

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

**Interview with
Dr. Eugene Saenger**

**by
Gary Stern
and
Jonathan Engel**

**at
Cincinnati, Ohio**

**on
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Advisory Committee on Human Radiation Experiments

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Interviewers: Gary Stern and Jonathan Engel

GARY STERN: It's October 20, 1994 and we're meeting again with Dr. Eugene Saenger. I'm Gary Stern. With me is Jonathan Engel also from the Advisory Committee on Human Radiation Experiments, Dr. Saenger and Joseph Parker, his attorney. I guess, like I said, we sort of want to ask a few followup questions on the Cincinnati stuff and then move into a couple of other areas. Hopefully, it won't take much more than an hour, hour and a half. We have to leave by 3:30.

I guess one of the topics the Committee is looking into is the whole history of informed consent and the whole issue of ethics in the practice of medicine on human subjects. So we're trying to understand the progression in this area, and I guess you had mentioned last time when we talked about how you instituted written informed consent in 1965, even ahead of the requirements of HEW at the time and the hospital. I guess we want to both - I'd like to ask you first, what was the procedure before that. I guess there was oral consent and how did that work and actually what did you say to the patients and how did you describe things to them?

DR. SAENGER: Well, we had adopted at the onset of our project, had agreed among the several principles who are physicians that patients would have informed consent. Now in this institution, this was sort of the rule, I'm not sure how it is handled in other studies and so on, but

we made this a very final part of our program. Each physician, in talking with the patient would explain what was going on. To the extent they thought was reasonable, would tell you this is a terrible thing or not a terrible thing, or you were going to get very sick or you weren't going to get very sick, and that it may make you feel better or it wouldn't and so on. I was not party to those conversations but the substance of them we had discussed for openers each time the personnel turned over that we wanted this discussed, because this was a thing that I thought was important. Whenever I have handled any patient, I have always made it my business to tell you exactly what was going on.

Anyhow, that's how it started out and we used several physicians. They each may have done this slightly differently, maybe one guy would draw a picture and another guy would try words, so that we felt very comfortable that the patients were given some form of consent. We were able to document these in some of the charts, because it would say, it was explained to the patient, or the patient went home to talk to his family, various things. I don't want to give the idea that it was systematic recording because it wasn't. But in an anecdotal sense, we did.

GARY STERN: So it wasn't a practice to actually make that part of the chart or forms.

DR. SAENGER: Not part of the chart, just part of the - same thing as when you come in and get a physical examination, so you have explained to you what the form of therapy is going to be because you see, these patients would have perhaps surgery, they would have maybe some localized form of radiation where you just treat a particular organ, or they would have some

chemotherapy at the time. When the clinicians, including the medical oncologist and the residents were in on it and so on, would think that they would be offered full-body radiation, or partial body radiation, that this would be explained to the patient within the reasons that he could, you know within the limits of his understanding. As you read the literature on it, informed consent, I have a ton of papers here, we've really gone into this, there's a continual discussion, the theoreticians who say that everybody - my life is my own, I am the captain of my soul and all that good stuff. Then the second thing that happens is, supposing I lay something out so brutally to you that you decide to jump off the cliff or somebody can't understand it. There have been studies that have been going on forever that if you go back and give some involved statement to a patient and you ask him a week or a month later, did he understand it, the guy says, I guess you did, if he wants to stay on your good side or your bad, you never told me a thing. So you have all of these choices.

Anyhow, that's what we did up until we got a directive, I finally found that letter, it just surfaced today by a strange coincidence. We got the letter from the DASA giving us the copy of the document from DOD and HEW where they were talking about investigational drugs and fulfilling the criteria of the FDA and that's the point at which we instituted the written informed consent. 1965.

GARY STERN: That's right. It was your response to that letter about drugs and then ...

DR. SAENGER: Then I said, what the hell. Before we get into some long, drawn out thing about is radiation a drug or it's not a drug, or there's an investigation on it, we're going to have written, informed consent.

GARY STERN: That was the trigger.

DR. SAENGER: That was what I consider to be about a second trigger. The first trigger was when we made the contract with DOD. We had insisted on the item that no patient would be treated or maintained for his cancer using DOD money. And, that was the fundamental concept of this whole program, which separated the patient from the research. Research was actually a study of the by-products of the patient, but it was not connected with therapy, it was two-prong evaluation.

Anyhow, that was the method by which we got into, or the route by which we got into written informed consent. Now, you can always argue that the form is not sufficient, or you would have done it differently, etc., etc. But that argument goes on today.

GARY STERN: I noticed the form did go through several generations, and I guess what was curious how, how that development worked, and what prompted the changes, as well as - because I think the very first form just said we described, this confirms the risks and benefits, or whatever were described. And then later, reading through the various forms, you start to describe what the risks actually are.

DR. SAENGER: Well, we have the opinion at the beginning of this, when we developed the short form, people who discussed the short form with the patients had a pretty good idea what the risks were. When the IRB, it was called the Committee on Faculty Research, they had a variety of names, was formed, we thought that we should, to be good citizens, we should submit our project to this Committee, which was primarily concerned with NIH grants and so on. We could have regarded ourselves as being out of the - you have no jurisdiction of any type. We decided we would go and have them approve this or if they didn't approve it, they could make changes and so on. That was the genesis of all these changes that were made in the consent form, because if you read the history of consent forms, really large collection of papers, everybody takes a swing at what the consent form should be. You end up with three pages, or in some cases, six pages. We have a few examples of consent forms, until a consent form gets so heavy that really nobody could understand it. I think people can devise consent forms for people like yourselves, you can read it and say, the hell with it [Saenger clarification - so what], I'll just sign it, otherwise I won't get treated. There's a pretty good history in the medical literature of the failure of people to understand consent forms. So it depends on who's sitting in the interrogator's seat as to whether you think the consent form that I developed is sufficient or not. Nevertheless, as these suggestions were made, they were made by people who have considerable experience in doing clinical research, and you know, people said we ought to do this, that and the other, and we did it. The final phase of this, which I think is fairly unique, is that within the last two or three years of the project, we had a two-day informed consent.

GARY STERN: How did that work?

DR. SAENGER: It worked fine, because we would explain, Dr. Silberstein was the person who did all this, in that phase. He would explain to somebody the first day what the problems were, what was going to happen, what the risks were, etc. or what the benefits were. Then he had the patient and a representative come back the next day, the representative could have been the patient's mother or cousin, or some family person, or it could have been the patient's minister. And you go through the whole thing with the minister, and the patient and family were all happy with this desperate situation, and the signature would be affixed. It would not be affixed in the first day, but on the second day.

JONATHAN ENGEL: May I ask, did any patients having considered Dr. Silberstein's talk, come back and refuse treatment in some cases?

DR. SAENGER: Yes, we had several people who refused treatment.

JONATHAN ENGEL: Would they then go on to alternative cancer treatments or would they (inaudible).

DR. SAENGER: Some of them said, I give up. And that could be any number. But there were people who refused for various reasons, the family refused and said we're going to go somewhere else. I think it's important to understand in this context, these people all had very far advanced cancer. All this stuff about they gave them the treatment and the mother's life may have been prolonged had they not been treated, are examples of woolgathering.. These people were so

badly off, I was surprised some of them lived as long as they did. The second part of that, when people get in that state, they don't really care if they have informed consent or anything, they just say, doctor, if can you do something for me, just do it. I think this is found over and over again in the medical literature, in talking with people who deal with other desperate diseases. People don't go through all this fine-tuning. They may do that for having your eyes [Saenger clarification - your corneas] scraped off so you don't have to wear glasses, things like that. But for this kind of thing, when you have terminal cancer, you're not in any great way of saying, if I offer you some treatment - doctor, if you think it will help and not hurt me too much, do it.

JONATHAN ENGEL: You're not really in a position to negotiate.

DR. SAENGER: That is correct. At least I don't think the patient is, I mean, if you're very wealthy or very important, or something like that, you may be able to negotiate. But even then the negotiations are pretty lucrative [Saenger clarification - conjectural].

GARY STERN: I know that some of the criticisms of informed consent on the forms that you institute goes to how you laid out the risks. I've read through various critiques, both internal faculty review commissions and outside, and I think there's two different sets. One has to do with the issue of some of the side effects, nausea and stuff like that. People weren't informed that this could cause them this type of reaction and discomfort. And I understand, I think we talked a little bit about this the last time. That was sort of intentional, that was part of the study. I guess, is that your sense, and maybe to followup, I'm curious if it's your feeling that that kind

of study could still be done today. I've talked to various other people who've said, perhaps today under current standards, you have to tell them all side effects and you might not be able to do the type of study you were looking at, in terms of the iatrogenic effects.

DR. SAENGER: We think a lot of that is in the mind of people who know a great deal about people's reactions. My answer to your comment is we have an instruction to all people connected with this, all staff, physicians, nurses, techs, etc., that they were not to ask the question, are you nauseated, do you feel like vomiting, because it's the same suggestibility as in a child, if you say to a child or even an adult, "God, you look terrible today, I mean, is it true that you ate some spoiled corn beef or something? Do you feel like throwing up?" and the first thing you know, you feel sicker than a dog. If I wait until you tell me you're sick, I get a somewhat considerably different reaction.

Now, if we were interested from the DOD point of view in nausea monitoring. (Inaudible). The instructions which were on many of the charts was explicit, was don't ask the patient within the first three days whether they had nausea, vomiting, malaise, etc. This didn't say anything about giving you medication for that, because if you said you were sick or nauseated or whatever, you will get medication for it and so on. At the end of three days, that was the end of that particular study. What the critics have done, in listening to them on several occasions is they try to get this all compounded with the fact that you're going to have nausea, vomiting and all kinds of other symptoms as your cancer progresses, and not only in three days, but in a month or two or six of your downhill course, you're going to have all of these manifestations, So that there's no way we

will take any responsibility for the development of these symptoms, other than that first three-day period. If you read in our 1973 paper, we outline this very explicitly.

GARY STERN: So those warnings and discussions didn't apply after three days, and after then

DR. SAENGER: And it's all there, it's all written down, it's not a matter of interpretation.

GARY STERN: Then the question is, if you weren't doing the DOD study and just treating the same people with the same treatments of radiation without having that specific concern, would you have put that on, would you normally put that on the informed consent, and tell them this as part of the risk, you might experience nausea.

DR. SAENGER: Would I do that? I would not do that because of just the reason I said. I mean, most of these people, if they get nauseated or vomit, you're going to see that, and these are very explicit things. It's not some sort of thing to do on your bed count. If you start to throw up and all that, I think you would get taken care of. But again, if you tell everybody all the terrible things that are going to happen, the patient becomes more likely to have the complaints. My wife the other day had some little tumors taken off her face. After she came home, the next week or two, she became very uncomfortable. one of them is here. one of them is there. So I said to the plastic surgeon, you know my wife is having a horrible time. You know, "didn't you tell her about that?" He said, "no I knew she was miserable." And, this was a very painful procedure because you stretch the skin and all that. "But if I tell her this she could really be

climbing the wall." Well, she figured this all out, you know. She got through it. Surprisingly she would. But again, it would have been even more upsetting had she been going around feeling (inaudible) I think this is generally the thing, mostly - I spent three weeks in the hospital this summer. If I had known all the things I found out, I would have had a very bad time. That depends on your philosophy. I guess what people have to know.

GARY STERN: Right. Well, the other area, issue that has been raised has to do with potential risk of death from radiation itself, especially at the higher dose radiation from the bone marrow suppression, whether to the extent there perceives to be the risk, heightened risk of death from the radiation treatment, patient should have been informed of the possibility that there's a 1 in 4 possibility or 1 in 10, whatever. I'm curious whether, you have feelings about that.

DR. SAENGER: My feeling about that, in this particular patient of this type, to say that your chances are 1 in 10 or 1 in 5 or 1 in 3 of dying within a week, two weeks, six weeks, eight weeks, or 2 years, is not the kind of guesstimate I would care to make. If I took a person like yourself and you had a tumor of certain size and degree of malignancy, if you're reasonably healthy going into it and all, then we can make some guesstimates. When we go back over the data, and we compared our patients to patients who had not had therapy within our group, or patients who had done other studies, we had found that our patients did not deviate in any way from what a group of patients of a similar size would have manifest had they been treated by some other method. So when you look at, you see, you can't really tell, in my judgment. You

take one patient and you say, I'm going to determine what your outcome is going to be.

Compared to what?

GARY STERN: I think in reviewing your second proposal in '66, '67, a couple of the faculty did say, "well, the current data seems to suggest that there might be a 1 out of 4, or 25% of the patients you treated so far have died in a short time, possibly from these effects." They were concerned about it and I think their response was though you can deal with this through the consent process by just telling people, there's, at least experience to date that suggests that there might be a 1 in 4 chance.

DR. SAENGER: I remember that point, but I was interested if we had been able to determine which patients were going to die early. We presumably would have all those patients early on in the study die, and then we would have said, "hah, we recognize these criteria indicate early death," so we'll eliminate all those patients from the study. And, we'll have them all bunched up in the period say 1960-62 or 63 and we'll have all the long life patients out at the end because we know much more about how to pick patients. The fact of the matter is, the patients were pretty randomly distributed through the 10-year period, 11 years. These are pretty skilled doctors. They were some of our leading oncologists here and around the country. If they had been able to be that good at picking these far advanced patients, the patients would have been grouped, the early deaths would have been grouped early on. One of the other things we'd say, "well we notice in comparison patients," so we would have done some very sick patients and included them all at the end. But if they're randomly distributed along, what does that tell you about my

[Saenger clarification - our] judgment? It may be somewhat limited. It's very hard to tell people when they're going to die, [Saenger clarification - considering the extent of their disease].

GARY STERN: Is that your sense, because I think, again we're trying to understand, from the timeframe back then and the current timeframe in the development of the issue of informed consent, that today, if you had a sense, just a statistical sense, would you think today more likely that that would be a standard part of informed consent, that even if we don't know specifically in your instance, we know that a statistical matter is that there's a potential risk of death, and would there be any reason not to tell people that?

DR. SAENGER: The potential risk of death, I mean, whether it's a death in two weeks or six weeks, or eight weeks. What will I say to them? What will I say to you if you may die in a week but you may go six? To me, it's very unrewarding, this kind of speculation. I know if you don't have your hand in the tiller, it's very easy to make statements like this. But when you're dealing with patients...

GARY STERN: I guess the suggestion was that there is, especially at a high dose of radiation, does cause bone marrow suppression in a certain timeframe that I mean as you say in the forms that can lead to infection and bleeding, which then will be treated. And I guess my understanding is the possibility that, you know, depending on the conditions, that that infection could cause serious complications and possibly death from the suppression itself and I guess it

would be that specific reaction to the radiation treatment that raises the potential. That's what we're curious about. Again, that's what others seem to have commented on, at least.

DR. SAENGER: I'm sure these are all important points. I don't say that the questions are not important. All I'm saying is that the solution, I mean the right answer. However, the right answer is how do you determine what's right? In other words, if I say to you, you should've recognized this patient was very, very sick and was going to die. The worst of it is the patient didn't die. The best example of that is in those plutonium cases that you're looking into. The problem with the plutonium cases and why they raised so much hell about it was not [Saenger clarification - complained so vigorously about it was not] the fact that the patients died, it was the patients who didn't die who came along four years later, doc, I'm loaded with plutonium. You see, and everybody said it's the most disgraceful thing I've ever heard in (inaudible). The idea was that they were to take patients who were so sick that they wouldn't live, they could follow the metabolism for a week or two or three, and then the patients would kind of wither up and die and they'd all be thrown in the bone yard and that would be the end of it. Then these patients had the nerve to live you see, and the only think that hasn't happened yet is that somebody hasn't come along saying, "if we hadn't given them that plutonium, they wouldn't have lived so long." You see, and that sounds like sort of a dumb question, but when you start to think about it a little bit. And I mean still that claim is as good as any other.

GARY STERN: It's difficult because I think, my sense is today, and actually my uncle was diagnosed with cancer of the colon and just this week is starting chemotherapy and there's

certainly been discussion about what he wants to know. What all the options are, what the effects are? What are the potentials at every sort of level. He's sort of very keen minded about that, understanding kind of all the details. It seems like more common today that there would be, could be at least a kind of a detailed discussion of the side effects and even, my understanding of chemo as well, there's ...

DR. SAENGER: Has he been operated on?

GARY STERN: Yes, he was already operated on.

DR. SAENGER: And they found that the tumor was not totally removed, so they want to give him chemotherapy.

GARY STERN: That's right.

DR. SAENGER: The question now is, how much, what condition is he in? How old is he? How much vigorous does he have? And, what does he really want to know? It's always interesting to make a speculation on one case, but since you don't even look at this in a statistical sense, that's why I say (inaudible). And the other thing, the question that comes in is that in, I think even in our daily reports, and you know all these cases that have been written up, we don't go into the prior, the details of the prior therapy. A lot of these people had a lot of prior therapy with chemicals and radiation and so on. In one small section of their life, we had what turns out

to be rather modest doses of radiation. We've traced this all the way up through 1991, you see and people were getting doses of anywhere from 600 to 1,000 rad, either whole or partial body radiation during the '80s, so what we were doing couldn't have been such a great thing.

[Saenger clarification - In order to clarify my responses to the last several questions and comments, I take the liberty of inserting a paragraph from our November 14, 1962 DASA report (DA-49-146-XZ-029), page 2. "Nevertheless, it is essential to consider further well planned studies in patients so long as the following criteria are fulfilled: 1) There is a reasonable change of therapeutic benefit to the patient. 2) The likelihood of damage to the patient is no greater than that encountered from comparable therapy of another type. 3) The facilities for support of the patient and complications of treatment offer all possible medical services for successful maintenance of the patient's well being.

The type of patient usually selected for whole body radiation exposure is an individual with cancer which is far enough advanced either by direct extension of tumor or by metastatic spread so as to eliminate consideration of attempts at curative therapy. Usually these patients receive nonspecific supportive treatment of palliative treatment by surgery, radiation or chemicals. The consequence of these forms of therapy are usually helpful but sometimes the sequelae or complications of the various treatments are in themselves life threatening and constitute a hazard to the patient. Hence, whole body radiation therapy is no more likely to produce untoward sequelae than many other currently accepted treatments of other types."]

GARY STERN: Actually, I wanted to ask you about that, as well. You've mentioned to us and in your Congressional testimony as well that subsequently, they're using much higher doses. I'm curious what your understanding is, what those doses are used for. Are they used for anything other than bone marrow transplants, where I think it is pretty common to use high doses and for hematologic disorders. Or are they used for other types of localized, solid tumor treatments as well?

DR. SAENGER: The way this whole situation evolved was that between say, 1970 and 1985, roughly, something like that, were a considerable number of studies where patients were given larger doses of either whole or partial body radiation, to see if, to relieve pain, which was one of the major indications, and some people thought they could change the relationship between the host and the patient, I mean, between the host and the tumor. But subsequently now, it's gone mostly to giving massive doses of chemicals, then giving radiation to suppress the bone marrow, take the bone marrow out, give more radiation, to give more chemicals, give drugs, whatever, and then before the marrow fails, you would reinfuse the marrow that you had taken out, the autologous marrow, and then the patient can recover. So that's a somewhat different approach. In the evolution of where we were, way back to now, and there's no question there's a considerable change in the way these entities are used. but it didn't all stop when in 1971. I mean there were a number of trials carefully done. A lot of people said this was very good therapy, this considers the treatments went on in 1994, it doesn't make it quite as important as it did then, with the exception of the use of bone marrow suppression in the need for autologous marrow. That's the principle, and for tumors other than hematological tumors, were principally addressed.



JONATHAN ENGEL: Is there a judgement call? The way you stated it, effectively, the DOD research was really about the analysis of the excretion of deoxycytidine effectively, the crux of the DOD project is really the analysis of the excretion of the deoxycytidine and dosimetry in the urine. Had you not started on this project back in 1960, would you have turned to total body radiation for treatment in mass cancer independent of the DOD? I'm sort of curious if you were considering that type of therapy independent of this kind of DOD study.

DR. SAENGER: I was obviously considering it because otherwise, how could we have done it? There's a question that we just take these patients and treat them for purposes of our DOD contract. I don't think I would have been comfortable in that. Here again, this was mentioned early on that we were interested, and the reason we waited for a long time was that we wanted to get sufficient numbers of patients to determine whether the treatment was effective or not. When the president of the university cut off the contract, we stopped it.

GARY STERN: Actually, I want to ask you two points related to that. As we just mentioned, that has been another criticism that you were doing the treatments solely because of the DOD contract. (end of side 1)

DR. SAENGER: We've been preparing this for some time for a variety of different purposes, but in here we have some material which may, we've got one on informed consent and one of them here is called "Was the treatment meant therapeutically?" and the other one is "How can the quality of life and length of life of the cancer patient be determined?"

GARY STERN: That's in this packet here?

JOSEPH PARKER: I can't remember if it's last time he gave the history (inaudible).

GARY STERN: Yeah, you did give us that. No, you did explain that, because one question has been you submitted a proposal to DOD in 1958, it took them two years essentially to approve it, and then on approval, the treatments began and I guess a question arises, well if you're planning the treatments anyhow, why wouldn't you have started treatments even without - and you didn't need the DOD money to actually do the treatments. That was just for, and why couldn't you have just started the treatments in '58 when you were ready to start, in a sense, regardless of whether you got the DOD money.

DR. SAENGER: No, we had to, we hired some people. We had laboratory equipment to set up.

GARY STERN: That's for the DOD grant?

DR. SAENGER: Well yes, I mean for the DOD grant and all like that. It proceeded as one, as really a sort of a two-pronged investigation. And you'll see, we try and clarify that in this document here.

GARY STERN: Okay, well that's easy.

DR. SAENGER: And the only part, which I think has sort of been, you know everybody said, "well I'm either DOD or else." When you think about it, I mean, we talked to people who are knowledgeable in working with cancer. The things we were looking at and we discuss that in her, (inaudible) too much. The substances we were looking for and the effects of radiation were equally important in treating cancer as compared to the needs and desires of the DOD. And one of the answers, you would say well why did you take cancer patients, (inaudible) cancer patients? The DOD wants nice healthy young guys like you. I would be delighted to use guys like you, but I don't think you would have volunteered for this. We were interested in the effect on the normal individual, so-called, and the cancer patient and we set out to do this investigation, so it's a little hard to separate these things, even quite as cleanly as some of the critics would like to imply.

GARY STERN: Another point, or question that has been raised is, I think in your original proposal in '58, you say that treatment will only be for males because females, menstruating females would affect amino acid urea would effect your ability to try to find the dosimeter and therefore, I guess my question is, if you were just treating people as cancer patients, whoever came in the door, in a sense, how does that square with only looking for certain types of people. Did you keep out people like menstruating women for treatment because they didn't fit the DOD profile. I mean that what (inaudible). I'm not quite sure how it actually progressed.

DR. SAENGER: There were two points, you always start off in these proposals, if you read enough of them, with stars in your eyes. White males, age 21-29 who are in fine condition. The

first thing you know you get a bunch of arthritics and so forth, females as well as males. You say, well, we certainly want to do a certain amount of work, we need to have material, maybe it would be interesting to see how the sick people compare to the well people, and so on and so forth. I don't think any of these, at least my experience and other people's, proposals, you always get that extra select group of volunteers that you want. We found that we got old people, much older than we had anticipated, we had people who were much sicker than we thought we would get. And before we got as sophisticated at the end there, we got this bone marrow so we wouldn't be afraid of you know, really using people, as we tried to give higher dosing, that was the point at which we got, we were terminated. All we were trying to do was make our protocol as realistic as possible.

GARY STERN: So, in fact, the actual practice in patient selection didn't, wasn't consistent with the original proposal, in a sense. I gathered from the last time we talked that you said the radiation treatment wasn't even experimental in the sense that it was just treating cancer patients as they came in, the assessment was made whether they needed radiation treatment or chemo or surgery, they would go to whichever department, it didn't matter who the patient was. Did that, in fact, transpire, regardless of who the patient was and so if it was a menstruating woman who you thought the best treatment would be the radiation treatment, as opposed to something else, you would use them even if they didn't fit.

DR. SAENGER: I guess one of the major problems is we didn't find enough menstruating women who would be part of this, we had a few women who were in their late 40s and 50s. I

don't think we had any, with the exception of one (inaudible), I don't think we had any very young, we had no young women. And I'm pretty sure none under the age of 30. I don't think under the age of 40.

GARY STERN: I see. Actually, I did have one more question on the informed consent. I noticed in the later forms, there was a signature space for patient or normal subject and I was just curious, what was the difference between a patient and normal subject, were normal subjects -

DR. SAENGER: We didn't have any normal subjects.

GARY STERN: Did you anticipate it or was that a problem?

DR. SAENGER: Yes, its always. In fact, I can't answer your question. I don't know how "normal subject" got in that, I don't remember that. If you say it was in the consent form,

GARY STERN: Yes, it's in the letter.

DR. SAENGER: We did have a lot of copies of, we had no normal persons. We didn't ask. We did not solicit volunteers.

GARY STERN: I guess with respect to the cancer treatment, I was reading through the Suskind report and they kind of seem to break down the patients into three types of categories,

hematological diseases, then there was the generalized tumors, where the treatment would be for pain relief and such, and then there was a third category called localized or chest cavity tumors that hadn't spread at that point. The Susskind report said it made total sense for the first two, it was questionable about treating the third category.

DR. SAENGER: Do you remember where that was?

GARY STERN: I actually have a copy here.

DR. SAENGER: You do? Let me see.

GARY STERN: I think it's the whole issue of (getting copy of report out and turning pages).

DR. SAENGER: This is the part about urines? What's your concern?

GARY STERN: Patients with a) wide-spread tumors that are relatively radiosensitive is one category and then b) the patients with widespread tumors which are relatively radioresistant, but they're widespread, and c) patients with tumors in which the spread is limited to the abdominal inner-chest cavity. And then at the very bottom, the study was the rationale for treating patients would have appeared reasonable for categories a) and b) and questionable for patients in category c).

DR. SAENGER: Well, the only thing I can say about it is I don't know what number of patients in category c), what the numbers were and who they were, but the patients with the abdominal and chest cavity radiation, those were the partial bodies.

GARY STERN: Is that right?

DR. SAENGER: To a fair degree, yes.

GARY STERN: I think that's -

DR. SAENGER: And that had been true in many studies after the ones we did, that we gradually learned that if the tumors were confined to the chest or the abdomen, to treat those portions of the body. Our cut off would be just to use the xiphoid as the lower end of the sternum as the cut off point.

GARY STERN: Right, cause I think, that's something that we've been trying to understand. I think, part of what we will probably try to do in the course of the Committee's work and for the final report, is to some extent, as much as we can a sort of history of TBI, how it developed and progressed from the beginning of time into the present and perhaps place your work and others that the DOD did within that context. There's always been the contrast between using TBI for radiosensitive tumors and like hematological type diseases and then for solid tumors and I think in the Susskind report, it's on page 12, they say when they surveyed the literature, it said "no

information is available to the Committee which indicates that this form of treatment is used elsewhere in radioresistant disseminated or localized cancers as used at the University of Cincinnati." And so I was just trying to understand the context if you were aware of anyone else doing, dose treat patients when you were doing...

DR. SAENGER: This is the thing about, a quick summation.

GARY STERN: Page 2 of "Was the treatment done therapeutically?" These are the ones you cited in the packet you presented with your Congressional testimony, I think these (inaudible) proposals, 23.

DR. SAENGER: We have some, we had a considerable number more we've looked at since then. [Saenger clarification - Following this interview we forwarded to the Committee a reference list of 29 papers that recorded the uses of Total Body Radiation between 1956 and 1993.]

GARY STERN: We are trying to do a survey in general, if we could just get a listing of those publications, if that's easy for you, then we could - or if that's something you could put together and send us.

JOSEPH PARKER: We can make a list.

GARY STERN: Cause, that's one of the questions we're trying to figure out is precisely the answer to the point you're making there is how it's used in other than the conditional lymphomas and leukemias and so that would be very helpful.

JOE PARKER: One thing I want to say because of something you said, not all patients in the study have the same dosages.

GARY STERN: No, we're fully aware of that. There's obviously a broad perspective of dose and disease and all that. And that's what we're trying to understand, what the rationale is. That's why I was struck by what the Susskind report said. It sort of broke it into three generalized categories, and said it seemed reasonable for the two, questionable for the third. We're just trying to assess where they're coming from.

It was just pointed out to me a couple days ago, an article that you co-authored in 1956 with Mr. Budd, Dr. Budds, in The American Surgeon, do you remember that article?

DR. SAENGER: Not very well.

GARY STERN: There's a striking quote, if I can read to you. that sort of plays into this, it said, "an important rule," this was from 1956, "is that therapeutic doses of isotopes should not be given to patients in the terminal state if the patient will not live for at least three to six months,

especially when therapy is only palliative, such treatment should be withheld." I was just sort of curious, I believe that may have been isotopes as well as external or something.

DR. SAENGER: Let me try to clarify. One of the problems that we ran into is that when patients become terminal, everybody gets desperate, they want to do something. And when we wrote that paper, radioisotopes were new, very new, and of course they had this sheen of newness and there were certain preparations which were given to patients with certain tumors, depending on what it was. And what we found was that we'd find some patient who maybe lived for a week or something like that and somebody'd give him an enormous dose of some radioactive material with the idea of trying to straighten this tumor out [Saenger clarification - shrink the tumor]. And, what would happen was that the patient became, it didn't help the patient because when you use radiation therapy, your goal is to take the patient (inaudible) at least two months, because that's the length of time it takes to get, you know to see an effect from a practical point of view [Saenger clarification - the patient became a major problem for the nurses without obtaining any clinical relief. If the patient could not survive for at least two months, giving radiation therapy was futile]. Radiation rarely acts, other than certain radiosensitive tumors, in a shorter period. So that was sort of a benchmark. Well what would happen to these people is, all of a sudden we ended up with a whole ward of people full of radioactivity and this radioactivity was coming out of orifices in the body that they didn't start out with or some of them just came out through the rectum, the old vomiting and so on and so forth. And it became a tremendous problem to keep the ward clean from radioactivity. So we began to suggest rather pointedly, if you don't think the patient is going to live for a couple

months, we're not going to give them any radioactive material and we got to the point of going up and seeing people and trying as best we could determine that we could get some advantage. Sometimes the people who were not experienced in the field, they would want to get radioactive materials that were not relevant to the patient's needs, for instance, if the patient had a carcinoma of the colon, like we were talking about, and you gave him radioiodine and that didn't have anything to do with carcinoma of the colon. You wouldn't go there. You go to the thyroid. You see, and there were lots of inappropriate indications which we tried to (inaudible) as a genesis for (inaudible).

GARY STERN: Is there any connection between that and the external, total body radiation that you were doing?

DR. SAENGER: The only thing, a certain amount of this isotopic work in nuclear medicine, was essentially whole-body radiation. It's another way of getting whole body radiation. We had done a lot of that ever since we started, particularly in treating cancer of the thyroid and some other cancers, leukemia, a little bit of leukemia. a lot of polyseptemia there, there would be phosphorus and so on to get a whole body effect.

GARY STERN: Another area. question related that we're interested in is in the context of the work that you were doing, and the work you were doing for DOD with respect to what other institutions are doing and what the Department of Defense and other government agencies were interested in, and we actually just recently came upon a document from the DNA regarding a

Navy whole body radiation project also looking for a biological dosimetry. Right around 1962 there was a copy of it. We were wondering if you were aware of it, because it seems like it's possibly redundant to what you were doing and if you had any familiarity with what the Navy was doing or if this work was ever coordinated with your work.

DR. SAENGER: I'd like to tell you that I was familiar with this. I knew that something along this line was going on. When you say was it coordinated, I'm not sure that the, I think these things were sort of coordinated maybe at DASA's office, but they and we had one or two meetings I think. Somewhat came out in some discussions we had last time, I think you know people had (inaudible) go to the memorial in the name of Dr. so and so. I think we had one meeting down in Texas. It was not a really tight thing. There's an interesting aspect to this. If you look at the budget of these things, here's a big project, how much was in it? \$15,000. Tell me what you're going to buy, even in that market. You've got \$600,000, divide that by 11, \$55,000 a year, we're going to pay for a part-time secretary and a technician. I mean, this isn't some big project like you're thinking about, and reading about now. These are all very small projects. I know we did about eight patients a year. Well I mean it didn't amount to anything. That's what I say, to say were we familiar with the \$15,000 project. Could be or not. I knew Dick King, I will say. I knew he did most of that work. (inaudible) Dickie and I were good friends. I knew of his work, and did we ever sit down and have a formal meeting about it? No.

GARY STERN: That's what we were trying to understand is it seems like part of the Army had several grantees or contractors like yourself and Sloan Kettering, then the Air Force had several

grantees or contractors like yourself and then the Navy was doing the same thing. We're just trying to get a broad contextual sense of how did they interact, was there some kind of coordination or were they being redundant, was there sort of typical interservice rivalry, each doing their own thing.

DR. SAENGER: I think you have to be very careful about redundancy [Saenger clarification - the importance of redundancy] because one of the things you have to realize, if I come out with a test and say that in today's market I have a certain gene that determines, I can figure your baldheadedness and my baldheadedness and make them look like these two guys, and somebody says, how do you know that's so? And I say, I know that's so because I do very good work. And a fellow says, well yes, but let's see who's going to confirm that. How many different places will you go to, serving different populations of patients, to be sure all these results are the same? I say well, let's have 5 or 10 projects and in that market in those days, where everybody thought the Russians have gotten another weapon, they said we'll have as many as we can get. Anybody who's willing to do anything that will tell us something about the biological response to radiation, we're all for it. I think if that isn't reflected in your analysis of the situation, you have kind of missed a major point. Let me go one step further. You say well, who is the project officer? Well, the project officer in a sense was a bit. a part of his responsibility was to scurry around, see who was doing work in this area. could it be co-opted into the framework of the DOD in those days, and the guy said well I got a project here and the other guy, he came from the University of South Dakota, another guy came from Harvard, another guy - these all were project officers - I got a great guy over here. I know his work very well. but he used to date his

daughter. And another guy said, I know so-and-so because he's working on this. And out of all this comes all these data you see. You're sitting out in Washington trying to decide what this means. Now you want to look at it from a so called ethical point. But when you think what the purpose of the work was, that's why you're seeing these projects and if you miss that point, it's almost impossible to understand, then you go on and say well, we're going to have a really coordinated study so we can put all these groups together. And you folks have a really coordinated study, going around for a year and a half and find out how this radiation is used, and you say how well coordinated are you? You haven't met every week to discuss your progress. Chances are, you're not. One guy out here, one guy out there. It's very hard, without spending a hell of a lot of money, based on \$15,000 worth of work, to spend \$3,000 depending on Washington to say, Houston.

GARY STERN: In that sense, I understand what you're saying, but our charge is simply to tell the whole story and just understand the complete picture as best we can, and that's why

DR. SAENGER: But that's a significant part of the story.

GARY STERN: Absolutely. And therefore, we're still at the stage of trying to figure out who was doing what. And then we want to take into account the context of what you just described and so I just follow that up, if you were aware of any other research that was going on that we might not even know about. I think we asked you last time about classified research. Secret research, and you answered that you hadn't done any, as I recall. But we were just curious if you

were aware of anyone else who might have been doing that or if any reports or studies that were being produced in a classified context, either by the government labs, or by the military services themselves.

DR. SAENGER: My only answer to that is, I would never do classified research. Not because I'm against it, but we're not equipped to do that here. We're not that big an operation. I think we have identified, with the exception of a small project like this, Dr. E. R. King, E. Richard King, you're familiar with his work. His was some small part. I don't know what the other DOD laboratories were, I don't think they actually started in those days.

GARY STERN: I think they started in the early '60s. That's right.

DR. SAENGER: Then that would be the place to look.

GARY STERN: But you're not familiar with

DR. SAENGER: Other than what Fletcher and Dubinsky did in Houston and Collins and Loeffler and so on. That's about it.

GARY STERN: That's your understanding of the universe, basically.

DR. SAENGER: I mean off hand.

GARY STERN: We're just trying to get a sense you know of, another aspect of this is the interplay between secrecy and national security and public health and secrecy and openness and secrecy and (inaudible).

DR. SAENGER: What we did was available.

GARY STERN: I understand that, and that's why we're trying to understand if there's anything out there that we might be missing that you might be familiar with or know, just from your contacts or communications throughout these years, or if there's even any contacts you had, you were a consultant and you did have a clearance and were a consultant for nuclear accidents.

DR. SAENGER: My consultant work was almost entirely in nuclear medicine. Teaching, residency, in the Armed Services, about nuclear medicine. Occasionally, when I go down to San Antonio, I would maybe have some occasion to visit Brooks Air Force Base but I will say that they pulled everything pretty close to their chests there. I don't think there's any sense of classification, they were just kind of - there are certain investigators who don't want to talk to you until your work is all finished because they're liable to take my idea and run off and do it themselves.

GARY STERN: In that kind of situation where you were at Brook or something like that, you didn't come across any research, not just TBI but sort of biomedical research related to radiation that they might have been doing that was classified or secret.

DR. SAENGER: Not that I can, and I mean, it doesn't come up in the front of my brain. And I don't think even in the western DOD laboratories or AEC laboratories, they were doing work of that nature. You can always go out to Berkeley or Los Angeles and dig around in those DOE labs and see what the early history was. I don't recall.

GARY STERN: We are doing that, but we thought, we're just inquiring around, if you have any sense, if nothing else, for the record, to the extent you have a clearance, we have people on our Committee who are cleared, would there be anything that you knew or were familiar with that might still be secret that you're bound not to talk about except possibly that you could talk to us or our staff in a classified setting.

DR. SAENGER: My clearance enabled me to get into a base at Sandia when I lived in Albuquerque, and I had an occasional reason to be cleared for something. There was no substantive thing that I could communicate to either one of you. If you want to pay my trip to Washington, I'll tell you what I know secretly. I don't have anything (inaudible).

GARY STERN: I thought I recalled from the last meeting that you did some consulting when there were accidents at some of the production facilities, is that right?

DR. SAENGER: Where?

GARY STERN: I don't recall specifically, but I thought you were involved when there was a nuclear accident, that you would consult on how to deal you know with the hazards from the gas.

DR. SAENGER: I did that. That was done for AEC, ERDA, and NRC, and those are mostly civilian, I can't remember any non-civilian incidents. I was never part of the Broken Arrow scenario. Are you familiar with that?

GARY STERN: I guess not. Actually I'm not personally...

DR. SAENGER: Broken Arrow was flying from there to Topeka and all of a sudden a nuclear weapon drops out of the bomb bay because somebody kicked the wrong lever and it splatters all over somebody's farm and some of the higher explosives catches fire and somebody said, "God there was plutonium in there." Everybody says, "God, I'm getting cancer and dying." That was all run by HEW.

GARY STERN: So you weren't involved in it.

DR. SAENGER: No. We discussed it one time.

GARY STERN: I understand Sandia was the centerpin for the preparedness for nuclear accidents.

DR. SAENGER: That was true. And for accidents within the service, now the services managed to take care of those things themselves. And I'm not...

GARY STERN: So you weren't involved in any of that?

DR. SAENGER: There was a Janus project or something like that. I don't remember exactly where it started or left off. I know they had some sort of mysterious office there which they played very close to their chest. I don't remember. (inaudible)

GARY STERN: I thought even when you did some of this consulting for AEC and NRC that reports sometimes would be written up, but you weren't quite sure what happened to those?

DR. SAENGER: Well for instance, let's say at your hospital or your factory or something, you had a certain spill of radioactivity, thought there was human exposure and possibly human damage, that one of us physicians would be called. We would go and make an interview, make a visit, or maybe we'd do the whole - I learned how to do it over the phone after awhile. And then we would make a report and this went to the Division of Compliance which is still what they call it, I think. And all these different organizational changes. And then in those days they would either assess a penalty, or restrict a use or various things like that. But in addition to that, there was a very questionable function which we were supposed to carry out, which was to advise the injured party as to how best to be treated for his condition. The only problem was that there was no authorization under the Atomic Energy Act for us to offer this kind of advice,

and if you gave some advice which maybe wasn't the best, and you did it in Ohio then they could sue me, jerk my license and so on, and they could also cause me a lot of grief if I lived in West Virginia. So, finally, so not to get into that part of it, unless they wanted to make a separate contract and become an outside consultant and that happened very rarely.

GARY STERN: So, the Division of Compliance might still have these reports.

DR. SAENGER: I think you can find these reports, if you want to know about the accidents.

GARY STERN: Yeah.

DR. SAENGER: I think you can find those at REAC/TS.

GARY STERN: Which is -

DR. SAENGER: That's the training center down at Oak Ridge. Gloria do you have that letter from ORISE we looked at my visit down there.

GLORIA: The one you just gave me the file?

DR. SAENGER: Yes. Could you find it for me?

GARY STERN: That would be great. We're trying to look at the whole universe and even nuclear accidents were often then utilized as a way of gathering information, understanding effects and that

DR. SAENGER: We have a whole literature on this. That's not very hard to come by. It would save you an awful lot of traveling. All these reports, there were reports made by all these agencies to Congress.

GARY STERN: All right. So we should be able to get those.

DR. SAENGER: This is the - see I'm going out there to give a lecture and course sometime in about a week or two. And the operation is now called ORISE. They changed that acronym, the fellow to talk to down there, two people, one who is Dr. Robert Ricks or Dr. Shirley Fry, and tell them you would like to get into, they should have a registry of radiation access going back to the year 1. Because they are supposedly a repository for all the activities of AEC, those several agencies, and NRC. Now whether the NRC (inaudible) I don't know.

GARY STERN: This is terrific. Is it possible to get a copy - these are - I see, just the name.

DR. SAENGER: The activity is called REAC/TS.

GARY STERN: Let me write that down.

DR. SAENGER: This is in the Medical Science Division. I can give you Rick's phone number, call him up, ask him to do a lot of things so when he sees me next time, he'll talk to me. Ricks is at 615/576-3130 or Shirley Fry at 615/576-3265.

GARY STERN: This has been very helpful. I guess one other area we would like to pursue a little bit, is some of the work you've done on radiation dosimetry with respect to children. This is actually a topic that a colleague of ours, Dr. Sandra Thomas, has been looking into. She has prepared some questions that, I'm less familiar with this area, but I'm asking on her behalf. In fact, following this, she might want to contact you directly, if that's okay. What we've done on the Committee, we're trying to divide up into different topics and issues and one way we've broken this out is by subject population and we're looking at one subject population that is children. And we know that you've written on this area for a long time. And Dr. Thomas was reading your 1960 article on the occurrence of cancer following therapeutic radiation for benign conditions in childhood. I'm just going to read her question. In your subject population, there were several medical conditions that led to radiation treatments. In your article, you mention that at the time, the popularity of radiation treatment for at least one of these conditions, thymic enlargement, was decreasing. The question is, what do you think are the reasons for decreased interest in radiation therapy for this condition?

DR. SAENGER: The problem with the condition was it was spurious. It was not an abnormality. What happened was my uncle was one of the first people who did some of this with radiation. I used to do a fair number of these. What happened with an infant, a newborn, is

that we, in the early days of diagnostic radiology, we didn't have these fancy holders which would sit an infant up, strapped in a position erect. (inaudible) that position, baby down. Take a short focal distance from the film, from the target to the patient and then the rays would come out, and you would see this huge thymus, this really enormous thing, it looked like a total chest, and the child would say have a cough, a running fever, have flu, or crud, or dropsy or I don't know, anything, some vague condition, and you'd give him some radiation therapy and you would take the film two weeks later and this thymus would have shrunk down, look like a normal chest, even though they'd been lying down. Then, the child usually felt better because the radiation therapy was very efficacious in curing infections. The original way this was found out was, that when they used to take pictures of the mastoid, people with purely mastoiditis. The children who got X-rayed had better outcomes with the mastoiditis than the ones who were not. And for a long time, that's how infections were treated. To make a long story short, when we started to take pictures of the child in the upright position, the chest looked like your chest except it was a little baby. We didn't have this big thymic mass. The thymus is sitting anteriorally in the chest, the film is in the back, so everything - in the lying down position, it makes it look like a big mass, and the thymus is very radiosensitive. When you go back to these children, six months later or something like that, and you lay them down the same way, the child has no symptoms, but this big (inaudible) shadow. It turned out to be a spurious condition. This did not have anything to do with the underlying fact that the child may have had bronchitis or bronchial pneumonia or viral pneumonia or something like that. But that was the reason for the decrease in the usage of thymic therapeutic, irradiation of the thymus. It was not a real medical -

[Saenger clarification (for the sake of clarity of thought) - The problem with the condition was it was spurious. It was not an abnormality. What happened was my uncle was one of the first who treated "enlarged" thymus with radiation. The reasons for the chest x-ray were croup, upper respiratory distress, etc. In the early days before the 1950's chest x-rays of infants were obtained in the supine position with a short focal film distance. Since the thymus is anterior in the chest it appeared as a large mass. After radiation therapy the radiosensitive thymus shrank and in two or so weeks the chest film taken in the supine position showed the large thymic mass had shrunk. Usually the patients complaints were relieved since infections clear after this kind of treatment. If, however, the supine chest x-ray was repeated 6 months later, the gland appeared to be large.

Finally, when we placed the infant in the erect position with a focal film distance of about six feet, the thymus was no longer enlarged irrespective of symptoms.

GARY STERN: I gather there were other therapies that were mentioned that have since been abandoned in that article. We were curious what you think led to those, was it the concern about long term effects or were there other more effective remedies, therapies that were developed.

DR. SAENGER: Let me answer it this way. The other conditions which we used to treat, we used to treat a lot of cervical abnormalities, big swelling glands. In an era when there was a tremendous amount of scarlet fever, whooping cough, mumps, measles, and so on, in the winter months, we would have patients lined up in the hall out there in one part of this little hospital, where I treated these enlarged glands. We treated maybe 50 over times 3 in a period of three

days. These things would shrink down [Saenger clarification - conditions shrunk] and the patient would be greatly relieved. The other otitis we relieved, sinusitis, there's a whole longer list of things we treated. Now, when did we stop doing that? Because first, the sulfanilamides came around and then the antibiotics came along, and it turned out the patient did well without radiation. Then, finally some of us developed some of these papers where we found that some children in long term followup developed carcinoma of the thyroid and that had a very chilling effect.

Now, the only interesting part of this which I speculate to, if you had been reading about the gradual ineffectiveness of antibiotics, in the days back (inaudible) streptococci, staph, etcetera. All these sort of [Saenger clarification - I speculate about the possibility today of gradual increasing ineffectiveness of antibiotics, the situation may become similar to what kinds of conditions we treated prior to the 1950's] .

JONATHAN ENGEL: Resistant bacteria?

DR. SAENGER: Yes, because they were all becoming resistant. And sooner or later, you're going to find a bunch of organisms that are so resistant to the antibiotics that you have to do something else. I'm going to bet that somebody will start radiation. You'll be right back to where you were in 1940. I treated a lot of the thymic and head and neck patients but I had been taught to shield the thyroid because if you didn't do that, you would irradiate the vocal chords and sometimes you have the chance of edema of the chords and the patient would either have to

have a tracheotomy or one thing or another. So I never treated any of them where I exposed the thyroid, so I didn't get any thyroid cancers dogging me. So you might tell that to Dr. Thomas. If she wants to talk to me, she should give me a buzz. Is she a physician?

GARY STERN: She is a physician. Another question she has, if a method is found useful for diagnosis and therapy in adults, is it then simply applied to children without additional testing or were different standards used then?

DR. SAENGER: When you say testing, are you telling me, are you asking me whether there was a control group and a treated group and you compare the diagnostic procedures and see whether it's more efficacious or is this just something that I take the adult thing and cut it down to size and pop it in -

GARY STERN: I guess that's the question, is that how it was done?

DR. SAENGER: That's how it was done. I think that was pretty true throughout the country. I don't think I'm telling anything that isn't. [Saenger clarification - The initial demonstration of the effectiveness of x-rays in treating infections was that patients who had x-rays for mastoiditis, a dreaded disease in those days, had a far better response in the x-rayed ear than in the one not treated.]

GARY STERN: Did you try to do animal models, using infant animals? .

DR. SAENGER: If you go back through the literature, I'm sure you can find a lot of this done on animals, they were bigger centers. There's no question that these were tested, certain procedures where there's catheter passing, angiography, various things like that, looking at very esoteric organs which were not readily apparent. Doing new things. There was certainly good animal work. A lot of it done. But if you take the general radiography that was done in children, maybe you will find something in the adult, you cut it down to size and pop it into the kid.

GARY STERN: There wasn't a heightened sensitivity towards children or infants that they would be more radiosensitive.

DR. SAENGER: There was.

GARY STERN: Back then there was, even before -

DR. SAENGER: Absolutely. Minimization of dose, radiation hygiene was extremely important, much more so in pediatrics than it was in adults. Much more of a stress on it. Much more shielding, much more care, the indications were more carefully scrutinized.

GARY STERN: So they were less likely to do nontherapeutic or metabolic or physiological research on children than on adults because of their sensitivity.

DR. SAENGER: This is a very hot topic. We have studies here. You know, bone densitometry, certain studies of the chest, where we were taking frequent chest X-rays for children who were chronically ill. I don't know if it was in cystic fibrosis, sudden respiratory distress syndromes, things of that sort. We've done a lot here. Dr. Kereiakis, who's our physicist here, has done a lot with children to minimize the dose and to be sure - sometimes they'll take these kids two and three times a day, they'll cut the dose down so far that the amount of radiation children get compared to what it was when I was doing pediatric radiology is trivial. All kinds of data, a whole bunch of (inaudible), a whole new team over there, that is looking at reduction of dose in treating - that's a very hot area. People are extremely sensitive and have been from the time I started pediatric radiology in 1945, 1946, I guess. For about a year I worked over there. I didn't like it very much. [Saenger clarification - People are extremely sensitive to this issue and have been from the time I started pediatric radiology in 1945, 1946. For about a year I worked over there.]

GARY STERN: We are curious how you did that study of the long term effects in 1980s, studying the folks back from the '60s and notice this higher incidence of thyroid cancer. How was that received at the time or was there resistance to those findings?

DR. SAENGER: No, I don't think so. There are two different groups. The infamous group up at the University of Rochester, and our group here, and there were one or two others, and they sort of came along. And you say, why were there so many studies. Our study was the second one. What it did was to confirm Dr. Hempellman's findings. That sort of made it more

important, because it's of much greater value to know that some other person working in an entirely different place can confirm what you find. It's of value itself, to make a big fuss and hullabaloo about it. You see that all the time in the history of science, if you're looking at that. You'll find the very eager beaver who's out there saying how good it is, but no one can reproduce his findings. This is again, getting back to this other subject. It's one reason that there are multiple groups around.

GARY STERN: Okay, I think that's basically all we have at this time. Again, we very much appreciate your cooperation and willingness to talk, you've been very helpful. This is important to the Committee, and an important resource. Like I say, Dr. Thomas may want to give you a call to followup. If you have any additional questions, we probably can just do it over the phone. This just worked out since you were in town.

JOE PARKER: I gathered from what you said is that these interviews are really what you need, you don't need him to show up at this public hearing tomorrow at the open mike.

GARY STERN: That's right. And actually it's not, just to clarify, it's not an open mike, it's an open invitation for anyone to talk, but I think we have a full schedule at this point. And the Committee has been appearing in various places around the country to grant interested people, the public an opportunity to present their views to the Committee and I think there might even be a waiting list tomorrow. You're certainly welcome to come and watch at this point.

JOSEPH PARKER: I don't think that's our intent but we didn't want anyone to think we're
ignoring