## YALE LAW SCHOOL

**NEW HAVEN, CONNECTICUT 06520** 

TO: THE ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS

FROM: JAY KATZ, M.D.

**TOPIC:** RESERVATIONS ABOUT THE PANEL REPORT ON CHARGE I

I should like to add the following findings and observations to the majority opinion:

- (1) There is ample evidence in the records available to us that the consent to participation was not obtained from the Tuskegee Syphilis Study subjects, but that instead they were exploited, manipulated, and deceived. They were treated not as human subjects but as objects of research. The most fundamental reason for condemning the Tuskegee Study at its inception and throughout its continuation is not that all the subjects should have been treated, for some might not have wished to be treated, but rather that they were never fairly consulted about the research project, its consequences for them, and the alternatives available to them. Those who for reasons of intellectual incapacity could not have been so consulted should not have been invited to participate in the study in the first place.
- (2) It was already known before the Tuskegee Syphilis Study was begun, and reconfirmed by the study itself, that persons with untreated syphilis have a higher death rate than those who have been treated. The life expectancy of at least forty subjects in the study was markedly decreased for lack of treatment.
- (3) In addition, the untreated and the "inadvertently" (using the word frequently employed by the investigators) but inadequately treated subjects suffered many complications which could have been ameliorated with treatment. This fact was noted on occasion in the published reports of the Tuskegee Syphilis Study and as late as 1971. However the subjects were not apprised of this possibility.
- (4) One of the senior investigators wrote in 1936 that since "a considerable portion of the infected Negro population remained untreated during the entire course of syphilis. .an unusual opportunity (arose) to study the untreated syphilitic patient from the beginning of the disease to the death of the infected person." Throughout, the investigators seem to have confused the study with an "experiment in nature." But syphilis was not a condition for which no beneficial treatment was available, calling for experimentation to learn more about the condition in the hope of finding a remedy. The persistence of the syphilitic disease from which the

- victims of the Tuskegee Study suffered resulted from the unwillingness or incapacity of society to mobilize the necessary resources for treatment. The investigators, the USPHS, and the private foundations who gave support to this study should not have exploited this situation in the fashion they did. Unless they could have guaranteed knowledgeable participation by the subjects, they all should have disappeared from the research scene or else utilized their limited research resources for therapeutic ends. Instead, the investigators believed that the persons involved in the Tuskegee Study would never seek out treatment; a completely unwarranted assumption which ultimately led the investigators deliberately to obstruct the opportunity for treatment of a number of the participants.
- (5) In theory if not in practice, it has long been "a principle of medical and surgical morality (never to perform) on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science" (Claude Bernard 1865), at least without the knowledgeable consent of the subject. This was one basis on which the German physicians who had conducted medical experiments in concentration camps were tried by the Nuremberg Military Tribunal for crimes against humanity. Testimony at their trial by official representatives of the American Medical Association clearly suggested that research like the Tuskegee Syphilis Study would have been intolerable in this country or anywhere in the civilized world. Yet the Tuskegee study was continued after the Nuremberg findings and the Nuremberg Code had been widely disseminated to the medical community. Moreover, the study was not reviewed in 1966 after the Surgeon General of the USPHS promulgated his guidelines for the ethical conduct of research, even though this study was carried on within the purview of his department.
- (6) The Tuskegee Syphilis Study finally was reviewed in 1969. A lengthier transcript of the proceedings, not quoted by the majority, reveals that one of the five members of the reviewing committee repeatedly emphasized that a moral obligation existed to provide treatment for the "patients." His plea remained unheeded. Instead the Committee, which was in part concerned with the possibility of adverse criticism, seemed to be reassured by the observation that "if we established good liaison with the local medical society, there would be no need to answer criticism."
- (7) The controversy over the effectiveness and the dangers of arsenic and heavy metal treatment in 1932 and of penicillin treatment when it was introduced as a method of therapy is beside the point. For the real issue is that the participants in this study were never informed of the availability of treatment because the

investigators were never in favor of such treatment. Throughout the study the responsibility rested heavily on the shoulders of the investigators to make every effort to apprise the subjects of what could be done for them if they so wished. In 1937 the then Surgeon General of the USPHS wrote: "(f) or late syphilis no blanket prescription can be written. Each patient is a law unto himself. For every syphilis patient, late and early, a careful physical examination is necessary before starting treatment and should be repeated frequently during its course." Even prior to that, in 1932, ranking USPHS physicians stated in a series of articles that adequate treatment "will afford a practical, if not complete guaranty of freedom from the development of any late lesions..."

In conclusion, I note sadly that the medical profession, through its national association, its many individual

societies, and its journals, has on the whole not reacted to this study except by ignoring it. One lengthy editorial appeared in the October 1972 issue of the Southern Medical Journal which exonerated the study and chastised the "irresponsible press" for bringing it to public attention. When will we take seriously our responsibilities, particularly to the disadvantaged in our midst who so consistently throughout history have been the first to be selected for human research?

Respectfully submitted,

(sgd.) Jay Katz, M.D.