



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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Belmont Oral History Project

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## INTERVIEW

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

*INTERVIEWER: Bonnie, if you could give us your name and the degrees you have and your current title, position.*

MS. LEE: Bonnie Lee. My real name actually is Bernice but few people know that, and I have a BA in philosophy, which I got actually after working for the National Commission, and my current title is associate director for human subject protection policies for the Food and Drug Administration in the Office of the Commissioner.

*INTERVIEWER: Could you tell us, just to start off, when the work of the Commission began, what was your role?*

MS. LEE: Actually, my role began before the work of the Commission began. I was, I had left government and received a call and was asked to come back to government to help to establish the National Commission as well as the President's biomedical research panel which was also being formed at the same time, and so my role was to serve as the Commission's administrative officer, getting all of the different members' names, staff on board, and all sorts of other administrative systems that needed to be established so they could operate.

*INTERVIEWER: And were you aware of why it was that the Commission was formed?*

MS. LEE: Oh, very much so. I had worked previously as staff to the Tuskegee syphilis study ad hoc advisory panel, and through my work on that panel, not only of course the abuses that occurred during the Tuskegee study, but by working on the panel I had gained experience through working under the Federal Advisory Committee Act, which had just recently gone into existence, and that meant that panels and Commission had to operate very much in the public domain with open meetings, prior announcements, sharing materials, and it was for that reason I think that I was asked to come back to work for the Commission.

Also I had worked previously in the area of human subject protection and had followed much of Senator Kennedy's legislation and was aware that he was establishing this Commission.

*INTERVIEWER: You bring up an interesting point. Could you tell us a little bit about the political climate at the time.*

MS. LEE: Clearly, I think at the time, research was seen as a potential evil, certainly a very risky enterprise, perhaps not evil, but a risky enterprise, and there were a number of different, either research or close to research activities that were in the news, that caused people to say this is something to be avoided or this is something that needs far more oversight.

The Relf sterilization cases were some examples. The Tuskegee study was another. There was a lot of concern about psychosurgery and its misuse.

The idea was we needed more protections. I think that changed later, certainly with the AIDS epidemic, where suddenly research was then seen as potentially providing benefits that you couldn't get any other way. Certainly, back in the early '70s, that was not the view at all.

*INTERVIEWER: What impact did that political climate have on the work of the Commission?*

MS. LEE: I think that the political climate--well, for one thing, the National Commission in, just in its, the way it was established, was a novel Commission in so far as the legislation made it very explicit that whatever recommendations the National Commission made, had to be adopted, or an explanation needed to be made for why those recommendations were not adopted.

It was given far more "teeth" than a lot of other Commissions had. I think, if I'm remembering your question--tell me your question one more time.

*INTERVIEWER: How did that political climate affect the Commission's work?*

MS. LEE: Oh, I think it made its work or the importance of its work far more important than it would have been otherwise.

I mean, there was a lot of interest in what we did, from not only consumer groups, patient groups, but also Congress, and also the Department of Health and Human Services which was responsible for staffing it.

And I think because of that, the Commission was able to have far greater impact in the area of human subject protection than other Commissions have since.

*INTERVIEWER: : We look back from this vantage point or this viewpoint and see that Tuskegee really seems to stand out as one of the issues that was very much in the news at the time. But was it like that at the time as well?*

MS. LEE: I think it was and, ironically, I think it continues to be. Certainly with African Americans, if you ask now, I think to the general person on the street, what do you think of research? what do you think of participating in research? for African Americans you'll get almost an instantaneous "Tuskegee." "It's bad." You know. I mean, just what we were talking about--the view of research in the early '70s.

I don't know, even with the President's apology, whether that very bad taste in the mouth will ever go away, because I think that we tend to look at ourselves as moral people, and to think that in the '70s, that in the '60s, that we could have allowed that research to continue, even though it began in the '30s and it might have been a different climate, it is rather shocking and I think we, we continue to have a lot to make up for there, and to show that in fact research is very good.

Research is critically important. I don't want anyone to think I don't think that because I do. But it has to be done properly and if it's not, we all lose, including the researchers who won't get people to participate as research subjects because of concerns about abuses or not being truthful.

*INTERVIEWER: Your work has kept you almost at the heart of human subject protections over time. Do you think a study like Tuskegee could happen today?*

MS. LEE: Oh, I would love to say absolutely not but I don't know. I don't want to, want to appear naive either. There are people who don't seem to have or don't think about what is the right thing to do, don't have a high moral conscience. And I'm surprised when I see that, and I have not seen anything that would approach the Tuskegee study.

But we continue to monitor studies, to look at how they're designed. One reason we have the whole IRB review system is to try to ensure that that type of study could never happen again, certainly not to that degree.

Whether there can be research that some people would say would be unethical, yes, I think there will be always room for discussion, always room for some disagreement, but not to that level.

*INTERVIEWER: Today, some people think that the Commission's work is completely represented by the Belmont Report. Is that how you see it and is that how it looked in the 1970's?*

MS. LEE: Absolutely not. The legislation that created the Commission again was very specific in terms of what reports it was supposed to issue. One was the Belmont Report, which was the basic ethical principles underlying research and their application, as well as the boundaries between research and practice.

They also were required to do reports on children, on the, those institutionalized as mentally disabled, psychosurgery, a special study.

There were a number of different reports that they came out with and I should have checked the number, but well over a half dozen, and each one of these reports contributed significantly to the regulatory structure as well as to our thoughts on human subject protection today.

The regulations that came out in 1981 on institutional review boards and informed consent were based, in very large part, on the National Commission's report on institutional review boards.

The subpart D regulations which were based, in large part, on the National Commission's report on children.

The beauty of the Belmont Report is, unlike the other reports which are fairly specific, the beauty of the Belmont Report is that it really gives you a thought process to use in considering the ethics of a research study, the risks, the benefits, whether informed consent will be adequate.

It doesn't give you answers. It's not as though one principle is going to totally overrule another. It doesn't give you, at all, absolute answers.

But it tells you how you can consider the research and I think that's very helpful. So it's--I'm not denigrating the Belmont Report when I say that the Commission did other wonderful things but the Belmont Report itself does not stand out as the only good thing that the Commission did.

*INTERVIEWER: Why do you think it's had such visibility over time, the Belmont Report?*

MS. LEE: Well I'm tempted to say because it's a masterpiece. I think that too often, when we want to write about something, we write absolutely everything we know about it and come up with a 300-page document and trying to find the kernels of truth within that mammoth document is hard. The beauty of the Belmont Report is it's short, it's succinct, it comes out with not just philosophically vague thoughts, it's written very well, and in about a dozen pages you have the tools you need to consider research, and I think it's--that is its beauty and that's given it its lasting quality.

*INTERVIEWER: As you look back on your experience with the Commission, is there anything that stands out in your memory?*

MS. LEE: It was a wonderful group to work with. They--I--well, let me preface it by saying not just the Tuskegee panel. There have been a number of different commissions and panels that I've observed over the years, and I can honestly say that under the leadership of Ken Ryan and all of the individual members, they worked really hard at coming up with thoughtful advice. They listen to each other. It was an exceptional group and I think too often we think that well, we can establish a committee or a panel to study an issue and we'll come up with a really good product.

Sometimes that happens but I think more often people tend to have their own agendas and those agendas may be good, certainly represent a view of an issue. But it's hard for a group in a limited period of time to learn to work together very effectively, and the National Commission did, and I think that's why all of the reports are so, so good, and it certainly brings back lots of happy memories, just dealing with the wonderful people who served on that Commission.

*INTERVIEWER: Which of all the topics generated the most discussion among the Commissioners and staff?*

MS. LEE: Because we went through a number of different years and a number of different topics, I don't know that I can pick out a single topic. I will tell you my worst meeting when I worked for the National Commission. One of my jobs was to make sure that all of the meetings ran smoothly, that everyone had what they needed, all the materials were properly distributed and everything, and we had a meeting in San Francisco on psychosurgery, on--it was actually, I believe, an open hearing, and we were in a hotel, and at one point a group of ex-mental patients pulled out all of these picket signs from inside their jackets and began chanting, because they were very opposed, I suppose, to any type of recommendation that might deal with psychosurgery.

And we almost got kicked out of the hotel. Certainly it was not a smooth-running meeting and--but that was the worst meeting. All of the other ones were quite good.

There was a lot of thoughtful debate about--these were not easy topics, and so on, on the hard part of any of these topics that you might consider, you know, do you protect children by saying they will not participate in research? Or do you protect children by ensuring that they do participate in research, so that you can find out, for example, how a product will in fact work or not work in children. There's a tension there and you have to work out safeguards, and I think that the Commission tried very hard in each one of its reports to understand that there was a balance, and also to not recommend so--so much detail, for example, for regulations, that it would preclude individual thought by the IRB members. All of the discussions were good and were interesting.

*INTERVIEWER: And in that context, what did you see as your most important contribution to the Commission?*

MS. LEE: I think helping them to operate effectively in a transparent fashion. I was a dedicated believer in the Federal Advisory Committee Act and in the sunshine laws that went into effect in the early '70s, and as a result, as much as possible, we made sure that all of the materials that were made available to the Commission in a very organized way--we had large binders of material for every meeting--were made available to anyone in the public who wanted those materials in a less organized way, not giving them necessarily all the binders.

But certainly all of the materials, making sure that the, the rooms were accessible to people, making sure that meetings were announced ahead of time, just very much trying to be responsive, understanding that even if the Commission had come out with some wonderful recommendations, if they were done behind closed doors, without transparency, they would be far less likely to be accepted, and so I think that that's how I would see my biggest contribution.

*INTERVIEWER: A very important one as well.*

MS. LEE: Yeah, I think so, at a time when there was not much established about how you did that. No. And also I know that the Federal Advisory Committee Act came into existence in the middle of the Tuskegee Syphilis Studies, panel's recommend--the liberations and recommendations, and that was very difficult because those members were used to deliberating behind closed doors, and so suddenly, when the doors had to be opened, instead of talking to each other, the tendency was to talk to the press.



That's not how you deliberate and that's not how you come up with good recommendations. And so I think it was helpful to the National Commission to be required, from the beginning, to work in a public domain. But even at that time, a lot of committees I know were fighting it and were giving out the minimum, and I think that our rapport with the press was helped very much by the fact that we would say we're going to go on a site visit at St. Elizabeth's Hospital.

We can't obviously have everyone come along but we could have, you know, one or two press people, and, and they did. It was educational for them; it was educational for us.

*INTERVIEWER: Out of all the work that the Commission did, is there anything that you could look back on and say that was the most important contribution of the Commission?*

MS. LEE: I--not, not really because I think that all of their work was very important. I think that, you know, for example, the prisoner research, I think we all came in with certain preconceptions on who would be recruited as research subjects.

And I remember, when we went to Jackson State Prison in Michigan, and instead of finding that people were being used as research subjects who were prisoners, it turned out it was the best job in prison, had the best environment, had the best pay, and as a result, if there was any discrimination in terms of participating as research subjects, it was, it was considered a privileged job to be able to be a research pr--subject and--anyway, some of the preconceptions that we went in with were definitely influenced by facts that we were shown, once we were at the prisons.

And I think the Commissioners found their interviews with some of the prisoners to be very, very educational. But, no, I would not put one, one item as supreme for the Commission's work.

*INTERVIEWER: Do you think there's anything that the Commission might have done differently?*

MS. LEE: Probably. It's, it's--it's hard to say. I think that for one thing, they began to run out of time. On the other hand, I think you can only put forth a sustained effort for so long without beginning to burn out, and so, on one hand, I might be tempted to say it would have been interesting to see them go on and do more and have more time to do more.

On the other hand, I don't know how much you can ask of people in terms of years of work, doing their regular jobs as well as coming in for meetings every month. They, they did a lot.

*INTERVIEWER: Were there issues or ideas that you felt the Commission could have addressed or maybe should have addressed but didn't?*

MS. LEE: I think that today they might--well, they might have addressed things somewhat differently when it came to vulnerable populations.

On the other hand, the legislation that created them was fairly specific in terms of minimally, the vulnerable populations that had to be looked at, but they certainly--you know, one criticism I think that some people have had is that there are other vulnerable populations that perhaps need additional safeguards. As I get older, the elderly. Women. People who have life-threatening diseases.

Vulnerability can be expressed in a lot of different ways and certainly we have special protections for children, we have them for pregnant women, and fetuses, and we have them for prisoners. But we don't have special protections for every other vulnerable population that might be identified. I think that's good but I think that perhaps the Commission could have looked more specifically at what creates vulnerability and how the IRB might be able to address that vulnerability in their review, when in fact when the IRB is reviewing those protocols they're not going to know what your vulnerability is in all cases.

So that, that would have been interesting, if they could have done that.

*INTERVIEWER: You, Bonnie, along with many other people from the Commission and the staff, stayed in the human subject protections field and the emerging field of bioethics for a very long time. So what is your perspective, what changes have you seen, over time, in human subject protection, since the Commission?*

MS. LEE: Well, I'm tempted to say the more I see changes, actually, the more I see that things have not changed. There was a book, it was called The Institutional Guide for DHEW Policy for the Protection of Human Subjects. It's a little yellow book with Leonardo da Vinci's Vitruvian man on the cover. I know, because try to get a naked man printed on an NIH publication in the early '70s, is a whole 'nother story that we won't do here.

But if you look at that policy, the policy itself is almost identical to the 1981 HHS and FDA/IRB regulations that were based on the Commission's recommendations. The 1991 common rule, again, very similar. Details, certain administrative details have been added. For FDA, we have a few more exceptions to informed consent.

But generally, the basic rules, the basic structure of human subject protection and relying on institutional review boards has not changed. Do I feel it should change? I think refinement is always helpful. I don't believe in over-regulating. I'm a firm believer in only interpreting the regulations as requiring something, to the extent to which they were intended to require something.

I am concerned when I get calls from people who want to know where it says in the regulation that you must do X. Well, the regulation doesn't always say that you must do X, even though X is clearly the good thing to do.

I get calls from people who are afraid to think and, you know, if you remember what I said, one of the benefits of the Belmont Report is it does provide you with information on how to think.

You must use that information and not be afraid to use judgment, cause I'm convinced, in the end, that all of us, if we were to use the judgment that hopefully our mothers and fathers taught us to use, that we would make good decisions.

The problem is when you start looking to regulations to see what's right. Nowhere in our regulations do we say don't beat research subjects. Obviously the intention is you're going to treat all research subjects with respect. But it doesn't say that within the regulatory structure, nor should it.

If we tried to put everything in regulations, we would fail, which is why I prefer the current system and perhaps in areas where I know there's some confusion, yes, we need to add guidance. We spend a lot of time developing guidance, working on educational activities, but I don't want us to, trying to reinvent the wheel in some way. I don't think that that's functional.

*INTERVIEWER: Bonnie, you've talked about vulnerability of research subjects. At the time when the Belmont Report was written, the prevailing view was that vulnerable individuals such as children should be protected from research. However, currently, there are requirements that just the children's health act, to conduct more research involving children. What are your thoughts about this?*

MS. LEE: Well, I'm totally supportive of the Children's Health Act and the need to do research. I think perhaps, coming from Food and Drug Administration, more than any other agency, you recognize that although you might think something is good, you don't know something is good until you actually test it, and you're not going to know about potential

harms until a product is used extensively in a population.

So because children are not just little adults, and I have three children of my own, it's critically important that children be included in research but be included in a way where their interests are protected and their parents have said yes, knowingly, and where the risks have been looked at very carefully.

*INTERVIEWER: Over time, some feel that the focus has shifted away from protecting human subjects from risk and towards permitting access to innovations that may be helpful. Do you agree with that?*

MS. LEE: I don't know that there's been a shift. I think that there has been a recognition that people who are seriously ill, and especially people who don't have options, are willing to accept risks, that people in the normal healthy population would not accept and I will say personally that a couple years ago, when I went from the healthy population to the sick population, I suddenly realized I had a very different perspective than I had had before, and I think that is one of the reasons why, although I've always appreciated what research can do, it's so critically important, and it's why--it's not that you ignore the risks, but the potential for benefits are there, and it's very important to be knowledgeable of both. But you don't prevent people from potentially accessing something good because there are risks. Everything in life has risks.

On the other hand, that doesn't mean everyone has a right to pre--participate in research. Or that everyone should have a right to any type of product, regardless of the risk.

In some cases, we know that products--laetrile, I'm thinking of, for example, that were touted as potentially very good products to use, were not. They prevented people from taking products that might have been effective and people died as a result.

So there needs to be some controls but the control should not be because there are risks, then we--you shouldn't participate.

*INTERVIEWER: Do you believe that today's research environment is overly restrictive?*

MS. LEE: I tend to say no because I've been involved in developing the regulations that that research environment is working under.

I do think that in some cases, the interpretation of some of the existing regulations is done in a way with too much detail, with some federal people saying the regulations require X, Y, and

Z, when it's very hard, at least in my reading of those regulations, to see where they get X, Y and Z from the particular regulation.

It's where I would advocate the person thinking about what is the right thing to do but saying we, as federal people, should not dictate those regulatory requirements.

So I--you know, things can always be improved. There are certain areas, right now, for example, adverse event reporting, IRB review of problems involving unanticipated problems to subjects, but that--yes, that needs to be worked out. It's a very complex area, which go to the IRB, what should be reviewed by others, how to not overload the IRB system.

It's an area we're working on. It's an area that I'm very helpful that we will solve and we will fix. But I think that generally, the regulations are good, that people are not overly regulated. There are certain specific areas of research that I know have become political and, and restrictions have been put on those.

I'm not talking about those generally because they are so specific. Stem cell research, for example. I can't comment on that. It's outside of my specialty. Perhaps in those areas, yes, perhaps the restrictions are too severe. But I don't know. I could also say no, they're not. But I think we need to always look at it and to recognize that research can do good. I don't think that it's an area where we can be political or we can be overly restrictive.

I remember the ethics advisory board, many years ago, when there was an ethics advisory board, looking at research involving in vitro fertilization, at a time when that was totally new, and there were couples coming, saying this is our only hope to have a child.

Please, please, can we, you know, participate in this protocol?, and the political answer at the time was no. It was no for about a two-year period of time. The researcher finally died, not related to the question, but of age, and the research was finally approved because we thought, well, there could be benefit.

It's an example where, from one perspective, people said this research is bad, needs a great deal of regulation, and now I think in vitro fertilization is standard practice and is seen as a very good thing to pursue.

So I think we have to be very careful.

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

MS. LEE: Oh, absolutely not. I think that generally, subjects are better-informed today. They have better investigational products that are being made available to them. That's not to say that they're all going to be effective. But we've come a long way and I think that research subjects benefit from the science that has preceded us.

*INTERVIEWER: Do you think the HHS regulations appropriately embody the three ethical principles identified in the Belmont Report?*

MS. LEE: Well, by HHS, I'm assuming you're including FDA's regulations--

INTERVIEWER: Exactly.

MS. LEE: --and I think that they do. Certainly they were based, you know, written after the Belmont Report with full knowledge of what the Belmont Report contained, and I think that the only principle in the Belmont Report that could have been covered better in our regulations might have been the principle of justice, and the idea of selection of subjects, equitable selection of subjects.

Although that's mentioned in the regulations and is certainly there, I don't think that the regulations have gone very far in developing that concept.

Whether they should, I don't know. Perhaps we need more guidance on that. But generally yes, I mean, they do definitely incorporate all the principles.

*INTERVIEWER: There seems to have been a fair amount of discussion about whether the Belmont Report principles are absolutes that override all other considerations or whether they are factors to be used in balancing the risk of harm to individuals against the societal benefits of increased knowledge. What response would you have to those who are not satisfied with the situation?*

MS. LEE: Well, I think that the Belmont Report in fact provides factors that need to be considered. It's, it's certainly not an absolute. I don't think you'd want an absolute. If you had an absolute, there would be no need for institutional review boards or for other people to consider the research. Research is complex, has a lot of different things that need to be considered, and so by providing factors and how those factors can be applied, which is what the Belmont Report does, I think it's very--it's what you want from that report. So I'm, I'm not convinced by people who aren't happy with it.

*INTERVIEWER: The Commission's ethical framework which you mentioned so eloquently,*

*do you feel that it functions well in an international context?*

MS. LEE: You're talking about the Commission's framework of the Belmont Report. I think it does. I think that some of the issues that are perhaps less important here may become more important there, which is why these factors are good. You can say in this situation, you know, justice is more important than autonomy or, or whatever.

When you talk about research in, for example, in developing countries, I think that some of the principles of autonomy, and also justice, become far more complex.

If you have a developing country with a tribal society, for example, where normally, the autonomy of the individual doesn't really exist, it's the tribal chief who will decide what is appropriate for the tribe to participate in or not, autonomy has a very different meaning.

When you talk about justice or giving benefits back to the community, who is the community? You know, there have been a lot of discussion about what, what products should be made available to people. What are the alternatives? Are they the alternatives available in the Third World country for treatment or are they alternative that are available worldwide?

These are, are very difficult issues and yet I think they are dealt with as factors that need to be considered within the Belmont Report.

*INTERVIEWER: Is there any other topic that you feel we haven't touched on in this discussion, that you would like to elaborate on?*

MS. LEE: Not that I can think of, off the top of my head. No. I've enjoyed doing this, though. It brings back good memories.

INTERVIEWER: Thank you.

MS. LEE: Thank you.

–END OF INTERVIEW–