Oral History of the Belmont Report and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Interview with
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August 26, 2004

Belmont Oral History Project

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INTERVIEW

Interviewer: Patricia C. El-Hinnawy, Office for Human Research Protections staff.

INTERVIEWER: Miriam, just to begin, could you tell us your name, your current position and your academic training?

DR. KELTY: Sure. My name is Miriam Kelty and currently, I am associate director of the National Institute on Aging and director of the Institute's Extramural Activities Programs.

I am a psychologist by training, trained in both clinical psychology and in animal behavior and comparative and physiological psychology.

INTERVIEWER: When the work of the National Commission began, what was your role?

DR. KELTY: I was hired as the behavioral scientist. It was the National Commission for the Protection of Subjects of Biomedical and Behavioral Research and I was one of two behavioral social scientists that worked with the commission as staff.

INTERVIEWER: How did you come to work at the commission?

DR. KELTY: At the time that the legislation that established the commission was passed, I had been working at the American Psychological Association as the head of the Office of Scientific Affairs. One of the things I was in charge of was science policy. I was tracking the legislation and meeting with the consortium of social science associations and was very active in that. At that point, I was advocating self-regulation before the government regulated us.

I also at APA had a grant dealing with ethics of research and was working with a committee that eventually published a book on ethics of research with human subjects.

At the time the commission was being staffed, the director of the commission, Charlie Lowe, called a variety of associations and everybody he called in the area of behavioral and social sciences

recommended me, because I had been very proactive meeting with them, to try to get them to make some changes in policies to regulate themselves.

INTERVIEWER: Could you tell us a bit about what the political climate was like at the time of the commission?

DR. KELTY: The political climate at the time of the commission was conservative. I think most of us felt that, that climate was going to impact on the work of the commission.

INTERVIEWER: Did it have any impact or effect on the work of the Commission?

DR. KELTY: It may. It had an impact in that, we were very sensitive to the political climate on the conservative climate and since the first report that we were charged to produce was the report on fetal research, I, for one--and I think there were many others--were very concerned about what the recommendations would be. But, I think, in the end, the commission came up with very sensible recommendations that were much more moderate than I generally feared they would be.

INTERVIEWER: What about the issue of Tuskegee and the research that had gone on there? Did that have an impact?

DR. KELTY: The Tuskegee study certainly had an impact, though I saw it as one of a number of abuses that was reported at around the same time. The others were Willow Brook and the story of the abuses at the Jewish Chronic Disease Hospital in New York City. I believe the history of the legislation that established the commission referred to those other abuses.

So, Tuskegee might have been the most widely reported study, but I think it was an example of the kinds of abuses that could occur and highlighted, at least for me, the need to do, to provide guidance so that research would be done right, rather than have those kinds of occurrences happen in the future.

INTERVIEWER: Do you think that a study like Tuskegee could happen today?

DR. KELTY: I would hope that a study like Tuskegee would not go on for as long as it did, but I think that we've seen over and over again reports of abuses. So, whether it is like Tuskegee or not, I think the issues of poor information, inadequate consent and very questionable risk-benefit judgments could and do happen today.

INTERVIEWER: Today, some people look back at the National Commission's work and they see it as being represented by the Belmont Report. Is that how it looked at the time?

DR. KELTY: No. The Belmont Report was one of many reports that the commission developed. I think everybody appreciated that it was a very important report, but we were very much involved in the development of the other reports and the very hefty background papers that informed those reports.

As staff, we were assigned to be in charge of one or two or three reports each and we were very busy commissioning papers, making sure that we had a range of views expressed. The Belmont Report, by comparison, was short and sweet and rather quickly done.

INTERVIEWER: Do you have any recollection of how the Belmont Report was received at the time when it was released?

DR. KELTY: My recollection is that, the Belmont Report was well received from the beginning. It was to the point. It was clear and although there were some issues, which still remain with us--for example, what is just more than minimal risk that were the topic of very extensive discussion, basically the principles were very clear and very well received. It was seen as attending to the big picture and the important issues and not getting bogged down in the details.

INTERVIEWER: In the broader picture, as you look back on your experience with the commission, is there anything that stands out most?

DR. KELTY: Well, there were two things that stand out. One was process and one was product. The process thing was that the staff and the commissioners and the people that we worked with worked very closely and very well together. This day, 30 years later, I still feel a kinship with most of those people and still see a number of the people. We kind of pick up where we left off and are glad to see one another and catch up when we do.

In terms of the product, the thing that stands out for me is that, the materials that we produced really for the, almost the first time resulted in a body of literature that provided materials for discussion and teaching materials to start a whole new field, really, in academic discipline. So that, people that began to teach about ethics of research and to emphasize ethics of research in education and training, had materials to refer to and to use as discussion points.

There were very few materials available at the time that the commission was established. One was Jay

Katz's book, which is not to be minimized. It's a very big and very heavy-duty book. Also, Brad Gray's study had been published quite recently. Other than that, there wasn't a whole lot available. There were court cases and there were other things that were not so easy to come by.

INTERVIEWER: Interesting. Was there any topic that generated more discussion than others among the commissioners?

DR. KELTY: Fetal research was the first topic that was discussed, generated a tremendous amount of discussion. I think our explorations in making, coming up with recommendations about research with fetuses were much broader than the explorations around most other topics.

The other topics that generated a lot of, well, materials and discussion involved other vulnerable groups, children, prisoners, in particular.

INTERVIEWER: Was that the same among the staff as well as the commissioners, the same sorts of topics that generated discussions?

DR. KELTY: Among the staff, these topics generated discussions, but also, I think, the staff was, perhaps, somewhat more forward looking in that we were very cognizant of the fact that we were due to sunset in two years. Little did we know at that point that we would be extended to almost four years. We knew that we were mandated to complete 12 studies and we were dividing up the work. So that, different ones of us were at different stages of planning different studies and approaches to data collection at different times.

INTERVIEWER: What do you believe was your most important contribution to the commission?

DR. KELTY: I think my most important contribution to the work of the commission was my emphasis on the importance of empirical studies. I was involved in several empirical studies, the psycho-surgery study and the special study or two in particular. I think that the empirical approach that we took made a very well-rounded approach when it was combined with the philosophical papers and discussions.

I think the ability that we had to draw on data, particularly in research with fetuses, the special study and the psycho-surgery study where our recommendations or findings were somewhat different from what most of us expected, was an important contribution.

INTERVIEWER: Could you explain a little bit more about what the special study was?

DR. KELTY: The special study was a study of the social, ethical, legal, economic and maybe even political implications of future advances in biomedical and behavioral research and technologies. That is a study that we approached two ways. We had an empirical study, which was a very large survey effort in which five groups were queried about advances and responded to vignettes, scenarios that were prepared and presented to them.

The companion piece was known as the scholarly version. That was a more academic approach, a non-empirical approach that projected what kinds of advances there might be in research and technology.

INTERVIEWER: What were some of the conclusions of this special study?

DR. KELTY: Some of the conclusions--well, one of the conclusions that I found most interesting is that, five groups of people were surveyed. I don't remember exactly what they were, but examples might be lawyers, physicians and scientists, clergy, members of the public and there was some other one. All of them responded to the same questionnaires. It was surprising to me that the responses were very much similar.

What that said was that, members of the public were able to engage these topics. The topics were such things as, aside from the general survey questions, the scenarios related to sex selection of children, allocation of scarce resources, taking heroic measures and some other scenarios. It was very informative to see that people were able to understand the dilemmas that were posed and to respond and that the different social groups responded very similarly.

INTERVIEWER: No one else had mentioned the special studies. It was very good to hear that.

DR. KELTY: I guess nobody else mentioned it, because I was really the staff person in charge of that and I worked very closely with the contractors and the survey organization that conducted that study.

INTERVIEWER: If you could go back in time to the Commission, is there anything you would do differently?

DR. KELTY: No. I think there's not anything I would do differently. I think that the focus on abuse was more than suited my personal tastes. I think that, no matter what the rules and regulations are, there are going to always be a small number of abusers. I think it opened the way for us to think very proactively about the kinds of things that should be done, how to approach

ethical issues.

I think over time, we see that most of the questions that the commission dealt with have persisted. We haven't found any answers. There are not issues that there are answers to. The details may change, but the issues remain.

INTERVIEWER: At the time of the commission's work, were there any issues or ideas that you felt should have been addressed but were not?

DR. KELTY: At the time of the commission's work, perhaps because I was thinking quite a lot about the topic of the special study and about the future, I thought we could have emphasized or projected problems for the future a bit more, including globalization and international issues.

I think also that we might have focused more on multi-disciplinary research and brought more of a multi-disciplinary perspective to the reports and recommendations.

INTERVIEWER: Do you think revisiting those issues or ideas would be useful today?

DR. KELTY: I think we are doing it today. The commission's work is the kind of work that never finishes. There have been, as you well know, many groups, special commissions and task forces and offices now. We have a structure; we have now institutionalized the ethics of research in many ways as well as the regulation of research. So, we are revisiting these issues.

INTERVIEWER: What would you say about the impact of your work on the commission on the rest of your work life?

DR. KELTY: Well, my work life is still going on, but the commission did have a pretty major impact on my career. I continue to follow the issues, to be active in the area of research ethics and also responsible science, the conduct of science. I think it is an interesting area.

As far as my own career is concerned, I about ten years ago started a special interest group at NIH, the Bio-Ethics Interest Group, which I started to provide a discussion forum for ethical issues at NIH. It actually is much more of a seminar than a discussion forum, but does do some of each.

I've taught bio-ethics at the graduate level as a direct result of my work with the commission. I've written some. I am asked to consult at various times, both in clinical bio-ethics and research ethics. I regularly give talks and meet with students and trainees at professional societies, not only in my own field, but in other fields also. So, it has certainly had an impact on my work.

When I am ready to do something different from what I'm doing now, what I would like to do is continue to work in the area of bio-ethics.

INTERVIEWER: Since the time of the commission's work, what changes have you seen in human subject protections?

DR. KELTY: Since the time of the commission's work, we have seen much more discussion in the literature on human subject's protections, the development of a literature that has served as a frame of reference, so that particular aspects of policies or options or regulations are debated. We've seen, I think in some ways, a narrowing of the way we address questions of certain issues and, I think, a much broader awareness, both among the public and people who engaged in research and other aspects of science about how science is done and appropriate ways or the fact that we need to pay attention to appropriate treatment of humans who participate in research and of animals and of others, too.

I think also we've seen an increasing awareness of different cultural contexts and have begun to grapple with the fact that there are different values and different expressions of values and different traditions in different parts of the world.

INTERVIEWER: How do you think the ethical standards that were developed for this country apply in international settings?

DR. KELTY: I think their applicability in international settings is very mixed. It is important to remind ourselves whenever we think of doing research internationally that, the world isn't monolithic and we need to take into account what the history and background and current customs are in different countries.

For example, I remember a discussion not too long ago about a project that was being done in another country, in orphanages, where it was quite customary for the head of the orphanage to give permission for virtually anything that was done in that orphanage, including research. This really flies in the face of what we would consider responsible behavior in our country.

Yet, the specifics of that were very innocuous. The risk was very low. The likelihood of harm was very small. Yet, the issue of consent, which is very important for us, just was not important in that context. That's a very mild example.

When we talk about the developing world, when we think about tribal societies, when we think about

beliefs about the human body, medicine, ancestors, in the context of the genetic research that we're doing today, I think we need to do something different than what we did for [unintel] society.

INTERVIEWER: Over time, some feel that the focus has shifted away from protecting human subjects from risks and toward permitting access to innovations that might be helpful. Do you agree with this?

DR. KELTY: Well, I'm going to answer a different question. I think over time--at the time of the commission, we were very much aware of protecting what we saw then as vulnerable groups of people from research risks. I think we have come full circle to a time, in more recent years, when instead of excluding groups of people from research, we are much more focused on including groups of people in research.

So, recently we have seen, we have had policies about inclusion of children, inclusion of pregnant women and inclusion of all the groups that we were busy excluding in the early '70s. So, I think there has been a tremendous change.

You asked me about innovation, that we have shifted from protecting people to fostering innovation.

INTERVIEWER: To permitting access to--

DR. KELTY: To permitting access to innovation?

INTERVIEWER: Yes.

DR. KELTY: I don't see a dramatic change in that direction. I think we still exercise all the cautions that were recommended way back in the '70s in relation to permitting access to innovation. I don't think we are foisting innovation on people unduly.

INTERVIEWER: At the time the Belmont Report was written, the prevailing view was that vulnerable individuals, such as, children should be protected from research. However, there are currently requirements, such as, the Children's Health Act to conduct more research involving children. What are you thoughts about that?

DR. KELTY: My thoughts are that, that's appropriate. I think that the point has been made many times that we use treatments with children, but we have very little data about the impact of those treatments on children, particularly as far as drugs are concerned. I think as long as we practice what we preach, that it is possible and desirable to involve children in research.

INTERVIEWER: Do you think today's research environment is overly restrictive?

DR. KELTY: Well, I'm one of the minority who doesn't think that it's overly restrictive. Most of my academic colleagues feel very strongly that it's overly restrictive. I think the system by nature moves very slowly and so that the process for research, review and approval is much slower than most people involved in the process and users of the process. Both would like to see it faster, move faster.

I think that it is basically well-motivated and not overly restrictive.

INTERVIEWER: Do you think that subjects today are at any greater risk than they were 25 years ago?

DR. KELTY: No, I think subjects today are not at greater risks than they were 25 years ago. I think today, as well as 25 years ago, that there was some research and some treatment that is very risky, but that is in the nature of, well, the research or the treatment. I don't think it's a function of protection or lack of protection of subjects.

INTERVIEWER: Do you think that the current regulations appropriately embody the ethical principles identified in the Belmont Report?

DR. KELTY: Well, I think the regulations are designed to implement the principles embodied in the Belmont Report. Principles are, the principles were intended to provide guidance. The regulations are much more constricting; they are rules. As the regulations have been developed and embellished over time, they sometimes move pretty far from the general guidelines.

So, I think basically, yes, they are in the spirit of the principles of the Belmont Report, but at times, they certainly look as if, in my opinion, they are going too far. Though I think the system does have some checks and balances and, again, although it seems at times as if issues are never resolved, it, perhaps, is better that they remain unresolved than that they be resolved in too rigid and narrow a way.

INTERVIEWER: Do you think there are any changes that could be made that would bring the regulations more closely in alignment with the Belmont principles?

DR. KELTY: I think we can't go backwards. So, we have regulations today, which I think reflect the spirit of the Belmont principles, but have gone beyond the spirit into details, some of which I think

have gone too far.

I don't know that there is much more we can do, that there's much we can do about it now.

INTERVIEWER: As the commission defined the ethical principles for the protection of human subjects, was more weight given to some of the principles over others of them?

DR. KELTY: I think a lot of weight was properly given to the principle of respect for persons and that the others, they really follow from that. To me, that's a particularly important one.

INTERVIEWER: Could you explain why you feel that that is so much more important than the others?

DR. KELTY: I think that respect for persons is particularly important, because it is basic. It is fundamentally basic to informed consent and to the role of the person in the assessment of risk-benefit as well as the role of the researcher.

That's about it.

INTERVIEWER: Okay, that's fine.

DR. KELTY: I think personal justice also relates to respect for persons, though the commission dealt not so much with personally justice, but rather with distributed justice.

INTERVIEWER: Do you think a new edition of the Belmont Report is needed today?

DR. KELTY: I don't think a new edition of the Belmont Report is needed, but maybe some new appendices might be helpful for people. For example, we are still as perplexed about what slightly more than minimal risk is as we were umpteen years ago. Probably users would appreciate some additional guidance on some topics that are now more contemporary.

I think there were a number of topics that were addressed in the special studies, such as, genetics research. Innovative technology and so forth were not discussed with the same thoroughness as some of the earlier topics where we were at the very end of the term of the commission when we dealt with the special study. It also seemed sort of more pie in the sky when we were compared to developing recommendations that everybody knew would turn into rules and regulations concerning research with prisoners and children and so on and so forth.

So, I think some guidelines about genetics research, research involving social groups as opposed to

individuals, industry-sponsored research. International research, as I said before, might be useful for looking ahead.

INTERVIEWER: Do you see the Belmont principles as absolutes that override all other considerations or are they factors to be used in balancing the risk of harm to individual subjects against the societal benefits of increased knowledge?

DR. KELTY: I see them as guidelines and factors to be considered. I never saw them as absolute. I think that they touch on things that absolutely have to be considered, but I think that the principles themselves don't provide the conclusion of those considerations.

INTERVIEWER: Do you think that the regulatory protections for vulnerable populations is adequate or should be changed?

DR. KELTY: I think the regulatory protections are adequate, but I, myself, favor less regulation than more. So, I don't think the fact that we have regulatory protections or might have more stringent regulatory protections necessarily means that we would eliminate any of the abuses that can occur. I think those can occur with or without regulatory protections.

I think also we have to be very careful not to lump people into groups that are too homogenous. Not all children are the same. Not all people who are cognitively impaired are the same. Their cognitive condition may differ at different times.

One group that we never did develop regulations for, which is the subject of my main work now, are elderly people. I argued then, at the time of the commission and would argue now that, elderly people, older people are very heterogenous and have very different needs. I think it is good that we didn't develop regulatory protections for older people that might decrease their autonomy and reflect a lack of respect for how well they can function as opposed to how poorly.

INTERVIEWER: Do you think the regulatory approach to vulnerability should continue to be based on vulnerable population, rather than types of vulnerability that are applicable to individual subjects?

DR. KELTY: I think that the types of vulnerabilities make for an interesting alternative and, in some ways, might be more meaningful. I know that in any individual circumstance, it is very tempting to want to make the rules fit the individual situation. Yet, I certainly appreciate that, when we are talking about regulation on a national basis or law on a national basis, we really need to

deal with groups of people.

I think it would be a very interesting exercise to look at types of vulnerability instead of groups of people. That might be something for the future.

INTERVIEWER: Is there anything else at all that you would like to mention or talk about?

DR. KELTY: I can comment only that the--I think the work that the commission did was very important and I was very glad to be part of the initial group that looked at the big picture and developed the principles, though I don't think principles are the end all. They have their limitations.

I think it is kind of a more interesting thing to be involved in than some of the smaller questions that we have been asking more recently.

I think the work of the commission was important; that it has been lasting. It certainly shook up the research enterprise. I think we quite effectively started a national dialogue about research. I think people became more aware of research and, for better or worse, became more aware of some of the issues involved in how researchers interact with human subjects and the kinds of issues that impact on society that research provides a literal example of.

I guess, I think it has been for better, rather than for worse. I think it is good to have this kind of dialogue and will continue to be important.

INTERVIEWER: Thank you.

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