

Oral History of Dr. Ruth Kirschstein, Deputy Director of the National Institutes of Health
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Interviewers: Dr. Victoria Harden and Dr. Caroline Hannaway

Please Note: These Interviews Have Not been Verified for Accuracy

Hannaway: At the end of the last interview, we were talking about management styles of different directors of the NIH. Now we want to come back to your NIGMS career in the 1980s and move forward in time. In 1983 and 1984, you participated as a member of the NIH Liaison Committee in the Institute of Medicine study of the organizational structure of the NIH, which had the title of "Responding to Health Needs and Scientific Opportunity." We would like to know a little about the background of this study, about how it was conducted, and what its outcome was.

Kirschstein: It is something I do not remember a great deal about. There have been a number of studies of the NIH in the years that I have been here. The one that I remember most vividly was one I think we talked about before by the President's Biomedical Research Panel. Sometime probably after [Dr. Donald] Don Fredrickson, being that I had been director [of NIGMS] for quite a while, or in the early stages of [Dr. James] Jim Wyngaarden's directorship [of the NIH]--I think it was the latter, but I do not remember--the NIH was growing, but not perhaps as much as we wished. I think it was in that period where people talked about a disease-of-the-month club and when Congress was adding institutes related to new diseases that they wanted studied and so forth. I think that the Department [of HHS] and

maybe the NIH itself thought it would be a good idea if the IOM did a study of the organizational structure of the NIH. [Dr. J. Edward] Ed Rall, if I am not mistaken, was still here, and he was very keen on this. ----- I believe, was chair of the committee from Southwestern Texas [according to the report, James D. Ebert, President of the Carnegie Institution of Washington, was chair of the committee]. Like all these studies, it started off with the idea that the NIH was the most wonderful organization in the world but it was a little concerned about whether we had the proper balance between basic and clinical sciences. There is a volume somewhere here [in Dr. Kirschstein's office] which we got together when we organized the 1993 panel that was required by Congress, and so somewhere in my office and in Harold's [Dr. Harold Varmus] office, there is a copy of it. Whatever they were, the recommendations were not such that we did very much with them. I think it was one of those reports that basically went on the shelf, and that is about as much as I can remember. Liaison simply meant that all of the institute directors, or those of us who had been around for a while, were there to help them with their activities. We were not really part of the deliberations.

Hannaway: Thank you.

Harden: Let me ask a follow-up on that question about reports in general. How useful are these reports? Because they do get churned out year after year.

Kirschstein: Most of them are not very useful. It may have been in that era that

Congress passed--and we were just talking about this yesterday with people who came out to the Departmental Executive Secretariat--a requirement that the NIH submit a biennial report on itself to Congress. We have been doing that every two years for a very long time now. To our knowledge, nobody ever looks at them. We have asked, over several years, for legislation to be relieved of this obligation, and the Department has not been willing to let that happen. Yesterday, we were talking about the fact that, if you call attention to this requirement by saying you want it done away with, it may cause renewed interest. You have to balance one off against the other. So we decided we would put in a request again and then have a discussion about what to do. In point of fact, the reason that came up was that we were actually talking about whether the reports that come from the NIH are timely. We had told the Department [of Health and Human Services] that this one was going to be late, and yet nobody whatsoever from Congress seemed to care that it was going to be late. So that tells you something about the intensity of the interest.

Harden: But they still want you to do the report?

Kirschstein: Yes. Some staff person probably, in whatever year it was, thought that it would be a good idea for the NIH to be accountable in some way--and persuaded his member of Congress or the chairman of the committee or whatever of this. It gets into language and it gets buried and nobody remembers it thereafter. And that is these recurrent reports. Reports like

this are variably useful. The President's Biomedical Research Panel report was really a very important report. The reason it was important was that it was produced at a time when it was pivotal as to whether or not the NIH was going to grow in a somewhat exponential fashion, and it turned the tide toward doing that. This "Responding to Health Needs and Scientific Opportunities" report, I would say, was probably not very important. We had a report recently, which we will talk about when we come up to date, a new one that [Dr.] Leon Rosenberg was in charge of, the "Setting the Priorities" report, which we need to talk about in detail. But these reports vary rather considerably in their usefulness. When you have been in a place as long as Al [Rabson] and I have, you see a great deal of reinventing the wheel again and again.

Hannaway: Ideas come around again.

Kirschstein: They do.

Harden: Let us turn, if you will, to another subject. You know that we are working on a long-term project documenting the history of AIDS at the NIH. Can you recall when you first learned about this new disease and tell us what you remember about the very beginnings of NIH involvement with AIDS? I do not know whether this was very much on your mind at the time, but I thought I would ask you to think about it.

Kirschstein: It was not very much on my mind. I guess the first time I remember hearing about it was in the early 1980s, when it was announced either at

what was then a BID, Bureaus, Institutes, and Divisions meeting, that there would be an AIDS Coordinating Committee at the NIH and that [Dr. Anthony] Tony Fauci would be the director of it. Then we began to hear about AIDS from newspaper reports, and also Tony would report every so often. I was interested in it particularly because of my background in viral pathogenesis. NIGMS did very little related to AIDS. The thing that became more obvious was that people needed to stimulate really good research in the area. You know, it was a mystery and there were a great number of problems. We could see that it was probably going to take off, though I do not think anybody in the early 1980s realized what the magnitude of the epidemic worldwide was going to be. But, as it became clear that research needed to be stimulated, Tony Fauci was handling most of the extramural part of it. There were not very many good ideas, and scientists were putting in grant applications and people were being overwhelmed with work to get them reviewed. There was a small amount of research being done intramurally by Fauci's own laboratory, by [Dr. Robert] Bob Gallo, and by [Dr. Samuel] Sam Broder and some of his colleagues. When Sam was in the intramural program at the Cancer Institute, he had [Dr. Robert] Bob Yarchoan with him--and they worked on drugs.

Hannaway: Right.

Kirschstein: What became clear, as we learned to know about this virus, was that it was

going to be possible probably to have a somewhat targeted program to look for drugs. Jim Wyngaarden was very enthusiastic about that, and some money was provided through Congress. Most of the money went outside. But I think \$10 million was provided for intramural scientists to compete for getting money to work on AIDS in general and drugs in particular. It was the first time that the NIH had ever set up anything where intramural scientists prospectively, similarly to their colleagues in the extramural programs in the universities and medical schools, had to put together proposals to be peer reviewed prior to starting the work and compete with each other for the monies. Now, I said there was \$10 million. After about the first year or two, I cannot remember exactly when--I think I mentioned this before--I took Jim Wyngaarden and [Dr.] Marvin Cassman with me to a National Academy of Sciences meeting on structural biology, on the X-ray crystallography of proteins, and [Dr. Frederick] Fred Richardson from Yale was in charge of it. We knew it was going to happen, but Jim just got blown away, and he gave NIGMS half of that \$10 million, \$5 million, to set up a set of centers specifically to try to do an AIDS viral protein drug, rational drug design through structural biology. That was a wonderful program. We did it--Marvin was really the creator of it--as a cooperative group of people who came in and discussed what they were going to do, and we accepted applications that were not absolutely detailed. Our advisory council gave us the authority to

provide money to the people who were worthy and to have the flexibility to add monies as they got new ideas. Out of that has come something wonderful. We brought the investigators in every year to report, and all of them, except one or two, talked openly about their work. That has been perpetuated to this day so that every year NIGMS holds a structural biology of AIDS proteins and drug design meeting in June.

Harden: But these are extramural investigators?

Kirschstein: These are extramural people. Some of the intramural people are doing such work too, [Dr.] David Davies, for example. And he comes to the meeting and reports on what he is doing. But we did not give extramural money to them. That was the \$5 million that was intramural. In point of fact, if you want to come up to recent times, it was at the June--maybe it was the May--1993 meeting in a hotel downtown--and we did not know if he was coming or not, but on the second day [Dr.] Harold Varmus showed up. He and I chatted, and then he said, "I want to see you." So we arranged to meet. By that time there were rumors all over the place about the directorship, and I probably knew more than some people about it. But, anyway, [Dr.] Bernadine [Healy] had left or was about to leave, and Harold said, "I want to see you." So after that meeting, or the next day, we stayed downtown and sat and had a Coke and we talked. Harold asked me what I knew about being the director and I told him what it was like and so forth. He then said, "Well, who do you think I ought to get to work with

me?” and I said, “I think you ought to get Marvin Cassman to be the deputy. He would be wonderful.” He said, “No, no.” I suggested a couple of other people. Then he said, “Stop beating around the bush. I want you.” And that is how that happened.

Hannaway: This is a great story.

Kirschstein: Actually, I knew more about it than the rumors that were floating about because there was a search committee that was being run, in June of 1993, by [Dr. William R.] Bill Lynn. They had contacted me and I had had some sort of an interview. I did not think I was going to get the position. I am very happy that I did not. So I knew where Harold was in the process, but nobody else really knew.

Harden: I want to ask one more AIDS question here, which is really a broader question. I have a memory--you can correct me if I am wrong on this--that back in 1984-1985, right after it was clear that AIDS was a viral disease and was transmitted by blood, people knew that one way it could be stopped was by passing out clean needles and distributing condoms for safe sex. My memory is that I heard several people here at the NIH say this, and yet, of course, they knew they could not advocate these actions because of the political beliefs of the Reagan administration. Surgeon General David Satcher has recently talked a lot about the problems that government scientists and physicians face because of political limitations.

Kirschstein: Satcher is saying that now?

Harden: Yes, Satcher himself is talking about these problems.

Kirschstein: I do not know the details of this. I suspect the major person who would be able to tell you about this is Tony Fauci. But it was a very difficult time because clearly there was deep concern about sexual behavior. There was no question in the early 1980s that there were people--and there are some people today, still, who feel this--who said why are you going to spend any money on this disease? It is a disease that can be prevented. It is a disease that is the result of, this comes from them, "perverted behavior," and why should we waste our money on such. There was very almost right-of-Genghis-Khan type of thinking generally. It was a very, very conservative period in the administration, both with the Secretary, and Dr. [C.] Everett Koop initially, though he turned out to be very different in the end. So it was very difficult, and Tony can tell you about this better than I can. [Dr.] Wendy Baldwin can tell you about a study--I do not remember what year it was, probably in the late 1980s--that the Child Health Institute had actually funded as a grant--it passed muster in peer review--regarding sexual behavior among adolescents in North Carolina. It was the first and maybe the only time, in my memory, that we were ordered, after the grant was awarded, to terminate it by the then Secretary of the Department. In fact, Wendy, whose career was advancing very nicely in the Child Health Institute, was in enough "trouble" that we sent her off to Europe for several weeks for everybody to quiet down.

Harden: I remember that, yes.

Kirschstein: Indeed, there are those of us who believed that in one way or another, there are some other aspects of things which are immaterial to what we were talking about, but there are still people in the Department who remember it and her and have not always behaved appropriately.

Harden: That is very interesting.

Kirschstein: So what you are saying is undoubtedly true. Of course, some of this has continued in some way to the present, because although the administration is different and the Department's and the people's attitude and so forth is very different, we still have members of Congress who feel this way.

Harden: Sure.

Kirschstein: And we can hear them--a couple of them are on the Health and Human Services Appropriations Subcommittee--complaining bitterly about us spending money on AIDS. "Why are you spending on this"--and this is fact; I am not making this up. They have done the analysis of how much we are spending per AIDS patient per year compared to a patient with diabetes or heart disease. They use their own statistics on it. Some of them are gathered from the census data, some of them are gathered from, they say, the health statistics of the National Center for Statistics, and they are horrified. They try every which way to stop this.

Harden: I want to use the issue of AIDS funding and the political arguments that surround it to push you to think very broadly about your life and your

career here. You recall the discussions we had about polio and the controversy surrounding the vaccines, and the issues surrounding fetal tissue, animal issues and so on. As a physician and scientist in the twentieth century, your struggles with these issues will be looked back on as characteristic of the twentieth century.

Kirschstein: Oh, I agree.

Harden: Do you want to elaborate for the record? What factors were most important in shaping your views of AIDS? You have strong political and moral views. Did you ever waver? Did you ever feel lots of pressure? Or was it fairly clear to you as a doctor, how you thought about such things as the AIDS problem, or the polio problem? I realize I am not being terribly specific.

Kirschstein: First of all, I think my moral and ethical underpinnings came way before I ever came to the NIH. I have not wavered in them. I honestly believe that, whereas many people I know have become more careful, conservative--I do not mean that necessarily purely politically--in their outlook on things, if anything, I have become less so. Not that I have not been careful, but less conservative. I really do think that the moral-ethical underpinnings of medicine and medical research and this country require that. I think a lot of it stems from starting actually when I was born and grew up, which was the Great Depression through the New Deal, and primarily Nazism and World War II--again, you see things coming around. I mean, just look at

the news today--and a sense of what is right and wrong. On the whole, I would say that the scientific and administrative staff of the NIH has, despite the fact that now two of our leaders are politically appointed, kept its grounding extremely well, kept its eye on its mission, and done it remarkably well. I think, despite little blips and so forth, history will read it as being a remarkable institution, just as [Dr.] Lewis Thomas said, when he said something about, if we had not had the NIH, we would have had to invent it. I think that is absolutely right.

Harden: That is where I got the title of my first book!

Hannaway: I would just like to ask you a question that has occurred to me about the AIDS situation at the NIH. In addition to the good research that was done at the NIH, the NIH also became embroiled in a controversy over the discovery of the virus with the conflict between the French and Gallo and so forth. I wondered if you, as a director, had got involved in any way in the debate over this issue or the actions that were taken to try to investigate it. Is there anything that you would be able to tell us about that?

Kirschstein: Of course, I had known Bob Gallo for a very, very long time, even when I was part of the intramural program.

Hannaway: Right and he is a virologist.

Kirschstein: He is a virologist, and we have known each other well for a long time. He probably knows Al even better. Nevertheless, he is a very creative person. But I have no doubt that Bob, just as Salk and Sabin and some of the

others, these very creative people in a field that is extraordinarily competitive, driven by lots of things in their own past--you have read articles on Bob Gallo and you know about his sister and so forth--do things, or at least seem to do things, that may push the envelope. I cannot tell you whether there was anything wrong going on or not. I would guess, like so many discoveries, it was a thing that happened with both of them at the same time. I wish the controversy had not been so bitter between them. The only good thing that came out of that was when it was settled and we set up the French-American foundation that has used the money for research. Some of the controversy related to scientific misconduct is better left unsaid. I know a great deal about that because I had to review some papers. But, on the whole, they seem to have made some peace with each other, Bob has gone on to a fine institute [the Institute of Virology in Baltimore], and NCI has survived without him quite well.

Hannaway: Thank you. In 1982, you had the honor to be elected to the Institute of Medicine of the National Academy of Sciences, and we would like to know what issues you have worked on with committees of the Institute.

Kirschstein: The IOM is a very interesting organization. First of all, my election was absolutely stunning to me. I had no idea. To this day I do not have any idea who nominated me, and I do not know what happened, but I was delighted. It is an organization that I think is very important, but which, certainly in 1982 perhaps more than now, had the feelings of being either a

stepsister, or stepbrother, whatever you want to call it, or an orphan, compared to the National Academy of Sciences. I think there is no doubt that there was a group of people who wished that they could have put forward and had a National Academy of Medicine separate from the National Academy of Sciences. That is also true with the National Academy of Engineering, which at least is called a national academy as opposed to an institute. Like all organizations of that caliber, the running of the organization is in the hands of a fairly small group of people. The leadership will tell you that they encourage their members to volunteer for all sorts of activities, but, in general, with rare exceptions, they do not have NIH members participating very broadly. That is probably not a bad idea because they get their money from us. The organization started out with a modest amount of money, I presume from Congress, and maybe a little bit of money from some philanthropic pharmaceutical companies, but really was quite poor. It charges dues, which does not do anything for anybody. It is always doing studies which either are asked for by Congress or by some groundswell among its membership or by something that was reported in the press that made them think that they should do such a study, or, more often than not, something in which their senior staff are interested. The way you run that organization is you take scientists or science policy types and you put them on your staff with a contract--none of the employees are permanent--for three to five years, you give them a

base salary, whatever it is, and then you say, produce. So they think about things and they think of something that would be a nice idea, and then they come tin-cupping. I have told them that, too. I have told [Dr.] Bruce Alberts, I have told the others, particularly in the early days, "If it is something where the institute and the IOM group have a common interest, we will provide money and so will you." If it is something where somebody like myself is a member it can be helpful, and probably the most obvious example of that was the drug forum, which was one of the best groups we ever had at the IOM.. It ran about five, or seven years and ran out of steam, where [Dr. Samuel] Sam Thier, who was the president at the time--and that was probably in the late 1980s because the first couple of years that I was there, I would go to the annual meetings. I would occasionally help them out. There was a polio thing that they did, and they asked for some help. But I was not asked to do much, and it was clear that they felt that we should not do very much. But Sam Thier came out to see me as director of NIGMS, and said that he had been asked by the IOM to set up an organization which would try to mediate, bring together to the table, the pharmaceutical industry and the Food and Drug Administration, which were at loggerheads at that point. Because I had been at the FDA for a short while, and because NIGMS had the only named program, which was called Pharmacological Sciences, he thought that NIGMS should support this and that I should be a big player in it. I told him that although

we had a program called Pharmacological Sciences, all the drugs that the FDA was concerned about and that the manufacturers were making were related to cancer, hypertension, heart disease, diabetes, the more categorical disease institutes. At that time, NIGMS's budget was not growing by leaps and bounds. So I was not willing to be very supportive alone. He said, "Well, would you be the broker?" After consulting with my director of the Pharmacological Sciences Program, we decided we would. Being the broker meant that we had to go and beg for money from the other institutes. We put in the most. But we did make that group work because we went to the meetings we helped set the agenda, and actually did provide a real forum where there would be discussion. I began to get angry because they were trying to draw us into taking sides on the regulatory basis, but we refused to. We did a couple of things that were good, I think. The first was that it was at about the same time that I had begun doing work on women's health in the Department [of HHS], not here at the NIH, though we were thinking about research [on women's health]. There was this thing that occurred at the FDA at the time as a result of the FIAU [Fialuridine (FIAU) Clinical Trials] incident--I think we talked about that before.

Harden: Right.

Kirschstein: They would not allow women to participate in clinical trials if they were within childbearing age. In point of fact, the FDA was defining

childbearing age as anything from 13 to 55, so that essentially left women in general out of clinical trials. It was also at the same time that Pat [Patricia] Schroeder and other congresswomen were being pretty vocal about the fact that we do not have any data on women, as all the trials are being done in men. So we put on a forum, to which people from all over the world who knew something about it came, on the evidence that showed which drugs were being tested and if there were any that affected women differently than men. That was a very useful thing. We followed that, and the FDA gradually changed--it took them some time--their requirements. We followed that with a study that was, in many people's view, even more pertinent because physicians throughout the country were also using drugs and vaccines in children with no data whatsoever on whether they were safe, no less efficacious, in children. That is perhaps even a little more dangerous in the sense that we know that the child's immune system matures over some years, we know that his-her reproductive system is immature, we know that the nervous system changes, etc. We followed that with a forum on the use of drugs in children. It has only been in the last year that the FDA, prodded by [Dr.] Duane Alexander, and a group who he pushed here, has finally required that there be data on children, and if the package insert is going to say so, that it must say something about that. So that was very useful. There were a number of other parts of the drug forum. I thought it went very well. I

think [Dr. Christine] Chris Carrico, who was the director of the Pharmacological Sciences Program, and I can take a fair amount of credit for that. There were other committees that I served on. I used to go to all sorts of things. I am a member of one of their [IOM's?] organizations, one of their subsections, the Basic Science Subsection, and we work very hard to increase the number of women in the membership in the IOM and of minorities too. That is something of a disgrace.

Hannaway: I meant to ask how many women there were at the Institute when you were elected.

Kirschstein: I cannot remember. We would have to look. But it was not very many.

Hannaway: No.

Kirschstein: I have no doubt that that is why I got in as early as I did, because other people of my ilk were not being admitted. They were pretty careful. They did not want people replaced with directors of NIH, and I guess [Dr.] Carl Kupfer and I were both elected at the same time, and [Dr.] Claude Lenfant the next year. It has been very gradual. I would have thought Tony Fauci would have been in before I was, and so forth, but it was a little bit later along the way for him. But, as president, Sam Thier started something that has made the IOM a little better. He went out actively to recruit financial backing from all sorts of foundations and organizations, and industry, and he set in place an endowment, which the IOM had not had before. That has made it a much more stable organization. It is an interesting

organization because, according to its by-laws, the IOM is limited in the number of its members, and every so often they pass a law that increases it, as opposed to the National Academy of Sciences, which is limited in the number of members per section but can expand--no, it cannot; it is limited also--but allows all its members to vote. The IOM requires you to become an emeritus member when you are 65 and you lose your voting privileges. You can nominate, but you lose your voting privileges, and that is because they did not want to people it just with old-timers. It makes it less interesting to be a member, but you are compensated for that by being able to nominate people.

Hannaway: It sounds as though these institutions are built on the European models.

Kirschstein: Yes.

Hannaway: Like the French Academy of Sciences.

Kirschstein: Yes, very much so.

Hannaway: And the Royal Society in England and so on.

Kirschstein: Yes.

Hannaway: You have already mentioned in this discussion that you were on a PHS task force on women's health issues. That was going to be our next question. We would like to know about the formation of this group and what it accomplished.

Kirschstein: I thought I had talked about that.

Hannaway: Yes, you have already indicated some of that.

Kirschstein: But anyway.

Hannaway: Well, also about your continuing up to the end of the 1990s, before we come to the Office of Research on Women at the NIH.

Kirschstein: I think I told you that Dr. [Edward N.] Brandt decided that he was going to put together the task force. He did that under the influence of several very fine women who were on his staff at the time, either deputy assistant secretaries or directors of various offices. He asked each agency to have two representatives. When he came to the NIH, he asked Jim Wyngaarden to name one representative and then told him that he wanted me to be the other one. That is because Ed and I had known each other for a long time. We had served--did I tell you--

Hannaway: No.

Kirschstein: I thought I had done that.

Hannaway: I do not think so.

Kirschstein: He wanted to do this, and he asked every agency head to name two people. Then he called Jim Wyngaarden and he said, "We need to have two people, but I want you to know I want Ruth to be one of them." Before that, having rather purposefully, first of all, identified myself as the proponent of basic biomedical research as the director of NIGMS, and second, because I really do not want people to think that my career has been predicated on only being interested in things that relate to women--in fact, there were people who said, when I went to NIGMS, "Oh, now we

are going to have an institute that only hires women.” And we did. We have more women than men in scientific positions at NIGMS than the other institutes, but that is because a health scientist administrative career is a very attractive thing for women. There were very good women who were here because their husbands were here for other reasons, and we gave them jobs. But, anyway, I had not particularly been active in these things. I had never joined the American Women in Science organization, which in those days, in the 1980s, was a pretty radical organization. It has become much calmer now. And so Jim said okay.

Then, after they got their group together, I got a phone call from one of the women on Brandt’s staff, Glenda Cooks [sp?], who said, “I want to come out to see you.” I said, “Sure. Why do you want to come?” “We have to write the charter for the task force.” I said, “Well, write it.” And she said, “No. We have to write it.” I said, “Why?” And she said, “Didn’t Ed Brandt tell you? You are going to be the chair of this task force.”

So she came out and we wrote the charter, and she said, “You have to be the chair.” I said, “Well, let me make the other woman whom Wyngaarden had chosen from the NIH, [Dr.] Doris [H.] Merritt, my co-chair.” Brandt offered to give me an executive director or secretary. It was a good thing because Doris Merritt, whom he named as co-chair, left to go back to Indiana University within six months. Then I picked another co-chair who promptly left, and after that, I did not bother. But Valerie

Williams, a magnificent African-American woman who had started out as a presidential management intern, worked with me the whole year.

Without her, I could not have done it. We had our first meeting and made a couple of interesting determinations and observations. One of the things we observed was that probably nobody had ever written a real report on women's health issues before, at least for our Department [HHS]. That turned out to be wrong, and I will come back to the story in a minute. The second thing goes with the question you were asking about condoms and sex and so forth. It was at the time when clearly the right-to-life movement was in full swing, and our Department was absolutely hell-bent on not doing anything related to reproductive health. We knew that if we considered women's health only in terms of her reproductive ability that we would have to get into those issues. Halfway through the first year, or second year, a woman came to see me and said--I do not remember her name--"Do you realize you're reinventing the wheel?" I said, "What?" She said, "I wrote, under contract, a report on women's health issues that [Dr. Julius] Julie Richmond"--when he was the assistant secretary for health." He was Ed Brandt's immediate predecessor, a wonderful man and good friend. "I turned it in to him on the day he left office, the day basically that Ronald Reagan was sworn in." She said, "Somebody threw it away," because most of the report was related to problems of contraception and the need for access to abortion and so forth. And she

sent me a copy. So we knew. We determined that what we really needed to do and what would make a difference, even before we knew about her report, was to talk about women's health through the life span--in her childhood, adolescence, young adulthood, menopausal years, and the elderly years--and we had a chapter on each. In addition, we had some special chapters and some special reports in it, on fetal alcohol syndrome in women who drink, and on women of color. We began thinking about some of the AIDS issues, and we came back to that subsequently, and some of the other things. We also went around the country and held a series of public meetings, which we announced in the *Federal Register* and sent out flyers about, to invite women to come in and tell us what their issues were what was concerning them about their health. We used that to put together our recommendations in our chapters in addition. We held one big public meeting here with the FDA. We held another one here on our own. But each agency was asked to put together its own internal group. And we, Doris Merritt and I, put together a group of people from the NIH. Again we asked each institute to nominate somebody to be in the group, and we got nothing but women's names. I said, "We are not going to have this. Women's health is as important to men as it is to women," and I asked [Dr. Mortimer] Mort Lipsett and Duane Alexander to join us. As long as he could Mort did [attend], and Duane too. We also tried to do that in the regular task force as well. Brandt was in something of a hurry,

and we told him that we did not think we could complete our task before late 1985. He asked us for an interim report, which we put together, and it was published in *Public Health Reports* as the first report. Then the volume came out subsequently. It actually turned out to be a primer. I think, having said I was not going to do anything like this, I am really very proud of it. And we made a whole series of recommendations.

Incidentally, one of the chapters was on the issue related to women as caregivers for their families and the problems involved in that--not just for their children, but for the elderly in their families, whether it is their husband's parents or their own or an aunt or an uncle or a brother or a sister of a woman whose parents cannot handle that person for some reason. So women have their own problems concerning their health because they are in some ways so busy taking care of the health of everybody else. When you do surveys, you see that women go to doctors more frequently than do men. Partly, I think, it is because they are so conscious of symptoms because they are so busy doing other things. But when it comes to choices, such as when the family has a limited amount of money or there is no healthcare insurance, women will ensure that their children are taken care of and that the "breadwinner," the man, is taken care of. They will not get vaccinations, and so forth because it is more important for the people they care for to be taken care of. That is an interesting cultural and societal thing. We put forward a whole series of

recommendations, almost all of which have been implemented in one way or another, the most important of which was that women be included in clinical trials and that the excuse not be there that you are worried about things such as pregnancy, and that agencies be accountable for it. Part of the problem was that I was so busy with the task force that I did not pay attention to whether the NIH was implementing that recommendation, and that is when the Congress found that the NIH was not implementing the recommendation that the task force had made.

Hannaway: This was in 1987?

Kirschstein: Yes. Our first recommendation was that, having done this task, there was a lot more to do, and we did not want anything put on the shelf, and that there needed to be a continuing body. Dr. Brandt accepted that, turned around, and appointed everybody on the task force to a coordinating committee on women's health for the Public Health Service and appointed me to be the chair. I remained the chair until 1993, and we had regular meetings. Valerie Williams left and went with Dr. Brandt to the University of Oklahoma, where she is now an associate dean for students or something, an absolutely wonderful woman. So I needed some help, and I had somebody in NIGMS who did it part time for me, named Agnes Donahue [?sp.]. Then she got hired downtown, and [Dr. James] Jim Mason allowed her to provide that assistance so that I could continue. Jim Mason and I worked closely together. He and I actually co-chaired the

coordinating committee for a long time. How they moved here [to the NIH], was that, in 1993, I felt--it had been 10 years--that the office downtown, the Office of Women's Health, needed a full-time person. By that time, it was 1990 or 1991...

Harden: Ninety-one, I think.

Kirschstein: Ninety-one, when NIH had set up its office, and I had run it for a year at the same time as being director of NIGMS and running the office downtown. I suggested to [Dr. Philip] Phil Lee that he appoint a full-time director, and he did. He gave her the glorious title of associate director for, deputy assistant secretary for health, women's health, Susan Blumenthal [?sp.]. And without so much as a thank-you letter, I got a notice in the mail one day that she had assumed the chairmanship. Nobody ever sent me a thank-you letter.

Hannaway: After 10 years of work!

Kirschstein: She called me up to complain because the NIH had not thanked her for putting on a conference, and I said, "Well, you should worry." She apologized.

Hannaway: Good.

Harden: I want to preempt here because we are going to run out of time. You already brought up the fact that this was the period of time when you had to face breast cancer, and at the same time you were involved with the women's health issues. Now, you have talked a little about this in the

past, about how the Institute directors saved your seat and rooted for you, and that you did not miss any time. I understand from physicians I know who treat this disease that many women fall apart. You did not fall apart. How did you think about this as a woman, as a physician?

Kirschstein: There were a couple of things, first of all, that I guess made things happen the way they did. The first was the enormous support from my husband that was absolutely, just incredible. The second was that I had been through a couple of things before. I had a major time when I had a piece of my lung out for tuberculosis and had been on therapy for a year. And I am a great believer in work and focusing your mind on lots of things to keep you on the straight and narrow. I had watched a mother who had been very courageous about her illness. I had lost my mother to breast cancer six months before I had been diagnosed. It was very unusual because her breast cancer started when she was 85, which is very unusual. She did not want to have anything done. We finally persuaded her to have surgery, which she had to, and she would not let them treat her afterwards. We agreed and we thought we knew it was not going to be good, and she died in September of 1982. It was 10 days from now [April 15], on April 26, in 1983, when I knew that I had it. I knew that it was bad. I did not know how bad. Al figured that one out very quickly. Then he found what I needed, and that was [Dr.] Marc Lippman, who was at the Clinical Center, and Marc offered me a very horrendous protocol, but I was

determined to do it. We sort of structured our lives around being able to work, not doing anything else, and getting better, and we did it. But without Al, I could not have done it. I mean, he was wonderful. I also had terrific help at the Institute and tried to make everything better, so it worked out. I do not know that there is anything else to say about it. I won't tell you that I was not scared; I was. I do not think, and I did not think then, that I was going to make it. Nobody else had with this. The average survival was less than a year. It will be 16 years next week or the week after. Al was convinced I was going to survive, and he knew that what Mark had done was a very courageous, very involved therapeutic regimen. I followed it to the T. Everybody has to figure out how best they do things. The first time I got chemotherapy, when I was told that "You're going to get sick," and they gave me some pills for getting sick, I went home--it was about five o'clock in the evening--they had arranged it so that the clinic was Wednesday afternoons, and I went late and then I would go home with my papers. I was not sick when I got home, so I said, "I had better eat in order to..." And I got violently ill. The first thing I did was take one of the pills and I passed out? I am a tiny person. I weigh 106 or 107 pounds. I learned if I had to take anything--and I tried not to--but about one quarter of that pill was about right for me, but nobody ever told me that. The other thing I think everybody has to figure out is I learned that it was better not to eat, and when I ate, to eat small amounts frequently

rather than three large meals a day. So everybody figures, and should figure, things out for themselves. There were also women at the clinic who really had much harder lives. There were two women whose husbands left them when they found out, and left them with small children that they had to handle. There were women who were coming from up north somewhere, from down south somewhere, coming for this therapy, staying overnight and then going back home. There were a lot of people who were having a harder time. I did a lot of counseling with women. And so be it.

Harden: So you were being a role model.

Kirschstein: Yes, I thought about that, and I still do. People come now and talk about it. Everybody seems to know. For a long time, I would not tell anybody. I did tell Jim Wyngaarden and I told [Dr. Thomas] Tom Malone, who was the deputy director, a very close friend, and I told my deputy, and that was all. But the Institute figured it out pretty well. We just did not talk about it.

Harden: Am I wrong to say, then, that your work really gave you a focus and something to steady you?

Kirschstein: Absolutely, absolutely. I determined that I was not going to give in.

Harden: You have already said that this particular experience did not have a major impact on the way you thought about women's health issues.

Kirschstein: No, I do not think so. This happened at the same time we were doing the report, and I was not going to let them do a special section on breast

cancer or anything of the sort. Recently, in fact in 1993, the breast cancer women--there were two groups, but there was one man who organized and got that set of, what was it, 200,000 signatures that they went to the White House--went to see Donna Shalala, and I was still co-chair of the coordinating committee. It was just before Susan had been appointed, and so I was invited down to that meeting. And Shalala turned to me, and said--I am sure she knew--"I want a meeting put on in which all these women can come, and we will do some science, we will listen to them, and we are going to put together a national breast cancer action plan, and I want you, Ruth, to run the meeting." By the time we got around to it, I was acting director of NIH. She knew what was going to happen. That is a different story, and I am not sure I know how she did. I mean, she and Harold obviously had talked about it. So I got some of the people that I knew could help me with meetings, and, in November of 1993, just after Helen came--we began planning it in August, I guess--we had a meeting. We started in Lipsett Auditorium and then had breakout sessions all over Building 10 with advocates, patients, physicians, scientific sessions, and all sorts of things. Then we developed an action plan, which we worked on afterward, we worked in the Secretary's conference room downtown, and finally published. For a while, I remained active in implementing that plan, and then Susan decided she wanted to do it, so I let her do it.

Harden:

I want to stop here for today. Thank you, Dr. Kirschstein.

