogg Center on the Tuskegee University campus. Acting Surgeon General Audrey Manley will be there to represent you. According to our contacts, the men and their families are some of your most loyal supporters. They are said to be very excited to be invited to the White House and are looking forward to concluding this terrible ordeal.

III. PARTICIPANTS

Pre-brief participants

Maria Echaveste

Kitty Higgins

Ben Johnson

Elizabeth Drye

David Satcher

Ann Lewis

Carolyn Curiel

Event Participants

Survivors, Wives and Widows of Survivors, Children and Grand Children of Survivors

Members of Congress

Representatives of National Black Associations and Organizations

Government Officials

IV. PRESS PLAN

Open Press

V. SEQUENCE OF EVENTS

- o Event briefing for YOU and THE VICE PRESIDENT in the Red Room
- o YOU and THE VICE PRESIDENT proceed to Blue Room and greet the Following guests:

Dr. David Satcher
Congresswoman Maxine Waters
Congressman Earl Hillard
Congressman Louis Stokes
Herman Shaw
Charlie Pollard
Howard Carter
Fred Simmons
Fred Moss
Ms. Gwendolyn Cox, Daughter of Sam Doner, Survivor
Mr. North R. Hendon, Grandson of Ernest Hendon, Survivor
Attorney Fred Gray (Counsel for survivors)

- o Survivors are announced into the East Room
- o YOU and THE VICE PRESIDENT are announced into the East Room
Accompanied by Dr. Satcher and Mr. Shaw.
- o THE VICE PRESIDENT makes remarks and introduces Dr. Satcher.
- o Dr. Satcher makes remarks and introduces Mr. Shaw.
- o Mr. Shaw makes remarks and introduces YOU.
- o YOU MAKE remarks and proceed to the Blue Room for receiving line.

**NOTE: The receiving line will flow from Red to Blue to Green.
Guests proceed to State Room for reception following receiving line.**

VI. REMARKS

To be provided by Speech writers

VII. ATTACHMENT

- 1) Biographic information on survivors

WHSO LAYOUT DRAFT 2 *SDM*

a/o 5/6/97; S. Warren

TUSKEGEE EVENT

Friday, May 16, 1997

POTUS TIME: 1:45 p.m.
Invite Time: 1:30 p.m.
EV Gate Opens: 1:00 p.m.
Approx. 180 Guests/Open Press/Business Attire

Carbon-Currier 

12:45 p.m. IN PLACE TIME

1:00 p.m. East Visitors Gate opens and guests proceed to East Room.

1:45 p.m. **THE PRESIDENT** and **THE VICE PRESIDENT** arrive in Red Room for briefing.

1:50 p.m. **THE PRESIDENT** and **THE VICE PRESIDENT** proceed to Blue Room to meet and greet the following guests:
Dr. Satcher
Mr. Shaw
4 survivors

2:00 p.m. **PROGRAM BEGINS**

THE PRESIDENT and **THE VICE PRESIDENT** are announced into East Room accompanied by Dr. Satcher and Mr. Shaw.

THE VICE PRESIDENT makes remarks and introduces Dr. Satcher.

Dr. Satcher makes remarks and introduces Mr. Shaw

Mr. Shaw makes remarks and introduces **THE PRESIDENT**.

2:30 p.m. **THE PRESIDENT** concludes remarks and proceeds to Blue Room for receiving line.

Note: The receiving line will flow from Red to Blue to Green.

Guests proceed to State Room for reception following receiving line.

2:55 p.m.

THE PRESIDENT departs.

Guests depart East Gate.

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Harris, Conn
Rabner

DRAFT TUSKEGEE QUESTIONS AND ANSWERS

Political + Policy

Q. Why is an apology coming forward now? What is there to be gained by such a gesture and how do you respond to those who might see it as politically motivated?

A. Even though this study was stopped some 25 years ago, it's never too late to make it clear from the highest levels of government that what happened at Tuskegee was very wrong and tragic and not something we ever condone. It is also important to make it clear that we are pledged to making sure this never happens again in our country. Most importantly, we have a moral obligation to apologize on behalf of the U.S. Government.

In fact, last year during a conference at Tuskegee sponsored by the U.S. Department of Health and Human Services on minority participation in research, the Tuskegee Study Legacy Commission was created to help all of us move beyond the Tuskegee Syphilis Study. The purpose of the Legacy Committee was to transform the legacy of minority distrust of the health and medical establishment into positive efforts to close the health gap between blacks and whites.

One of the principal recommendations of that Committee was that President Clinton publicly apologize to the living participants, their families and to the Tuskegee community.

We view this as more than symbolic, as more than just a verbal apology. This is not just a wrong, but a wrong in which the U.S. government is at fault. On one hand, today we're taking a major step toward publicly atoning for Tuskegee. On the other hand, we're hoping it will help move us further toward restoring lost confidence in government and distrust of medical science and public health institutions -- especially by African Americans and other minorities. That's been the legacy of the study. We are also concerned about regaining the confidence and trust of those individuals whose own health has been affected directly and indirectly by Tuskegee.

To those who would ascribe political motives to this, we would say that the only politics at work are the politics of doing what's right. It's always the right time to do right, and in this case, the time to do right is right now. That's all we're concerned with.

Q. Why do you think prior Administrations refused to issue an apology? Why has it taken until almost the end of the 20th century for the victims to receive some sort of official apology from their government? Can you say an apology was previously ignored for political reasons?

A. We can't speak for any Administration but this one. But this is not the kind of issue that you can look at in any sort of political context and make judgments that way. This was a human tragedy. Pure and simple. Through the years since Tuskegee was halted, various Administrations have addressed an assortment of Tuskegee-related issues

in their own way. Whether or not a formal apology should have been offered much earlier than today is not as important as our being here today to take care of that omission.

Q. When was the prospect of a formal apology raised to this Administration and whose idea was it?

A. The idea of an apology to the Tuskegee participants has been raised by numerous people, both in and out of government. We've heard from a number of community leaders, public health professionals, research and advocacy groups -- some who have felt all along that there needed to be a formal apology. Because of the mistrust that Tuskegee created with public health activities and how it's impacted African Americans' involvement in medical research and receipt of health care, some have felt that only a formal apology could begin the process of [re]building trust.

Q. Should the principals in the Tuskegee study be identified and prosecuted retroactively? Can they be prosecuted? ✓

A. First of all, you're talking about something that was initiated more than 60 years ago and was brought to a halt 25 years ago. The passage of time alone -- as well as the presence of so many unknown factors about what happened then and what mindset individuals had -- would make something like that extremely difficult. Successful prosecution would be unlikely. But more importantly, it would be counterproductive to even discuss that. There is nothing to be gained from pursuing that course. Everything we do with respect to Tuskegee should be about healing and learning from it. We must address Tuskegee in a positive way that takes us forward.

Q. Ideally, how would you like to see the Tuskegee participants respond to this apology?

A. We would hope that each and every one of these men and their families will now know deep down in their hearts and souls that their government -- through their President -- is genuinely sorry and accepts full responsibility for what happened at Tuskegee many years ago. More than anything we would hope they see our sincerity, which we believe is apparent by our doing this before the entire world.

Q. What do you say to African Americans and other minorities who will continue to view the medical research establishment skeptically, despite today's apology? How can this one apology help restore any confidence they might have had?

A. We know that one apology -- no matter how formal or how big -- is not going to be enough for some people to have their faith restored. We don't expect it to be a magic bullet. And we know that many of the policy and institutional changes in the area of research volunteers that have occurred since Tuskegee aren't enough to alleviate some people's fears either. We would just hope that people would continue to watch what we

do as much as what we say, and if they do that, they will see -- not just with today's apology, but over time -- an undying commitment to prevent this from ever happening again. We cannot rewrite past history. But we can write tomorrow's history and ensure that future generations never have to experience this humiliation. I think these gentlemen would agree that the only victory to be gained is to make sure this can never happen to their sons, daughters, granddaughters, grandsons and great-grandchildren.

Q. Besides today's formal apology, what is the biggest contribution the Clinton Administration has made in addressing the Tuskegee situation?

A. Even though many safeguards are now in place to protect research participants, our Administration has gone a step further to ensure that we promote only the highest ethical standards when it comes to human research. In October 1995, the President established the National Bioethics Advisory Commission to review all current regulations, policies, and procedures with respect to human research to make sure these high standards are being met. This panel is comprised of non-government members and is funded and led by the U.S. Department of Health and Human Services. *and [unclear] [unclear]*

There are a few more newer approaches we're taking to further improve our bioethics research:

To promote community participation in research, which is important when you consider the impact the Tuskegee study had on an entire community, Secretary Shalala at HHS is convening within 90 days from today a series of workshops on community participation in research. The workshops will involve a broad spectrum of academic institutions and community groups and are intended to produce a report containing recommendations to enhance our community involvement in research studies.

To help incorporate more community perspectives in the planning and carrying out of research, we're asking CDC, NIH, the Health Resources Services Administration (HRSA) and SAMHSA to join with a variety of partner organizations to recommend within 90 days from today materials and other strategies for improving ethical training in bioethics courses.

Also, we're going to be offering to promising students bioethics fellowships for postgraduate study beginning in September 1998 -- and we'll make special efforts to recruit minorities. The more we diversify the bioethics field, the more input we'll have in our research efforts and that can only be helpful to keeping research ethically and medically sound. ✓

Q. Has the government done all it can to help the Tuskegee participants?

A. With something as tragic as this, we don't think we can ever reach a point where we can say, "OK. We've done enough. That's it." It's the kind of situation that we must always monitor and be prepared to respond to. We're not talking about just the initial

participants in the study, but each succeeding generation of their families. We must make sure that our government is there for all of them and that's why our Government can never say "We're done." That's why the Tuskegee Health Benefits Program is in place to address the needs of family members as time goes on.

Q. Should the Tuskegee victims receive more monetary compensation?

A. The issue of monetary compensation was addressed when the settlement agreement was reached in 1974, shortly after the study was stopped. I think we've long moved past just attaching dollar signs to what happened at Tuskegee to another level of concern, and that is making sure it never happens again and that we continue to meet our obligations with these men and their families as our government has pledged to do.

Q. In light of the age and feeble condition of the participants, why was the decision made to hold the formal apology program at The White House rather than in Alabama near their homes?

A. We don't see it as a matter of who should travel where. We believe it's about making the strongest possible statement that we can about how reprehensible this whole episode was and how sincere we are in our apology. And we think the White House is the best and only location to demonstrate -- not only to the participants and their families, but to the entire world -- that we consider this apology from our government to be of utmost importance. Having this ceremony in The White House establishes quite clearly the priority we give this. As for the travel of participants to Washington, we helped to make arrangements for them to be here and we are paying their expenses. We have worked closely with these gentlemen and their families to ensure their safe and comfortable travel to and from Washington for this event.

Q. Was what happened at Tuskegee racism?

A. We cannot escape the fact that the problems of the Tuskegee experiment are wrapped in elements of racism and discrimination. If we all think back, the racial attitudes and climate in our country at that time certainly played a major role in the many improprieties of the study.

For example, there was some merit to choosing Macon County, Alabama as a focus of a study on syphilis, given the fact that it had the highest syphilis rates in the country at the time. But to mislead and misinform these men and then to withhold treatment from them after cures became available was in and of itself discriminatory.

Q. Looking back at how the Tuskegee study unfolded and comparing it to the checkpoints in place today, at what point along the spectrum do you think an experiment like that would be stopped now?

A. I think our research checks and balances are so strong now that it would be very tough for a Tuskegee Study to even get off the ground. And furthermore, the greater diversity of decisionmakers in government, research and in the Public Health Service today is instrumental in keeping this kind of thing from ever getting started. Certainly we can say that if such a study managed to start up, it would raise so many red flags so quickly that any life it would have would be very short.

Q. This apology, while welcomed by many, may ring hollow for the families of 28 participants who died from untreated syphilis. What can you say to them?

A. We would say to them that we don't pretend to skirt the fact that these deaths were cruel and unnecessary. But that doesn't mean that we cannot strive as hard as we can today to make sure that those gentlemen didn't die in vain. Their deaths are and will always be crystal clear reminders of our obligation to work to protect and ensure the health of all people in this country, not just some. And those who died from untreated syphilis will always be symbols of our obligation to address the special health needs of our minority citizens in a dignified and respectful manner. Certainly each loss will forever represent a huge void in the hearts of their family and friends. But our country feels each of these losses too, as they are 28 stains on the fabric of our nation's democracy and freedom. We will all pay a price for these tragic deaths.

Q. Some have suggested a memorial to the participants on the campus of Tuskegee University. What's your feeling on that?

A. The Department of Health and Human Services has been discussing with Tuskegee a proposal to establish on campus a Center for Bioethics in Research and Health Care. We're announcing today that we're providing a planning grant to Tuskegee to pursue this project. Ultimately, such a facility 1) will house a museum containing documents and other materials from the study; 2) help educate researchers and the public about the significance of the study; and 3) provide opportunities for training in bioethics in partnerships with other academic institutions.

The Center will really do two things: make Tuskegee a focal point for ongoing discussion about how we can address the negative legacy of the study; and be a living and lasting memorial to the people who participated in the Tuskegee study as well as their families -- for generations to come.

Q. Last month, Public Citizen raised some very serious allegations about ongoing HHS-sponsored research, mainly that some of the HIV mother-to-child transmission research underway in developing countries is unethical. How can you assure the public in light of the pain and anger caused by Tuskegee that we're not treading down that same path even lightly?

A. Let me first of all make clear what our work is in this area. We're dealing with some extremely tough issues here. We're balancing very delicately the need to help some

poorer countries achieve some of the same promising results we have in fighting AIDS and at the same time be cognizant of special sensitivities and perceptions that may arise from our efforts. When it boils down to it, we're just trying to find effective ways of preventing mother-to-child HIV transmission that can be used in these developing countries, where HIV/AIDS has taken a devastating toll. While AZT has now become a promising standard of care treatment regimen here in the United States, developing nations aren't able to do that because of affordability problems and also because of the differences in the nature of health problems between our country and theirs. Our sole goal is to help these nations find treatment regimens that are effective for their specific populations.

We've taken extra steps to ensure that these trials go beyond ethical and medical standards. We're working very closely with the World Health Organization, UNAIDS and the host governments within those countries to design trials. We're not doing this in a vacuum. Not only that, but these trials have been reviewed by our Centers for Disease Control and Prevention as well as the NIH institutional review boards that were created in the wake of the Tuskegee experiments. We've even involved the review boards within the host countries.

You're talking about a situation today where each and every move is scrutinized before, during and after to make sure that we go beyond the standards and that we're ethical in every way. This is not a situation like Tuskegee where you apparently had a group of people conducting research under their own twisted standards, arbitrarily making decisions and keeping details and information to themselves. It's definitely a new day.

Q. A report in The New York Times earlier this week quotes the top government official involved in protecting humans in research as saying there is "unchecked" research going on. What is he referring to and how can that give people any kind of comfort, especially in light of Tuskegee?

A. You're speaking of Dr. Gary Ellis, head of the Office of Protection from Research Risks, and he's drawing a very distinguishable line between government-sponsored research and research that's financed by private sources. Privately financed research -- except that that involves FDA approval of a device or drug -- is not subject to the same strict rules that apply to government research, and keep in mind that Tuskegee involved government research.

As for privately financed research, some legislation has been discussed, but the Clinton Administration hasn't taken a position on any specific proposals at this time. We will be guided by the National Bioethics Advisory Commission on this issue and some of the action steps we announced today will enhance protection of all human subjects.

We look forward to working with leaders in the Congress like Senator Glenn -- who has introduced a bill to expand protection to private research -- to address these gaps as well. We're confident that through working with the research community and the Congress we will be able to expand protection beyond government research.

Q. What is the cost of the planning grant for the Center for Bioethics Research?

A. The planning grant is about \$200,000.

Q. What is the government doing now to restore communities' trust and participation in clinical research? What strategies work?

A. A number of projects underway now are demonstrating quite clearly the benefits of community participation and partnership between the science community and citizens. I'll give you some examples.

Project LinCS, Linking Together Communities and Scientists, brings together communities and scientists in partnership in various communities across the country to build trust in the development and implementation of HIV prevention biomedical research -- specifically vaccine research.

In places like San Francisco, Philadelphia, and Durham (N.C.), community advisory boards are working with the medical science community on such issues as study protocols, interview guides, recruitment, and interpretation and presentation of study results. What we're learning from Project LinCS is being shared broadly.

Project Direct is a community-based intervention project in Raleigh, N.C. that targets collaborative diabetes education and outreach efforts to the high-risk population in the

African American community. Technical experts, citizens, and community leaders plan and implement the project together in work groups focusing on intervention strategies that are culturally relevant.

Also, CDC is working through a number of different partners to enhance research and educational efforts that involve minority populations. For example, they're working with the *Congress of National Black Churches* and the *National Association of Black Psychologists* on culturally appropriate diabetes and tobacco prevention initiatives. And they're working with the Minority Health Professions Foundation (a consortium representing 11 HBCUs) on some 15 research projects to develop community-based and culturally sensitive initiatives in such areas as occupational health and safety in low income populations, violence prevention and learning disabilities in incarcerated youth.

Finally, another example is our work with communities to reduce the burden of cancer on minority communities. Through the National Black Leadership Initiative on Cancer, we've built more than 60 community coalitions that have reached out to 15 to 20 million African Americans nationwide. The goal of these coalitions is to mobilize cancer prevention and control activities within African American communities -- with the ultimate objective being to reduce cancer incidence and mortality and remove barriers that limit African Americans' access to quality cancer control services.

Q. Does the Administration support Senator Glenn's bill to expand human subjects protections to the private sector?

A. The Clinton Administration hasn't taken a position on any specific proposals at this time, but we look forward to working with leaders in the Congress like Senator Glenn -- who has introduced a bill to expand protection to private research. Overall, we will be guided by the National Bioethics Advisory Commission on this issue. But some of the action steps we announced today will enhance protection of all human subjects, including improving the way we educate medical professionals in bioethics. It's important that the educational process help increase sensitivities to the importance of protecting humans subjects, and we believe the fellowship program and the Center that will be built at Tuskegee -- as well as the partnerships that will be formed from that effort -- will go a long way toward emphasizing the utmost in ethics and principles in training tomorrow's biomedical researchers.

Q. How many fellowships will HHS award? How much will the program cost?

A. The details of all of that are still being worked out. But everything will be laid out in detail when we make the announcement to the applicant community. Conceptually, we're looking at a fellowship program that will include a short-term training component as well. We'll definitely have more to say about this.

but we expect to have at least 6-8 per year

Q. What is being done to strengthen bioethics training?

A. Three of the four concrete steps that have been announced here today to better protect human research subjects involve strategies to improve bioethics training.

First, the Center for Bioethics at Tuskegee that we are awarding a planning grant for will serve as both a living memorial and a focal point for discussions about strengthening bioethics training throughout the nation.

Second, the President has directed Secretary Donna Shalala to work with private medical research organizations to develop training materials for researchers that would help them build their work on core ethical principles of respect, justice and informed consent. We're not wasting any time. We're looking at having those materials ready in one year.

Thirdly, we're committing to post-graduate fellowships in bioethics, beginning in September 1998, with a special commitment to recruiting promising African American and other minority students.

These are new and tangible efforts that will blend in with what we're already doing in human subjects protection to build an even stronger system to protect any of our citizens from suffering as the men and families of Tuskegee did.

Q. What will the center ultimately cost and will HHS fund it?

A. The Department is prepared to award up to \$200,000 to Tuskegee to support a planning grant. Tuskegee University will be asked to develop a plan and a budget for the establishment of a Center for Bioethics in Research and Health Care. Plans for the Center will address the creation of a museum at Tuskegee, Alabama; efforts to provide public education regarding the Study and bioethics; a plan for providing technical assistance to produce educational materials for public and professional educators; and a plan to develop partnerships with schools of medicine and public health to provide opportunities for students to receive training in bioethics.

Major Witness Sticks to Story In Bomb Trial

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By JO THOMAS

DENVER, May 13 — In a high-stakes assault on the Federal Government's star witness, Timothy J. McVeigh's defense lawyer today sought to portray his client's former close friend as a liar and an opportunist, motivated by the hope of avoiding many years in prison himself.

But after two days of searching cross-examination, the friend, Michael J. Fortier, stuck to his testimony that Mr. McVeigh, filled with hatred for the Government, had cased the Federal Building in Oklahoma City as part of his meticulous planning for the worst terrorist attack in United States history.

And when the lead prosecutor, Joseph H. Hartzler, led Mr. Fortier through a redirect examination, his questions resulted in a new disclosure that supported Mr. Fortier's testimony: At the very spot where Mr. Fortier said his friend had planned to park a getaway car, agents from the Federal Bureau of Investigation later found the key to the Ryder rental truck that had carried the bomb.

The testimony of Mr. Fortier comes two years after he agreed to plead guilty to four lesser bombing-related charges, and to testify against Mr. McVeigh and his co-defendant, Terry L. Nichols. Mr. McVeigh and Mr. Nichols are charged with murder and conspiracy in the April 19, 1995, blast, which killed 168 people; Mr. Nichols will be tried later.

Although the Government has said

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it did not need Mr. Fortier's testimony to convict Mr. McVeigh, Mr. Fortier gave the most detailed account yet about Mr. McVeigh's activities and statements in the months before the bombing. But like many Government witnesses in criminal cases, Mr. Fortier presented ample opportunities for cross-examination.

Mr. Jones tried to discredit Mr. Fortier by reading from transcripts of F.B.I. wiretaps in which Mr. Fortier cursed the press and the Government and said he would like to make money by selling his account of the bombing.

"Would you agree with me, Mr. Fortier, that you have transformed yourself?" Mr. Jones asked today.

When Mr. Fortier said, "No, sir, I wouldn't agree with you," Mr. Jones replied, "Well, certainly you would agree with me that your testimony and statements today are different than the ones before, aren't they?"

Mr. Fortier answered: "Before May 17, I was lying to the F.B.I. and to the media and other people."

The answer did not suit Mr. Jones. "That wasn't the question I asked you, Mr. Fortier," he retorted. "The question I asked you is whether your statements today are different than the ones before May 17."

Mr. Fortier said, "Yes, they are."

In his sessions with the prosecutors, Mr. Jones persisted, "Did you go over things like responding to my question by saying, 'Well, I was lying then and I'm not lying now'?"

Mr. Fortier answered, "Mr. Hartzler has never coached me on what to say."

Mr. Jones snapped back: "I didn't ask you whether he coached you. I asked you whether you had discussed those matters. And incidentally, was it suggested that you answer by saying, 'I haven't been coached'?"

Mr. Fortier replied, "No, sir, it wasn't."

Despite Mr. Jones's relentless attack on Mr. Fortier, for the moment, the witness's testimony has seemed to have helped only Mr. Nichols. Mr. Fortier, who will be sentenced when both trials are over, testified that Mr. McVeigh told him before the bombing that Mr. Nichols wanted to drop out of the plot and did not want to mix the bomb.

Mr. Jones also tried to discredit Mr. Fortier by aiming at his testimony that Mr. McVeigh had asked him to rent a locker in Kingman, Ariz., in the fall of 1994. He was unable to find one, he said, but when Mr. McVeigh and Mr. Nichols showed up at his home a few days after this request, they told him they had found one.

"Well, how did he know you hadn't been able to find one?" Mr. Jones asked.

When Mr. Fortier replied, "I don't know," Mr. Jones said, "Is it possible, Mr. Fortier, that what really happened is that you and your wife went out to find a storage shed on your own, didn't have anything to do with Tim McVeigh, you needed someplace to put this stuff that you had stolen from other people, because you didn't want to leave it in your house?"

Mr. Jones had already underscored admissions from Mr. Fortier on his direct examination that he had used and sold drugs, and had stolen items from a local National Guard Armory and a local airport.

Mr. Jones also zeroed in on testimony in which Mr. Fortier said he had sent off for a false identification kit so Mr. McVeigh could apply for credit card advances he never intended to repay. Mr. McVeigh had been asking him to give him money from his own credit cards, Mr. Fortier testified, and he did not want to do this.

"So then you decided to help him commit a crime to get a false ID?" Mr. Jones asked.

Mr. Fortier answered, "That's cor-

rect, to get him off my back."

Mr. Jones repeated, "To get him off your back."

When Mr. Fortier said, "Yes," Mr. Jones asked, "Well, what else are you willing to do to get somebody off your back, Mr. Fortier?"

Mr. Fortier replied, "I don't understand the question."

Mr. Jones persisted: "Like the F.B.I. What are you willing to do to get them off your back?"

Mr. Fortier answered, "I was willing to lie to them."

Mr. Jones retorted, "No, you were willing to cooperate with them, weren't you?"

Mr. Jones also ridiculed Mr. Fortier's admission on cross-examination that he could not remember just how he and Mr. McVeigh got from Interstate 35 to downtown Oklahoma City the day he said they cased the Federal Building. But later, Mr. Hartzler reminded Mr. Fortier that he had gotten in Mr. Hartzler's van and showed the prosecutor the route around the building and the alley where Mr. Fortier said Mr. McVeigh intended to leave the getaway car.

"So you independently on your own directed us to that alley and told us about that alley and where Mr. McVeigh was going to park?" Mr. Hartzler asked.

Mr. Fortier replied, "Absolutely."

Referring to the truck used to carry the bomb, Mr. Hartzler asked, "Did you know at that time that the F.B.I. had found the key to the Ryder truck in that alley?"

Mr. Fortier replied: "No, sir. This is the first I've heard of that."

The last witness of the day was Charles C. Edwards, design engineering manager for a company that makes ignition keys and locks for the Ford trucks bought by Ryder. Mr. Edwards said the F.B.I. had asked him to make a door and ignition lock to fit a keycode for a Ford truck. When it was made, the key found in the alley fit, he testified.

The New York Times

WEDNESDAY, MAY 14, 1997

'Unchecked' Research on People Raises Concern on Medical Ethics

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By SHERYL GAY STOLBERG

WASHINGTON, May 12 — On the outskirts of the nation's capital, tucked away on the sixth floor of a suburban office building, there is a little-known computer data base: a state-by-state accounting of the experiences of every cat, dog, hamster, guinea pig, chimpanzee, rabbit or farm animal used in a laboratory experiment.

Here in the Government's Division of Animal Care, one can discover precisely how many guinea pigs were subjected to biomedical research in 1995 (333,379). Or how many chimpanzees felt pain during research but were comforted with medication (19,712). Civil servants have compiled such numbers for 31 years, ever since Congress passed the Animal Welfare Act.

But there are no comparable figures for people. "We have better information about animal experiments than we do about human experiments," said R. Alto Charo, of the President Clinton's National Bioethics Advisory Commission.

More than two decades after the Federal Government issued regulations to protect human subjects of medical experiments, the research landscape has changed so much that many doctors and scientists are not necessarily covered by the rules. For example, an entire area of study, embryo research, has grown in the private sector over the last 20 years.

The regulations were the direct legacy of the notorious Tuskegee study, which was halted 25 years ago, amid revelations that the Government had withheld treatment for syphilis to black men in Tuskegee, Ala., without their consent.

The Federal regulations were aimed at establishing the twin pillars of ethical research for subjects of federally-financed studies: the assurance that patients would be warned of risks and that an independent panel would evaluate the experiment before it was conducted.

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experiment before it was conducted.

But as President Clinton prepares to issue a formal apology to the subjects of the Tuskegee study on Friday, there is mounting concern that the Government's protections do not go far enough.

On Capitol Hill, Representative Christopher Shays, Republican of Connecticut, convened a hearing last week to determine the scope of lapses and violations of ethics in experiments. He was startled by the testimony, including accounts of ethics panels, institutional review boards, or I.R.B.'s, set up as profit-making ventures to evaluate proposed experiments for research groups that pay them.

"I found it amazing," Mr. Shays said. "I am struck by the fact that we have I.R.B.'s that can be created by anyone, that we don't even know how many there are. I think the more we get into this the more we are going to realize how casual this process really is."

Moreover, certain privately financed research is not bound by the rules. The loophole means some people — no one knows how many — are participating in studies that are wholly unregulated. When there are complaints, there is nothing the Government can do.

"There is unchecked human experimentation taking place," said Dr. Gary B. Ellis, director of the Federal Office for Protection from Research Risks. How much is impossible to determine. But documents obtained from the research protection agency revealed several examples of possible lapses, though the names of those making the complaints were withheld.

In one instance, the parents of a 3-year-old boy with a rare genetic disease enrolled him in an experimental bone marrow transplant program in 1990, at a state university hospital. The parents said their son emerged from the treatment with profound brain damage, unable to walk, talk or feed himself. There was no way to know if the treatment caused the damage, but in a 1991 letter to the protection agency, his parents said that the consent form they had signed had not fully explained the risks of the procedure.

"Had we been informed of this risk we would not have consented to the transplant," the couple wrote. "We are now faced with the expense and challenge of caring for a brain-damaged child who will now live a much longer life span because they corrected his disease."

In another case, an Oregon breast cancer patient complained that the hospital in which she had received chemotherapy had released information from her medical records to researchers without her consent.

In both cases the research was privately financed, so Dr. Ellis could not investigate. "We have incident after incident where we get to the point where we determine that we don't have the authority," he said. "It's very frustrating."

Senator John Glenn, Democrat of Ohio, has been seeking to close this gap. He introduced a bill, the Human Research Subject Protections Act of 1997, that would require informed consent and board review of all experiments, regardless of who paid for them. The bill also would create criminal penalties for violators — a provision that has drawn criticism from the Pharmaceutical Research and Manufacturers Association of America, which often finances private research.

"We believe in informed consent and our companies bend over backwards when we deal with patients," said Mark Grayson, the group's spokesman. But criminal penalties were unwarranted, he said.

Dr. William E. Gibbons, who directs research on genetic testing of embryos at the Jones Institute for Reproductive Medicine in Norfolk, Va., was also skeptical, saying his scientists already follow Federal guidelines.

"How bad a problem do we actually have?" Dr. Gibbons asked. Replied Senator Glenn: "One violation is too much."

Experts point out that the debate over ethics in human experiments is occurring at a time when medical research is safer than it has ever been. History is dotted with scientific horrors beyond the Tuskegee study, notably the gruesome Nazi experiments of World War II and human radiation experiments financed by the Government during the cold war.

These low points in the annals of medicine gave rise to the current system. The concept of informed consent, that patients must be told in advance about how the experiment might help or hurt them, is rooted in the Nuremberg Code by which the

Nazi experiments were judged in postwar trials. But it was not until 1974, two years after the Tuskegee study was disclosed, that the Federal Government enacted a set of comprehensive rules designed to protect volunteers for research.

Informed consent was one cornerstone of the new rules. The creation of institutional review boards was

the other. Today, these provisions are so universally accepted they are referred to as the Common Rule.

The Common Rule applies to three research categories: studies supported by 17 Federal agencies that adhere to it, including the Department of Defense; experiments to prove the efficacy of a new medicine or device and gain the Food and Drug Administration's approval, and research paid for with private money but conducted by academic researchers whose employers have signed agreements with the Government. About 450 universities now require that their scientists to adhere to the Common Rule.

Although it has been updated six times in the past 23 years (there are now specific provisions for children, prisoners and pregnant women) many ethics experts say the nature of research has changed so dramatically since the Common Rule was drafted that a thorough re-examination is in order.

"The old model presumes that you would do research to find out some important new basic facts about health," said Dr. Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania. "Current research might be for a pharmaceutical company to put a new drug on the market to compete with the five ones that are already there for, say, insomnia or weight loss. The risks and benefits may be different."

In addition, Dr. Caplan said, the boom in research paid for by private industry has created a new phenomenon: commercial review boards that have generated a wave of what Dr. Caplan called "I.R.B. shopping."

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What, if anything, Congress can do about lapses is unclear; Government has traditionally been loath to interfere with the private practice of medicine, and no regulatory system is foolproof. "The situation that we have created is generally effective," Dr. Harold Varmus, director of the National Institutes of Health, told Representative Shays last week. "But it's not perfect."

But Ms. Charo, of the bioethics commission, said she believed that expanding the Common Rule to cover all research would be a good first step. At least, she said, regulators might then be able to gather basic statistics for humans as they do for other species. After all, she added wryly: "I'm an animal too."

The New York Times

WEDNESDAY, MAY 14, 1997

'Unchecked' Research on People Raises Concern on Medical Ethics

A1

By SHERYL GAY STOLBERG

WASHINGTON, May 12 — On the outskirts of the nation's capital, tucked away on the sixth floor of a suburban office building, there is a little-known computer data base: a state-by-state accounting of the experiences of every cat, dog, hamster, guinea pig, chimpanzee, rabbit or farm animal used in a laboratory experiment.

Here in the Government's Division of Animal Care, one can discover precisely how many guinea pigs were subjected to biomedical research in 1995 (333,379). Or how many chimpanzees felt pain during research but were comforted with medication (19,712). Civil servants have compiled such numbers for 31 years, ever since Congress passed the Animal Welfare Act.

But there are no comparable figures for people. "We have better information about animal experiments than we do about human experiments," said R. Alto Charo, of the President Clinton's National Bioethics Advisory Commission.

More than two decades after the Federal Government issued regulations to protect human subjects of medical experiments, the research landscape has changed so much that many doctors and scientists are not necessarily covered by the rules. For example, an entire area of study, embryo research, has grown in the private sector over the last 20 years.

The regulations were the direct legacy of the notorious Tuskegee study, which was halted 25 years ago, amid revelations that the Government had withheld treatment for syphilis to black men in Tuskegee, Ala., without their consent.

The Federal regulations were aimed at establishing the twin pillars of ethical research for subjects of federally-financed studies: the assurance that patients would be warned of risks and that an independent panel would evaluate the experiment before it was conducted.

Continued on Page A15

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experiment before it was conducted. But as President Clinton prepares to issue a formal apology to the subjects of the Tuskegee study on Friday, there is mounting concern that the Government's protections do not go far enough.

On Capitol Hill, Representative Christopher Shays, Republican of Connecticut, convened a hearing last week to determine the scope of lapses and violations of ethics in experiments. He was startled by the testimony, including accounts of ethics panels, institutional review boards, or I.R.B.'s, set up as profit-making ventures to evaluate proposed experiments for research groups that pay them.

"I found it amazing," Mr. Shays said. "I am struck by the fact that we have I.R.B.'s that can be created by anyone, that we don't even know how many there are. I think the more we get into this the more we are going to realize how casual this process really is."

Moreover, certain privately financed research is not bound by the rules. The loophole means some people — no one knows how many — are participating in studies that are wholly unregulated. When there are complaints, there is nothing the Government can do.

"There is unchecked human experimentation taking place," said Dr. Gary B. Ellis, director of the Federal Office for Protection from Research Risks. How much is impossible to determine. But documents obtained from the research protection agency revealed several examples of possible lapses, though the names of those making the complaints were withheld.

In one instance, the parents of a 3-year-old boy with a rare genetic disease enrolled him in an experimental bone marrow transplant program in 1990, at a state university hospital. The parents said their son emerged from the treatment with profound brain damage, unable to walk, talk or feed himself. There was no way to know if the treatment caused the damage, but in a 1991 letter to the protection agency, his parents said that the consent form they had signed had not fully explained the risks of the procedure.

"Had we been informed of this risk we would not have consented to the transplant," the couple wrote. "We are now faced with the expense and challenge of caring for a brain-damaged child who will now live a much longer life span because they corrected his disease."

In another case, an Oregon breast cancer patient complained that the hospital in which she had received chemotherapy had released information from her medical records to researchers without her consent.

In both cases the research was privately financed, so Dr. Ellis could not investigate. "We have incident after incident where we get to the point where we determine that we don't have the authority," he said. "It's very frustrating."

Senator John Glenn, Democrat of Ohio, has been seeking to close this gap. He introduced a bill, the Human Research Subject Protections Act of 1997, that would require informed consent and board review of all experiments, regardless of who paid for them. The bill also would create criminal penalties for violators — a provision that has drawn criticism from the Pharmaceutical Research and Manufacturers Association of America, which often finances private research.

"We believe in informed consent and our companies bend over backwards when we deal with patients," said Mark Grayson, the group's spokesman. But criminal penalties were unwarranted, he said.

Dr. William E. Gibbons, who directs research on genetic testing of embryos at the Jones Institute for Reproductive Medicine in Norfolk, Va., was also skeptical, saying his scientists already follow Federal guidelines.

"How bad a problem do we actually have?" Dr. Gibbons asked. Replied Senator Glenn: "One violation is too much."

Experts point out that the debate over ethics in human experiments is occurring at a time when medical research is safer than it has ever been. History is dotted with scientific horrors beyond the Tuskegee study, notably the gruesome Nazi experiments of World War II and human radiation experiments financed by the Government during the cold war.

These low points in the annals of medicine gave rise to the current system. The concept of informed consent, that patients must be told in advance about how the experiment might help or hurt them, is rooted in the Nuremberg Code by which the

experiments were judged in postwar trials. But it was not until 1974, two years after the Tuskegee study was disclosed, that the Federal Government enacted a set of comprehensive rules designed to protect volunteers for research.

Informed consent was one cornerstone of the new rules. The creation of institutional review boards was the other. Today, these provisions are so universally accepted they are referred to as the Common Rule.

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Although it has been updated six times in the past 23 years (there are now specific provisions for children, prisoners and pregnant women) many ethics experts say the nature of research has changed so dramatically since the Common Rule was drafted that a thorough re-examination is in order.

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What, if anything, Congress can do about lapses is unclear; Government has traditionally been loath to interfere with the private practice of medicine, and no regulatory system is foolproof. "The situation that we have created is generally effective," Dr. Harold Varmus, director of the National Institutes of Health, told Representative Shays last week. "But it's not perfect."

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The New York Times

WEDNESDAY, MAY 14, 1997

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Tom/EK

Are we for
this?
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

F A S C I M I L E

DATE _____

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(NAME AND ORGANIZATION)

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Questions and Answers Tuskegee Syphilis Study

Q1. What was the purpose of the Study? What was its official title? How long was it conducted?

A1. The U.S. Public Health Service Syphilis Study was officially called the "Study of Untreated Syphilis in the Negro Male" in Tuskegee. It began in 1932 as a study of untreated syphilis in 400+ African-American men who were at least 25 years of age and had syphilis for 5 years or longer. A year later a control group of 200+ African-American men without syphilis were added to the study. The study was undertaken to compare the course of untreated syphilis in black men with the results of an Oslo study on untreated syphilis in whites. The study was funded by the U.S. Public Health Service. The study was stopped in 1972.

BACKGROUND: The Syphilis Study was supposed to last 6–12 months with the purpose of documenting the course of disease and using that information to obtain funding for treatment. After a year, it was decided to continue the study until the men died. The Alabama Department of Health agreed to allow the study to be conducted in that state with the stipulation that some treatment be provided. The Tuskegee Institute and the local white physicians in Macon County also agreed to the study. The study was stopped in 1972 after a news story about the study caused public outcry. Left untreated syphilis remains in the body and begins to damage the internal organs including the brain, nerves, eyes, heart, blood vessels, liver, bones, and joints.

Q2. Why was it conducted in Tuskegee?

A2. In 1926, the U.S. Public Health Service conducted surveys of the prevalence of syphilis in Macon County, Alabama, which was one of several sites surveyed in the United States. The prevalence of syphilis among African-Americans was particularly high and many people remained untreated.

BACKGROUND: In 1930, the Macon County Syphilis Control Demonstration Project began; this project provided treatment which was a combination of neoarsphenamine and mercury. This project was funded by the Rosenwald Fund. About 1400 patients were enrolled in the project; none of them received the full course of treatment because funding ended. In 1932 the Tuskegee Syphilis Study was started. The study was undertaken to document the course of untreated syphilis with the intention that the information could be used to obtain funding for treatment.

Q3. Why is the President issuing an apology for the Study now? Is this apology politically motivated?

A3. The President is issuing an apology in an effort to redress the wrongs of the past. He is apologizing now because it is the opinion of many that the legacy of the Study continues to have an adverse effect on the health of African-Americans. The Study continues to figure prominently in discussions of the difficulties experienced by the African-American population in obtaining access to medical care, being forthright with their physicians, participating in clinical trials, donating organs, and accepting advice from public health officials regarding prevention of diseases such as AIDS.

Q4. What was the Public Health Service's Involvement? Who planned and implemented the Study?

- A4. The U.S. Public Health Service funded the Syphilis Study and was responsible for the design and implementation of the study. Throughout the 40 years many physicians who were members of the U.S. Public Health Service were involved in the study, including designing the study, examining patients, analyzing results from the study, and publishing findings.

Q5. How many people were recruited into this Study?

- A5. The total number of men enrolled in the study is not clear. It is generally accepted that over six hundred (600) African-American men were enrolled in the study, approximately 400 (399) African-American men who had syphilis and 200 (201) who did not.

BACKGROUND: Researchers told the men that they were being treated for "bad blood", a local term used at the time to describe several ailments, including syphilis. In exchange for taking part in the study, the men received free medical exams, free meals and burial insurance, but no treatment for syphilis. Although originally planned for months, the study actually went on for 40 years. When penicillin became the widely accepted treatment for the cure of syphilis in 1946, the question arose concerning the advisability of treating all those in the Study group. A decision was made at that time not to recommend treatment because: (1) no data were available on the efficacy of penicillin treatment in the late stage of syphilis, and (2) whether there were short- or long-term side effects of this drug had not been documented. The decision at the time -- although misguided-- was made that the possible risks to the patients from treatment outweighed their risks from the disease. And the men were not treated because there was a desire to complete the Study because no other data were available that would document the long-term effects of untreated syphilis.

Q6. What has been done to compensate Study participants and their descendants? Who is eligible for the compensation program?

- A6. The Tuskegee Health Benefit Program is a comprehensive health benefit program that pays for all necessary medical services not covered by other insurance programs. In addition to Study participants, the program is also available to wives, widows, and offspring who may have been infected with syphilis as a result of withholding treatment for Study participants. The program is currently administered by the National Center for HIV, STD, and TB Prevention within the Centers for Disease Control and Prevention.

BACKGROUND: On March 3, 1973, the Secretary of the Department of Health, Education, and Welfare (HEW), Dr. Casper Weinberger, directed the Public Health Service to provide study participants with necessary medical care. Men and their families were offered comprehensive health assessments and lifetime medical services.

In addition, on July 23, 1973, Mr. Fred D. Gray filed a class action lawsuit on behalf of the Study participants against the United States government and others. The action, Pollard v. United States, U.S. District Court for the Middle District of Alabama, Northern Division, did not go to trial. Instead, on August 28, 1975, the parties entered into a Stipulation of Settlement that was ultimately approved by the court. A cash payment of \$37,500 to every living man with syphilis who was alive on July 23, 1973; \$15,000 to the heirs of each of the deceased men with syphilis; \$16,000 to every living member from the group of controls who was alive on July 23, 1973; and \$5,000 to the heirs of each of the deceased controls.

Q7. How much money was spent to fund the Study? How much money has been allocated for the Tuskegee Health Benefit Program?

- A7. Records are not available that outline the cost of the Study. During the most recent fiscal year

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(1995), expenditures for the Tuskegee Health Benefit Program totaled \$2,789,715.

Q8. What procedures have been put in place to ensure that studies such as Tuskegee does not happen again?

A8. In 1974 the National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Also in 1974, Federal Regulations were developed creating institutional review boards (IRBs) that review and approve research involving human subjects. A critical part of this assurance is "informed consent," which identifies who is conducting the study, describes the background of the study, and specifically details the risks and benefits to subjects who choose to participate. In October 1995, the President established the National Bioethics Advisory Commission to review all current regulations, policies, and procedures with respect to human research to make sure these high standards are being met. Today, every institution which receives Federal funds to conduct research on human subjects must provide an assurance that it will adhere to Federal regulations governing research on human subjects.

BACKGROUND: The activities of local IRBs are among the many steps in place to ensure that a study such as the U.S. Public Health Service Syphilis Study does not happen again. A critical part of this assurance is "informed consent," which identifies who is conducting the study, describes the background of the study, and specifically details the risks and benefits to subjects who choose to participate.

Q9. Where are the records stored and how can they be requested for review?

A9. The Syphilis Study in Tuskegee records are stored at the National Archives Southeastern Branch located in East Point, Georgia. These records were transferred to the ownership of the National Archives, in accordance with Federal records management regulations, for safekeeping. The medical records, which contain personal medical information, are closed to the public until the year 2030. However, the administrative records are open for the public review.

Q10. How long was the Study continued after it was determined that syphilis could successfully be treated with penicillin? Why was the Study halted?

A10. Penicillin became known as an effective therapy for syphilis in the mid-1940's and became the standard of cure for treatment for syphilis in 1947. The Study continued for approximately 25 years after penicillin became the standard of treatment for the disease. The study ended in 1972 following a review of the study by the Tuskegee Syphilis Study Ad Hoc Advisory Panel who found the study to be unethical and recommended that it be terminated. ✓

Q11. Was this Study considered ethical at the time it was conceived?

A11. This question is complex because the ethics of the study must be judged on two different dimensions. First, the men with syphilis were untreated, and secondly, the men were never informed about the purpose, risks and benefits of the study, nor did they consent to participate in the study.

Regarding the issue of treatment, in retrospect, the Study appears to have met ethical standards of the day at its outset, when penicillin (or other effective syphilis treatment) was unavailable.

Regarding the second issue, the Study was never ethical because the men were never informed about the study and never asked to consent to their participation in the Study.

BACKGROUND: However, most current consent documents include explicit information stating

(or at least imply) that should new information or treatment become available, participants will be notified and offered treatment. Such issues are also considered during the annual ethical review process now required for each new research protocol. It is not unusual for current studies to be halted because effective treatment has become available.

Q12. Who made the decision, once penicillin became the standard of cure for syphilis, not to notify Study participants about the availability of this treatment? Why was this decision made?

A12. In 1943, Dr. John Mahoney reported the first cures of primary and secondary syphilis with penicillin. When this drug became the widely accepted treatment for the cure of syphilis in 1946, the question arose concerning the advisability of treating all those in the Study group. A decision was made by PHS at that time not to recommend treatment because: (1) no data were available on the efficacy of penicillin treatment in the late stage of syphilis, and (2) whether there were short- or long-term side effects of this drug had not been documented. The decision at the time -- although misguided -- was made that the possible risks to the patients from treatment outweighed their risks from the disease. And, the men were not treated because there was a desire to complete the Study because no other data were available that would document the long-term effects of untreated syphilis.

BACKGROUND: Later, in the 1950s, the recommendation was changed, reflecting that penicillin was an effective treatment for the late stage of syphilis. Also, there was a desire to complete the Study because the data that were available on the long-term effects of untreated syphilis were considered potentially flawed in that they came from a study that lacked controls and included limited autopsy results.

Q13. Why do rates of syphilis continue to be the highest among African-Americans in the South?

A13. It is not entirely clear why the rates of syphilis are highest among African-Americans in the South. Multiple factors are probably involved. Certain populations in the United States, especially economically disadvantaged African-Americans in some urban settings and in the rural South, have many interrelated and competing problems including poor access to quality medical care and substance abuse. These problems are often compounded by lack of knowledge about the symptoms, consequences, and prevention of syphilis and, in some communities, by social or religious norms that limit education about syphilis or other sexually transmitted diseases (STDs). Currently, CDC is conducting community-based syphilis intervention programs in five southern states (Arkansas, Louisiana, Mississippi, South Carolina, and Texas). The program is called, "Innovations in Syphilis Prevention in the United States: Reconsidering the Epidemiology and Involving Communities."

BACKGROUND: In some communities, the legacy of distrust left by the Tuskegee Study also is probably a contributing factor. However, these high syphilis rates and the resulting increased risk of HIV infection and high rates of syphilis in newborns can be eliminated. The country, overall, is now at historically low rates of infectious syphilis. Most communities in the United States, including almost 70% of counties, have already eliminated this infection. Approximately 50 percent of infectious cases of syphilis are now concentrated in less than 1.5% of counties.

Q14. What evidence exists that the Tuskegee experience continues to discourage minority populations, especially African-Americans from accessing health care, participating in clinical research, or has had an adverse impact on their trust in government health officials?

A14. It may never be possible to document fully the impact of the syphilis Study on minority

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populations. Health care behaviors, decisions to participate in clinical research, and attitudes toward government health officials are all shaped by many factors that are difficult to evaluate. Furthermore, in some families and communities, the Study in Tuskegee may no longer be named explicitly as a problem, but, instead have been incorporated as the foundation for a range of conspiracy theories or generalized distrust of "the government."

BACKGROUND: The evidence that is available includes a study conducted by a researcher at the University of Alabama Health Studies at Tuscaloosa. African-Americans in general reported less interest in participating in health promotion and research because of their knowledge of the Study. African-American males in particular reported a high degree of resistance because of knowledge of the Study. The university study investigated the effect of the Study on participation in health promotion activities and research studies by African-Americans. The results may have implications for researchers recruiting African-American subjects for research studies and participation in health promotion, disease prevention, and health education programs. Data from the university study were presented at the 1995 American Public Health Association's Annual Meeting in San Diego. In addition, many other scholars have collected evidence to support the same or similar conclusions.

Q15. What was the involvement of the Tuskegee Institute in the Study?

A15. The Institute was aware of the Study and was consulted during the Study period regarding one or more areas.

Q16. We understand that there is a group called the Tuskegee Legacy Committee which made some recommendations regarding actions that should be taken to heal the wounds left by the Study. Did the President accept all of the recommendations of that group? If not, why?

A16. One of the principal recommendations of that Committee was that President Clinton publicly apologize to the living participants, their families and to the Tuskegee community. Also the committee recommended the establishment of a center at Tuskegee University to preserve the national memory of the study and transform its legacy. We are doing both.

BACKGROUND: Last year during a conference at Tuskegee sponsored by the U.S. Department of Health and Human Services on minority participation in research, the Tuskegee Study Legacy Commission was created to help all of us move beyond the PHS Syphilis Study in Tuskegee. The purpose of the Legacy Committee was to transform the legacy of minority distrust of the health and medical establishment into positive efforts to close the health gap between blacks and whites.

Q17. Is it really likely that a study begun more than 60 years ago and stopped nearly 25 years ago continues to have an impact today?

A17. Yes. The Study continues to be discussed by the mass media, academicians, and "the public" as an example of how certain minority groups (in this case, African-American men) can be exploited for seemingly "good" reasons, such as medical research. Obviously, other factors such as segregation, discrimination, and hate crimes against African-Americans, have also contributed to the mistrust some African-Americans have of the medical establishment, but the Study itself continues to figure prominently in discussions of the difficulties experienced by the African-American population in obtaining access to medical care, being forthright with their physicians, participating in clinical trials, donating organs, and accepting advice from public health officials regarding prevention of diseases such as AIDS.

Q18. Is syphilis an important health problem for the United States today?

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A18. Syphilis is a serious, chronic infectious disease. It causes ulcers that allow the AIDS virus to be transmitted much more efficiently between people. The bacteria that cause syphilis can cross the placenta to kill the fetus or cause permanent neurologic damage in the baby. Recent studies suggest that heterosexual HIV transmission in the United States still largely follows the geography of the syphilis epidemic of the late 1980s and early 1990s.

Q19. What can we do about syphilis today?

A19. Today, syphilis is a disease that is inexpensive to diagnose and easy to cure. In 1997, we are approaching the lowest rate of syphilis ever reported in the United States. However, reported infectious syphilis rates are approximately 60 times higher among African-Americans than among white Americans, and syphilis is highly concentrated across the South. Syphilis elimination would eliminate both an important factor contributing to higher rates of HIV infection among African Americans and an unnecessary cause of fetal and infant mortality and disability.

Q20. Are you going to be the next Surgeon General?

A20. THAT IS THE PRESIDENT'S PREROGATIVE. I WOULD NOT PRESUME TO SPEAK FOR HIM.

Q21. How many of the original Study participants are going to Washington for the apology event?

A21. ~~Four (4)~~ 5

Q22. Who is paying for the participants to attend the Washington apology event?

A22. CDC is paying the expenses (travel, lodging, food) for 39 people; including ~~four~~ 5 original Study participants, family members of several Study participants, and escorts.



FAX TRANSMISSION

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Office of the Secretary

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BARRY FOIVPAT Lewis

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TOTAL NUMBER OF PAGES TRANSMITTED:

Seven +

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COMMENTS:

Tuskegee
Q/A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

Note to:

Elizabeth Dye-

Pat Lewis-

Barry Toiv-

From: Victor Zonana

Tuskegee Q's and A's

This draft set of Q's and A's, addressing mainly broad political matters, has cleared through HHS. A second set, originated by CDC and dealing with medical issues and the Tuskegee specifics, is being tweaked will be forthcoming later this afternoon.

Victor

A handwritten signature in black ink, appearing to read "Victor", is written over the printed name "Victor". The signature is stylized with a long, sweeping line extending from the top of the letter "V".

DRAFT

1

DRAFT TUSKEGEE QUESTIONS AND ANSWERS**Political**

Q. Why is an apology coming forward now? What is there to be gained by such a gesture and how do you respond to those who might see it as politically motivated?

A. Even though this study was stopped some 25 years ago, it's never too late to make it clear from the highest levels of government that what happened at Tuskegee was very wrong and tragic and not something we ever condone. It is also important to make it clear that we are pledged to making sure this never happens again in our country. Most importantly, we have a moral obligation to apologize on behalf of the U.S. Government.

In fact, last year during a conference at Tuskegee sponsored by the U.S. Department of Health and Human Services on minority participation in research, the Tuskegee Study Legacy Commission was created to help all of us move beyond the Tuskegee Syphilis Study. The purpose of the Legacy Committee was to transform the legacy of minority distrust of the health and medical establishment into positive efforts to close the health gap between blacks and whites.

One of the principal recommendations of that Committee was that President Clinton publicly apologize to the living participants, their families and to the Tuskegee community.

We view this as more than symbolic, as more than just a verbal apology. This is not just a wrong, but a wrong in which the U.S. government is at fault. On one hand, today we're taking a major step toward publicly atoning for Tuskegee. On the other hand, we're hoping it will help move us further toward restoring lost confidence in government and distrust of medical science and public health institutions -- especially by African Americans and other minorities. That's been the legacy of the study. We are also concerned about regaining the confidence and trust of those individuals whose own health has been affected directly and indirectly by Tuskegee.

To those who would ascribe political motives to this, we would say that the only politics at work are the politics of doing what's right. It's always the right time to do right, and in this case, the time to do right is right now. That's all we're concerned with.

Q. Why do you think prior Administrations refused to issue an apology? Why has it taken until almost the end of the 20th century for the victims to receive some sort of official apology from their government? Can you say an apology was previously ignored for political reasons?

A. We can't speak for any Administration but this one. But this is not the kind of issue that you can look at in any sort of political context and make judgments that way. This was a human tragedy. Pure and simple. Through the years since Tuskegee was halted, various Administrations have addressed an assortment of Tuskegee-related issues

in their own way. Whether or not a formal apology should have been offered much earlier than today is not as important as our being here today to take care of that omission.

Q. When was the prospect of a formal apology raised to this Administration and whose idea was it?

A. The idea of an apology to the Tuskegee participants has been raised by numerous people, both in and out of government. We've heard from a number of community leaders, public health professionals, research and advocacy groups -- some who have felt all along that there needed to be a formal apology. Because of the mistrust that Tuskegee created with public health activities and how it's impacted African Americans' involvement in medical research and receipt of health care, some have felt that only a formal apology could begin the process of [re]building trust.

Q. Should the principals in the Tuskegee study be identified and prosecuted retroactively? Can they be prosecuted?

A. First of all, you're talking about something that was initiated more than 60 years ago and was brought to a halt 25 years ago. The passage of time alone -- as well as the presence of so many unknown factors about what happened then and what mindset individuals had -- would make something like that extremely difficult. Successful prosecution would be unlikely. But more importantly, it would be counterproductive to even discuss that. There is nothing to be gained from pursuing that course. Everything we do with respect to Tuskegee should be about healing and learning from it. We must address Tuskegee in a positive way that takes us forward.

Q. Ideally, how would you like to see the Tuskegee participants respond to this apology?

A. We would hope that each and every one of these men will now know deep down in their hearts and souls that their government -- through their President -- is genuinely sorry and accepts full responsibility for what happened at Tuskegee many years ago. More than anything we would hope they see our sincerity, which we believe is apparent by our doing this before the entire world.

Q. What do you say to African Americans and other minorities who will continue to view the medical research establishment skeptically, despite today's apology? How can this one apology help restore any confidence they might have had?

A. We know that one apology -- no matter how formal or how big -- is not going to be enough for some people to have their faith restored. We don't expect it to be a magic bullet. And we know that many of the policy and institutional changes in the area of research volunteers that have occurred since Tuskegee aren't enough to alleviate some people's fears either. We would just hope that people would continue to watch what we

do as much as what we say, and if they do that, they will see -- not just with today's apology, but over time -- an undying commitment to prevent this from ever happening again. We cannot rewrite past history. But we can write tomorrow's history and ensure that future generations never have to experience this humiliation. I think these gentlemen would agree that the only victory to be gained is to make sure this can never happen to their sons, daughters, granddaughters, grandsons and great-grandchildren.

Q. Besides today's formal apology, what is the biggest contribution the Clinton Administration has made in addressing the Tuskegee situation?

Even though many safeguards are now in place to protect research participants, our Administration has gone a step further to ensure that we promote only the highest ethical standards when it comes to human research. In October 1995, the President established the National Bioethics Advisory Commission to review all current regulations, policies, and procedures with respect to human research to make sure these high standards are being met. This panel is comprised of non-government members and is funded and led by the U.S. Department of Health and Human Services.

There are a few more newer approaches we're taking to further improve our bioethics research:

To promote community participation in research, which is important when you consider the impact the Tuskegee study had on an entire community, Secretary Shalala at HHS is convening within 90 days from today a series of workshops on community participation in research. The workshops will involve a broad spectrum of academic institutions and community groups and are intended to produce recommendations to enhance our community involvement in research studies.

To help incorporate more community perspectives in the planning and carrying out of research, we're asking CDC, NIH and the Health Resources Services Administration (HRSA) to join with a variety of partner organizations to recommend within 90 days from today materials and other strategies for improving ethical training in bioethics courses.

Also, we're going to be offering to promising students bioethics fellowships for postgraduate study beginning in September 1998 -- and we'll make special efforts to recruit minorities. The more we diversity the bioethics field, the more input we'll have in our research efforts and that can only be helpful to keeping research ethically and medically sound.

Q. Has the government done all it can to help the Tuskegee participants?

A. With something as tragic as this, we don't think we can ever reach a point where we can say, "OK, We've done enough. That's it." It's the kind of situation that we must always monitor and be prepared to respond to. We're not talking about just the initial

participants in the study, but each succeeding generation of their families. We must make sure that our government is there for all of them and that's why our Government can never say "We're done." That's why the Tuskegee Health Benefits Program is in place -- to address the needs of family members as time goes on.

Q. Should the Tuskegee victims receive more monetary compensation?

A. The issue of monetary compensation was addressed when the settlement agreement was reached in 1974, shortly after the study was stopped. I think we've long moved past just attaching dollar signs to what happened at Tuskegee to another level of concern, and that is making sure it never happens again and that we continue to meet our obligations with these men and their families as our government has pledged to do.

Q. In light of the age and feeble condition of the participants, why was the decision made to hold the formal apology program at The White House rather than in Alabama near their homes?

A. We don't see it as a matter of who should travel where. We believe it's about making the strongest possible statement that we can about how reprehensible this whole episode was and how sincere we are in our apology. And we think the White House is the best and only location to demonstrate -- not only to the participants and their families, but to the entire world -- that we consider this apology from our government to be of utmost importance. Having this ceremony in The White House establishes quite clearly the priority we give this. As for the travel of participants to Washington, we helped to make arrangements for them to be here and we are paying their expenses. We have worked closely with these gentlemen and their families to ensure their safe and comfortable travel to and from Washington for this event.

Q. Was what happened at Tuskegee racism?

A. We cannot escape the fact that the problems of the Tuskegee experiment are wrapped in elements of racism and discrimination. If we all think back, the racial attitudes and climate in our country at that time certainly played a major role in the many improprieties of the study.

For example, there was some merit to choosing Macon County, Alabama as a focus of a study on syphilis, given the fact that it had the highest syphilis rates in the country at the time. But to mislead and misinform these men and then to withhold treatment from them after cures became available was in and of itself discriminatory.

Q. Looking back at how the Tuskegee study unfolded and comparing it to the checkpoints in place today, at what point along the spectrum do you think an experiment like that would be stopped now?

A. I think our research checks and balances are so strong now that it would be very tough for a Tuskegee Study to even get off the ground. And furthermore, the greater diversity of decisionmakers in government, research and in the Public Health Service today is instrumental in keeping this kind of thing from ever getting started. Certainly we can say that if such a study managed to start up, it would raise so many red flags so quickly that any life it would have would be very short.

Q. This apology, while welcomed by many, may ring hollow for the families of 28 participants who died from untreated syphilis. What can you say to them?

A. We would say to them that we don't pretend to skirt the fact that these deaths were cruel and unnecessary. But that doesn't mean that we cannot strive as hard as we can today to make sure that those gentlemen didn't die in vain. Their deaths are and will always be crystal clear reminders of our obligation to work to protect and ensure the health of all people in this country, not just some. And those who died from untreated syphilis will always be symbols of our obligation to address the special health needs of our minority citizens in a dignified and respectful manner. Certainly each loss will forever represent a huge void in the hearts of their family and friends. But our country feels each of these losses too, as they are 28 stains on the fabric of our nation's democracy and freedom. We will all pay a price for these tragic deaths.

Q. Some have suggested a memorial to the participants on the campus of Tuskegee Institute. What's your feeling on that?

A. The Department of Health and Human Services has been discussing with Tuskegee a proposal to establish on campus a Center for Bioethics in Research and Health Care. We're announcing today that we're providing a planning grant to Tuskegee to pursue this project. Ultimately, such a facility: 1) will house a museum containing documents and other materials from the study; 2) help educate researchers and the public about the significance of the study; and 3) provide opportunities for training in bioethics in partnerships with other academic institutions.

The Center will really do two things: make Tuskegee a focal point for ongoing discussion about how we can address the negative legacy of the study; and be a living and lasting memorial to the people who participated in the Tuskegee study as well as their families -- for generations to come.

Q. Last month, Public Citizen raised some very serious allegations about ongoing HHS-sponsored research, mainly that some of the HIV mother-to-child transmission research underway in developing countries is unethical. How can you assure the public in light of the pain and anger caused by Tuskegee that we're not treading down that same path even lightly?

A. Let me first of all make clear what our work is in this area. We're trying to find effective ways of preventing mother-to-child HIV transmission that can be used in

developing countries, where HIV/AIDS has taken a devastating toll. While AZT has now become a promising standard of care treatment regimen here in the United States, developing nations aren't able to do that because of affordability problems and also because of the differences in the nature of health problems between our country and theirs. Our sole goal is to help these nations find treatment regimens that are effective for their specific populations.

We've taken extra steps to ensure that these trials go beyond ethical and medical standards. We're working very closely with the World Health Organization, UNAIDS and the host governments within those countries to design trials. We're not doing this in a vacuum. Not only that, but these trials have been reviewed by our Centers for Disease Control and Prevention as well as the NIH institutional review boards that were created in the wake of the Tuskegee experiments. We've even involved the review boards within the host countries.

You're talking about a situation today where each and every move is scrutinized before, during and after to make sure that we go beyond the standards and that we're ethical in every way. This is not a situation like Tuskegee where you apparently had a group of people conducting research under their own twisted standards, arbitrarily making decisions and keeping details and information to themselves. It's definitely a new day.

**PRESIDENT CLINTON RECOGNIZES SURVIVORS
OF THE PUBLIC HEALTH SERVICE SYPHILIS STUDY AT TUSKEGEE**
May 16, 1997 --- DRAFT ---

Today, President Clinton recognized the injustice done to the survivors of the Public Health Service syphilis study at Tuskegee. The President formally apologized to survivors, their families and the nation for the unethical, egregious study that left 400 African American men untreated for syphilis. The Public Health Service began the experiment in 1932 and did not end it until 1972 -- many years after penicillin was available to treat the disease.

Today, President Clinton also signed an executive order extending the charter of the National Bioethics Advisory Commission (NBAC) to October, 1999 to ensure a continued, national focus on bioethical issues. Building on the work of the President's Advisory Committee on Human Radiation Experiments, an NBAC subcommittee will make recommendations this fall for further strengthening protections for human research subjects.

President Clinton also announced 4 additional steps the Department of Health and Human Services (HHS) will take to ensure we learn from the PHS syphilis study, rebuild trust, and protect human subjects in the future.

- o **Building a lasting memorial.** The President announced that HHS will award a grant to Tuskegee University to plan a Center for Bioethics in Research and Health Care at the University. The Center would be a lasting memorial and would support efforts to address the legacy of the syphilis experiments and strengthen bioethics training.
- o **Increasing Community Involvement and Restoring Trust.** It has been almost a quarter century since the Study was halted; however, its legacy still impedes efforts to conduct promising research, particularly involving minorities, and to provide the best health care services to all Americans. Today, the President directed the Secretary of HHS to issue a report in 90 days detailing effective strategies to involve communities, especially minority communities, in clinical research, and to increase participation and trust.
- o **Strengthening Researchers' Training in Bioethics.** The President directed the Secretary of HHS to develop training materials to help researchers further community acceptance of clinical research. Working with private organizations, including the Association of American Medical Colleges, the Association of American Universities, the Association of Schools of Public Health, and the National Association for Equal Opportunity in Higher Education, HHS will prepare course materials that build on core ethical principles of respect for persons, beneficence, justice, and informed consent, emphasizing the effective application of these principles in diverse populations. The President directed HHS to complete the materials within six months.
- o **Providing Post-Graduate Fellowships to Train Bioethicists, Especially Minorities.** To increase and broaden our understanding of ethical issues in clinical research, HHS will offer fellowships, beginning in September 1998, to promising students enrolled in bioethics graduate programs. HHS will make special efforts to recruit minorities currently underrepresented in the field.