

May 16, 1997

**REMARKS BY THE PRESIDENT
IN APOLOGY FOR STUDY DONE IN TUSKEGEE**

The East Room

THE PRESIDENT: Ladies and gentlemen, on Sunday, Mr. Shaw will celebrate his 95th birthday. (Applause.) I would like to recognize the other survivors who are here today and their families: Mr. Charlie Pollard is here. (Applause.) Mr. Carter Howard. (Applause.) Mr. Fred Simmons. (Applause.) Mr. Simmons just took his first airplane ride, and he reckons he's about 110 years old, so I think it's time for him to take a chance or two. (Laughter.) I'm glad he did. And Mr. Frederick Moss, thank you, sir. (Applause.)

I would also like to ask three family representatives who are here -- Sam Doner is represented by his daughter, Gwendolyn Cox. Thank you, Gwendolyn. (Applause.) Ernest Hendon, who is watching in Tuskegee, is represented by his brother, North Hendon. Thank you, sir, for being here. (Applause.) And George Key is represented by his grandson, Christopher Monroe. Thank you, Chris. (Applause.)

I also acknowledge the families, community leaders, teachers and students watching today by satellite from Tuskegee. The White House is the people's house; we are glad to have all of you here today. I thank Dr. David Satcher for his role in this, I thank Congresswoman Waters and Congressman Hilliard, Congressman Stokes, the entire Congressional Black Caucus, Dr. Satcher, members of the Cabinet who are here, Secretary Herman, Secretary Slater, members of the Cabinet who are here, Secretary Herman, Secretary Slater. A great friend of freedom, Fred Gray, thank you for fighting this long battle all these long years.

The eight men who are survivors of the syphilis study at Tuskegee are a living link to a time not so very long ago that many Americans would prefer not to remember, but we dare not forget. It was a time when our nation failed to live up to its ideals, when our nation broke the trust with our people that is the very foundation of our democracy. It is not only in remembering that shameful past that we can make amends and repair our

nation, but it is in remembering that past that we can build a better present and a better future. And without remembering it, we cannot make amends and we cannot go forward.

So today America does remember the hundreds of men used in research without their knowledge and consent. We remember them and their family members. Men who were poor and African American, without resources and with few alternatives, they believed they had found hope when they were offered free medical care by the United States Public Health Service. They were betrayed.

Medical people are supposed to help when we need care, but even once a cure was discovered, they were denied help, and they were lied to by their government. Our government is supposed to protect the rights of its citizens; their rights were trampled upon. Forty years, hundreds of men betrayed, along with their wives and children, along with the community in Macon County, Alabama, the City of Tuskegee, the fine university there, and the larger African American community.

The United States government did something that was wrong -- deeply, profoundly, morally wrong. It was an outrage to our commitment to integrity and equality for all our citizens.

To the survivors, to the wives and family members, the children and the grandchildren. I say what you know: No power on Earth can give you back the lives lost, the pain suffered, the years of internal torment and anguish. What was done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States government did was shameful, and I am sorry. (Applause.)

The American people are sorry -- for the loss, for the years of hurt. You did nothing wrong, but you were grievously wronged. I apologize and I am sorry that this apology has been so long in coming. (Applause.)

To Macon County, to Tuskegee, to the doctors who have been wrongly associated with the events there, you have our apology, as well. To our African American citizens, I am sorry that your federal government orchestrated a study so clearly racist. That can never be allowed to happen again. It is against everything our country stands for and what we must stand against is what it was.

So let us resolve to hold forever in our hearts and minds the memory of a time not long ago in Macon County, Alabama, so that we can always see how adrift we can become when the rights of any citizens are neglected, ignored and betrayed. And let us resolve here and now to move forward together.

The legacy of the study at Tuskegee has reached far and deep, in ways that hurt our

progress and divide our nation. We cannot be one America when a whole segment of our nation has no trust in America. An apology is the first step, and we take it with a commitment to rebuild that broken trust. We can begin by making sure there is never again another episode like this one. We need to do more to ensure that medical research practices are sound and ethical, and that researchers work more closely with communities.

Today I would like to announce several steps to help us achieve these goals. First, we will help to build that lasting memorial at Tuskegee. (Applause.) The school founded by Booker T. Washington, distinguished by the renowned scientist George Washington Carver and so many others who advanced the health and well-being of African Americans and all Americans, is a fitting site. The Department of Health and Human Services will award a planning grant so the school can pursue establishing a center for bioethics in research and health care. The center will serve as a museum of the study and support efforts to address its legacy and strengthen bioethics training.

Second, we commit to increase our community involvement so that we may begin restoring lost trust. The study at Tuskegee served to sow distrust of our medical institutions, especially where research is involved. Since the study was halted, abuses have been checked by making informed consent and local review mandatory in federally-funded and mandated research.

Still, 25 years later, many medical studies have little African American participation and African American organ donors are few. This impedes efforts to conduct promising research and to provide the best health care to all our people, including African Americans. So today, I'm directing the Secretary of Health and Human Services,

Donna Shalala, to issue a report in 180 days about how we can best involve communities, especially minority communities, in research and health care. You must -- every American group must be involved in medical research in ways that are positive. We have put the curse behind us; now we must bring the benefits to all Americans. (Applause.)

Third, we commit to strengthen researchers' training in bioethics. We are constantly working on making breakthroughs in protecting the health of our people and in vanquishing diseases. But all our people must be assured that their rights and dignity will be respected as new drugs, treatments and therapies are tested and used. So I am directing Secretary Shalala to work in partnership with higher education to prepare training materials for medical researchers. They will be available in a year. They will help researchers build on core ethical principles of respect for individuals, justice and informed consent, and advise them on how to use these principles effectively in diverse populations.

Fourth, to increase and broaden our understanding of ethical issues and clinical

research, we commit to providing postgraduate fellowships to train bioethicists especially among African Americans and other minority groups. HHS will offer these fellowships beginning in September of 1998 to promising students enrolled in bioethics graduate programs.

And, finally, by executive order I am also today extending the charter of the National Bioethics Advisory Commission to October of 1999. The need for this commission is clear. We must be able to call on the thoughtful, collective wisdom of experts and community representatives to find ways to further strengthen our protections for subjects in human research.

We face a challenge in our time. Science and technology are rapidly changing our lives with the promise of making us much healthier, much more productive and more prosperous. But with these changes we must work harder to see that as we advance we don't leave behind our conscience. No ground is gained and, indeed, much is lost if we lose our moral bearings in the name of progress.

The people who ran the study at Tuskegee diminished the stature of man by abandoning the most basic ethical precepts. They forgot their pledge to heal and repair. They had the power to heal the survivors and all the others and they did not. Today, all we can do is apologize. But you have the power, for only you -- Mr. Shaw, the others who are here, the family members who are with us in Tuskegee -- only you have the power to forgive. Your presence here shows us that you have chosen a better path than your government did so long ago. You have not withheld the power to forgive. I hope today and tomorrow every American will remember your lesson and live by it.

Thank you, and God bless you. (Applause.)

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

May 16, 1997

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Thank you, and God bless you. (Applause.)

END

2:41 P.M. EDT

WHITE HOUSE TUSKEGEE CEREMONY

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

I. PURPOSE

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

II. BACKGROUND

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

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

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

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

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

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

III. PARTICIPANTS

Pre-brief participants

Maria Echaveste

Kitty Higgins

Ben Johnson

Elizabeth Drye

David Satcher

Ann Lewis

Carolyn Curiel

Event Participants

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

Members of Congress

Representatives of National Black Associations and Organizations

Government Officials

IV. PRESS PLAN

Open Press

V. SEQUENCE OF EVENTS

- o Event briefing for YOU and THE VICE PRESIDENT in the Red Room
- o YOU and THE VICE PRESIDENT proceed to Blue Room and greet the Following guests:
 - Dr. David Satcher
 - Congresswoman Maxine Waters
 - Congressman Earl Hillard
 - Congressman Louis Stokes
 - Herman Shaw
 - Charlie Pollard
 - Howard Carter
 - Fred Simmons
 - Fred Moss
 - Ms. Gwendolyn Cox, Daughter of Sam Doner, Survivor
 - Mr. North R. Hendon, Grandson of Ernest Hendon, Survivor
 - Attorney Fred Gray (Counsel for survivors)
- o Survivors are announced into the East Room
- o YOU and THE VICE PRESIDENT are announced into the East Room Accompanied by Dr. Satcher and Mr. Shaw.
- o THE VICE PRESIDENT makes remarks and introduces Dr. Satcher.
- o Dr. Satcher makes remarks and introduces Mr. Shaw.
- o Mr. Shaw makes remarks and introduces YOU.
- o YOU MAKE remarks and proceed to the Blue Room for receiving line.

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

VI. REMARKS

To be provided by Speech writers

VII. ATTACHMENT

1) Biographic information on survivors

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

Today, President Clinton recognized the injustice done to the participants of the Public Health Service syphilis study in Tuskegee, Alabama. The President formally apologized to survivors, their families and the nation for the unethical study that left 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.

- 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.
- o **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.
- o **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.
- o **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.

CHRONOLOGY

Public Health Service Syphilis Study in Tuskegee

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

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

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

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DRAFT TUSKEGEE QUESTIONS AND ANSWERS

Political + Policy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and other agencies

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.