NLWJC - Kagan

DPC - Box 030 - Folder 018

Health - Tuskegee Study Event

DEPARTMENT OF HEALTH & HUMAN SERVICES
Chief of Staff
Washington, D.C. 20201

MAY 9 1997

NOTE TO ELIZABETH DRYE

Attached please find the following 3 documents pertaining to the White House event for the Survivors of the Tuskegee Study that can be used as background material as you put together fact sheets.

1. Action Steps for Annoucement by President following the Apology

2. Chronology of the Tuskegee Study

3. Draft Directive from Secretary Shalala to the Operating and Staff Division Heads in the Department

We will forward brief write-ups on the Survivors and their families, as well as Qs and As, next week.

Please call me with any questions.

Mary Beth Donahue

CHRONOLOGY
Tuskegee Syphilis Study

1926 - Public Health Service (PHS) survey of incidence of syphilis begun in Macon County, Alabama, one of several sites in the United States.

1930 - Macon County Syphilis Control Demonstration Project begun. PHS received funding from the Rosenwald Fund. Treatment was a combination of neoarsphenamine and mercury. None of the 1400 patients received the full course of treatment.

1932 - Funding for the control demonstration project from Rosenwald Fund ended.

1932 - Tuskegee Syphilis Study begun. 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. Funded by the Public Health Service. 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. Plan was to document course of disease and use that information to obtain funding for treatment. The Alabama Department of Health agreed to study with stipulation that some treatment be provided. Tuskegee Institute and local white physicians in Macon County also agreed to the study.

1933 - The Study continued past the original 6 - 12 months. It was decided to continue the study until the men died. Control group of 200+ men without syphilis added to the study.

1947 - Penicillin widely available for the treatment of syphilis.

1950 - Recommendation for the use of penicillin in late syphilis established.

1957 - Responsibility for Study transferred to the Communicable Disease Center (now Centers for Disease Control and Prevention [CDC]).

1972 - News of the study reported in the New York Times, Los Angeles Times, and Washington Star. Tuskegee Syphilis Study Ad Hoc Panel composed by the Public Health Service to investigate the Study.

1972 - Study terminated by the Department of Health, Education, and Welfare (now the Department of Health and Human Services).

1973 - Public Health Service directed to provide necessary medical care. Men and their families contacted and given information about the study. Men and their families offered comprehensive health assessments and lifetime medical services. Tuskegee Health Benefit Program congressionally established and administered by CDC. Class action lawsuit filed by Mr. Fred Gray on behalf of the living Study participants and heirs of deceased participants.

1974 - National Research Act signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

1974 - Federal regulations developed to review and approve research involving human subjects.

1975 - Class action suit settled. 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 is released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

1996 - Tuskegee Syphilis Study Legacy Committee established and report issued with their recommendations 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."

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Suggestions for What the President Will Include in an Apology for the Tuskegee Syphilis Study

The following steps are designed to strengthen bioethics training, involve more minorities in bioethics, and increase communication and partnerships among researchers and communities.

Fellowship and Training Program:

We need more bioethicists who are experts in teaching the design and conduct of ethical human subjects research. Furthermore, minorities are under-represented in the field of bioethics. We need to diversify the field by increasing the number of individuals, especially minorities, who have postgraduate training in bioethics and who will eventually become recognized leaders in the field.

Therefore, the President will state that the Department of Health and Human Services (HHS) will offer fellowships in September 1998 to promising students to receive postgraduate training in bioethics and that special efforts will be undertaken to recruit minorities into these fellowship programs.

*NIH does not want to include specific programmatic detail here. Programmatic details will be described in the announcement to the applicant community. For the purposes of this document, it is entirely adequate to say that there is a fellowship and a short-term training program available in September 1998.

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The National Institutes of Health (NIH) is currently developing a short-term training program to focus on bioethics. The goal of such training is to increase the understanding of the relevance of ethics in the conduct of research. The short-term mechanism has the potential of involving a broad base of the research community.

Within 60 days after the apology, the NIH will announce the establishment of the bioethics training program and solicit applications from the research community to participate in this program. Furthermore, the Centers for Disease Control and Prevention (CDC), NIH, and the Health Resources and Services Admiistration (HRSA) will convene a meeting of the three agencies to discuss collaborative efforts with academic institutions on bioethics training. This fellowship program will be promoted as a Departmental fellowship in bioethics. The first group of fellows will be selected and supported for the academic year beginning in September 1998.

Community Participation in Research:

Research involving human volunteers is essential for developing the new knowledge needed to combat the health problems facing this Nation and the world. The successful conduct of research is enhanced by partnership with the communities that is built upon a trusting relationship. However, there is compelling evidence that today many communities do not have this trust. As a result,

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many people, especially minorities, are unwilling to participate in research which ultimately could improve the health of these communities.

Therefore, the President will ask the Secretary, HHS, to develop and disseminate strategies to assist researchers in their outreach to communities, especially minority communities, as a step toward increasing their partnership and collaborative participation in research. The Department has already identified a number of successful approaches for involving communities in research. For example, Project STAR in Durham, North Carolina, where CDC is collaborating with the community in research on AIDS and HIV infection, and an NIH study of coronary heart disease risk factors involving 4000 minority participants in Jackson, Mississippi, and the NIH outreach to minorities on cancer treatment through the minority community-based cancer oncology program and the National Black Leadership Initiative on Cancer. The long-term effect of building partnerships with communities is to foster trust between the community and the government which supports much of this research.

Within 90 days of the apology, the Secretary will convene workshops involving academic researchers and community organizations to develop additional innovative strategies for enhancing community participation in research and to discuss case studies of successful and unsuccessful community outreach. The proceedings from these workshops will be made readily accessible

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to researchers and the public, e.g., via the Internet and other means of public communication.

Bioethics Training Courses and Materials:

Successful training in bioethics in research will require appropriate courses and training materials. There is a need for more information about how to incorporate community perspectives into the planning and conduct of research. Therefore, the President will request that CDC, NIH, and HRSA collaborate with other partners to develop additional materials for bioethics courses, highlight existing high quality bioethics programs, and encourage sharing of knowledge, training, and curricula within the research community.

The Belmont Principles--respect for persons, beneficence, and justice form the framework of training courses in bioethics. The training will focus on ethical principles underlying the conduct of research; the complexities of applying the Belmont principles to the processes of informed consent and risk/benefit analysis; ethical responsibilities inherent in selecting a research question and a research design; ethical selection of participants; and methods for increasing community participation in research. The goal of such training is to provide researchers with the tools to apply these ethical principles in the recruitment and retention of participants in research.

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Within 90 days of the apology, CDC, NIH, and HRSA will make recommendations on bioethics training materials for use in research institutions. The goal of such training is to provide researchers with the tools to apply ethical principles to gain greater participation of minority communities. The new training materials will be completed within one year. In addition, these agencies, in collaboration with professional societies, will develop strategies to disseminate information on bioethics training.

DRAFT 5/9/97 (2:00 pm)–MEMORANDUM TO OPDIV AND STAFFDIV HEADS

FROM Sec HHS

Subject: Ethics in Human Subjects Research

As you know, on May 16, 1997, the President formally apologized to the remaining survivors and relatives of nearly 400 impoverished African-American men who were left untreated for syphilis, even when penicillin became widely available, while participating in a Public Health Service research study generally known as the Tuskegee Syphilis Study.

It has been almost a quarter of a century since the Study was halted; however, its negative legacy still impedes our efforts to conduct critically necessary basic and applied research, particularly involving minorities, and to provide the best health care and services to all of our citizens. This event has become a metaphor in racial and ethnic minority communities for suspicion and mistrust of government and health care, in general, and research, specifically.

The President's apology brings symbolic closure to this tragic episode in our history. However, we must now do all that we can to restore trust by ensuring and demonstrating our commitment to the highest ethical principles in the Department's activities, especially in the conduct of research involving human subjects.

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 the Protection from

Research Risks, the promulgation of regulations for the protection of human research subjects (45 CFR 46), 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 persons who volunteer to participate in research studies.

To build on these efforts, we will undertake the following action steps 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 fellowships 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, e.g. educational or research institutions, 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.

- HHS will develop and disseminate strategies to assist researchers in their outreach to communities--especially minority communities--to foster partnership and enhance the

involvement of minorities in research studies.

These steps will be undertaken to strengthen the informed use of bioethical principles in the conduct of research, involve more individuals, especially minorities, in bioethics, and increase communication and partnerships among researchers and communities. I view this as an opportunity to ensure that the research activities conducted or funded by this Department are based on ethical principles. Through these efforts and the commitment of each and every one of us, we can rebuild trust while protecting the well-being and dignity of all persons whom we serve.

Donna E. Shalala

Health-Tuskegee

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 participants of the Public Health Service syphilis study in Tuskegee, Alabama. The President formally apologized to survivors, their families and the nation for the unethical study that left as many as 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.

- **Building a lasting memorial.** The President announced that HHS will award a planning grant to Tuskegee University to pursue establishing 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.

- **Increasing Community Involvement and Restoring Trust**. The legacy of the PHS study 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 convene a workshop and, within 120 days, issue a report detailing effective strategies to more fully involve communities, especially minority communities, in research and health care.

- **Strengthening Researchers' Training in Bioethics**. The President directed the Secretary of HHS to develop bioethics training materials to help researchers effectively apply ethical principles in diverse populations. In partnership with private organizations[1], within one year, HHS will complete and disseminate course materials that build on core ethical principles of respect for persons, beneficence, justice, and informed consent, and that help ensure researchers successfully apply these principles in all communities.

- **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.

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[1]Partners will include the Association of American Medical Colleges, the Association of American Universities, the Association of Schools of Public Health, the National Association for Equal Opportunity in Higher Education, and the Association of Minority Health Professions Schools.

Health - Tuskegee

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Health Tuskegee

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1 Extend NBAC charter to Oct 1999.
recs this fact be further strengthening protections for human research subjects

2 Planning grant for Center at Tusk.
museum/archives / research, study + center etc.

3 P directive to HHS to
- develop bioethics training materials, in conjunction w/ leading medical + research orgs.

4 - report on effective strategies to involve comms, espec. min comms, in research + health care (building on partic progs that have been successful)
disseminate nationwide

5 - provide postgrad fellowships to students in bioethics grad progs. Spec other to recruit minorities - currently underrep'ed.

While is designed to
a. strengthen ethical protections in research, espec involving human subjects
b. overcome legacy of exper. at Tuskegee by breaking down mistrust of med research in minority communities

Health-Tuskegee

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 approxiamtely 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

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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

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?

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 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

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

Health-Tuskegee

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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.

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 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 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?

too
Lefkowitz

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.

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.

Q. What is the cost of the planning grant for the Center for Biocthics 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. 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 form 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.

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.

not have to be careful

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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 six months.

Thirdly, we're committing to post-graduate fellowships in bioethics, beginning in September 1988, 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.

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Health-Tuskegee

CHRONOLOGY

Tuskegee Syphilis Study

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 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 protection to 16 other Federal agencies and to Federally-funded research.

1996: ~~HHS established the~~ The Tuskegee Syphilis Study Legacy Committee ~~which~~ 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."

Health-Tuskegee

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

Health-Tuskegee

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

Today, President Clinton recognized the injustice done to the participants of the Public Health Service syphilis study in Tuskegee, Alabama. The President formally apologized to survivors, their families and the nation for the unethical study that left as many as 400 African American men untreated for syphilis. The Public Health Service (PHS) began the study 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.

- **Building a lasting memorial.** The President announced that HHS will award a planning grant to Tuskegee University to pursue establishing 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 study and strengthen bioethics training.

- **Increasing Community Involvement and Restoring Trust**. The legacy of the PHS study 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, within 180 days, detailing effective strategies to more fully involve communities, especially minority communities, in research and health care.

- **Strengthening Researchers' Training in Bioethics**. The President directed the Secretary of HHS to develop bioethics training materials to help researchers effectively apply ethical principles in diverse populations. Within one year, HHS will complete and disseminate course materials, in partnership with private organizations,[1] that build on core ethical principles of respect for persons, beneficence, justice, and informed consent, and that help ensure researchers successfully apply these principles in all communities.

- **Providing Post-Graduate Fellowships to Train Bioethicists, Especially Minorities**. To increase and broaden our understanding of ethical issues in 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.

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[1]Partners will include the Association of American Medical Colleges, the Association of American Universities, the Association of Schools of Public Health, the National Association for Equal Opportunity in Higher Education, and the National Health Professions Foundation.

Health—Tuskegee event.

DRAFT

Suggestions for What the President Will Include in an Apology for the Tuskegee Syphilis Study

The following steps are designed to strengthen bioethics training, involve more minorities in bioethics, and increase communication and partnerships among researchers and communities.

Center for Bioethics in Research and Health Care:

The Department of Health and Human Services recently received a proposal from [redacted] Tuskegee University, to establish a Center for Bioethics in Research and Health Care, to be located at Tuskegee University. The Department will provide a planning grant to Tuskegee University to pursue establishing the Center which will: 1) house a museum for the preservation of documents and other materials from the Study; 2) assist in educating researchers and the public about the Study and its social, legal, and ethical significance; and 3) provide opportunities for training in bioethics through partnerships with academic institutions. The Center will serve as a lasting memorial and focal point for these and other efforts directed toward addressing the negative legacy of the Study, and would demonstrate the critical importance of acknowledging past wrongs, rebuilding trust, and facilitating scientifically sound and ethical research.

partner w/ others to train bioethicists in how to deal w/ minority communities

bring p. to ctr to study & fund training at other univs thru the ctr.

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Community Participation in Research:

Research involving human volunteers is essential for developing the new knowledge needed to combat the health problems facing this Nation and the world. The successful conduct of research is enhanced by partnership with the communities that is built upon a trusting relationship. However, there is compelling evidence that today many communities do not have this trust. As a result, many people, especially minorities, are unwilling to participate in research which ultimately could improve the health of these communities.

Therefore, the President will ask the Secretary, HHS, to develop and disseminate strategies to assist researchers in their outreach to communities, especially minority communities, as a step toward increasing their partnership and collaborative participation in research. The Department has already identified a number of successful approaches for involving communities in research, for example, through Project LinCS CDC is collaborating with several minority communities in research on AIDS and HIV infection. The NIH has developed the National Black Leadership Initiative on Cancer, has reached out to minorities on cancer treatment through the Minority-Based Community Cancer Oncology Program, and is studying risk factors for coronary heart disease

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in 4000 minority participants in Jackson, Mississippi. The long-term effect of building partnerships with communities is to foster trust between the community and the government which supports much of this research.

Within 90 days of the apology, the Secretary will convene workshops involving a broad spectrum of academic institutions and community organizations. The outcomes of the workshops will be proposed actions or recommendations for the HHS to enhance its community outreach activities. In fact, on May 16, CDC is conducting a workshop, "Community Partners for Prevention Research," to highlight successful partnering in several areas, including Harlem in New York City. Information from these workshops will be disseminated as a report to researchers to assist them in incorporating community perspectives into the planning and conduct of research.

Bioethics Training Courses and Materials:

Successful training in bioethics in research will require appropriate courses and training materials. There is a need for more information about how to incorporate community perspectives into the planning and conduct of research. Therefore, the President will request that CDC, NIH, and the Health Resources and Services Administration (HRSA) collaborate with other partners to develop additional materials for bioethics courses, highlight existing high quality bioethics programs, and

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encourage sharing of knowledge, training, and curricula within the research community.

The American Association of Medical Colleges, the American Association of American Universities, the Association of Schools of Public Health, and National Association for Equal Opportunity in Higher Education have all expressed an interest in partnering with the government to develop these new training materials which will be used by the institutions they represent. The training materials will provide researchers with the necessary ethical tools to recruit and retain participants in research.

The bioethics courses will build upon the existing ethical principles of respect for persons, beneficence, and justice. However, this new training will emphasize the application of these principles to the conduct of research; the complexities of applying the principles to the processes of informed consent in diverse populations and risk/benefit analysis; ethical responsibilities inherent in selecting a research question and a research design; ethical selection of participants; and methods for strengthening and enhancing community participation in research. The goal of such training is to provide researchers with the tools to apply ethical principles to gain greather participation of minority communities.

Within 90 days of the apology, CDC, NIH, and HRSA will make recommendations on bioethics training materials for use in

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research institutions. The new training materials will be completed within one year. In addition, these agencies, in collaboration with professional societies, will develop strategies to disseminate information on bioethics training.

Fellowship and Training Program:

We need more bioethicists who are experts in teaching the design and conduct of ethical human subjects research. Furthermore, minorities are under-represented in the field of bioethics. We need to diversify the field by increasing the number of individuals, especially minorities, who have postgraduate training in bioethics and who will eventually become recognized leaders in the field.

Do we really need more bioethicists? claim?

Therefore, the President will state that the Department of Health and Human Services (HHS) will offer fellowships in September 1998 to promising students to receive postgraduate training in bioethics and that special efforts will be undertaken to recruit minorities into these fellowship programs.

The National Institutes of Health (NIH) is currently developing a short-term training program to focus on bioethics. The goal of such training is to increase the understanding of the relevance of ethics in the conduct of research. The short-term mechanism has the potential of involving a broad base of the research community.

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Within 60 days after the apology, the NIH will announce the establishment of the bioethics training program and solicit applications from the research community to participate in this program. Furthermore, the CDC, NIH, and HRSA will convene a meeting of the three agencies to discuss collaborative efforts with academic institutions and community organizations on bioethics training and to build on existing model bioethics courses. This fellowship program will be promoted as a Departmental fellowship in bioethics. The first group of fellows will be selected and supported for the academic year beginning in September 1998.

Examples of Community Outreach Activities:

National Black Leadership Initiative on Cancer

The National Black Leadership Initiative on Cancer (NBLIC) was implemented in 1989 to stimulate the participation of Black American community leaders in cancer prevention and control activities so that they might work to mobilize their respective communities at the national, state, and grassroots levels. The foremost objectives of the NBLIC are to (1) reduce cancer incidence and mortality rates; (2) improve cancer survival rates; and (3) address the barriers that limit or prevent Black Americans from gaining access to quality cancer control services.

A primary focus of the NBLIC is building and maintaining effective community coalitions. Currently, 60 coalitions have been established within the six NBLIC regional areas. Thus far, the NBLIC has reached approximately 15 to 20 million Black Americans-over have of the U.S. Black population. In 1992, the National Cancer Institute funded the following institutions for three separate NBLIC projects:

- *Cancer Prevention and Control Program,* Minority Health Professions Foundation, Silver Spring, MD, which will coordinate community outreach activities and continue support for the regional structure.

- *Cancer Education and Prevention Resource Office,* Howard University, Washington, D.C., which will focus on explanation of behavioral models for use in prevention efforts.

- *Rural Intervention and Evaluation Program,* University of Maryland Eastern Shore, which will study outreach approaches for rural African Americans.

These projects are working synergistically within the original NBLIC regional structure to enhance and expand the work begun during the initial phase.

Minority-Based Community Clinical Oncology Program

One way to develop and implement effective cancer control and treatment strategies in minority populations is to include minorities in clinical trials research. Minority-Based CCOP (MBCCOP) was initiated in 1990 to provide minority cancer patients with access to state-of-the-art cancer treatment and control technology. Ten MBCCOPs are currently supported

involving over 275 physicians. In the MBCCOPs, more than 50 percent of the new cancer patients are from minority populations. Nearly 1,000 have been enrolled onto cancer prevention, control, and treatment clinical trials. MBCCOPs are located in eight states and Puerto Rico. Through this effort, the National Cancer Institute (NCI) aims to meet an important need of minority cancer patients and individuals at risk for cancer by establishing a system of oncology programs for participation in clinical research trials through the NCI network. In addition, the involvement of minority populations and their physicians in treatment and cancer control research provides opportunities for studies in selected high-risk minority populations that may lead to a better understanding of cancer etiology and control.

Atherosclerosis Risk in Communities (ARIC) (1985)

The ARIC study measures the association of coronary heart disease (CHD) risk factors with atherosclerosis and new CHD events in four diverse communities. Surveillance of health status, including follow up of hospital records and death certificates, is conducted for about 80,000 men and women in each community. About 4,000 subjects from each community receive repeated clinical examinations. One of these cohorts involves Blacks in Jackson, Mississippi; the other three reflect the ethnic and racial composition of the communities from which they are drawn.

CHD hospitalization and mortality rates increase with age and are greater in men than women in every age group. Results from ARIC indicate that in general, white men have higher hospitalization rates for CHD than Black men, but among younger men, Blacks have higher CHD mortality rates than whites. Black women have higher hospitalization and mortality rates than white women. Blacks have more hypertension and diabetes, higher insulin levels, higher levels of some clotting factors, and lower blood potassium levels than whites, but they have less triglyceridemia than whites for a given obesity level. Findings from ARIC also confirm that blood levels of lipoprotein(a), a type of cholesterol that is an independent risk factor for CHD, are twice as high in Blacks as in whites.

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BACKGROUNDER: Project LinCS

Project LinCS: Linking Communities and Scientists grew out of recognition that, although the decision to participate in a clinical trial is an individual one, it happens within a community context. The project goals are, first, to identify the means by which communities can define and communicate their concerns about intervention trials, and second, to develop ways communities, researchers and government agencies can work together to design and implement effective biomedical HIV prevention research, especially vaccine research.

The testing of HIV vaccine candidates for use in the U.S. provides social challenges equal to the biomedical challenges surrounding vaccine development. First, antibody responses resulting from immunization may expose trial participants to social risks such as discrimination in access to insurance, medical care, and employment. Second, individuals targeted for recruitment into large-scale efficacy trials (e.g., gay and bisexual men, injecting drug users, racial/ethnic minorities) will be drawn from communities that have been historically marginalized and disenfranchised. Finally, these communities exhibit a strong distrust of the Federal government and public health research, especially around the issue of HIV/AIDS, thus presenting a third set of challenges for the successful implementation of HIV vaccine trials.

Study communities include the San Francisco gay community, injecting drug users in Philadelphia, and the Durham, North Carolina, African-American community (Project STAR). Community advisory boards at each site provide on-going guidance for the development of study protocols, interview guides, participant recruitment, interpretation of study results, development of recommendations, and presentation of results to the communities.

Project LinCS will provide researchers and communities with information on how individuals define "community" and the importance of diversity of opinion and perspective within communities. Such information is critical to the development of meaningful collaboration between researchers and communities. Recognizing that the issue of trust is also critical to collaboration, Project LinCS has collected in-depth information on factors that lead to distrust. Just as importantly, the community is providing suggestions for building trust during biomedical research.

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CHRONOLOGY
Tuskegee Syphilis Study

1926 - Public Health Service (PHS) survey of incidence of syphilis begun in Macon County, Alabama, one of several sites in the United States.

1930 - Macon County Syphilis Control Demonstration Project begun. PHS received funding from the Rosenwald Fund. Treatment was a combination of neoarsphenamine and mercury. None of the 1400 patients received the full course of treatment.

1932 - Funding for the control demonstration project from Rosenwald Fund ended.

1932 - Tuskegee Syphilis Study begun. 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. Funded by the Public Health Service. 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. Plan was to document course of disease and use that information to obtain funding for treatment. The Alabama Department of Health agreed to study with stipulation that some treatment be provided. Tuskegee Institute and local white physicians in Macon County also agreed to the study.

1933 - The Study continued past the original 6 - 12 months. It was decided to continue the study until the men died. Control group of 200+ men without syphilis added to the study.

1947 - Penicillin widely available for the treatment of syphilis.

1950 - Recommendation for the use of penicillin in late syphilis established.

1957 - Responsibility for Study transferred to the Communicable Disease Center (now Centers for Disease Control and Prevention [CDC]).

1972 - News of the study reported in the New York Times, Los Angeles Times, and Washington Star. Tuskegee Syphilis Study Ad Hoc Panel composed by the Public Health Service to investigate the Study.

1972 - Study terminated by the Department of Health, Education, and Welfare (now the Department of Health and Human Services).

1973 - Public Health Service directed to provide necessary medical care. Men and their families contacted and given information about the study. Men and their families offered comprehensive health assessments and lifetime medical services. Tuskegee Health Benefit Program congressionally established and administered by CDC. Class action lawsuit filed by Mr. Fred Gray on behalf of the living Study participants and heirs of deceased participants.

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1974 - National Research Act signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

1974 - Federal regulations developed to review and approve research involving human subjects.

1975 - Class action suit settled. 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 is released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

1996 - Tuskegee Syphilis Study Legacy Committee established and report issued with their recommendations 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."

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Health-Tuskegee event

Suggestions for What the President Will Include in an Apology for the Tuskegee Syphilis Study

The following steps are designed to strengthen bioethics training, involve more minorities in bioethics, and increase communication and partnerships among researchers and communities.

#1 **Center for Bioethics in Research and Health Care:**
The Department of Health and Human Services recently received a proposal from Dr. Benjamin Payton, President of Tuskegee University, to establish a Center for Bioethics in Research and Health Care, to be located at Tuskegee University. The Department will work with Tuskegee University to establish the Center which will: 1)house a museum for the preservation of documents and other materials from the Study; 2)assist in educating researchers and the public about the Study and its social, legal, and ethical significance; and 3)provide opportunities for training in bioethics through partnerships with medical schools and schools of public health. The President will state that the Center would serve as a lasting memorial and focal point for these and other efforts directed toward addressing the negative legacy of the Tuskegee Syphilis Study, and would demonstrate the critical importance of acknowledging past wrongs, rebuilding trust, and facilitating scientifically sound and ethical research.

#2 **Community Participation in Research:**

Research involving human volunteers is essential for developing the new knowledge needed to combat the health problems facing this Nation and the world. The successful conduct of research is enhanced by partnership with the communities that is built upon a trusting relationship. However, there is compelling evidence that today many communities do not have this trust. As a result, many people, especially minorities, are unwilling to participate in research which ultimately could improve the health of these communities.

Therefore, the President will ask the Secretary, HHS, to develop and disseminate strategies to assist researchers in their outreach to communities, especially minority communities, as a step toward increasing their partnership and collaborative participation in research. The Department has already identified a number of successful approaches for involving communities in research, for example, Project STAR in Durham, North Carolina, where CDC is collaborating with the community in research on AIDS and HIV infection, and an NIH study of coronary heart disease risk factors involving 4000 minority participants in Jackson, Mississippi, and the NIH outreach to minorities on cancer treatment through the minority community-based cancer oncology

program and the National Black Leadership Initiative on Cancer. The long-term effect of building partnerships with communities is to foster trust between the community and the government which supports much of this research.

Within 90 days of the apology, the Secretary will convene workshops involving a broad spectrum of academic institutions and community organizations. The outcomes of the workshops will be proposed actions or recommendations for the HHS to enhance its community outreach activities. In fact, on May 16, CDC is conducting a workshop, "Community Partners for Prevention Research," to highlight successful partnering in several areas, including Harlem in New York City. Information from these workshops will be disseminated to researchers to assist them in incorporating community perspectives into the planning and conduct of research.

#4 **Fellowship and Training Program:**

We need more bioethicists who are experts in teaching the design and conduct of ethical human subjects research. Furthermore, minorities are under-represented in the field of bioethics. We need to diversify the field by increasing the number of individuals, especially minorities, who have postgraduate

training in bioethics and who will eventually become recognized leaders in the field.

Therefore, the President will state that the Department of Health and Human Services (HHS) will offer fellowships in September 1998 to promising students to receive postgraduate training in bioethics and that special efforts will be undertaken to recruit minorities into these fellowship programs.

*NIH does not want to include specific programmatic detail here. Programmatic details will be described in the announcement to the applicant community. For the purposes of this document, it is entirely adequate to say that there is a fellowship and a short-term training program available in September 1998.

The National Institutes of Health (NIH) is currently developing a short-term training program to focus on bioethics. The goal of such training is to increase the understanding of the relevance of ethics in the conduct of research. The short-term mechanism has the potential of involving a broad base of the research community.

Within 60 days after the apology, the NIH will announce the establishment of the bioethics training program and solicit applications from the research community to participate in this

program. Furthermore, the Centers for Disease Control and Prevention (CDC), NIH, and the Health Resources and Services Administration (HRSA) will convene a meeting of the three agencies to discuss collaborative efforts with academic institutions and community organizations on bioethics training and to build on existing model bioethics courses. This fellowship program will be promoted as a Departmental fellowship in bioethics. The first group of fellows will be selected and supported for the academic year beginning in September 1998.

#3 **Bioethics Training Courses and Materials:**

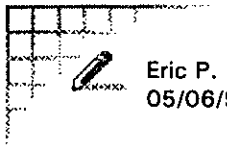
Successful training in bioethics in research will require appropriate courses and training materials. There is a need for more information about how to incorporate community perspectives into the planning and conduct of research. Therefore, the President will request that CDC, NIH, and HRSA collaborate with other partners to develop additional materials for bioethics courses, highlight existing high quality bioethics programs, and encourage sharing of knowledge, training, and curricula within the research community. Research institutions have indicated a strong interest in having these new materials available to them.

These courses will build upon the existing ethical principles of

respect for persons, beneficence, and justice. However, this new training will emphasize the application of these principles to the conduct of research; the complexities of applying the principles to the processes of informed consent in diverse populations and risk/benefit analysis; ethical responsibilities inherent in selecting a research question and a research design; ethical selection of participants; and methods for strengthening and enhancing community participation in research. The goal of such training is to provide researchers with the tools to apply these ethical principles in the recruitment and retention of participants in research.

Within 90 days of the apology, CDC, NIH, and HRSA will make recommendations on bioethics training materials for use in research institutions. The goal of such training is to provide researchers with the tools to apply ethical principles to gain greater participation of minority communities. The new training materials will be completed within one year. In addition, these agencies, in collaboration with professional societies, will develop strategies to disseminate information on bioethics training.

Health - Tuskegee



Eric P. Goosby
05/06/97 08:51:37 AM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Re: medical research

Eleana:

Background:

A Public Watch group made up of some leading epidemiologists and ethicits, wrote a letter under Sid Wolfe's signature (ethicits) accusing the CDC and NIH of unethical conduct in 15 studies based in thrid world countries (mainly cental and western Africa). These studies are focused on looking at perinatal transmission of HIV. As you recall in 1994 in the AIDS Clinical Trials Group (ACTG) study 076, it was shown that when AZT was orally admnistered to HIV positive pregnant women during gestation (2nd trimester to term) and intravenously at delivery, followed by oral syrup with the newborn for 6 weeks, the transmission of HIV went from 27% to 8%.

Issue:
The studies in question do not offer the known, proven effective intervention of AZT to the study participants, but offer unproven cheaper variations on the AZT interventions (oral preparations; less time on drug ; other antiretrovirals are tried).
This was justified by the CDC by making one basic assumption: the standard of care these countries does not include AZT of any kind, therefore, if they are randomized to a study arm that inlcudes some form of AZT it is better then their current situation. In addition, each of the study arms has the potential and likelyhood of being effective.

The Public Watch group has accused HHS of a "Tuskegee-like" process and demands the studies be stopped.
CDC points out all of these studies which began in 1993 (before 076 results) went through institutional review boards (IRB's) both in the US and in each hosting country, and contend they are ethical in design.

HHS is in the middle of a review that has a broad spectrum of opinon. This will come to completion by Friday of this week, or earlynext week. The potential for it coming up at the ceremony is small but present in my estimate. The concerned groups have no obvious connections with the Tuskegee survivors.

I would be happy to talk with you about this further.

Eric

Health - Tuskegee event

May 5, 1997

MEMORANDUM FOR ELENA KAGAN

FROM: Elizabeth Drye

SUBJECT: 3:00 Monday Meeting on Tuskegee Policy Options

Attached are HHS's proposed policy announcements for the Tuskegee apology. As we discussed briefly, the proposals target the right problems but commit us mainly to processes and don't involve enough concrete action. Further, HHS's ideas don't adequately reflect the Advisory Committee on Human Radiation Experiments (ACHRE) recommendations for strengthening ethics in research.

HHS proposes three actions:

1) **Establish postgraduate fellowships in bioethics and recruit minorities into the fellowship program.** This is a modest step; we should list it third and edit out our process commitments, but otherwise leave it as is.

2) **Foster increased community participation in research.** The Department commits to hold a conference, identify strategies that work, and disseminate successful programs. The work meets an important need. We should ask HHS to strengthen this action -- and increase support for it -- by reaching out this week to leaders in the field, seeking their commitment to participate, and describing some ideas that hold promise.

3) **Strengthen bioethics training.** The President would direct CDC, NIH and HRSA to develop materials for bioethics programs, highlight what works, and spread successful programs. The President would also "encourage research institutions to strengthen their efforts in bioethics training..." Here, HHS's goal is on target, but HHS doesn't commit to sufficient actions to meet the goal.

   We should push HHS to lend depth and specificity to this effort. It responds directly to ACHRE's recommendation that we "ensure the centrality of ethics" in research involving human subjects. ACHRE found that researchers have an insufficient appreciation of ethical concerns and limited knowledge of ethics rules. ACHRE recommended we consider a number of specific actions to raise the profile of ethics in research (see Recommendation 9, attached), including: establishing competency in research ethics as a condition of grants; requiring certain NIH grantees to offer programs in the responsible conduct of research; and encouraging the nation's leaders in biomedical research to spearhead efforts to elevate research ethics. HHS's proposal -- to develop a process to develop training materials -- won't be meaningful unless we work with leaders in the field to change the culture in the research community and unless we hold researchers accountable.

I suggest we focus in today's meeting on the training and community outreach proposals. I'd like to ask HHS to respond specifically to the actions ACHRE identified. Mary Beth told me Friday that HHS will not produce anything new -- beyond what's in this document -- for May 16th, but I think by adding definition to HHS's proposed actions, and by reaching out to key people in the research and bioethics community before the event, HHS can produce something more meaningful over the next week.

Attachments

Suggestions for What the President Will Include in an Apology for the Tuskegee Syphilis Study

The following steps are designed to strengthen bioethics training, involve more minorities in bioethics and increase communication and partnerships among researchers and communities.

Fellowship and Training program:

The President will propose that training fellowships be offered to promising students to receive postgraduate training in bioethics. Presently, there is a dearth of minorities who have postgraduate training in bioethics and are recognized as leaders in the field of bioethics. Therefore, special efforts will be undertaken to recruit minorities into the fellowship program. The goal of the fellowship program is to create a cadre of individuals, including minorities, who will have expertise in the ethical conduct of research involving human subjects and become future leaders in the field of bioethics.

The HHS agencies will develop short-term training that could be a component of a research fellowship program to focus on bioethics. The goal of such training is to increase the understanding of the relevance of ethics in the conduct of research. The short-term mechanism has the potential of involving a broad base of the research community.

Within 60 days after the apology, CDC, NIH, and HRSA will convene a meeting of the three agencies to discuss plans to implement a fellowship program and the short-term training program. This fellowship program will be promoted as a Departmental fellowship in bioethics. The first group of fellows will be selected and supported for the academic year beginning in September 1998.

Community Participation in Research:

The President will ask the Secretary, HHS, to develop strategies to assist researchers in their outreach to communities, especially minorities, as a step toward increasing their participation in research. The Department will (1) identify successful approaches for involving communities in research and the principles, knowledge, and skills that should lead to success; and (2) develop mechanisms for disseminating this information to researchers involved in community-based research. The long-term effect of building partnerships with communities would foster trust between the community and the researcher and, ultimately, between the community and the government which

supports the research.

Within 90 days of the apology, the Secretary will convene workshops involving academic researchers and community organizations to develop strategies for enhancing community participation in research and to discuss case studies of successful and unsuccessful community outreach. The proceedings from these workshops will be made readily accessible to researchers and the public, e.g., via the Internet and other means of public communication.

Bioethics Training:

The President will request that CDC, NIH, and HRSA collaborate with other partners to develop materials for bioethics courses, highlight existing high quality programs, and encourage sharing of knowledge, training and curricula within the research community. Informal inquiries indicate that there is likely to be broad support for this activity. The President will encourage research institutions to strengthen their efforts in bioethics training that emphasizes the relevance of ethics to research. The Belmont Principles -respect for persons, beneficence, and justice should form the framework of training courses in bioethics. The training should focus on ethical principles underlying the conduct of research; the complexities of applying the Belmont principles to the processes of informed consent and risk/benefit analysis; ethical responsibilities inherent in selecting a research question and a research design; ethical selection of participants; and methods for increasing community participation in research. The goal of such training is to provide researchers with the tools to apply these ethical principles in the recruitment and retention of participants in research.

Within 90 days of the apology, CDC, NIH, and HRSA will develop a process for developing bioethics training materials for use in research institutions. The task force will be completed within one year. In addition, these agencies, in collaboration with professional societies, will develop strategies to disseminate information on bioethics training.

government in 1991. Although the Common Rule now affords all human subjects of research funded or conducted by the federal government the same basic regulatory protections, the work of the Advisory Committee suggests that there are serious deficiencies in some parts of the current system. These deficiencies are of a magnitude warranting immediate attention.

The Committee was not able to address the extent to which these deficiencies are a function of inadequacies in the Common Rule, inadequacies in the implementation and oversight of the Common Rule, or inadequacies in the awareness of and commitment to the ethics of human subject research on the part of physician-investigators and other scientists. We urge that in formulating responses to the recommendations that follow, the Human Radiation Interagency Working Group consider each of these factors and subject them to careful review.

Recommendation 9

The Advisory Committee recommends to the Human Radiation Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

A national understanding of the ethical principles underlying research and agreement about their importance is essential to the research enterprise and the advancement of the health of the nation. The historical record makes clear that the rights and interests of research subjects cannot be protected if researchers fail to appreciate sufficiently the moral aspects of human subject research and the value of institutional oversight.

It is not clear to the Advisory Committee that scientists whose research involves human subjects are any more familiar with the *Belmont Report*[6] today than their colleagues were with the Nuremberg Code forty years ago. The historical record and the results of our contemporary projects indicate that the distinction between the ethics of research and the ethics of clinical medicine was, and is, unclear. It is possible that many of the problems of the past and some of the issues identified in the present stem from this failure to distinguish between the two.

The necessary changes are unlikely to occur solely through the strengthening of federal rules and regulations or the development of harsher penalties. The experience of the Advisory Committee illustrates that rules and regulations are no guarantee of ethical conduct. The Advisory Committee has also learned, in responses to our query of institutional review board (IRB) chairs, that many of them perceive researchers and administrators as having an insufficient appreciation for the ethical dimensions of research involving human subjects and the importance of the work of IRBs. The federal government must

work in concert with the biomedical research community to exert leadership that alters the way in which research with human subjects is conceived and conducted so that no one in the scientific community should be able to say "I didn't know" or "nobody told me" about the substance or importance of research ethics.

The Advisory Committee recommends that the Human Radiation Interagency Working Group institute, in conjunction with the biomedical community, a commitment to the centrality of ethics in the conduct of research involving human subjects. We urge that careful consideration be given to the development of effective strategies for achieving this change in the culture of human subjects research, including, specifically, how best to balance policies that mandate the teaching of research ethics with policies that encourage and support private sector initiatives. It may be useful to commission a study or convene an advisory panel charged with developing and perhaps implementing recommendations on how best to approach this challenge for the research community.[7]

The Committee suggests that such an examination include consideration of the following:

- Extending to all federal grant recipient institutions and all students and trainees involved or likely to be involved in human subject research the current federal requirement that institutions receiving NIH National Research Service Award training grants offer programs in the responsible conduct of research.
- The role of accrediting bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- Establishing competency in research ethics as a condition of receipt of federal research grants, both for institutions and individual investigators.
- Incorporating of research ethics, and the *differences* between the ethics of research involving human subjects and the ethics of clinical medical care, into curricula for medical students, house staff, and fellows.
- Encouraging the nation's leaders in biomedical research to spearhead efforts to elevate the importance of research ethics in science.

Recommendation 10

The Advisory Committee recommends to the Human Radiation Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

1. Mechanisms for ensuring that IRBs appropriately allocate their time so they can adequately review studies that pose more than minimal risk

Health-Tuskegee

Elizabeth Drye
04/07/97 05:38:45 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Tuskegee status

Cab Affairs is putting together meeting on this at noon ~~tomorrow,~~ Tuesday. HHS will do their show and tell then, I assume. Ann Lewis is looped in. Public Liason is in charge of the overall event, and Ben Johnson knows and agrees we need to engage ~~on policy announcements~~. I can cover tomorrow's meeting unless you want to ~~go~~. 122 OEOB at 10:00 am.

?
(

Health –
Tuskegee

Elizabeth Drye
04/07/97 09:29:00 AM

Record Type: Record

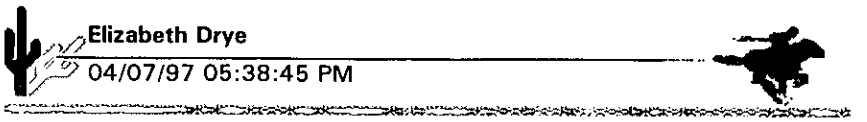
To: Elena Kagan

cc:
Subject: Re: Tuskegee

Message Creation Date was at 7-APR-1997 09:29:00

HHS had agreed to put more policy options together. I haven't been managing this -- have only weighed in vis a vis radiation event. This is OPL's event as I understand it, so I've assumed we're in a consulting, not a driving, role. I'll check w/HHS and OPL on status and take a look at HHS's policy options and get back to you.

Health - Tuskegee



Elizabeth Drye
04/07/97 05:38:45 PM

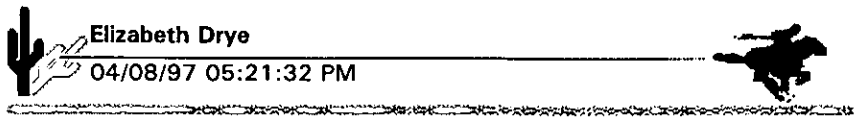
Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Tuskegee status

Cab Affairs is putting together meeting on this at noon tomorrow, Tuesday. HHS will do their show and tell then, I assume. Ann Lewis is looped in. Public Liason is in charge of the overall event, and Ben Johnson knows and agrees we need to engage on policy announcements. I can cover tomorrow's meeting unless you want to go. 122 OEOB at 10:00 am.

Health-Tuskegee



Record Type: Record

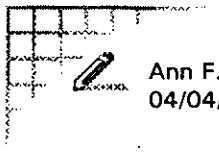
To: Elena Kagan/OPD/EOP

cc:
Subject: Tuskegee Update

The lawyer for survivors held a press briefing today, which has precipitated a lot of questions re President's position on an apology. Scheduling is looking at a mid-May date for the apology event. At our meeting, we agreed to advise Rahm/McCurry that the WH should say in this news cycle that the President decided in March to issue an apology and will meet w/survivors as soon as that meeting can be scheduled. Kitty in particular felt that POTUS would not be happy to see news reports that he's still considering what to do when he signed a memo a month ago saying we should go ahead w/the apology. I agreed. Not sure yet how McCurry's office has followed up.

HHS has put three policy proposals on the table to announce at an event -- one with some promise, but I've asked them to flesh it out more. I'll keep you posted.

Health - Tuskegee Event



Ann F. Lewis
04/04/97 01:27:30 PM

Record Type: Record

To: Robert B. Johnson/WHO/EOP, Maria Echaveste/WHO/EOP, Elena Kagan/OPD/EOP

cc: Stephanie S. Streett/WHO/EOP
Subject: Tuskegee

Looking at the materials on Tuskegee, it seems that we need to make some decisions to move the process forward:

1. Exactly what is the substance of this event: that is, in addiiton to an "apology" from the President, what are the policy corrections or announcements that would be made and who would be resposnible for implementing them ? I think I remember something going to the Bioethics Commission --what else ? Has DPC signed off on a package ?

2. What are the options for the President's time ? One hour is going to be very hard to find. How important is it that the President be there personally, or can we find a way to release his letter + policy ? Can we offer a range of options that make it easier on scheduling ?

A related question: where are we on announcing the next Surgeon General ? Could this event be handled --not as part of his announcement -- but as a subject he takes up immediately upon assuming office ?

3. I raise these questions not because I think the event is less important but becaues I do think it imprtant to taek some action and am concerned that the constraints on the President's time mean we have to be creatiev in thinking how to achieve it.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

JAN 24 1997

TO: Kitty Higgins
Assistant to the President

FROM: Bill Corr
Chief of Staff

SUBJECT: Request for Presidential Message for the Tuskegee Study of Untreated Syphilis in African-American Males

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BACKGROUND

The Tuskegee Study began in 1932 in Macon County, Alabama, a rural area with a high rate of untreated syphilis. The Study was established after surveys revealed a high prevalence of syphilis, particularly in rural areas of the South. Prevalence among African-Americans was particularly high and many of those persons remained untreated. This long-term study of untreated syphilis was initiated by the Public Health Service (PHS), currently a part of the Department of Health and Human Services (HHS), in conjunction with the Tuskegee Institute, with the approval of State and local officials. PHS provided the direction and funding for the study. The Study enrolled approximately 400 African-American men with syphilis and 200 control men.

Penicillin became known as an effective therapy for syphilis in the mid-1940's. While medical opinion was not universal, penicillin was viewed as a useful therapy to long-term sufferers of syphilis. Tuskegee Study participants remained untreated even after penicillin became the standard of care for treatment of syphilis in the late 1940's. It was not until the study gained notoriety in a New York Times front-page headline in 1972 and the details of the study were exposed in the accompanying article that the surviving men received treatment. The Study ended in 1972 following a recommendation by the Tuskegee Syphilis Study Ad Hoc Advisory Panel and the adoption of the recommendation by the Secretary of Health, Education and Welfare (HEW, which is now HHS).

In 1973, HEW Secretary Weinberger directed the PHS to provide Study participants with comprehensive medical care for the rest of their lives. The program, the Tuskegee Health Benefit Program, is administered within the Centers for Disease Control and Prevention (CDC). The program pays for all medical services not covered by other insurance programs for study participants, wives, widows and certain descendants. Regulations for review and approval of experiments on human

tag on to HBO
pre-screening announcement?
HHS - w/ target audience

other ideas: (Presidential) extend ethics comm'n? (2 yrs?)
Outreach - get min. involved in biomed research.
Bioethics training

proclamation?
pres. stmt w/ Malala event?

subjects were instituted in the 1970s to ensure studies such as Tuskegee do not happen again.

The establishment of the Tuskegee Syphilis Study Legacy Committee was supported by CDC and was an outgrowth of a meeting sponsored by CDC and HHS in 1996. Its purpose was to preserve the memory of the Study, and to transform the legacy into renewed efforts to bridge the gap between the health conditions of black and white Americans. In their May 1996 report, the Committee urges the President to apologize on behalf of the government and issued a number of recommendations to assure the nation that research like the Tuskegee Syphilis Study would not be duplicated. The recommendations include: the development of an Ethics Center at Tuskegee University to conduct public education on the Study and its legacy; a Minority Health Initiative; training programs to better educate health care workers on conducting research in communities of color; and a clearinghouse to help investigators conduct ethically responsible research.

National Apology Feb. 22nd.

ISSUES OF CONCERN

Federal, State and local government officials allowed hundreds of socially and economically vulnerable African-American men in Macon County to continue to suffer from syphilis when there were available treatments but did not advise them of it.

There has been massive publicity and a Congressional public hearing on the Study. Numerous articles have been written arguing that the Study has predisposed many African-Americans to distrust medical and public health authorities. The Study has been discussed by the mass media, academicians, and the public as an example of how certain minority groups can be exploited for medical research.

The Study continues to be described as a significant factor in the low participation rate of African-Americans involvement in research trials, organ donation, accessing simple medical care, and accepting advice from public health officials regarding prevention of diseases such as AIDS. The Study and its legacy continue to be used by bioethicists and others as the quintessential example of the abuse of human research subjects in the United States.

REQUEST

The Government has neither apologized for not informing participants of a possible treatment nor apologized to survivors and their families. An official apology issued by the President during National Black History Month in February would help bring closure to this chapter and restore the Federal government's credibility in minority communities, especially the African-American community. It would also likely increase public trust in government and could enhance minority participation in government-sponsored research and health programs.

just an apology - no other recommendations should come already. trivialize it by playing w/ other things

11 survivors
JS: Event - as w/ radiation on proclamation

talk abt safeguards put in place to prevent abuse happening again
HBO - premiere NYT Feb 16. damning of pub health service

Bruce —
FYI
Elena

MEMORANDUM

TO: Don, Ann, Rahm

FROM: Eli

RE: Possible Presidential Involvement/Action on "Tuskegee Study"

DATE: Thursday, January 30, 1997

A quick report on a meeting this afternoon with Kitty Higgins, Elena Kagan, HHS Chief of Staff Bill Corr, and Assistant Secretary for Health Philip Lee.

Background

As you know, between 1932 and 1972 the Public Health Service (now part of HHS), together with the Tuskegee Institute, conducted a long-term study of untreated syphilis known as the "Tuskegee Study." For the purposes of the study, federal, state and local officials allowed about 400 African-American men to go untreated for syphilis, even though treatment was available. (11 of these men are still alive.) The study was stopped only after it became public in 1972. The government then agreed to provide medical care to the victims and their families for the rest of their lives.

The Government's Study

In 1996, CDC and HHS sponsored a Tuskegee Syphilis Study Committee (technically the President's committee, although I do not believe he has ever publicly commented on the issue). In May, 1996, the Committee issued a report which recommended that the President apologize on behalf of the government. The report also suggested initiatives in minority health, training for health care workers serving in minority communities, and a clearinghouse to help investigators conduct ethically responsible research. The study has gotten a great deal of media attention, much of it focussed on the fact that the incident has fueled African-American distrust of government and public health authorities.

HHS's Request for a Presidential Event or Message

HHS is now requesting some kind of Presidential involvement -- ranging from a proclamation or press statement, to an actual Presidential event. They initially asked that this happen before February 10th (which is clearly impossible), because that is when an HBO movie about the Tuskegee Study will premiere; at the very

least, they would like to do this by the end of February, which is African-American History Month.

HHS was arguing that the President should simply issue an apology, since that was the Committee's main recommendation. Apparently, HHS was not prepared to act on any of the Committee's other recommendations. Kitty, Elena and I agreed that it is almost certainly not worth Presidential involvement unless we can show real action. HHS promised to report back ASAP with possible steps that could be taken.

The key questions are:

Is this issue worth the President's involvement, even if we can show action?

If so, is it better to quietly issue a proclamation or statement or to design an actual event?

If not, should HHS do something on their own?

Please advise; once we receive more options from HHS, we plan to hold another meeting on this issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

JAN 24 1997

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subjects were instituted in the 1970s to ensure studies such as Tuskegee do not happen again.

The establishment of the Tuskegee Syphilis Study Legacy Committee was supported by CDC and was an outgrowth of a meeting sponsored by CDC and HHS in 1996. Its purpose was to preserve the memory of the Study, and to transform the legacy into renewed efforts to bridge the gap between the health conditions of black and white Americans. In their May 1996 report, the Committee urges the President to apologize on behalf of the government and issued a number of recommendations to assure the nation that research like the Tuskegee Syphilis Study would not be duplicated. The recommendations include: the development of an Ethics Center at Tuskegee University to conduct public education on the Study and its legacy; a Minority Health Initiative; training programs to better educate health care workers on conducting research in communities of color; and a clearinghouse to help investigators conduct ethically responsible research.

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Document No. _____

Elena Kagan Rm 018

WHITE HOUSE STAFFING MEMORANDUM

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

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			Vervaeer	✓	
BERGER					
LINDSEY					

REMARKS:

Please advise. Note policy issue and scheduling request

RESPONSE:

Call Gibbons and schedule mtg

- 1st half of March
- issue short -
  option of 0.0 mtg w/ ??
  surviving survivors ??
  Staff Secretary Ext. 6-2702 medical ctr.
- thy steps

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

'97 FEB 14 AM 11:43

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

Elena -
Can you look into this?
BR

To: Staff Secretary

From: Ann Lewis

Date: 2/19/97

Re: Tuskegee Study suggestions

I would be more comfortable discussing a Presidential statement on this issue if I knew what it might say -- do we have a copy of the statement to atomic veterans ? Assuming the right language can be developed, I agree with a message plus some positive action.

I leave it to the policy people to decide what the action should be, but am skeptical about extending a commission and asking them to " explore ways to involve minorities ..." . If they haven't done it so far -- and I fully agree with the description of attitudes in much of the minority community -- are they the people to reach out now ?

Timing: Given the limited time available to us, I assume this would be a written message rather than trying to put together an event. The statement could be released this weekend if we get approved text (although we also have the 2/24 event going out to minority press) or on February 28, when the President is not expected to have a public schedule, for the next weekly press cycle.

CC: Kitty Higgins
Bruce Reed