



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

## INTERVIEW WITH DR. DONALD SELDIN

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*Interviewer: Bernard A. Schwetz, D.V.M., Ph.D., Director, Office for Human Research Protections*

DR. SELDIN: My name is Donald Wayne Seldin. I'm William Buchanan Professor of Internal Medicine at the University of Texas Southwestern Medical School. I'm a member of the Department of Medicine. I have been Chairman of the department from about 1952 to 1988. Since that time, I've been a professor of medicine--after I stepped down from the Chair.

*INTERVIEWER: What was it about your background in the 1970s that led to your being asked to be a Commissioner?*

DR. SELDIN: In the 1970s I wrote several articles and gave a number of talks that had to do with matters of biomedical ethics. And these talks constellated about such issues as informed consent, respect for persons, beneficence and the like.

I also was interested in the philosophy of medical education, and tried to, again, write several articles arguing for a kind [inaudible] model. And I think these were the reasons why I was asked to serve as a Commissioner on the National Commission for the Protection of Human Subjects.

*INTERVIEWER: Did you anticipate, when the Belmont Report was released, that decades later we would continue to see it as probably one of the best reports that's been written by a commission or a committee that advised the federal government?*

DR. SELDIN: Well, the Belmont Report was an interesting event. Belmont is a small community outside of Washington, D.C.. So the name of the report immortalizes the community of Belmont.

It was simply a summary of the various thoughts, ideas, principles that had governed the Commission for its three or four years in session. These were formalized in the Belmont Report.

No, I did not anticipate that the report would have such longstanding status, or have such wide repercussions.

*INTERVIEWER: Who did you think would be the group that would benefit from the report? For whom was it actually written?*

DR. SELDIN: Well, the group was assembled--that is, the National Commission was assembled in Belmont. It was divided into a series of work forces. Several people worked on, let's say, issues of autonomy. Still other groups worked on issues of, let's say, beneficence, or non-maleficence, or justice. And these various components were then brought together, discussed broadly, and then formalized.

So the Belmont Report represented then the consensus view of some of the basic themes that had worked through the Commission in its four years of existence.

*INTERVIEWER: But was it written specifically with the intent of protecting subjects of research? Or was it for investigators? Or--for whom?*

DR. SELDIN: Well, the mandate was--the National Commission for--the mandate for the Commission was the National Commission for the Protection of Human Subjects of Biomedical Research. But there's no question that the Belmont Report examined issues outside of the research domain, as well.

So that issues, for example, of how one interacts with patients; how one conducts oneself with people of limited autonomy--all of these things had implications far beyond the research sphere.

*INTERVIEWER: Did you anticipate that the principles of the Belmont Report would be translated into regulations?*

DR. SELDIN: It's very interesting that certain ethical principles became government regulations. I think that was almost unprecedented, that a series of moral principles would be engraved in actual, official regulations subsequently. So, as one member of the Commission, I never anticipated that that would transpire.

Nevertheless, I think it's worked very well, because it has focused on very important rallying points, which every physician should bear with him in his or her interaction with patients--inside or outside the research sphere.

*INTERVIEWER: How was the report received by the community when it was released?*

DR. SELDIN: I think it was--the report was--the Belmont Report, in general, was very favorably received. I don't recall any violent hostility. There were, to be sure,

considerable criticisms.

The criticisms largely focused on the--what was called--subsequently called--"principle-ism;" that is, the various principles that the Belmont Report enunciated that govern the interaction between physicians and patients and experimental subjects. The principles were very broad. They very often conflicted with one another. They were hard to translate back to patients. And these constituted issues which were criticized.

Actually, the criticisms may have been true, but they don't in any way gainsay the value of the principles in calling to the attention very critical issues which physicians should bear in mind when they interact with both patients and human subjects in research settings.

So, even though there was a lot of criticisms, a lot of concern about the generality of the three great principles enunciated in the Belmont Report--respect for persons, beneficence and justice--even though there were criticisms, nevertheless, the assertion of these principles had a very healthy effect, in my view, on the conduct of research and the interaction of physicians and patients.

*INTERVIEWER: The question has been argued whether the three principles should be used independent of each other or whether, for example, respect for persons might trump one of the others, as you consider a protocol.*

DR. SELDIN: Well, it's interesting that these principles are not part of a cosmic ontology which is fixed in the universe. They're just human principles.

Now, someone has said that one of the great features of moral dilemmas is not only a conflict between good and evil, it's a conflict between good and good. And the principles do very often conflict with one another. So that, for example, one has the anti-paternalism embodied in the principle of respect for persons, conflicting with beneficence, when the physician wishes to, so to speak, override something that has to do with respect for persons. And the two principles come into conflict, and one has to adjudicate which principle--or what other principles might bear in mind to resolve the issue. So, for example, there's a very interesting question posed by the room search. Patients who abuse, let's say, laxatives may lie about it. And one of the best ways to identify the patient is to identify the presence of laxatives. And to do that, the patient has to be lured out of the room for an illegitimate excuse so that one could search pocketbooks and drawers for laxatives and diuretics, which would then make the diagnosis.

To do this is an act of beneficence, in a sense, that one is trying to help the patient. On the other hand, one is violating the patient's sense of autonomy. And the question you would

want to raise is: is this a legitimate procedure? Is this allowable in some moral sense?

One can say that when the assault on autonomy is minor, and the stakes are high for beneficence, in that instance one might say that the room search is justifiable.

So the principles of the Belmont Report do come into conflict with one another. But they're not absolute principles, and one can argue how much weight one should give one versus the other versus other considerations so as to come to a judgment.

How much agreement or disagreement was there among the Commissioners in how to use the three principles? Well, there was a fair amount of agreement. I think that, by and large--this is just my own view--most Commissioners weighed very heavily in favor of autonomy--respect for persons. The principle of beneficence--that is the physician acting on behalf of the patient--was very often attacked on grounds of paternalism, invading privacy.

Someone had the interesting dilemma of research in the prisons. We visited--the Commission visited several prisons to find out about research conducted in prisons. It turns out that prisoners liked research very much, if you asked them about it. Prison is a boring place--among other things. And the research activities were, so to speak diverting, attractive in many ways. Moreover, the subjects were paid a certain small amount of money to serve as research subjects. So many people thought that research in prisons, if it were conducted with some dignity, with informed consent and so forth, is justifiable.

Still others felt that the prison is a garrison, is an oppressive environment, and it doesn't matter what the individual prisoners would say, because the environment was such that it would corrupt any possibility for an informed judgment. So many Commissioners felt that research in prison should be banned, no matter what the patients thought, no matter how careful one were.

On the other hand, a prisoner in prison still has rights; they're still human beings, and they still have prerogatives. And one can argue that if appropriate guidelines, appropriate protections were put in place, one should honor this.

The Commission decided to recommend that research in prisons be banned. One was operating with a conflict, clearly, between a quality of informed consent and autonomy on the one hand, and beneficence on the other. But there was a big difference on the Commission. I was one of those, for example, who thought we should permit, under appropriate circumstances and with appropriate guidelines, research in prisons.

*INTERVIEWER: How much impact was there on the thinking and the discussions of the*

*Commissioners from the Tuskegee experiment?*

DR. SELDIN: Well, I mean, the Tuskegee experiment was one of the most appalling things ever done. It wasn't the problem for the Commission. People recognized that that sort of thing is intolerable. That wasn't a problem for anyone.

I mean, the injection of prisoners--or subjects--with an infected organism without their knowledge, without any kind of informed consent was terrible. Everybody recognizes it. It's a blot on the country, and we want to avoid anything remotely resembling that, if at all possible.

*INTERVIEWER: As you arrived at the three principles, was that driven largely by thoughts about preventing another Tuskegee?*

DR. SELDIN: I don't think so. I think Tuskegee was so obviously a violation of human rights that everyone would agree that that sort of thing is intolerable. The various principles that were discussed had to do with issues that had come up on the background of the Nuremberg trials, on the background of a number of publications, where it was quite clear that patients hadn't been appropriately informed or given appropriate consent to various kinds of research procedures.

There were also questions of justice; of the allocation of benefits as well as hazards in a fair-minded way. So a number of other issues that I think were less obvious, less easy to resolve, were major concern. How do you deal with people with compromised capacity for intellectual decision-making; for medical illness; for psychiatric illness and the like? All of these came up. And these principles played a role, but the emphasis was always on how to protect the subject.

*INTERVIEWER: Do you think a Tuskegee experiment could arise today?*

DR. SELDIN: I think that the great danger of that sort of event is posed by the very complicated problem the country has in dealing with the problem of terrorism. I don't think the analogy is exact, but I think that the handling of people, without appropriate protections has become a serious problem in the country. And while it is not a question of the Tuskegee experiment, it's a question of intimidation, of exploitation, of not honoring a person's autonomy,

And the great danger--to my mind--that has arisen is posed by various problems of dealing with terrorism, which are not easy to resolve because the question of appropriate limits--appropriate boundary rules--to protect, let's say prisoners, and yet the requirement to

get information that may forestall a great catastrophe conflicts with each other. And the guidelines we usually use--that is, the Geneva Convention--has been compromised in various ways. And I think that the closest thing we come to the kind of danger of the Tuskegee experiment rests in the way we treat prisoners who are suspected of being terrorists.

I'm not sure that there is a grave danger of a repetition of the Tuskegee experiment in the narrow setting of medicine. I think people are alert now, and sufficiently sensitized, to be very careful about that.

*INTERVIEWER: Are there issues of protecting human subjects of research today that you wish you had been able to anticipate or deal with back in the '70s?*

DR. SELDIN: I think that the issues today are simply amplifications of the issues in the '70s. We have broad problems, let's say, of various controls for research, where the object of research sometimes conflicts with the solution of the medical problems. This has to do with the treatment of drugs, the blind being of various experiments and things like that.

But I believe that the openness of American society--the application of various considerations--has gone a long way to protect people from abuse.

*INTERVIEWER: One thing that we talk about a lot today in protecting subjects is conflicts of interest; financial conflicts, institutional or professional conflicts of interest. The Belmont Report is essentially silent on conflict of interest. Was it something that you talked about? Is it different today than it was back then?*

DR. SELDIN: Well, the problem of conflict of interest has assumed almost the central role these days in discussing ethical medical procedures. And every grand rounds, every lecture, is accompanied by a statement of the lecturer to the effect that: "I have no financial interest," or "I have a financial interest;" "I have some financial interest."

And it turns out that many, many investigators have support, in one way or another--not only for drug companies, but other interested institutions. Now, the extent to which this influences the individual investigator toward prejudicing the formulation of results is a question.

I myself think this issue has been greatly overblown. I honestly do not think that there has been a monumental distortion of the value of various drugs because investigators have been, let's say, employed or supported by drug companies. But there's no question that that should have been a more important consideration built into the Belmont Report, and it

wasn't.

*INTERVIEWER: During the '70s there wasn't as much international research as we have today. A large percentage of the data to support INDs for the FDA come from studies outside the U.S. There's a great increase in research in other cultures. When the Belmont Report was discussed, when it was written, did you think of this as a domestic report, or were you taking into account the ethics in different cultures?*

DR. SELDIN: Well, the Belmont Report did not concern itself extensively with marketing research abroad. And there's no question that this has become, since that time, a considerable issue, because one way of evading constraints within the United States is sometimes to have research done elsewhere where these constraints don't apply. The results may be valuable, but the ethical procedures to get the results may be the sort of thing that wouldn't be tolerated here. And the question is to what extent such farmed-out research is legitimate. That wasn't discussed to any extent during the Belmont Report.

But clearly that has become a very serious problem these days, and people are alert to it. Whether that is appropriately controlled or not is not clear, because these international consortia are everywhere.

*INTERVIEWER: Do you think it would be appropriate or helpful to rewrite the Belmont Report, in view of the fact that we continue to write regulations, research continues to change in various ways?*

DR. SELDIN: Well, we have various commissions of various sorts. We have a Presidential Commission that looks at stem cell research, let's say.

We have another Presidential commission that looks at ethical procedures. Whether we need still another commission to rewrite the Belmont Report--I doubt.

I don't see that a massive commission, working for four years--as the Belmont Report did--is required now. But I do think that there ought to be specific attention paid to some of the issues we discussed a moment ago: farmed-out international research, the question of undue influence--things like that. These deserve to be looked at separately.

*INTERVIEWER: But from the standpoint of the three principles, do you think they still apply as a foundation for the rest of the discussions?*

DR. SELDIN: Well, the three principles that I mention really govern face-to-face personal encounters. Now, they can be broadened in various ways, particularly such things as



justice, where you talk about the fair distribution of rewards and penalties and so forth. But the question of autonomy, the question of informed consent, the question of beneficence--these are issues which largely are face-to-face personal encounters.

Now, issues of farmed-out research, let's say--let's say doing research in India, where such research would be prohibited in the United States, and where nevertheless there is a deliberate subsidy to some surrogate in India to conduct the research. That's different from the kind of principles that are incorporated in the Belmont Report. That's an aggregate problem--a broad social problem--and requires different attention.

You'd have to have different monitoring procedures, you'd have to have different criteria. You'd have to have intergovernmental interactions. I don't think that the principles enunciated in the Belmont Report, which focus more and more on face-to-face personal encounters, would embrace comfortably all these other aggregate considerations.

*INTERVIEWER: There has been a shift away from protecting human subjects from risk toward permitting access to potentially beneficial drugs, devices, medical products. Is that something that you're comfortable with?*

DR. SELDIN: The Belmont Report really emphasized such things as personal choice, personal decision-making--I'm talking about patients now; the ability to reject or accept certain interventions of one type or another which were experimental. More broadly speaking, the Belmont Report honored individual integrity; individual decision-making.

Access to medical procedures, access to insurance coverage--that's a different problem entirely. My own feeling is that in a certain sense that's equally if not more important than the Belmont Report; that the question of 40, 50 million uninsured; that the question of a collapse of emergency rooms around the country for various economic and social reasons; the increasing costs of medical care--all of this is a monumental aggregate problem which was not subsumed in the proceedings of the Belmont Report.

These issues are at least as important, if not more so, than the issues covered by the Belmont Report. I think that the access of people to first-rate medical care in the United States is an overriding ethical problem, not only financial problem, but ethical problem that this country must confront.

*INTERVIEWER: Do you think we are adequately distinguishing between research and the practice of medicine today?*

DR. SELDIN: Yes. I think that research procedures are reasonably covered by the search for new knowledge, and the guidelines having to do with that. The FDA specifies what

drugs are available for--let's say for therapeutic purposes. If you want to do research, you're not talking about therapy, you're talking about something in addition to therapy, and guidelines for research are pretty well in place. How well they're enforced you can argue about, but they're reasonably well in place.

*INTERVIEWER: Do you think the regulations of the FDA and of the Department of Health and Human Services appropriately use the three principles as the basis for the regulatory decisions?*

DR. SELDIN: The FDA largely concerns itself with efficacy and toxicity and balances the two. It also concerns itself with convenience--whether a drug is administered once a day or five times a day and so forth. It doesn't concern itself--it's not involved in face-to-face personal encounters and how that is governed.

So I think the FDA has a different purpose, a very important purpose, but it's somewhat different from the arena of the Belmont Report.

*INTERVIEWER: The HHS regulations to protect subjects in research are clearly focused on informed consent and making sure that investigators and sponsors are in compliance with the regulations. So, if you wanted to make more comments about that...*

DR. SELDIN: Well, I should say that the Commission early examined the issue of fetal research. But at that time the whole matter of stem cell research had not come to the fore. That was a later development in biomedical science.

But one of the issues that interested me all along was the question of--it's a rather philosophic issue, but it has very important practical implications--the question of what constitutes a person. This comes up over and over again in various considerations, particularly with fetal research, but also now with stem cell research.

There are some people who think that DNA--the linear sequence of DNA--specifies a person, so that a kind of biologic determinism is asserted, where the presumption is that if you knew the sequence--every bit of it--and you knew the potential specifications, you could predict the person.

Now, there's every reason, on the basis of what we know, to say that that view is wrong; that a person is formed not only by the linear sequence of DNA, but by various complex interactions--which I won't go into--between the DNA sequence, the between the DNA and the uterus, between the whole environment whereby the evolving fetus develops.

Now, this means that a person is far more complex than, say, a zygote in a plate. And the notion that one has a person when one has just the specification of something in the abstract is a naive way of formulating it.

We have in a person a very complex interaction between an environment which is, early, an intrauterine environment and later a subsequent environment which brings out the potential of DNA, its various interactions and so forth, in a way which is not predictable from the sheer reiteration of the biologic sequence. And this has very important implications for our attitude towards stem cell research, to fetal research and a variety of other things.

I don't have the time to go into it, but it's very interesting to me. Take the disease phenylketonuria. Here is a disease which is a genetic disease, but you don't get the disease if you don't take in phenylalanine. You just don't get it. It doesn't matter. The environment and so forth brings out the potential.

Now, this is very obvious, but in subtle ways the whole formation of a person is an enormously complex interaction. And it shouldn't be reduced to a matter of biologic determinism, which seems to be the drift these days.

*INTERVIEWER: When the Belmont Report was written, there was a prevailing view that vulnerable groups needed to be protected. But in research today there are more women in research studies than there are men. We have a big push to do research in children. We have research going on in prisoners. Do you think the regulations that we have adequately protect the vulnerable groups?*

DR. SELDIN: Well, in the first place, I think there should be research on vulnerable groups--yes, I do. I think it's very important that it not be automatically assumed that a woman is the same as a man. That seems to be presumptuous in various ways. I don't think a child is a small adult.

So, in justice to these individuals with their own human uniqueness--and we know a lot of a medical sort which would reinforce this--issues have to be examined. Now, obviously, if someone is vulnerable--as you say--there has to be protections built in.

I think the whole machinery of the IRB has been a very healthy development. My own feeling is that that's a very good development. And if the institutional protections are appropriately put in place, and appropriately monitored, I think that that affords a very dignified protection against most vulnerable groups.

I would even say the same of research in prisoners if the appropriate protection were put in

place. Not everybody agrees with me.

*INTERVIEWER: There have been people who have also said that we need to rewrite the regulations for protection of prisoners; Subpart C under the Common Rule. Do you think we could take on a task of that size today and still keep in mind the principles of the Belmont Report or would it be a regulatory activity?*

Well, I mean, you do the best you can. If you have the present situation, and it's bad, you try to improve it in various ways.

I think that--you know, one of the nice things about the National Commission was they tried to get information. One way is to talk to prisoners--just talk to them--and see what they're life is like. You know, that isn't written in the stars. We don't know about that.

If the research on prisoners is to the advantage of prisoners, and the advantage of society, and if appropriate protections can be put in place, I think it's very helpful.

*INTERVIEWER: We still don't have regulations on decisionally impaired people. Do you think that's critical?*

DR. SELDIN: Yes. I think it's very important if people are in one way or another impaired or defective, we have to have surrogate protections of various sorts. And I think this can be done.

I mean, it's possible to assemble appropriate structures which are fair. For example, in the neurologically impaired, it's possible to get people unconnected with the patient to participate in decision-making of a critical type. It's possible to assemble the disinterested people, so to speak--experts as well as non-experts--to participate in decision-making.

But I think these issues have to be examined because, otherwise, to approach such issues without appropriate information, on the assumption that these are just normal subjects with a slight amount of amputation is a mistake.

*INTERVIEWER: If you think back on the years of hard work as a Commissioner, was there some one thing that was particularly exciting, or particularly frustrating that comes to mind?*

DR. SELDIN: Well, I thought that one of the nice things about the National Commission was the emphasis on autonomy; on honoring an individual's capacity to make decisions. I sometimes thought it was overemphasized. There is a very precious bond between a physician and a patient, based on trust that is incorporated in the notion of beneficence that

sometimes gets pushed aside. But I do think that the attempt--right down the line--to respect people by allowing them to participate in the decision-making process, even if sometimes I think it was exaggerated, I think that was sort of noble. I liked it.

–END OF INTERVIEW–