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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: Tuskegee Health Benefit Program [partial] (1 page)	04/09/1997	b(6)
002. note	re: SSN and DOB [partial] (1 page)	n.d.	b(6)

COLLECTION:

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Elizabeth Drye
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FOLDER TITLE:

Tuskegee Apology

2014-0046-S

rc1384

RESTRICTION CODES

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

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

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*Butt... John Fletcher VVA
M.D. → Vanna Norman
Gamble & Wisconsin
Tuskegee Syphilis Study
Legacy Committee*

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

*\$ 2.8 million
Tuskegee Health Benefit Program
1974
Law suit settled in 1975*

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 approximately 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.

- one conf. today -
Atlanta*
- o **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.

*Project Links -
business research
communities, AIDS vaccine
IN some
cities - S.F.
Philadelphia, Durham
N.C. - community
boards working w/
medical research
community
protocols*

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.

¹Partners 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 Minority Health Professions Foundation.

*To Do - Translated
- Mich's
brief re.
1/22/97*



racharo @ facstaff.wisc.edu

05/12/97 10:16:07 AM

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cc:

Subject: Families of Tuskegee Men Feel Emotional Aftereffects

<http://www.nytimes.com/yr/mo/day/news/national/tuskegee-aftermath.html>

[banner] [SmithBarney]

[toolbar]

May 12, 1997

Families of Tuskegee Men Feel Emotional Aftereffects

[Image]

Related Articles [Image]

- * Clinton to Express Regret for Experiment on Blacks (April 9)
- * Tuskegee's Long Arm Still Touches a Nerve (April 13)

By CAROL KAESUK YOON

[T] USKEGEE, Ala. -- It has been 25 years since the nation learned that more than 400 black men infected with syphilis went untreated for decades in a federally financed experiment in this rural southern town laced with sandy roads and pine tree forests.

These men, who are expected to receive a presidential apology on Friday in Washington, have been the subject of countless academic studies, news articles and books, as well as a play and a made-for-television movie.

Yet their families -- the wives and children they may have unwittingly exposed to the disease -- have remained largely unseen and unheard, bearing in silence a legacy of anger and shame as well as possible damage to their health.

In an acknowledgment of the harm that may have been done, the federal government, since 1975, has been quietly running a small program that provides medical benefits to family members infected with syphilis.

"You get treated like lepers," said Albert Julkes Jr., 55, whose father was a participant in the project the government called the Tuskegee Study of Untreated Syphilis in the Negro Male. "People think it's the scourge of the earth to have it in your family."

Julkes, a retired customer service supervisor for a gas and electric utility, recounted his father's ordeal as he sat in the kitchen of his home just across the border in Columbus, Ga. "It was one of the worst atrocities ever reaped on people by the government," he said. "You don't treat dogs that way."

In 1974 the federal government began making well-publicized reparations to the men who participated in the experiment, in which they were led to believe they were receiving free medical care, when its actual purpose was to study the long-term effects of untreated syphilis on black men. But since 1975, the government has also been making amends to some of the families, providing lifetime medical benefits to the 22 wives, 17 children and 2 grandchildren with syphilis they may have contracted as a direct result of the lack of treatment accorded the men in the study.

"What they deserve is the best medical care we can provide," said Dr. Bill Jenkins, who in 1969, while a statistician with the National Center for Health Statistics in Washington, was among several people who unsuccessfully tried to end the experiment. Jenkins, who said he was appalled by the experiment and haunted by his unsuccessful effort to halt it, is now an epidemiologist and devotes himself to running the government's program to provide medical benefits to the men and eligible family members. "I try to give them the care that I would want to give to my mother," Jenkins said.

In addition to providing care to the family members, the program, at the Federal Centers for Disease Control and Prevention, known as the Participants Health Benefits Program, serves the eight surviving men as well. The program, formerly known as the Tuskegee Health Benefits Program, cost the federal government \$2.1 million last year, Jenkins said.

But while the program treats physical ills, the family members' emotional wounds have gone largely

unrecognized, some relatives say. The pain of Tuskegee is still very real even among grandchildren of the study participants, some of whom had not even been born when the study was officially ended after its existence was widely reported in the press in 1972.

"I'm angry about it, very very angry about it," said Carmen Head, whose grandfather, Freddie Lee Tyson, participated in the study. Miss Head, who is 22 and lives in Fairfax, Va., said family members had told her very little about her grandfather's participation. The subject is taboo, particularly with her grandmother, she said, adding, "It's a painful issue in my family."

Miss Head's mother, Lillie Head of Waterbury, Conn., is one of many family members no longer living in the South. Mrs. Head said she had never learned whether her father was one of the more than 400 participants with syphilis or if he was one of some 200 men without syphilis who were in a control group.

"It was something to be ashamed of, so it wasn't talked about," said Mrs. Head, 52, a high school physical education and health education teacher. "We were really very disturbed after we found out my father was a part of it."

Martha Jernigan, 49, a home health aide in Tuskegee, said she has two cousins who are descendants of men in the experiment and knows many other relatives of participants who are living in the area. "They thought we were animals, stupid, that we didn't know better," she said. "Times haven't changed when it comes to blacks."

Herman Shaw, 94, a survivor of the study still living on his family farm in Tuskegee, sat on his front porch on Thursday sifting through photographs of his late wife, Fannie Mae. Shaw was able to offer one of the few memories of a wife's reaction to learning the truth about the study. "She was somewhat shocked, may I say," he said, "because it was a disease. It wasn't anything that we'd heard about and nobody seemed to know about."

Dr. Vanessa Northington Gamble, a medical historian and physician who directs the Center for the Study of Race and Ethnicity in Medicine at the University of Wisconsin medical school, said such reactions are common among family members.

"There is a lot of pain that people still express and feel about what the government has done to them and their family members, their community," said Gamble, who has studied the experiment for years and is chairwoman

of the Tuskegee Syphilis Study Legacy Committee, a group of experts formed last year to press for an official apology.

"I talked to a woman in Wisconsin who knew that I'd been studying this," she recalled. "All of a sudden she started crying, saying her uncle was also in the study."

The lingering shame and a distrust of the government may be one reason that the number of family members in the health benefits program has never been high. Originally, 106 men who were in the experiment began receiving benefits in 1974, Jenkins said, but the number of wives appears never to have been very large. He said that in 1975, at what was probably the peak of participation by wives, only 50 had been tested. Of those, 27 were found to be positive for syphilis and eligible for the program.

In the study, which began in 1932, more than 600 men were recruited by government health workers, who led them to believe they were receiving free medical treatment. Throughout the 40-year study, the men were never told of the experiment and those with syphilis were never told they were infected. They never received any treatment for the disease, even when the use of penicillin became routine in the 1940s. When participants died, researchers offered their families free burials in exchange for the rights to do autopsies so they could gather their final data for the study, which researchers say was scientifically flawed from the start.

Jenkins said that when the true nature of the study became known, some family members became so distrustful of the government that they refused to be tested for syphilis. No effort was ever made to track down sexual partners of the men, other than their wives.

When the study was under way, some wives tried to enroll, believing the project was a reliable source of medical care. When they were turned away, many were upset, according to Dr. Jim Jones, a historian at the University of Houston and the author of "Bad Blood" (Free Press, 1993), which historians regard as the definitive account of the experiment.

Jenkins said another reason the number of wives in the program might be low is that the men chosen for the study were supposedly in a latent, non-infectious stage of syphilis, unable to transmit the disease to their wives. That point, however, is still being debated.

"It's unclear what stage of the disease the men were

at," Gamble said. "So that brings the issues around to the women and children."

Nowadays, the Tuskegee experiment is so notorious that scientists resist doing anything that could be construed as continuing the so-called research. "No one has ever studied the health consequences to the families, not to my knowledge," Jenkins said. "We will not compile the data in any way to make an assessment of them as a group. It would seem too much like another study." If such an effort is organized, he added, "I don't want to have anything to do with it."

But Jenkins said even if researchers knew how many family members were infected with syphilis, there is no way to be certain whether the syphilis was contracted from the men in the study. The test for syphilis is a blood test for antibodies to the disease. A positive result indicates only that a person had syphilis at some point in their lives, with no indication of when or from where the infection arose.

Fred David Gray, a lawyer who has represented the participants in the study since 1972, winning them an out-of-court settlement totaling \$10 million, said that in 1974, as part of that agreement, the government was ordered to provide lifetime health care for participants as well as some family members.

"I hope to see and I think what the men would like to see is some final closure," Gray said in an interview on Thursday in his Tuskegee office. He said in the last 23 years, he has given out settlement payments to some 6,000 heirs and participants. Despite the fact that the apology is expected this Friday, and Gray as well as four of the elderly survivors are planning to attend, Gray said he is continuing to press for the president to change the site of his apology to Tuskegee.

It was soon after Gray and some of the survivors of the experiment held a news conference here in April to request the government apology that the White House said one would be forthcoming. Gamble said the study legacy committee she heads had been pressing for months for an official apology.

But Jenkins said any form of apology should be seen not as an end but as a beginning.

"There's a tendency to believe that African-Americans are reluctant to participate in research because of this one study and I think that belittles the concerns of African-Americans," Jenkins said. "They are concerned about public health research because they're alienated

from American society in any number of ways and this study is the bellwether. It's much bigger than just this study and we're going to have to do a lot more work than just apologize for this."

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Elena Kagan

04/06/97 01:22:00 PM

Record Type: Record

To: Elizabeth Drye

cc:

Subject: Tuskegee

Message Creation Date was at 6-APR-1997 13:22:00

----- Forwarded by Elena Kagan/OPD/EOP on 04/06/97 01:26 PM

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 addition to an "apology" from the President, what are the policy corrections or announcements that would be made and who would be responsible 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 because I do think it important to take some action and am concerned that the constraints on the President's time mean we have to be creative in thinking how to achieve it.

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.

How many?

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

Part IV

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:

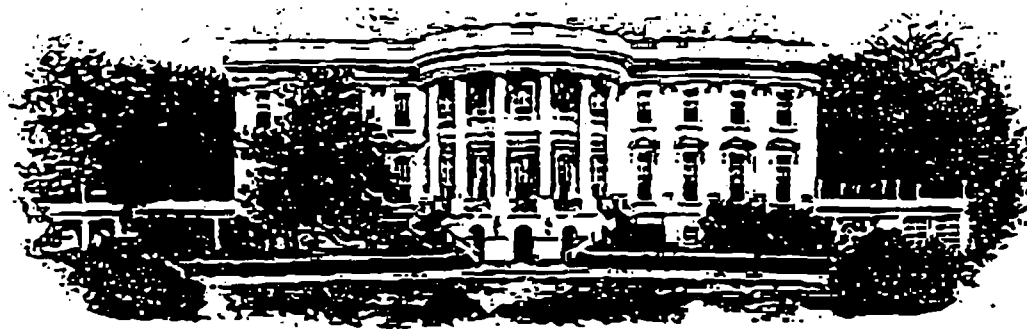
- Extending to all federal grant recipient institutions and all students and trainees involved or likely to be involved in human subject research the current federal requirement that institutions receiving NIH National Research Service Award training grants offer programs in the responsible conduct of 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.

mandatorily
training
exam

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



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Anne McGuire

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MESSAGE:

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May 2, 1997

Honorable William J. Clinton
President of the United States
The White House
1900 Pennsylvania Avenue
Washington, DC 20500

Pollard, et al. v. USA, et al., CV-4126-N
United States District Court for the Middle District of Alabama

Dear President Clinton:

As counsel for the living participants and the more than 6,000 heirs of deceased participants in the Tuskegee Syphilis Study, I write this correspondence to thank you for agreeing to apologize on behalf of the United States government to the participants and their heirs. This correspondence is further intended to encourage and solicit your reconsideration of the location for the apology. I appreciate very much participating in the conference call on Tuesday, April 29, 1997 with Mr. Ben Johnson of your office and others with regard to this most urgent matter.

In 1932, 623 African American men from Macon County, Alabama unwittingly participated in a health program financed by the United States government, the undisclosed medical purpose of which was to observe the effects of untreated syphilis on African American males. The Study ended 40 years later amid public outcry as a result of national media exposure. Today, only eight participants remain, the youngest of whom is 87 years old. Seven of the eight live in Alabama. Two of the eight live in assisted care facilities in Alabama. The men are aged and in declining health. As a group, they are not in the best of health to travel to Washington, D.C.

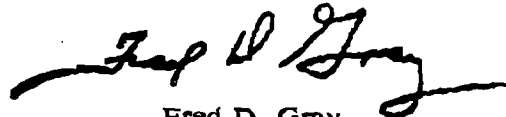
As a means to bring closure to the Tuskegee Syphilis Study issue, an apology from Tuskegee is fitting and proper. It would mean a lot to the men individually and as a group, since Tuskegee is where the tragic events unfolded. Such a meeting at such a place would undoubtedly lift the remaining participants' collective spirits, knowing that the same government

Honorable William J. Clinton
May 2, 1997
Page 2

that disregarded their rights as human beings 65 years ago when they were young and had their lives in front of them is now caring and conscientious enough to come to the same place, admit wrongdoing, and reassure minorities throughout the country of the integrity of our government and the integrity of clinical trials. Moreover, expected positive dialogue flowing from an apology from Tuskegee would only be surpassed by the increased minority confidence and participation in various clinical trials throughout the country, predictably resulting in treatment and cures for many dreaded diseases that plague our country.

Your favorable consideration of this request is greatly appreciated.

Very truly yours,



Fred D. Gray

FDG:j

cc: Mr. Ben Johnson

352 2642

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May 21, 1997

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**DISTRICT OF COLUMBIA
***ARIZONAHonorable William Clinton
President of the United States
The White House
1900 Pennsylvania Avenue
Washington, DC 20500

RE: The Tuskegee Study Apology

Dear President Clinton:

As counsel for the participants who attended the White House ceremony, the Tuskegee ceremony, Mr. George Key who was unable to attend, and the heirs of deceased participants in the Study, we want to express our genuine appreciation for your invitation to the White House, and the apology made in the East Room on Friday, May 16, 1997. Your consoling words and forthright candor with reference to the Study and the sincere way you spoke and apologized will remain forever in our hearts. You are truly a President who cares for all of the citizens of the nation. On their behalf, we humbly and respectfully accept the apology, and forgive the government for its misconduct.

As Mr. Herman Shaw stated in his remarks, "... we want to construct in Tuskegee a PERMANENT MEMORIAL, a place where our children and grandchildren will be able to see the contributions that we, and others, made to this country. I am glad that I have helped form the Tuskegee Human and Civil Rights Multicultural Center which will be for the purpose of creating such a lasting memorial." Mr. Shaw was referring to the Tuskegee Human and Civil Rights Multicultural Center of which he is a member of the initial board of directors. The Center is a non-profit, tax exempt organization incorporated in Macon County, Alabama, to establish, develop, promote and maintain the center as an educational, cultural and research center, a depository of historic material, exhibition of information with reference to the various ethnic or racial groups who have made contributions to the City of Tuskegee, Alabama, Macon County, Alabama, the State of Alabama, and the United States of America, particularly the contributions of original Native Americans, Caucasians or European Americans, and Americans of African descent.

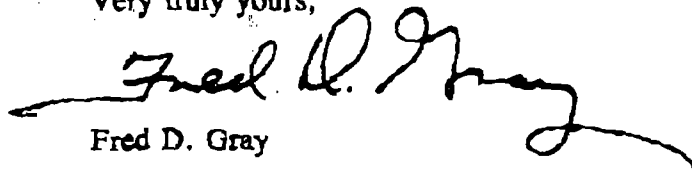
Honorable William Clinton
May 21, 1997
Page 2

When fully developed, the Center will not only recognize the contributions made by individuals, including the participants in the Study, but it will assist in bringing the races (red, white and black) closer together. In addition, it will also result in substantial economic benefit to the City of Tuskegee and Macon County. The participants and family members who attended the ceremony at the White House ratified and confirmed the creation of, and the objects and purposes of the Center. They requested that I solicit your assistance in fully developing the Center.

The first step towards developing such a memorial is appropriate planning. We are requesting your assistance and the assistance of the appropriate governmental agencies to help with technical assistance including planning grants for the Center.

We will always remember what you said and did on Friday, May 16, 1997

Very truly yours,

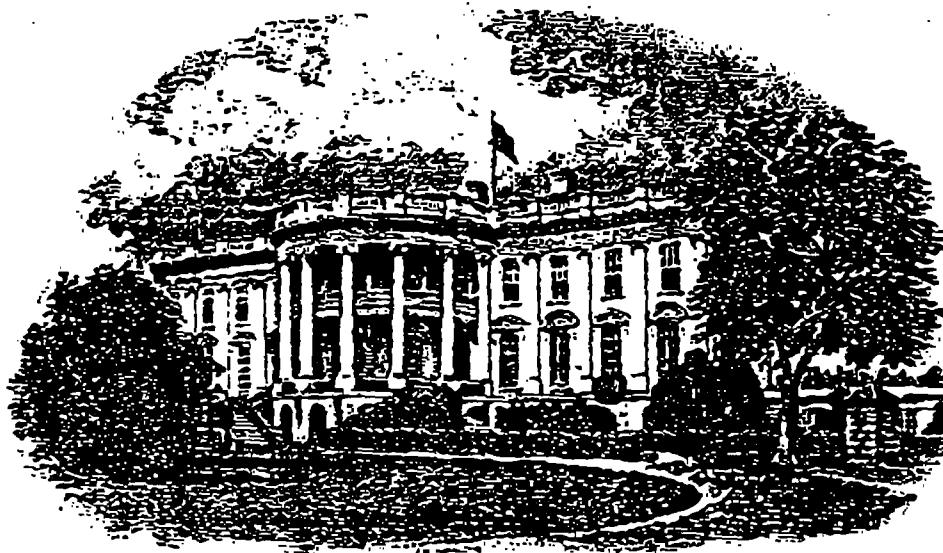


Fred D. Gray

FDG:j

cc: Mr. Ben Johnson
All participants
Family Members in Attendance at White House Ceremony

The White House
Office of Presidential Letters and Messages



facsimile from Sarah Freeman
phone: 202-456-5514
fax: 202-456-5426

To: Ann McBride

No. of pages (including cover): 5 Date: 6/5/97

Phone: x 62572 Fax: x 66704
x 62525

Comments: _____



F A S C I M I L E

DATE _____

TO: A. McQuire / Eliz Dye / Ben Johnson / A. Blocker
(NAME AND ORGANIZATION)RECIPIENT'S FAX NUMBER: () 604/7431/6622/2609FROM: Mary Beth Donahue
Deputy Chief of Staff
HHS
Telephone: 202\690-2431
Fax Number: 202\401-5783

NUMBER OF PAGES (INCLUDING COVER SHEET):

11

COMMENTS:

Attached are revised action
steps per DPL meeting 5/13.

Please do not forward or
recreate from this document
before talking to McQuire/Dye.

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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.

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. back to study
and training at other
univ. than the chr.

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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

VICKY

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 greater
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.

Dave
really
need
more
minorities
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.

7
b

Dick

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. (052008)

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 half 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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Senior Advisor
Office of Extramural Research
Office of the Director
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Bethesda, Maryland 20892
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BACKGROUND: 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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Office of the Director
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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."

2 ~~4~~

- ~~NIH~~ NIH — mammal unit. —

- apply to OPRR — for assurance on
implementation of Belmont ~~Principles~~ ^{Principles}. —

NIH — SAME — ~~still~~ ^{still} ruled talked to
us — ruled it out?

Ken Shein — Institute of Medicine
— biomedical research. —

Need Tuxon — Head of Drew — medical Center in Watts. —
was in ACTRE
former DC Commissioner. —

Ruth Faden 301-929-1468

Jim Childress - chair of NBAC subcommittee

Phil Caplan - race relations. issues larger
ones - take priority

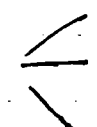
- Scientific research community
have to look ~~hard~~ at how to
do it right

- Create opps on conduct of scientists.
- NBAC - could convene. -

- Jack Gibbons / Shalala / Hartman

Leadership - institutionally / professionally
- deans of research. -

?

Major assns. 

Dept. of Medicine - changed pattern for its
fellows - curriculum on research ethics

- curriculum. -

NMA

- present on work on ethics as well -
- AMA - (peripheral - biomedical research)
- AAMC -

- AAAS -

- 50 top research universities. -
dominated by biomedical research

- subspecialties

Assn. of MB
Universities

- opinion leadership institutions. -

- Training materials are the least of our problems. -

A. Commitment. -

① What are the competency areas are - What do they need to know.

② How to get them there. -

③ Commitment to do that. -

- private sector UNIV. partnerships / financial conflicts of interests.

- Could spend \$ to develop curriculum - NOT adverse to it. - but need commitment

- influential opinion folks who agree we need to take this on.

- Varmus could do more. - creation of clinical biometrics program (NIBH) Zeke Emanuel. -

People getting various political considerations dominated. -

"ethics as a bridge"

- Jan Ceckler - Zeke Emanuel

Real —
— Not appear to be rhetoric —

— What hasn't been

— (Ruth ~~Rest~~ Kirshstein) —

— Ruth Kirschstein deputy director, NIH —

Jack ~~Johnson~~ ^{Jackson} — Senior Office Atlanta
Diane Snyder

Training

NIH/CDC — will join forces to fund
these — primarily in minority
institutions, particularly Tuskegee

HRSA/CDC/NIH

Not only at HBCU's
also at Hispanic

— Association of Amer Univ. (AAU)

— ADAMC —

— Neal Lane — Science Foundation

Currently — NIH has a req for every
clinical research grant — women/
minorities must be part of the
study population — Need to do
more of that. —

CDC - 16th workshop - presenters of
selected programs. ~

- Drew University in Watts in Los Angeles. -
family planning / maternal health
 - Advisory Com ASSIST is designing -
research studies. -
-

- Ethical content of training grants -

Clinical core curricula. -
NIH ~~studies~~

- Researchers have some training in ethics. - but not
how you work effectively in communities.
- Computer-assisted training w/

Every grant application -

- APHA - curricula are available -
 - bedside bioethics
 - research in the laboratory

Develop course materials - that gives
then a way to look at

at research —

Melham - minority hypertension program -

Sheers hearing

Dr. Varmus

Dr. Raus

Mary Pendergast

Satchcer

Peter Lorm

Lori Flynn - NBAC member

Nat Assn for mentally ill

Arthur Kaplan - bioethicists.

Maternal/infant AZT prenatal/labor/formula

WHO - said great but too expensive
for

- substitute treatment / loss AZT /

Is it ethical to do a placebo-controlled trial
in these circumstances. —

Standard of care is no AZT. (no cure)

* Ben - call Mengher -

An Old Experiment's Legacy: Distrust of New AIDS Drugs

AI

By LYNDIA RICHARDSON

Walter Williams, a 49-year-old Vietnam veteran in Harlem, tested positive for the AIDS virus eight years ago, but he has rejected his doctor's urging that he try the new drugs that have shown such promise in reversing the progress of the deadly disease.

After a short, nauseating stint taking AZT when it was the only drug approved to fight AIDS, he now tries to stave off ailments with a potpourri of natural remedies like dandelion, ginkgo and herbal pills derived from cat's claw, a rain forest plant.

And although he works at the Harlem United Community AIDS Center, passing out condoms and fliers promoting its counseling and support services, he often cannot contain his suspicions about mainstream medicine. He has heckled doctors at public forums when they talk of recruiting Harlem residents for AIDS research, accusing them of looking for human guinea pigs. What they call treatment, he calls poison.

These outbursts by Mr. Williams, who is black, are a rhetorical extreme, but they reflect a phenomenon that doctors, medical researchers and patient advocates say they have encountered repeatedly among blacks across the nation: a deeply held mistrust of the medical establishment, particularly concerning AIDS and its treatment.

While health-care experts scoff at talk of medical genocide, they recognize that the suspicions of black Americans are rooted in a historical fact: the Tuskegee syphilis study of 1932 to 1972, in which hundreds of black men who had the disease were monitored by Federal researchers but not treated, even after penicillin became available in the 1940's.

Medical experts say that they are becoming increasingly alarmed at the level of distrust, now that treatments have been developed that are effective for many people with H.I.V., the AIDS virus. Protease inhibitors — the first class of drugs shown to reduce the level of the virus in some patients' blood to undetectable levels — have been on the market for 16 months. Experts fear that cynical people will die when life-prolonging treatment is within their grasp.

"The fact that those populations that are most disproportionately having H.I.V. and AIDS are suspicious and therefore not taking medi-

Government laboratory in a plot to eliminate blacks, and that patients who take protease inhibitors are little more than guinea pigs for the Government. That many whites — and blacks — take protease inhibitors does little to erase the doubts.

"People have been dishonest before," Mr. Williams said, "and it gives me reason to question what they are doing and what they are saying."

Lingering Shadow Of Tuskegee

For Mr. Williams and for many other blacks who have H.I.V., it is in part the shadow of the Tuskegee experiment, not money or access to medical care, that keeps them from demanding new, life-prolonging drugs, taking part in clinical trials and seeking preventive treatment, said Dr. Stephen B. Thomas, the director of the Institute of Minority Health Research at Emory University's Rollins School of Public Health.

There are no statistics showing how many people are avoiding medical treatment because of distrust, but the institute is trying to quantify attitudes of blacks and whites. It hired Roper Starch Worldwide, a polling company, for a national telephone survey in February on attitudes about medical research and the Tuskegee experiment. The survey polled 1,000 people at random — 500 in black households and 500 in general population households, of which 84 percent were white.

Of the group of black respondents, 36 percent said they were very likely to be used as guinea pigs without their consent and 38 percent said somewhat likely, Dr. Thomas said. In the general group of respondents, 16 percent said they were very likely and 34 percent said somewhat likely to be used as guinea pigs. The margin of sampling error was plus or minus 4 percentage points.

"It doesn't matter what breakthroughs we have," Dr. Thomas said. "If the community doesn't accept it, it might as well not exist."

"We absolutely know how to stop the spread of AIDS, but that information has not been translated to African-American communities in ways that are credible to African-Americans to act on."

Of the 500 in the all-black group, 18 percent said they believed AIDS was a man-made virus; 9 percent in the general population agreed. When asked more specifically whether H.I.V. and AIDS were part of a plot to kill blacks, 9 percent of the respondents in the all-black group said it was definitely true, compared with 1 percent of the general group.

The National Association of People with AIDS, the Congressional Black Caucus and dozens of other groups concerned about longstanding medical suspicion among minorities have urged the Federal Government to publicly apologize for the Tuskegee experiment, hoping that would help counter such attitudes. On April 8, the White House announced that President Clinton would soon issue a formal apology.

In February, the same month the Black Caucus and other groups wrote to President Clinton, the Centers for Disease Control and Prevention released data showing that in 1996, for the first time, blacks accounted for a higher proportion of newly diagnosed AIDS cases than whites nationwide — 41 percent compared with 38 percent. Hispanic patients accounted for 19 percent.

In New York City, the death rate of black men from AIDS is twice that of whites and 30 percent greater than that of Hispanic men, according to the City Health Department. Among women, the black death rate is more than six times greater than for whites, and more than 46 percent greater than for Hispanic women.

The distrust seemed palpable in Harlem the other day, as Dr. Diana Williamson, an AIDS doctor and lecturer, talked about H.I.V. treatment options at a forum in the basement cafeteria of North General Hospital.

A janitor determinedly waved his hand high in the air from the back of the room. He said that a relative had recently died of AIDS and had asked before dying: "What really caused this? Where did it come from?"

Murmurs of "yeah" rose from the packed room filled with H.I.V.-infected men. Heads nodded as she posed familiar questions: Could this be a conspiracy or genocide?

"I don't know if it is genocide or a plot," Dr. Williamson replied, "but a hell of a lot of people are working hard and trying to stop it." She urged the group to move beyond their suspicion and get help.

I Just Can't Jump On the First Thing

Those entreaties failed to sway one listener, who tested positive but refuses any AIDS medication. She said that if the Tuskegee study had taught her anything, "it makes me aware that I just can't jump on the first thing they are willing to come out with."

"No one has taken that medication for over five years," she said. "Everyone is in clinical trial. I don't want to grow any new organs that God didn't give me."

The Tuskegee study is also a source of justification for Marvin Hamilton, 43, who ignored his doctor's advice last summer to start on protease inhibitors. He has kept an unopened bottle of big white capsules, Crixivan, in a plastic bag tucked inside a stereo cabinet.

"I just don't trust it," said Mr. Hamilton, who tested positive in 1992. "There's too many ifs about the medicine. There are people taking drugs like Crixivan and they are still on a study to me. They don't know what the long-term results are going to be. They're like a guinea pig."

Mr. Hamilton lives with his girlfriend, Carrie Booker, an administrative sales assistant for Family Circle magazine, in a small one-bedroom apartment with a ceiling fan in Harlem. Ms. Booker, 35, also has the AIDS virus and agrees with her boyfriend's reasoning.

"I'm not taking anything," she said. "If it's not broke, don't fix it. Everything is going O.K. with me."

In Ms. Booker's medical file, doctors have made three notations within the last year that she refuses to take protease inhibitors. But Ms. Booker said she had no interest in being treated like a laboratory rat. She said the recent HBO movie about the Tuskegee experiment, "Miss Evers' Boys," deepened her distrust of the medical establishment.

"They really don't know themselves," Ms. Booker said, "so in order to find out, they have to have

something or someone to test this stuff on and they use it on the people who are desperately seeking hope."

"Who's better to be a guinea pig than us?" she added. "Most of the time when they do studies, there are laboratory animals. But they've only done this test for six months and now already they are putting them in humans, us — blacks, Latinos — saying this helps if you use a combination of things. They just tell us the good things, but what is the other part of it? It tears down your liver. If you stop taking it, you can't take anything else to help you because your body becomes immune to the drugs. I just don't trust them."

Doctors say such attitudes are simplistic and ignore the benefits the drugs have already shown for many patients. But to combat the distrust, the New York State Health Department now funnels \$25 million annually to minority community organizations, including Harlem United Community AIDS Center.

Jeanne Bergman, senior policy analyst at Housing Works, a service and advocacy group for people with H.I.V. and AIDS in New York City, said that the challenge in minority neighborhoods was not just to make drugs available, but to build trust.

"I have been struck by our clients' extraordinary cynicism about the possibility that these drugs could work, and the absolute conviction that like Tuskegee, the AIDS drugs are part of a giant conspiracy," she said.

In the bitter cold on a recent morning, Mr. Williams and a colleague, Robert Lewis, approached strangers on the bustling streets near Harlem United. Some rushed by when AIDS was mentioned. Others quickly took the condoms that were offered.

Mr. Williams took AZT when it was the only drug around to fight the AIDS virus. He said he grew dizzy and short of breath. He had night sweats and no appetite, he said.

"They just gave me medicine and told me to take it," he said bitterly. "I trusted them and I got sick."

His doctor recommended he consider protease inhibitors but he was not interested. He said, though, that he does not foist his views on others. "I don't tell nobody not to take them," he said. "It's their choice."

Mr. Lewis, a tall, somber man, was told he had the AIDS virus while in prison on a robbery conviction in 1987. He said his reaction to AZT was so bad that he required four blood transfusions. The experience turned him away from drugs.

But after his weight fell to 129 pounds from 200, and tests showed that the amount of H.I.V. in his blood was dangerously high, he started on protease inhibitors a few months ago. "I wanted to live," he said. Now he takes 16 pills daily.

"I'm still suspicious and, in the long run, I don't know what it will do to me," said Mr. Lewis, whose weight has risen to 190 pounds, with the virus now undetectable in his blood. "I'm not relaxed on it but I can see how it has had a changing effect."

Continued On Page A20, Column 1

Continued From Page A1

cation now is a life-and-death issue," said Dr. Norma J. Goodwin, president of Healthwatch, an information service in New York aimed at improving the health of minorities.

While such suspicions are far from universal among black Americans — or confined to them — they are tenaciously held, experts in the health industry say. They include the belief that the AIDS virus was hatched in a

The New York Times

MONDAY, APRIL 21, 1997

A Tangled Web of Factors Led to Tobacco Talks

A1

By BARRY MEIER

On Dec. 23, as President Clinton made a Christmas visit to the Marine Corps base at Camp Lejeune, N.C., that state's Governor, Jim Hunt, had a peace message for the President: the time might be ripe for the White House to help bring together cigarette makers and their adversaries in settlement talks.

Mr. Clinton expressed interest in discussing the issue, said one Administration official familiar with events. His Yuletide trip to the tobacco state would prove a pivotal moment in the complex dance that led to the groundbreaking talks this month between tobacco companies, regulators and anti-smoking forces.

The important players in those events included Steven F. Goldstone, the chief executive of the RJR Nabisco Corporation, whose subsidiaries include R. J. Reynolds Tobacco; Bruce Lindsey, the deputy White House counsel, and J. Phil Carlton, a longtime political ally of Governor Hunt's who pleaded guilty three years ago to violating Federal wiretapping laws in connection with a political scandal. Soon plaintiffs' lawyers, state attorneys general and public health advocates were drawn into the drama, which also involved notable figures like George Mitchell, the former Senate majority leader.

The global settlement talks, which resumed yesterday in Chicago, have been heralded as a turning point in the nation's debate over the costs and health hazards of smoking. The negotiations are all the more extraordinary because now it is the cigarette industry, which vowed to battle its opponents endlessly, that is bargaining to buy peace and regulation on its own terms.

Those involved in the talks said

Continued on Page A13, Column 1

Continued From Page A1

that a convergence of factors is now bearing down on tobacco producers. New Food and Drug Administration regulations on advertising and marketing seek to curb cigarette sales to teen-agers. Several major trials against tobacco producers have started or are slated to start shortly, and potentially explosive industry documents may soon be disclosed.

"They are looking at major trial dates in Florida, Mississippi and Texas, and they don't want these documents waved around," said Steve Berman, a plaintiffs' lawyer from Seattle who represents four state attorneys general in the current talks.

Just as important, Mr. Berman and others add, tobacco companies are losing ground in the court of public opinion, and some new cigarette company executives like Mr. Goldstone, who was a senior partner in the New York City law firm of Davis Polk & Wardwell before joining RJR Nabisco in 1995, have roots outside the tobacco industry.

But those aligned on the other side of the bargaining table from cigarette makers also have their interests and vulnerabilities. Plaintiffs' lawyers, who have invested millions of dollars in smoking lawsuits, face uphill battles in winning them. Some state attorneys general have weak cigarette lawsuits and others have tied their political ambitions to reaching smoking accords. And both the White House, which is monitoring the talks, and public health advocates want to see a reduction in the number of teen-age smokers, a move that probably requires industry cooperation.

"The issue isn't about blood, it's about saving lives," said Matthew Myers, the executive vice president of the Coalition for Tobacco-Free Kids, an advocacy group in Washington and a participant in the settlement talks. "We can't let industry off the hook, but we have to keep their eye on the goal."

The tangled story of the settlement talks is, in its early chapters, one of false starts. Last summer, officials of the Philip Morris Companies approached the Clinton Administration with a counterproposal to the new F.D.A. regulations, one that was rejected as too weak. And soon after, a legislative settlement proposal drafted by John Sears, a political strategist who was a campaign manager for Ronald Reagan; Richard Scruggs, a plaintiffs' lawyer, and six state attorneys general collapsed under criticism that it was too favorable to the industry.

In the fall, Gov. Paul E. Patton of Kentucky, a Democrat, sought to pique White House interest in settlement talks as he toured with Mr. Clinton during the Presidential campaign, one Administration official said.

Sean Walsh, the press spokesman for Governor Hunt, said that he was unaware of any specific mention of tobacco during the President's visit to Camp Lejeune. But it only was after the election and Mr. Clinton's trip to North Carolina late last year that events accelerated. Governor Hunt and Mr. Goldstone, the RJR Nabisco executive, soon began discussing the selection of their emissary to the White House, said individuals familiar with those talks.

Mr. Goldstone had for months publicly expressed interest in a legislative resolution to the problems facing cigarette companies, and he and Governor Hunt selected Mr. Carlton, a longtime ally of the Governor's who had also long represented RJR Nabisco, to handle the sensitive task.

"The Governor said to Mr. Goldstone that he thought that Mr. Carlton would be a knowledgeable person" to get involved, Mr. Walsh said. Mr. Carlton did not return telephone calls seeking comment, and Jason Wright, a spokesman for RJR Nabisco, said the company was declining to comment on any aspects of the settlement talks.

Mr. Carlton, a former North Carolina State Supreme Court Justice, is described by those who have met him as a charming, courteous lawyer who has played a vital role in getting the negotiations moving. But the lawyer is also not above playing hardball. In 1994, a Federal judge placed him on six months' probation and ordered him to pay a \$5,000 fine for his role in a scandal in which telephone scanners were used to gather intelligence on Mr. Hunt's opponent in the 1992 gubernatorial campaign, according to newspaper accounts.

It was on a Saturday in early February that Mr. Carlton arrived at the White House for a lengthy meeting with Mr. Lindsey, the deputy White House counsel. One Administration official familiar with events said that initial get-together ended with an agreement between the two men to stay in contact.

Some state attorneys general, plaintiffs' lawyers and anti-smoking forces, apparently unaware that the industry was moving to seize the initiative, had also started their own round of meetings at the end of last year, said lawyers involved in them.

The goal: to develop a unified bargaining strategy against cigarette producers.

"We were trying to figure out how to move as a group," said John Coale, a plaintiffs' lawyer from Washington.

The atmosphere was ripening for engagement. And as February progressed, the cigarette industry — which hired high-profile lawyers like Mr. Mitchell — and Clinton Administration officials were discussing ways of drawing negotiators together. Initially, Mr. Carlton suggested that a large meeting be held under

White House sponsorship, a proposal rejected by Administration officials, said one individual familiar with it. Soon, however, Mr. Lindsey, Mr. Mitchell and Mr. Carlton began to sound out selected lawyers and public health advocates about their interests in a meeting with industry, said several people who were called.

"The first phone call I got was from George Mitchell, who told me that he had been retained by the tobacco industry and asked if I would be open to listening," said Mr. Myers, the anti-smoking advocate. Mr. Coale said he had received a call

from Mr. Lindsey, the deputy White House counsel. Mr. Scruggs, a plaintiffs' lawyer from Pascagoula, Miss., who was a co-author of last year's failed proposal, also said that he had been called by the White House.

Mr. Lindsey declined to answer specific questions about his role in the tobacco talks. On April 1, an initial meeting was held in Washington between Mr. Carlton, Mr. Myers, Mr. Coale, Mr. Scruggs and Michael Moore, the Attorney General for Mississippi. Two days later, at a meeting in Crystal City, Va., both Mr. Goldstone and Geoffrey Bible, the chair-

man of Philip Morris, were also present, Mr. Scruggs said. Mr. Mitchell made a presentation on behalf of the industry, and attorneys general from the four states — Arizona, Florida, Mississippi, Washington — made statements of intent.

The talks have since hoppedscotched around to locations like Chicago and Tysons Corner, Va., and have included a growing number of industry lawyers, plaintiffs' lawyers and state attorneys general.

"It has been a moveable feast," said Richard Blumenthal, Connecticut's Attorney General.

Just what will be left at the end of the meal is still in doubt. Though the tobacco industry has made some fundamental concessions, major issues

like the size of any settlement fund and the type of protection given to cigarette producers against current and future lawsuits are unresolved, said several lawyers involved in the talks. There is broad agreement, however, that any proposed plan will have to be instituted through Congressional legislation.

"We feel that the talks have been constructive to date," Mr. Myers said. "But the open question is whether price of a settlement will be too high."



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

F A S C I M I L E

DATE 5/14

TO: S. Doy
(NAME AND ORGANIZATION)

RECIPIENT'S FAX NUMBER: () _____

FROM: Mary Beth Donahue
Deputy Chief of Staff
HHS
Telephone: 202\690-2431
Fax Number: 202\401-5783

NUMBER OF PAGES (INCLUDING COVER SHEET):

3

COMMENTS:

F4I - we are also
running the attached
by WH Press - just thought
you should know we are doing
this -

To : Mary Beth Donahue@IOS.IO
Cc :
Bcc :
From : Victor Zonana@ASPA@OS.DC
Subject : satcher op-ed
Date : Wednesday, May 14, 1997 at 3:19:16 pm EDT
Attach :
Certify : N
Encrypt : N

Satcher was asked by Atlanta paper to prepare an op-ed for Friday's paper.

I gave provisional o.k., pending a reading.

I have only minor suggestions: Is it OK w/you?

Draft OPINION EDITORIAL for the Atlanta Journal Constitution
to run on Friday May 16 (day of the apology)
Requested by the editor of the Perspective section, deadline 10 am Thursday,
maximum 500 words

Today an historic event will occur. Our President will acknowledge the tragedy of the Tuskegee Syphilis Study and apologize on behalf of the government for decisions made many years ago that still haunt us today.

The "Tuskegee Study of Untreated Syphilis in the Negro Male" which has become known as the Tuskegee Syphilis Study was wrong for many reasons. While the study, begun 1932 by the Public Health Service, in Macon County, Alabama, may have been initiated with good intentions???, it was unethical. It was unethical because the study participants were never informed about the purpose of the study, were never asked to give their informed consent to participate in the study and were intentionally misled about receiving treatment. More importantly, when effective treatment for syphilis became available in 1947, it was withheld from the men involved in the study. The study was not stopped until 1972 after a news story about the study caused public outcry.

To this day, the legacy of this study continues to contribute to the mistrust many Americans-- especially African Americans-- have towards the medical and research establishment. Because of this deep mistrust, minorities may not obtain medical care, be forthright with their physicians, participate in research, donate organs, or accept advice from their doctor or public health officials regarding prevention of diseases.

The participation of minorities in research is absolutely imperative in order to find new or better treatment for disease and conditions which disproportionately affect minorities. However, if African Americans decide not to participate in research studies and clinical trials of new treatments, their ability as individuals and as a community to make informed decisions when they are facing such illness is greatly diminished.

While African Americans still have higher rates of disease primarily due to poverty and lack of access to medical care, we must do all we can to make sure it is not due to mistrust of government or the medical establishment. Much has been done since the Tuskegee study ensure the protection of study participants.

° Since 1974, people taking part in research have been protected by regulations which require informed consent and review of the study by institutional review boards.

° Today every institution which receives Federal funds to conduct research involving human subjects must adhere to Federal regulations governing research on human subjects .

° Current informed consent forms include statements that say participants will be notified if a new treatment becomes available. Such issues are also considered during the annual ethical review process now required for each new research project.

Even with these precautions in place, we must be vigilant in our efforts to protect human subjects regardless of age, gender, race or ethnicity. We must pay special attention to the protection of vulnerable populations -- our children, our poor, our people of color, our elderly as well as those in other countries that may benefit from our studies.

The 21st Century will bring with it incredible opportunities to prevent diseases, injuries, and disabilities. The future will also bring new ethical challenges. As much as possible we must prepare ourselves to meet those challenges. How can we do that?

° The research community must never compromise human dignity for the sake of science. We must hold to the highest ethical standard, constantly monitor ourselves and be open at all times to public scrutiny.

° Medical school and public health students must not graduate without receiving bioethics training.

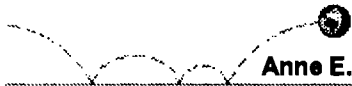
° We need for public and private research institutions to require on-going training and continuing education courses for those who work as researchers.

° State and local health departments must be involved as partners to develop policy to ensure protection of human subjects.

° We must involve affected communities more in planning, implementing, interpreting, and translating research.

° We must work to reach out of the scientific and medical community to stay in touch with changing perceptions and criticism of our work.

In short, our work and our policies must always be guided by clearly defined values and principles



Anne E. McGuire

04/24/97 05:27:30 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Tuskegee Meeting

There will be a 1:00 meeting on Tuesday, April 29 in room 472 to discuss the Tuskegee event scheduled with the President. Please let me know if you will be attending.

Message Sent To:

Robert B. Johnson/WHO/EOP
Elizabeth M. Toohey/WHO/EOP
Kathryn O. Higgins/WHO/EOP
Tracey E. Thomson/WHO/EOP
Maria Echaveste/WHO/EOP
Eli G. Attie/WHO/EOP
Ann F. Lewis/WHO/EOP
Kevin S. Moran/WHO/EOP
Elizabeth Drye/OPD/EOP
PALMIERI_J @ A1 @ CD @ LNGTWY
Laura A. Graham/WHO/EOP

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 to ^{requiring research organizations to} establish ^{local} ethics boards ^{to review and} approve ^{consent and review} research involving human subjects. ^{boards}
New-funded

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

3

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

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

3

DRAFT

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

4

**PRESIDENT CLINTON APOLOGIZES
FOR THE PUBLIC HEALTH SERVICE SYPHILIS EXPERIMENT
AT TUSKEGEE
May 16, 1997 --- DRAFT ---**

Today, President Clinton apologized to the victims, their families, and the nation for the Public Health Service syphilis experiment at Tuskegee. The President condemned the unethical, racist PHS study of untreated syphilis in approximately 400 African American men, conducted from 1932 to 1972, and apologized on behalf of the U.S. government.

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

- o **Building a lasting memorial.** The President announced that HHS will award a grant to Tuskegee University to plan a Center for Bioethics in Research and Health Care at the University. The Center would be a lasting memorial and would support efforts to address the legacy of the syphilis experiments. It would house a museum to preserve the study's history, teach researchers and the public about the study; and provide bioethics training through partnerships with medical schools and schools of public health.
- o **Increasing Community Involvement and Restoring Trust.** One legacy of the PHS syphilis study is that members of minority communities have often been reluctant to volunteer in clinical trials of new medical therapies. To ensure all Americans share in the benefits of research, we must restore trust. Today, the President directed the Secretary of HHS to issue a report [in 90 days] on effective strategies to involve communities, especially minority communities, in clinical research to increase participation and trust..
- o **Strengthening Researchers' Training in Bioethics.** The President directed the Secretary of HHS to develop bioethics training materials for the research community. Working with associations of higher education, medicine, and public health, HHS will prepare course materials that build on core ethical principles of respect for persons, beneficence, justice, and informed consent, emphasizing the effective application of these principles in diverse populations. The President directed HHS to complete the materials within one year.
- o **Providing Post-Graduate Fellowships to Train Bioethicists, Especially Minorities.** To increase and broaden our understanding of ethical issues in clinical research, HHS will offer Departmental fellowships in bioethics, beginning in September 1998, and will make special efforts to recruit minorities currently under represented in the field.

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.

**RECOMMENDED LIST OF PARTICIPANTS/NOTIFICATION CALLS for
WHITE HOUSE EVENT on TUSKEGEE SYPHILIS STUDY**

WHITE HOUSE

POTUS*

VPOTUS?

White House staff

HHS

Donna E. Shalala

Secretary of Health and Human Services

Jo Ivey Boufford

Acting Assistant Secretary of Health

Audrey Manley

Acting Surgeon General

✓ **David Satcher**

Director, Centers for Disease Control and Prevention

✓ **Harold Varmus**

Director, National Institutes of Health

Earl Fox

Acting Administrator, Health Resources Services Administration

Clay Simpson

Deputy Assistant Secretary for Minority Health

Henry Foster

Senior Advisor to the President on Teen Pregnancy and
Youth Initiatives

SURVIVORS

(See Attachment I)

Survivors' attorney:

Fred Gray

FORMER HHS OFFICIALS

Dr. Louis Sullivan

Former Secretary of the Department of Health and Human Services

Dr. Merlin K. DuVal

Assistant Secretary for Health and Scientific Affairs

(Dr. DuVal requested the investigation of the circumstances
surrounding the Tuskegee Study in 1972)

LEGISLATIVE

(See Attachment II)

STATE/LOCAL OFFICIALS

Fob James, Jr., Governor of Alabama
Ronald Williams, Mayor of Tuskegee
Donald Williamson, State Health Officer
Patricia Clay, Director Macon County Health Department

GROUPS

(WH Office of Public Liaison)

CIVIL RIGHTS ORGANIZATIONS

(WH Office of Public Liason)

TUSKEGEE UNIVERSITY

Dr. Benjamin F. Payton
President, Tuskegee University

TUSKEGEE SYPHILLIS STUDY AD HOC ADVISORY PANEL

Chairman Broadus Butler
President, Dillard University

8 members (note: Ron Brown was member of panel in his position as
General Counsel of the National Urban League)

TUSKEGEE LEGACY COMMITTEE

Chairwoman Venessa Gamble
Associate Professor of Medical History & Family Medicine
University of Wisconsin

13 members

***HIGHLIGHTING INDICATES FIRST TIER LIST**

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: Tuskegee Health Benefit Program [partial] (1 page)	04/09/1997	b(6)

COLLECTION:

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

FOLDER TITLE:

Tuskegee Apology

2014-0046-S

rc1384

RESTRICTION CODES

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

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

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

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

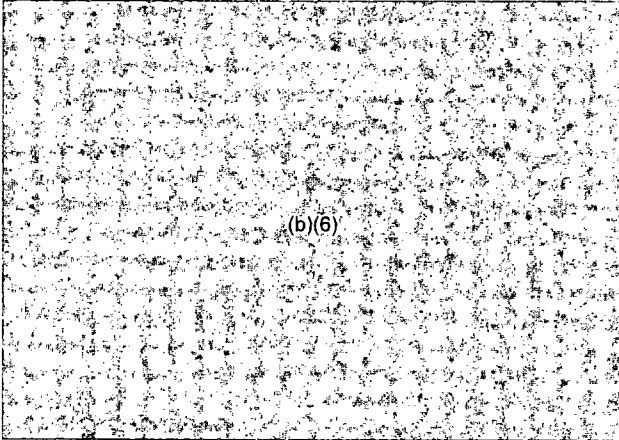
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

ATTACHMENT I

TUSKEGEE HEALTH BENEFIT PROGRAM
(Status of Program as of December 1996)
April 9, 1997

	<u>Total Number</u>	<u>Able to Travel</u>	<u>Comments</u>
Participants	8	6	 (b)(6)
Wives/Widows	21	14	
Children	16	16	
Grandchildren	2	2	
TOTAL	47	38**	

*One participant's actual birthdate is questionable--available records indicate 1897; family says 1888.

**This number could increase substantially due to inclusion of necessary traveling companions/medical aides and possibly children of deceased participants.

ATTACHMENT II

- Members of the Congressional Black Caucus (See attached list)

- Senator Moseley-Braun

- Members of the Alabama delegation

 - Senator Shelby

 - Senator Jeff Sessions

 - Representative Earl Hilliard

 - Representative Robert E. Cramer

 - Representative Sonny Callahan

 - Representative Terry Everett

 - Representative Bob Riley

 - Representative Robert Aderholt

 - Representative Spencer Bachus

- Appropriations Committee

 - Senator Stevens

 - Senator Byrd

 - Senator Specter

 - Senator Harkin

 - Representative Livingston

 - Representative Obey

 - Representative Porter

- Labor and Human Resource Committee

 - Senator Jeffords

 - Senator Kennedy

 - Senator Frist

- Commerce Committee

 - Representative Bliley

 - Representative Dingell

 - Representative Bilirakis

 - Representative Sherrod Brown

 - Representative Waxman

**CONGRESSIONAL BLACK CAUCUS MEMBERS
105TH CONGRESS
(alphabetically)**

U. S. House of Representatives --

Rep. Sanford D. Bishop, Jr., 2nd CD, Georgia
1433 Longworth HOB, Washington, D.C. 20515 225-3631

Rep. Corrine Brown, 3rd CD Florida
1610 Longworth HOB, Washington, D.C. 20515 225-0123

Rep. Julia Carson, 10th CD, Indiana
1541 Longworth HOB, Washington, D.C. 20515 225-4011

Rep. Donna M. Christian-Green, Delegate Virgin Islands
1711 Longworth HOB, Washington, D.C. 20515 225-1790

Rep. William Clay, 1st CD, Missouri
2306 Rayburn HOB, Washington, D.C. 20515 225-2406

Rep. Eva Clayton, 1st CD, North Carolina
2440 Rayburn HOB, Washington, D.C. 20515 225-3101

Rep. James E. Clyburn, 6th CD, South Carolina
319 Cannon HOB, Washington, D.C. 20515 225-3315

Rep. John Conyers, Jr., 14th CD, Michigan
2426 Rayburn HOB, Washington, D.C. 20515 225-5126

Rep. Elijah E. Cummings, 7th CD, Maryland
1632 Longworth HOB, Washington, D.C. 20515 225-4741

Rep. Danny K. Davis, 7th CD, Illinois
1218 Longworth HOB, Washington, D.C. 20515 225-5006

Rep. Ronald V. Dellums, 9th CD, California
2108 Rayburn HOB, Washington, D.C. 20515 225-2661

Rep. Julian C. Dixon, 32nd CD, California
2252 Rayburn HOB, Washington, D.C. 20515 225-7084

Rep. Chaka Fattah, 2nd CD, Pennsylvania
1205 Longworth HOB, Washington, D.C. 20515 225-4001

Rep. Floyd H. Flake, 6th CD, New York
1035 Longworth HOB, Washington, D.C. 20515 225-3461

Rep. Harold E. Ford, Jr., 9th CD, Tennessee
1523 Longworth HOB, Washington, D.C. 20515 225-3265

Rep. Alcee L. Hastings, 23rd CD, Florida
1039 Longworth HOB, Washington, D.C. 20515 225-1313

Rep. Earl F. Hilliard, 7th CD, Alabama
1314 Longworth HOB, Washington, D.C. 20515 225-2665

Rep. Jesse L. Jackson, Jr., 2nd CD, Illinois
313 Cannon HOB, Washington, D.C. 20515 225-0773

Rep. Sheila Jackson Lee, 18th CD, Texas
410 Cannon HOB, Washington, D.C. 20515 225-3816

Rep. William J. Jefferson, 2nd CD, Louisiana
240 Cannon HOB, Washington, D.C. 20515 225-6636

Rep. Eddie Bernice Johnson, 30th CD, Texas
1123 Longworth HOB, Washington, D.C. 20515 225-8885

Rep. Carolyn C. Kilpatrick, 15th CD, Michigan
503 Cannon HOB, Washington, D.C. 20515 225-2261

Rep. John Lewis, 5th CD, Georgia
229 Cannon HOB, Washington, D.C. 20515 225-3801

Rep. Cynthia A. McKinney, 4th CD, Georgia
124 Cannon HOB, Washington, D.C. 20515 225-1605

Rep. Carrie P. Meek, 17th CD, Florida
401 Cannon HOB, Washington, D.C. 20515 225-4506

Rep. Juanita Millender-McDonald, 37th CD, California
419 Cannon HOB, Washington, D.C. 20515 225-7924

Rep. Eleanor Holmes Norton, Delegate, District of Columbia
1424 Longworth HOB, Washington, D.C. 20515 225-8050

Rep. Major R. Owens, 11th CD, New York
2305 Rayburn HOB, Washington, D.C. 20515 225-6231

Rep. Donald M. Payne, 10th CD, New Jersey
2244 Rayburn HOB, Washington, D.C. 20515 225-3436

Rep. Charles B. Rangel, 15th CD, New York
2354 Rayburn HOB, Washington, D.C. 20515 225-4365

Rep. Bobby L. Rush, 1st CD, Illinois
131 Cannon HOB, Washington, D.C. 20515 225-4372

Rep. Robert C. Scott, 3rd CD, Virginia
2464 Rayburn HOB, Washington, D.C. 20515 225-8351

Rep. Louis Stokes, 11th CD, Ohio
2365 Rayburn HOB, Washington, D.C. 20515 225-7032

Rep. Bennie G. Thompson, 2nd CD, Mississippi
1408 Longworth HOB, Washington, D.C. 20515 225-5876

Rep. Edolphus Towns, 10th CD, New York
2232 Rayburn HOB, Washington, D.C. 20515 225-5936

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1230 Longworth HOB, Washington, D.C. 20515 225-1510

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407 Cannon HOB, Washington, D.C. 20515 225-8699

U.S. Senate --

Sen. Carol Moseley-Braun, Illinois, 224-2854
320 Hart Senate Office Bldg., Washington, D.C. 20510

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Tuskegee Apology

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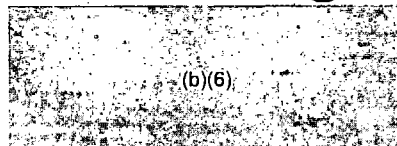
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William Combs

Tuskegee



[002]

~~any other news release~~

event

- apology - front page news
- bioethics training - work w/schools
- fellowships
- extend NBAC's charter

no ACTRE announcement
EO signing?

Issue statement - Phil Thinks no

- less impact
- bioethics event for addiction offenders others

both

- strengthen bioethics -

- issue apology

- sign fellowship program

- Sign EO on clarified research

- Legislation - women minors

NBAC Min

Thurs. Ed event. -

Sat - Child Summit

APRS - Women/minority/Adolescent men

- What would it take to have clearing

- T-Sat
- April 9th cancelled
-

PHOTOCOPY
PRESERVATION

CONF: Mary Beth,
Ann McGuire,
Jennifer Palmeri.

April 8, 1997

Lanagers / Tuskegee

held press conference 4/8

Event - Apology -

- (1) BTW CDC and NIH - ethics curriculum for
schools of ~~management~~ medicine and public health.
- minority community / subcomponents, -
- (2) CDC / NIH / HRSA Health resources and Services
Administration 6-8 graduate fellowships a
year - in bioethics.
- (3) Asking NBAC - how to get communities
more involved in the design of study,
- Harold Shapiro confirmed -
not best place to put this consideration.
POBUS came back to
Secretary HHS ~~and~~ with plan
for greater community involvement of
design of clinical studies.
- work with communities we go into,
e.g., to do vaccine studies. -
- 8 survivors - 3 can travel. 7 widows can travel.
Very old. -

8 members —

— 23-24 people families of survivors —

Ben / Andy — Leg / Affairs

Johnson }

NAACP

Black leadership forum

— NBA e = community involvement —



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

F A S C I M I L E

DATE _____

TO: S. Dwyer
(NAME AND ORGANIZATION)

RECIPIENT'S FAX NUMBER: () _____

FROM: Mary Beth Donahue
Deputy Chief of Staff
HHS
Telephone: 202\690-2431
Fax Number: 202\401-5783

NUMBER OF PAGES (INCLUDING COVER SHEET): _____

COMMENTS:

~~Additional CDC~~
~~question~~
Chronology updated
w/ DPC edits.

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. ^{the} 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

GRAY, LANGFORD, SAPP, MCGOWAN, GRAY & NATHANSON

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CHARLES D. LANGFORD
ERNESTINE S. SAPP
WALTER E. MCGOWAN
FRED D. GRAY, JR.**
STANLEY F. GRAY***
ALLAN NATHANSON***

March 26, 1997

ALSO LICENSED:
*OHIO
**DISTRICT OF COLUMBIA
***ARIZONA

Honorable William Jefferson Clinton
President of the United States
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Pollard, et al. v. USA, et al., CV-4126-N
United States District Court for the Middle District of Alabama

Dear President Clinton:

I represent 623 African American men from Macon County, Alabama in what has become known as the Tuskegee Syphilis Study. They were solicited by United States Public Health Service officials and employees to participate in a health program financed by the United States government in 1932. The undisclosed medical purpose was to observe the effects of untreated syphilis on African American males. Poor, uneducated, misinformed African American men were persuaded to take part in a health program by officials who told them they were beneficiaries of a new health program wherein their illnesses would be cured and they would receive free medical examinations, free transportation to some appointments, free meals, and burial insurance.

Forty years after the initiation of the experiment, national news media exposed the Study. The men heard, for the first time, of the Study and that they had syphilis. They were used as human guinea pigs in a cruel, inhumane experiment conducted by the Public Health Service with the sanction of the United States government. Some died and all suffered as a result of penicillin not being administered. In 1973, I filed a lawsuit on behalf of these participants and the heirs of deceased participants in the United States District Court for the Middle District of Alabama seeking redress for injuries done to them. In 1974, the case was settled with the government paying certain designated amounts to the living participants and certain designated amounts to the heirs of deceased participants. Under the settlement, the United States was ordered to continue a health care program and death benefits for these participants.

Hon. William Jefferson Clinton
March 26, 1997
Page 2

The United States government's active involvement in this tragedy is well documented. Defendants in the case included the United States of America; Casper Weinberger as Secretary of the Department of Health, Education and Welfare, and others. The United States knew that the unwitting participants had syphilis and failed to treat them; the Public Health Service failed to fully disclose to the men that they had syphilis and failed to treat them, while misrepresenting to them that they were being properly treated for whatever diseases they had. Perhaps you are not aware, Mr. President, that over the years, the United States government has never expressed regret or remorse, sympathy, sorrow, or other sentiments to these citizens and the affected families for the government's role in the Study. You now have the opportunity to act.

As President, you have shown courage and commitment to right wrongs, making hard decisions such as decisive action with respect to welfare reform; you have successfully tackled difficult issues such as the process of negotiating peace in Middle East territories, and you recently awarded to African American servicemen the Medal of Honor for courageous acts in war dating to World War II. We believe you will do what is fitting, necessary, proper and appropriate in remedying this wrong and acknowledge the participants' contribution to the nation. I am informed that several persons and organizations have requested that an apology be made to the participants. We are further informed that you have discussed this matter or related matters with the Hon. Donna Shalala, Secretary of Health and Human Services. Proper action at this time will likely result in African Americans' viewing with less skepticism and apprehension requests to participate in legitimate medical programs which seek cures for illnesses and diseases. Aggressive action and appropriate assurances from your office could generate dialogue and improve confidence in various clinical trials that will result in an increase in minority participation in programs, tests and studies designed to bring an end to dreaded diseases such as cancer.

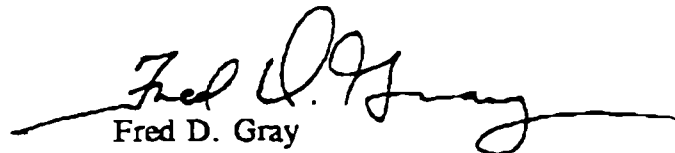
There are eight living participants, the youngest of whom is 87 years old. In view of the fact that these men and their heirs have suffered substantially, the remaining participants and I would consider it an honor to meet with you to discuss an appropriate manner to resolve the issue. On behalf of these men, we are ready, willing and able to share their views with you or your representatives at your convenience.

Incidentally, I appreciate the private audience with you at the conclusion of your rally at Birmingham-Southern in Birmingham, Alabama on Thursday, October 25, 1996. At that time I presented to you a copy of *Bus Ride To Justice*. Chapter 17 contains a true and accurate account of my clients' participation in the Tuskegee Syphilis Study.

Hon. William Jefferson Clinton
March 26, 1997
Page 3

We look forward to hearing from you at your convenience with reference to this matter and pray that you continue to rapidly recover from your recent injury and resultant surgery.

Very truly yours,


Fred D. Gray

FDG:j

Newspaper Montgomery Advertiser

Date April 2, 1997

Page 6A

Apology Due

Clinton Should Come To Tuskegee

FOR 40 YEARS the U.S. government conducted the now infamous Tuskegee syphilis experiment, leaving poor, semi-literate black males in rural Macon County to suffer the ravages of the disease untreated.

The time for the government to formally apologize to the surviving victims and their families is long past.

The U.S. Public Health Service began the so-called experiment in 1932. Treatment was withheld from 399 men with syphilis so the researchers could study how the disease spreads and kills. The men weren't told they had the disease nor were they given penicillin after it became the standard treatment in 1947.

It was not until 1972 that the study came to light. The government settled a lawsuit filed in 1974, paying \$10 million to 6,000 victims of the experiment and their heirs.

IT IS NOT the first time the government has secretly used its own citizens as unknowing guinea pigs. President Clinton in 1995 issued an apology to the victims of secret Cold War-era radiation experiments.

Next week the remaining survivors of the experiment will gather at the Shiloh Baptist Church in Notasulga, one of the sites where the men gathered for the study, to demand a formal apology.

Despite our flaws, this is a great country. It remains great, though, only by acknowledging when it is wrong and by rectifying its mistakes.

An official apology should be forthcoming quickly. Tuskegee would be a good place for President Clinton to deliver it.

04/03/97

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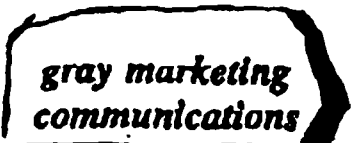
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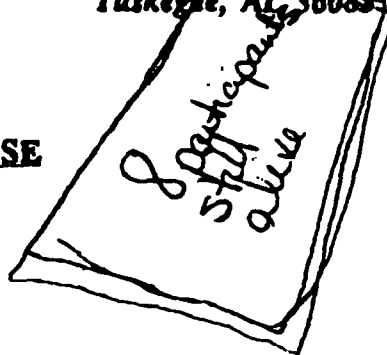
Tuskegee, AL 36088

(334)727-1188

Fax #
212-512-1053
Carol Rober

FOR IMMEDIATE RELEASE**MARCH 31, 1997**

Call back
on Thursday



CONTACT:
Joanne Bibb or
Trudy Powell
(334)727-4830
Deborah Gray
(334)727-1188

Call
Pat Rivers
Use under
1 minute

**GOVERNMENT APOLOGY FORTHCOMING
IN TUSKEGEE SYPHILIS STUDY?**

Remaining participants in the Tuskegee Syphilis Study, the 40-year experiment financed by the United States government and conducted by the United States Public Health Service to observe the effects of untreated syphilis in African Americans, will seek an audience with the President and an apology from the government at a news conference on April 8, 1997, at 10 o'clock A.M., at Shiloh Baptist Church, Notasulga, Alabama, one of the collection sites for the participants in the Study.

Accompanied by Attorney Fred D. Gray, legal counsel for the participants in the Study, the men will also express their views and concerns in relation to injustices depicted in the recently aired HBO film, "Miss Evers Boys". "This movie is in no way representative of the actual events which I endured for 40 years", said Charlie Pollard, lead plaintiff in the lawsuit against the United States government and other entities for wrongful acts conducted during the Study.

"To allow men to suffer and die in the name of science is insidious and vile", said Gray.

"HBO's depiction of the men is equally disheartening. It is an intolerable distortion of history.

ronically, Miss Evers Boys was initially aired during Black History Month on February 22, President Lincoln's birthday. This movie has been shown repeatedly through the powerful means of television, stereotyping Black images even further before a mass audience. Not only is it a cruel affront to the survivors of the Tuskegee Syphilis Study and the descendants of all the men, but equally an affront to the entire African American community", Gray further stated.

"There is a reason that African Americans and other minorities do not participate in large numbers in test programs for cures of diseases and illnesses." Gray commented further, "aside from their frequently simply not being considered, many remember all too well the Tuskegee Syphilis Study and the inhuman treatment of the 600 plus African American men."

DIRECTIONS TO SHILOH BAPTIST CHURCH

Shiloh Baptist Church is located on Alabama Highway 81, approximately 8 miles North of downtown Tuskegee, Alabama. Exit off Interstate 85-North at the Tuskegee-Notasulga ramp (Exit 38), proceed North on Highway 81 approximately 5 miles to Shiloh Baptist Church on the right.

BIOGRAPHICAL INFORMATION

Participants in "The Tuskegee Syphilis Study"

Herman Shaw - Mr. Shaw was born on May 18, 1902 (94) to Frank Shaw and Elijah Bickerstaff in Tallapoosa County, Alabama. His family moved to Plano, Texas in 1909. In 1922 he graduated from the 9th grade as valedictorian of his class. His last year of study included such courses as Latin, Algebra, European Civilization and Physical Geography. He was married to Fannie Mae Greathouse for 62 years. He had two children. Herman Shaw, Jr., received a B. S. degree from Alabama A & M and a Masters from North Carolina A & T. Mr. Shaw has a daughter, Mary Mullins, who lives in Tallapoosa County and is a graduate of Tennessee A & I University. Mr. Shaw has six grandchildren and one great grandchild. For 44 years he worked at the Tallassee Mill in Tallassee, Alabama. The proud owner of a 1941 International Tractor which is still in good condition. In addition to operating his farm, he recently sold his livestock. He drives a 1989 Park Avenue Buick and has driven a Buick automobile since 1914. He belongs to the New Adka Baptist Church on Highway 50 in Tallapoosa County.

Pollard, Charlie W. - Mr. Pollard was born on April 13, 1906 (91) in Macon County, Alabama to Alma Grimmatt Pollard and Lucius Pollard. He was married to Louisa Woods for 54 years. He has one daughter Ralphine Harper. He was educated at the Shiloh School (building is located next door to Shiloh Missionary Baptist Church) which at that time only went through the 7th grade and only went to school seven months a year. He has remained a life long resident of Notasulga, is a community leader and was one of the community leaders who worked for civil rights and cooperated with Dr. C. G. Gomillion in helping to get people registered to vote and get people elected. He is a farmer, having raised cattle, corn, cotton and other crops. He is a property owner and has been for many, many years. At the time the Tuskegee Syphilis Study story broke, he was selling cows at a stock yard in Montgomery, Alabama and he is the lead plaintiff in the case of *Pollard, et al. v. USA, et al.* He came to Mr. Gray's office two days after the story broke and was the leading force in being responsible for retaining Mr. Gray to represent him and the other participants in the Tuskegee Syphilis Study. He is also a member of Shiloh Missionary Baptist Church, one of the areas where he was recruited to be a participant by Nurse Eunice Rivers and Dr. Murray D. Smith, the health officer of Macon County.

Howard, Carter - Mr. Howard was born February 18, 1904 (93) in Macon County, Alabama to Ruthie Taylor Howard and George Howard. He grew up in the Oak Grove Community. He went to a one room school and finished the 5th grade. He is single. He is a member of Mt. Ester A.M.E. Zion Church. He has been a farmer and his last work was as a carpenter. His health is not too good, having received a pacemaker recently. Hunting has been one of his hobbies.

Simmons, Fred - Mr. Simmons according to the government's records was born on April 6, 1897 (100) in Macon County, Alabama. His parents were Amy Brown Simmons and Hines Simmons. He was born in and grew up in the New Hope Community. He was married to Margaret Tolbert Simmons. He had 21 children. Fourteen are deceased and seven are living. He has many grandchildren and great-grandchildren. He went to the New Hope School, received very little education, stopping in the second or third grade. He is a member of Mt. Pleasant Baptist Church. His work experience includes plowing, pulpwooding, public work on the railroad, and a little farming.

Hendon, Ernest - Mr. Hendon was born on February 12, 1907 (90) in Macon County, Alabama to Mary Hendon and North Hendon. He is single. He attended the Macon County Training School finishing the 12th grade. He has about six or seven nieces and nephews. He is a member of Sweet Pilgrim Baptist Church. He has been a farmer most of his life and worked in Cleveland, Ohio for a chemical company for about 28 years. He is in good health.

ACHRE Findings and Recommendations on Protecting Human Subjects in the Future

Based on its review of current human subject protections, the Advisory Committee found, among other things, that

[H]uman research involving radioisotopes is currently subjected to more safeguards and levels of review than most other areas of research involving human subjects. The Advisory Committee further finds that there are no apparent differences between the treatment of human subjects of radiation research and human subjects of other biomedical research. (Finding 20)

[T]oday research involving human subjects sponsored by the government may be classified and conducted in secret, but it must comply with the provisions of the Common Rule. (Finding 21)

[I]n comparison with the practices and policies of the 1940s and 1950s, there have been significant advances in the protection of the rights and interests of human subjects of biomedical research. However, we also find that there is evidence of serious deficiencies in some parts of the current system for the protection of the rights and interests of human subjects. (Finding 22)

ACHRE Recommendation on the Centrality of Ethics

ACHRE recommended that active efforts on a national scale be made to ensure that human subjects researchers fully understand the ethical implications and responsibilities of their work, and the centrality of ethical decisions. (Recommendation 9)

Response

Responsibility for the ethical conduct of research begins with researchers and extends to their institutions and the Institutional Review Boards (IRBs). The Administration has multiple efforts underway to reach, educate, oversee, and hold accountable each layer of the research system. The Administration is also taking steps to promote understanding of, and consensus about, ethical issues.

Responsibility for ethical conduct of research begins with researchers and extends to their institutions, and the Institutional Review Boards (IRBs).

National Bioethics Advisory Commission

The National Bioethics Advisory Commission (NBAC), a national deliberative body of private citizens, was established by the President to provide guidance to all Federal agencies on the ethical conduct of human behavioral and clinical research, and the applications of that research. NBAC was established, in part, to respond to ACHRE, and the Administration expects NBAC will choose to address the key issues identified in ACHRE's recommendations. NBAC will not be able to review all issues raised by ACHRE. The Administration has been careful to ensure that issues not taken up by NBAC will be addressed elsewhere.

As a first priority, NBAC will seek to improve protection of the rights and welfare of human research subjects. The Executive Order establishing NBAC, required each agency to review its current human subjects research in light of the Advisory Committee recommendations and report the results to NBAC. NBAC is currently reviewing these documents. Appendix C details specific activities currently being carried out by the agencies as a result of their reviews.

NBAC's meetings are public and provide a forum for dialogue on ethics issues. NBAC has heard presentations on issues related to genetic research, including cloning, as well as the broader area of human subjects research. Members of Congress, Congressional staff, and representatives from diverse organizations including the Task Force on Radiation and Human Rights, the College of American Pathologists, the Biotechnology Industry Organization, and Citizens for Responsible Care in Psychiatry and Research testified on ethics issues and on NBAC's mission. Further information can be obtained from the NBAC Web Site (www.nih.gov/nbac/nbac.htm).

Education

ACHRE's report made clear that a key to preventing the repetition of past mistakes is thorough and continuing education about ethics and how they apply to current human subjects research. The Administration is responding to ACHRE's specific recommendations by co-sponsoring educational programs with external groups such as medical schools, universities, and scientific societies. The goals of these educational efforts are to strengthen human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-federally funded human subjects research with relevant ethical considerations.

Part of the ongoing educational process is a reinforcement of the importance of Institutional Review Boards (IRBs) at institutions conducting federally funded research. These IRBs are local groups

The Executive Order establishing NBAC, required each agency to review its current human subjects research in light of the Advisory Committee recommendations and report the results to NBAC.

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whose membership and responsibilities are regulated by the Federal government. They are responsible for reviewing and approving the ethical content of all proposed human subjects research projects. IRBs are a linchpin in the protection of human subjects, and their credibility and effectiveness depend on adequate awareness of basic ethical topics.

Similarly, educational programs are also being targeted at government-regulated research that is not government-funded (e.g., FDA-regulated research sponsored by the pharmaceutical industry). In September of 1996, the FDA sponsored its first nationwide conference on human subjects protection.

Government employees who have responsibility for supporting or overseeing human subjects research are also targeted for educational programs. Thus, Federal agencies are implementing training programs to educate senior level officials on regulations and policies governing this research. For example, NASA is working with international research partners to develop common ethical principles that ensure the protection of human subjects. DOE educational efforts target laboratory staff, field office personnel, and program officials.

Despite the vigor with which all parties embrace the informed consent process, it is not well understood.

Information Gathering

ACHRE's report highlighted the limited state of knowledge regarding some key issues in human subjects research. Most importantly, NBAC will be reviewing and evaluating the IRB process.

In addition, Departments have pooled resources to sponsor research on the informed consent process. The informed consent process is intended to help each potential research subject decide whether to participate in research by providing advance information about the research. Information includes a description of the nature of the research, the subject's role and potential risks, and the subject's rights and responsibilities. Despite the vigor with which all parties embrace the informed consent process, it is not well understood. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent. The National Institutes of Health (NIH), VA, and DOE are committed to supporting research that will more fully illuminate the informed consent process. A Request for Applications (RFA) to conduct research on this issue was published in the fall of 1996, and Fiscal Year 1997 monies are earmarked to support this RFA.

ACHRE Recommendation on Institutional Review Boards

ACHRE recommended specific changes to IRBs in five critical areas (Recommendation 10):

- (1) mechanisms to ensure a stronger focus on studies that pose more than minimal risk to subjects;
- (2) better means of explaining to potential subjects the distinction between research and treatment, the realistic likelihood of medical benefit to the subject from participation, and the potential for discomfort and pain;
- (3) ensuring that potential subjects fully understand the sponsors and purposes of the research;
- (4) ensuring that potential subjects fully understand the financial implications of participation; and
- (5) recognition that the IRBs must decide if the quality of the science justifies the risk to the subjects.

The Administration anticipates specific recommendations from NBAC regarding reform of IRBs, including recommendations that address ACHRE's concerns.

Response

The Administration agrees that there are indications that the IRB system is not always adequate to ensure protection of human subjects. NBAC has undertaken to review the current IRB system and intends to finish that project within a year. The Administration anticipates specific recommendations from NBAC regarding reform of IRBs, including recommendations that address ACHRE's concerns.

In the interim, agencies are informing IRBs of ACHRE's recommendations and are working to improve IRBs.

The Office for Protection from Research Risks (OPRR), part of NIH, is undertaking a national effort to educate the research community about ACHRE's recommendations. OPRR and FDA support an annual public meeting for individuals interested in the governance of human subjects research. In addition, OPRR, in cooperation with FDA and local academic institutions, has held discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, Houston, and San Diego.

OPRR and the FDA make extensive use of public meetings, forums, hearings, and electronic media to address evolving issues on human subject protection. OPRR and FDA also regularly mail information directly to IRBs and other interested parties. FDA seeks public input through the *Federal Register* and by mailing proposals to the IRB and clinical investigator communities. In October 1995, FDA issued



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

*Elena Kagan**8:30*
10:30
9:30 here
10:30
9:45-10:45
7431

Washington, D.C. 20201

F A C S I M I L E

DATE

TO

NAME AND ORGANIZATION

FROM:

MARY BETH DONAHUE
DEPUTY CHIEF OF STAFF
DHHS
Telephone: (202) 690-7431
FAX: (202) 401-5783

RECIPIENT'S FAX NUMBER ()

NUMBER OF PAGES (INCLUDING COVER SHEET):

COMMENTS:



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.

A handwritten signature in cursive script, appearing to read "Mary Beth Donahue".

Mary Beth Donahue

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.

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.

DRAFT

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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 Administration (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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

F A S C I M I L E

DATE

5/14

TO:

(NAME AND ORGANIZATION)

S. DRYE

RECIPIENT'S FAX NUMBER: ()

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Deputy Chief of Staff
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NUMBER OF PAGES (INCLUDING COVER SHEET):

3

COMMENTS:

Additional Q + A
to what you were ~~not~~
sent earlier today

Research on Human Subjects: Talking Points

(Zonana, HHS: 690-6343)

Background: A Page One story in this morning's New York Times quotes the government's top official involved in protecting human subjects as saying there is "unchecked research" taking place. This statement is juxtaposed with President Clinton's planned apology to the surviving participants of the U.S. Public Health Service's notorious syphilis experiment in Tuskegee. The following points can be made if asked about the article:

- As the article makes clear, the U.S., has made great strides in addressing research abuses since the Tuskegee experiment was uncovered and ended in 1972. Informed consent, and local review, are the key ethical principles that guide the conduct of federally funded research.
- The "unchecked research" the story references does not include federally funded projects. Indeed, federally funded research – and private research aimed at securing approval of a drug or device by the Food and Drug Administration – is very closely monitored.
- As science evolves, we must be constantly vigilant to ensure that human research subjects have the protection they deserve. Although we have not taken a position on proposed legislation that would extend protections to privately funded research, we will be announcing several action steps on Friday that will enhance protection of human subjects. We will also continue to be guided by the National Bioethics Advisory Commission on this subject.

Q and A's follow

Q. And A. On Protecting Human Subjects of Research
May 14, 1997

Q. In today's New York Times, the government's top official involved in protecting human subjects participating in research, says there is "unchecked" research going on. How can this be the case? And you are just about to apologize for Tuskegee?

A. First, let's separate two things--research supported by the federal government and certain privately financed research that is not bound by federal rules. Gary Ellis, the head of the Office of Protection from Research Risks, was referring to the latter-- privately financed research does not fall under the strict rules that apply to government research.

Q. Do you think that people participating as research subjects in federally funded projects are now adequately protected?

A. The system we have in place today--which relies heavily on informed consent and on review at the local level-- is strict and generally effective. It is not perfect. That is why we are about to announce some enhancements to the system for protecting human subjects involved in federally funded research. These primarily relate to increasing community involvement and strengthening bioethics training.

Q. Well, what about all the research that is being done under private financing?

A. The Federal government simply does not have jurisdiction over that research. There is some legislation that has been discussed that would cover privately financed research. The Administration and the DHHS have not taken a position on any specific legislative proposals at this time.

Certainly, the protection of human subjects of research is of vital importance. The National Bioethics Advisory Commission that ~~I have set up~~ will help guide us in these matters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

F A S C I M I L E

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5/14

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Elizabeth Dwyer

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COMMENTS:

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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

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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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5-13-97 : 7:11PM :

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BACKGROUND: 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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DEPARTMENT OF HEALTH & HUMAN SERVICES

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F A S C I M I L E

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NUMBER OF PAGES (INCLUDING COVER SHEET): 7

COMMENTS:

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.

Request of Awarding
- Planning grant to Tuskegee
- line item approp.

#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

- Houston hypertension
- Reed Rixon
- People we list

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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

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NUMBER OF PAGES (INCLUDING COVER SHEET):

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COMMENTS:

DRAFT TUSKEGEE QUESTIONS AND ANSWERSPolitical + PolicyMacar Comm
Polsner

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. Should the Tuskegee victims receive more monetary compensation?

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

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

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

Q. Was what happened at Tuskegee racism?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. What is being done to strengthen bioethics training?

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

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

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

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

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

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

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