

April 12, 1994

MEMORANDUM FOR RECORD

SUBJECT: Trip Report -- Congressional Hearing on Saenger Research, Cincinnati, Ohio, April 11, 1994

1. The Subcommittee on Administrative Law and Government Relations, chaired by Representative John Bryant of the House Judiciary Committee, convened "Hearings on Radiation Experiments Conducted By the University of Cincinnati Medical School with Department of Defense Funding" at 10:00 a.m., Monday, April 11, 1994, in U.S. District Courtroom Number 822, U.S. Post Office/Federal Courthouse Building, Fifth and Walnut Streets, Cincinnati, Ohio. A copy of the hearing's agenda is at Tab A. Subcommittee members in attendance were Representative Bryant and Representative David Mann (of Cincinnati). Representative Robert Portman (also from the Cincinnati area), although not a Committee member, was invited to sit on the panel since his district includes the University of Cincinnati.
2. In his opening statement Representative Bryant explained the Subcommittee's interest. I was not able to obtain a copy of Representative Bryant's opening statement. The following summary is from my notes. He stated that the Committee has jurisdiction over compensation issues for the Government and that the Committee had already conducted hearings (February 2, 1994) that included testimony on the Cincinnati experiments. He viewed these experiments as serious and "most egregious" with one of the fundamental issues being informed consent. Representative Bryant expected the committee to be involved with this subject for a while to come and that more hearings would be conducted before there was a markup for any legislation.
3. At Tab B are copies of Representatives Mann's and Portman's opening statements. Representative Mann's statement identified two primary issues of concern: "1) Did the patients knowingly consent to the experiments? And (2) Was this type of treatment appropriate for the types of illnesses suffered by the patients. By this I mean, absent the \$8,000 - \$10,000 per patient in Department of Defense funding would whole body radiation have been an appropriate therapy?"

Representative Portman also stated two issues of concern to the Federal government in his opening statement. "The first is the appropriateness of the Federal government compensating the victims and their families. If it is determined that the patients involved were not clearly informed in accordance with the standards for informed consent in force at the respective times of the experiments, or that these experiments became vehicles primarily for testing not treatment, then compensation, in my view, would be appropriate.

Representative Bryant said, if the information was important why didn't the Department of Defense (DoD) fund work on its own people, or would the DoD not have funded research such as this on its own people. Dr. Soper cited the 1953 directive on use of military personnel in research. He was then asked if DoD attempted to find out what was going on with patients when contracts were modified or renewed. The lack of records, which Dr. Soper pointed out was due in part to regulatory-based destruction criteria, did not indicate this was done. Representative Bryant then asked if project officers monitored effects on patients. Again, Dr. Soper's response was that the available records did not indicate such, although the DoD has been trying to locate project officer files. He did relate his own experiences as a contracting officer at DNA as an example of what was required in the 1970s/1980s. In response to the question of whether any of the contract officers were still alive, Dr. Soper said that one officer is dead, one officer is medically impaired, and that one he spoke with offered little information.

When his turn at questioning came, Representative Mann asked if anyone in the Pentagon cared where the patients came from, their race, IQ, and their socio-economic background. Dr. Soper responded that nothing in the files indicated such concern. Dr. Soper was then asked if total body radiation experiments were done at the University of Cincinnati prior to and after the cessation of Pentagon funding. Dr. Soper indicated that similar research was being conducted at Baylor University and Sloan-Kettering Hospital. Dr. Soper referred again to the Sloan-Kettering and Baylor studies later when asked if he was aware of any other studies funded by DoD. Representative Mann then asked how a proposal was submitted to the Pentagon in the 1950s. Dr. Soper replied that he was not completely familiar with the procedures in force then, but did describe current policy. He was then asked by Representative Mann if the 1953 document, which was once Top Secret, was now unclassified and, if so, wanted a copy for the record. Dr. Soper said a copy would be provided. Representative Mann also asked if the informed consent provision of this memo, which Dr. Soper pointed out contained detailed information, applied in the case of the Cincinnati experiments. Dr. Soper said no because it did not cover medical research conducted under contract. Representative Mann also wanted to know if the DoD knew why the National Institutes of Health (NIH) discontinued its support of the experiments in the 1960s because of "moral concerns". Dr. Soper replied that the DoD was trying to find information on this matter.

Preceding his questions, Representative Portman expressed his concerns about the DoD's efforts in regard to contacting former DoD personnel involved with the Saenger research and the need to redouble efforts to identify DoD's role. Representative Portman then asked if there was any documentary evidence that the radiation was for the purpose of treating cancer. Dr. Soper replied that early documents do not reflect treatment of cancer, but that it is open for interpretation and that the Advisory Committee will make an evaluation. When asked if there should have been more oversight Dr. Soper said absolutely yes. Representative Portman then wondered why there was no DoD-produced summary report on the experiments once they were discontinued and asked if the lack of a report was unusual. Dr. Soper replied a report would have been helpful. Representative Portman then wanted to know if there are any documents out there that Dr. Soper was aware of that have not been released. Dr. Soper replied not to his knowledge and reiterated the Department's desire to bring things out in

I believe the second issue from the federal government's standpoint is one of disclosure -- disclosure by the Department of Defense and the Cincinnati General Hospital and all other's involved -- of all relevant information concerning the cases."

Congressman Portman raised subsidiary issues of "full disclosure and safeguards". He noted that the House Government Operations Committee, of which he is a member, "has been exploring the possibility of holding hearings on disclosure of government information and safeguards."

4. Once the Committee's opening statements were completed the hearing began. The hearing was structured so that four panels (grouped by subject, for lack of a better term) appeared before the Committee. Panel I consisted of patient relatives. Panel II consisted of the research sponsors/supporters. Panel III members were those critical of the research. Panel IV was Dr. Saenger.

5. The general format allotted each panel member five minutes for an opening statement. Once witness opening statements were completed, each Committee member was allowed to question the witness. In some cases there were two rounds of questions. For the remainder of this report I will focus on the testimony of Dr. Soper, who appeared as part of Panel II.

6. Dr. Soper was accompanied by CAPT Robert L. Bumgarner, MC, USN, Director of the Armed Force Radiobiology Research Institute and Col. John F. Glenn, U.S. Army Medical Service Corps, who Dr. Soper identified as an expert on Federal, Department of Defense, and Army rules on the use of humans in research. I met Dr. Soper in the lawyer's lounge in the courthouse. I introduced myself, told him I was from JAYCOR and the RECC, and informed him I would be in the audience. I then introduced myself to CAPT Bumgarner and Col. Glenn.

7. Dr. Soper was the first witness from Panel II to speak before the Committee. A copy of Dr. Soper's statement with three attachments are at Tab C. Two of the attachments are the chronologies developed by RECC. It appeared that the five minute constraint on opening statements caused Dr. Soper to paraphrase his opening statement. Dr. Soper did emphasize that the Cincinnati research was to be reviewed by the President's blue ribbon advisory committee. He was followed by Dr. Cox, an expert witness who spoke favorably of the research. The final member of the panel to speak was Dr. Joseph Steger, President of the University of Cincinnati, who essentially pleaded the Fifth Amendment because of litigation over these matters.

8. After the witnesses completed their prepared statements, they were questioned by the committee. As a subjective observation, of all the witnesses who appeared, Dr. Soper received the most extensive questioning, except for, possibly, Dr. Egilman of Panel IV.

7. A summary of the question and answer session with Dr. Soper follows. The quality of the sound system in the hearing room was poor and I could not clearly hear some of what was said from where I was sitting.

open. No documents were to be retained and all that can be found will be released.

Representative Bryant ended Dr. Soper's questioning by returning to the NIH issue.

8. Highlights of other testimony:

a. Dr. Egilman charged that there was a DoD conspiracy that provided funds to targeted hospitals that served poor whites or African Americans, thus exploiting them for nefarious purposes.

b. Dr. Saenger essentially reiterated the points made in his final report. He did provide a clear description on how DoD funds were used. He explained that in the cost of a hospital stay there are expenses for the bed the patient occupies in the hospital, medication received, etc. DoD funds did not pay for these costs, only for supplementary tests and lab work. When asked if he would have gone ahead with the experiments if he had not received DoD funding, Dr. Saenger said yes he would have. He reiterated his claim that it was an unsolicited proposal but did acknowledge that he may have received information that DoD was interested in the type of research he proposed from talking to some people. He said, however, these people did not encourage or tell him to submit a research application.

c. From comments by Representatives Bryant and Portman additional hearings on this particular issue and radiation experimentation in general appears to be a foregone conclusion.

d. Issues that witnesses were questioned about involved informed consent, DoD funding, doses, patient reactions, the validity of the research methodology, patient selection, patient isolation techniques, Federal liability, the purpose of the research, the relationship between DoD and research institutions, oversight, and project officer responsibilities. I imagine that these issues will be relevant, in varying degrees, at other hearings and for other experiments.

e. At least one of the family witnesses alleged that her grandmother's signature on the consent form was forged. Representative Portman asked Dr. Steger if steps were being taken to protect the records in the possession of the University of Cincinnati. As best as I could hear Dr. Steger replied steps have or will be taken to protect the sanctity of the records.

f. In my opinion Dr. Soper acquitted himself very well in an environment that was not friendly.

g. It appeared that both Representatives Mann and Portman relied heavily on the documents provided them by RECC through Dr. Soper. Representative Mann seemed to frequently use and reference the University of Cincinnati's Ad Hoc Committee Report of 1972.

h. Representative Portman questioned Dr. Soper sharply about the existence of additional records relating to these experiments. This issue might be a potential time bomb for DoD. I do not know the extent of the file search at Suitland or the National Archives, but

if somebody goes to either place and finds a sizable cache of DoD files that contain information about the research, which may not be marked project officer or contract files, the DoD's entire effort might be open to question from less than friendly sources.

i. The hearing room was full and media coverage was intense. It was the lead story on the local five o'clock news that I saw in the airport, with more coverage promised later in the newscast.

j. I will do an in-depth review of the material at the tabs when the review of this report has been completed.

9. Dr. Saenger was the last witness. The hearing adjourned at approximately 3:00 p.m.



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