

REPORT ON CHARGE II

Transmittal Note from Chairman of Subcommittee on Charge II

This report on Charge II was prepared by the Subcommittee on Charge II (Ronald H. Brown, J.D., Jean L. Harris, M.D., F.R.S.H., Jay Katz, M.D., F.A.C.P., Fred Speaker, J.D., Jeanne C. Sinkford, D.D.S., Ph.D., Secretary, Vernal G. Cave, M.D., F.A.C.P., Chairman).

The provisional basis for this report which was the result of the earliest deliberations the panel dealt with is now amply substantiated by our documentations, conclusions, and recommendations under Charges I and III. On behalf of the entire subcommittee, the Chairman expresses deep thanks and appreciation for their splendid cooperation to Dr. Robert C. Backus, Mr. Robert Rawles, Mr. James Morant, Mrs. Jacqueline Eagle, and Mrs. Bernice M. Lee.

LETTER OF TRANSMISSION

October 27, 1972

Merlin K. DuVal, M.D.
Assistant Secretary for
Health and Scientific Affairs
Department of Health, Education,
and Welfare
Washington, D.C. 20201

Dear Dr. DuVal:

As Chairman of the Tuskegee Syphilis Study Ad Hoc Advisory Panel, I enclose our first report to you, relating only to the second charge of the three assigned to the Panel. Although one member of the Panel was in hospital on the day this report was put into form for transmission to you, her written suggestions concerning an earlier draft have been incorporated. Hence, the report represents concurrence of the Panel as a whole.

You will note that our initial recommendations call for some very early steps on your part. We as a Panel, along with the excellent staff that is assisting our work, stand ready to help you to implement the recommendations in any way.

It is our understanding, on the basis of the statements you made to us at our orientation meeting, that our reports to you, including this initial one, will be made public only by you whether or not you decide to accept and implement our recommendations.

Since agreeing on the enclosed report, two-thirds of our Panel have been able to engage in a first-hand investigation for two days, in Macon County, Alabama. Nothing that we have discovered through this recent field visit has afforded us cause to alter any part of the enclosed report concerning the second charge. The first-hand investigation, brief as it has been, has provided us with information and new understandings that will prove of great value in our subsequent work on charges 1 and 3.

Sincerely,

(sgd.) Broadus N. Butler, Ph.D.

Chairman
Tuskegee Syphilis Study
Ad Hoc Advisory Panel

October 25, 1972

**INITIAL RECOMMENDATION
OF THE
TUSKEGEE SYPHILIS STUDY AD HOC
ADVISORY PANEL**

The Charter of the Tuskegee Syphilis Study Ad Hoc Advisory Panel, issued on August 28, 1972, mandates advice on three specific aspects of the study of untreated syphilis initiated by the Public Health Service in 1932. Item two of the three charges requires the Panel to:

"Recommend whether the study should be continued at this point in time, and if not, how it should be terminated in a way consistent with the rights and health needs of its remaining participants."

Initially, the Panel has limited its deliberations and recommendations exclusively to this charge, and the recommendations contained in this report are intended to respond solely to this specific issue.

In determining our initial recommendations, the Panel has made inquiries which have led us to accept certain evidence outlined here. Though our research on the background and conduct of the Tuskegee Syphilis Study has not been completed, the Panel is satisfied that in the light of its preliminary findings, which will be fully documented at a later date, the recommendations set forth below are fully justified.

BACKGROUND

Since 1932, under the leadership, direction and guidance of the United States Public Health Service, there has been a continuing study, centered in Macon County, Alabama, of the effect of untreated syphilitic infection in approximately 400 Black male human beings previously infected with syphilis as subjects. In the pursuit of this study approximately 200 Black male human beings without syphilis were followed as controls. No convincing evidence has been presented to this Panel that participants in this study were adequately informed about the nature of the experiment, either at its inception or subsequently.

The United States Public Health Service from the onset of the study has maintained a continuous policy of withholding treatment for syphilis from the infected subjects. There was common medical knowledge, before this study, that untreated syphilitic infection produces disability and premature mortality. To date, including its earliest reports, this study has confirmed that untreated syphilitic infection produces disability and premature mortality. Since the late 1940's numerous medical

authorities have recommended treatment for syphilis with penicillin in all stages of the disease, including late latent syphilis and tertiary syphilis.

A technical and medical advisory panel convened in 1969 by the United States Public Health Service is reported to have recommended with some ambiguity, that the participants surviving at that time should not be treated. It is estimated that approximately 125 of the participants, including 50 of the controls, are still alive; and the current health status of the participants in the Tuskegee Study is not known.

RECOMMENDATIONS

I. Termination:

The study of *untreated* syphilis in Black males in Macon County, Alabama, now known as the "Tuskegee Syphilis Study," should be terminated immediately. With this most basic recommendation, the participants involved in this study are to be given the care now required to treat any disabilities resulting from their participation. In furtherance of this goal we recommend:

- A. That Select Specialists Group, composed of competent doctors and other appropriate persons, with experience in the problems arising from this study, be appointed by the Assistant Secretary for Health and Scientific Affairs, DHEW, no later than fifteen days after the adoption of these recommendations.
- B. That the members of the Select Specialists Group have had no prior involvement in the Tuskegee Syphilis Study.
- C. That the Select Specialists Group be composed of, but not necessarily be limited to, a dermatologist with experience in syphilology who will serve as Chairman, two internists (at least one of whom shall be a cardiologist), a radiologist, a neurologist, an ophthalmologist, a psychiatrist, a doctor of dental surgery, and a social worker.
- D. That the Select Specialists Group be solely charged to apply its expert diagnostic and therapeutic skills in order to safeguard the best interests of the participants and of others who may have been infected as a result of the withholding of treatment from the participants.
- E. That the Select Specialists Group be vested with the full legally permissible medical authority, medical supervision and medical judgment with regard to the treatment or referral of all of the surviving participants and others within and outside Macon County who may be identified, in cooperation with the

- appropriate medical societies and Health Departments.
- F. That the Public Health Service immediately inform all surviving participants of the nature of their participation in the study, and the desire of the Public Health Service to assess their current health status.
 - G. That the members of the "Subcommittee on Medical Care" of the Tuskegee Syphilis Study Ad Hoc Advisory Panel be ex-officio members of the Select Specialists Group to function primarily as liaison between the Select Specialists Group and the entire Panel.
 - H. That on completion of its charge, the Select Specialists Group submit a detailed report about its activities to the Tuskegee Syphilis Study Ad Hoc Advisory Panel through its Chairman. This report shall include, but by no means be limited to, the reasons for administering or withholding penicillin and other drug treatment for syphilis from untreated participants who are infected with syphilis.
 - I. That the highest priorities be given to this mission so that the charge to the Select Specialists Group shall be completed at the earliest possible date consistent with the best interests of the participants and the ethical responsibilities of the Department of Health, Education, and Welfare.

II. Assessment, Treatment and Care

- A. That arrangements be made with *all speed* for the immediate health assessment, treatment and care of all persons included in the study in a suitably adequate facility easily accessible to the surviving participants. That whenever a participant expresses the wish to be cared for or treated by physicians of his own choice, such choices be respected and given all necessary support.
- B. That every effort be made to preserve confidentiality with respect to the identification of any participant.
- C. That the United States Public Health Service's epidemiologists be mobilized, on a highest priority basis, to assist in locating all surviving participants as well as others who may have been infected as a result of the withholding of treatment from the participants.

III. Encouragement of Participation:

- A. That adequate arrangements be provided for maintaining present standards of living during the evaluation and treatment periods in order to minimize any economic barriers to the cooperation of the participants.
- B. That at a minimum, any benefits which have been promised to the participants in the past continue to remain in effect.

Respectfully submitted,

Broadus N. Butler, Ph.D.
Ronald H. Brown
Vernal Cave, M.D.
Jean L. Harris, M.D.
Seward Hiltner, Ph.D., D.D.
Jay Katz, M.D.
Jeanne C. Sinkford, D.D.S., Ph.D.
Fred Speaker
Barney H. Weeks

October 27, 1972

TO: ASSISTANT SECRETARY FOR HEALTH
AND SCIENTIFIC AFFAIRS

FROM: JAY KATZ, M.D.

SUBJECT: ADDENDUM TO PANEL REPORT ON
CHARGE II

I entirely concur in the Panel's recommendations and in the reasons given therefor. However, one additional piece of evidence lends even greater conviction, if any is still needed, to the decision to terminate the Tuskegee Syphilis Study. We have been informed that no scientific knowledge of any consequence would be derived from its continuation. The Panel felt that recording this fact might create the impression that it was *the* major reason for terminating the study. I believe that its inclusion should not, and would not, be so construed.

There are cogent reasons for not dismissing the issue of scientific merit. As long as society continues to favor the pursuit of medical knowledge for the possible benefit of the patients participating in research or for the benefit of future patients, a balancing of risks and benefits is inevitable. We must acknowledge this reality in order to confront such questions as: Do we wish to preserve this balancing process and, if we do, how might we learn to minimize inevitable harm to subjects and science? We urgently need to establish an orderly process which will permit the assessment of the conflicting claims inherent in decisions to initiate, continue or terminate research projects. Such an assessment might proceed in four steps: (1) a relentless inquiry into the harmful consequences to the participants; (2) an appraisal of the benefits which may accrue to science as well as to society; (3) a balancing of the risks to the participants against the benefits to them and/or science; and (4) an anticipatory rebuttal to the charge that either the interests of the participants or of science have not been sufficiently considered. In the light of the finding that no interests of science are surrendered by terminating the Tuskegee Syphilis Study, there is nothing to balance and nothing to rebut, and continuance of the study would for this reason alone be inadmissible.

I appreciate that had the conclusion been otherwise, the study would in all probability still have to be terminated because of the other findings set forth in the Panel's report, findings which will be further explored in our deliberations with respect to Charge One ("whether the study was justified"). Moreover, I should note that the four factors, listed above, do not directly address

themselves to such other important considerations as: who should be selected for research, what disclosures must be made to participants in research, etc. This will surely be considered in our response to Charge Three ("whether existing (research) policies are adequate and effective"). Finally, I also leave unconsidered for now another question which emerges from the finding of "no scientific merit": why was the study not terminated at a time prior to the appointment of this Panel? One of the benefits of including a finding of scientific merit in every assessment is that many more projects might be terminated sooner, because the reviewer would be hard pressed to make an affirmative finding on this issue.

Respectfully submitted,

(sgd.) Jay Katz, M.D.
