

The Medical Research Center
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BROOKHAVEN NATIONAL LABORATORY

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MEMORANDUM

DATE: July 18, 1973

W Lee
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BOX No. 1
FOLDER COHN-Whole Body Studies

TO: CIRC Committee
FROM: S. H. Cohn, Ph.D. *SHC*
SUBJECT: COMMENTS ON REPLY FROM
E. Saenger on CIRC 36G

There are several major errors and misunderstandings in Dr. Saenger's letter of 6 July 1973 which I wish to bring to the attention of the committee.

1. In evaluating the risk, Dr. Saenger states the radiation dose to the subject as 0.2 rad and adds a RBE factor of 100 to arrive at a dose of 20 rem. The dose, in fact, is .0277 rad and since there are no data for using the RBE of 100, the conservative RBE of 10 (NCRP and ICRP) when applied gives a dose of 0.277 rem!!
2. In criticizing the experimental protocol, an incidence of osteoporosis of 3.6% is derived. Presumably, Saenger derived this by dividing 6 million by the U.S. population, most experts, however, agree that the incidence of osteoporosis in the population of post-menopausal women is well over 25%
3. The question of benefit of the study is raised. It was emphasized in the protocol that if our hypothesis is correct, i.e. that the evidence of osteoporosis is related to the level of estrogen, the women receiving prophylactic estrogens obviously stand to benefit. Those women receiving only Ca supplements will benefit individually from the on-going medical supervision by a group of experts in this study. Should they develop overt osteoporosis, it will be detected early and they will be offered participation in our therapy program.

In this prospective study, the aim is to obtain basic information on the rate of development of osteoporosis and on developing rational bases for therapy or prevention. For example, if our basic hypothesis is correct, i.e. all women in this age group lose skeletal Ca at the same rate, then those who start with an inadequate skeletal mass at 50 will be the first to develop clinical symptoms of osteoporosis. This information will, hopefully, enable us to approach the problem of creating osteoporosis on a more rational basis. Further, I don't believe that it would be difficult to find a group of women who would be willing to spend a few hours a year in order to help in obtaining the required basic information in this disease process. They would, of course, stand to gain ultimately by any knowledge of the disease. For example, of the 50 osteoporotic patients now under study in our program a large number of the daughters of these women have already volunteered.

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4. The criticism is offered that the plan seems vague in that the patient can't determine when she is "within 5 years of menopause". The "5 years of menopause" obviously refers to 5 year post, as the title of the study clearly reads "post-menopausal women".
5. Saenger notes that 300 patients were studied by total-body neutron activation and asks where was this performed? He is clearly not familiar with the program here at BNL and the 12 publications that deal with the clinical applications of this neutron activation technique. In four of these papers that deal with the treatment of osteoporosis, the theory of the experimental use of the total-body Ca (skeletal mass) data is clearly delineated.

The protocol was written for the CIRC Committee who are familiar with previous protocols on these studies and the overall program.

6. I couldn't include reference to Chestnut's paper at the Nuclear Medical Meeting in June 1973, because CIRC 36G was submitted to CIRC in 1972 ---- interesting sidelight!!

Incidentally we are well aware of Chestnut's work and have evaluated the photon absorptiometric technique much more extensively than the U. of Washington group. The report on this study is now in preparation.

7. There are many other points in Saenger's letter that could be rebutted, but in the interest of the "welfare" of the CIRC committee, I will desist.

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