

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.
