



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

DR. TOULMIN: My name is Stephen Toulmin. I was born in London, England, but I've been living in the United States for the last 35 years. At the present time I have a university professorship at the University of Southern California, but I spent most of four years working at least half-time on the staff of the National Commission of which the Belmont Report was an outcome.

INTERVIEWER: Are you a physician?

DR. TOULMIN: I'm not myself a physician, although for 15 years I've spent at least half the week in contact--working with physicians.

My own background is primarily in the history of ideas, and from that point of view it was fascinating to be associated with a group of people who were concerned so closely with the development of medical ideas and, in particular, ideas about the interaction between the medical community and the population at large.

In this respect I think the National Commission for the Protection of Human Subjects, not only of biomedical but also of psychological research, was crucial. And I believe the activities of the Commission have had a profound effect, or have been iterating harmony with some profound changes in the relationship between the medical profession and the population at large.

Before the 1960s, physicians claimed the right to control, to govern, their own interactions, without the involvement of patients, the patients' relatives and religious advisors and the rest. The famous Dr. Osler at Johns Hopkins University was perhaps the most subtle and deep thinking of the older generation in this respect.

If you go back and look at newspapers from the period before the middle of the 1960s, you will find that it will be perhaps once a month that a serious matter of medical ethics gets into the columns of the newspapers. At the present time, it's very difficult to find a day when

issues of this kind—and they don't have to have to do with these disgraceful affairs in the Iraqi prison, they have to do with premature infants, with special diseases associated with particular racial and religious groups, and with starvation in different parts of Africa and the rest.

But they form perhaps one of the most important staples of political, social and moral discussion at the present time.

As an historian, I find it very interesting to go back and look at the beginnings of the National Commission. There is some reason for thinking that the Congress would have liked to be able to control the activities of individual physicians, but of course they quickly came to realize that it would be unacceptable politically to attempt to control activities of individual physicians in this way, and to that extent it was the research activities that went on in institutions that received government money in support of their research activities that became the focus of the activities of the Commission.

Historically, the person who did most to get the Commission started was a man whom I've seen several times on television today, namely Ted Kennedy, the senior Senator from Massachusetts. He was--the Kennedys were, as everyone knows--a Roman Catholic family, but Senator Kennedy was also a profound political thinker, and he saw that it was essential to find a way of identifying issues that the Congress could deal with in a politically acceptable manner.

At the time, the newspapers were full of reports of grotesque experiments which were allegedly taking place in Scandinavia on fetuses. And for the first four months of the activities of the Commission research involving fetuses was the central topic of the Commission's activities. But very quickly--as Dr. Seldin has made clear--the range of subjects which the Commission concerned with expanded, and included young children, prisoners, the mentally impaired, and the rest.

INTERVIEWER: The Belmont Report is unique in the amount of support people have by saying that it has held up for decades as one of the shortest and the most impact-causing report of any commission or committee report that's been written in the U.S. Did you think that the report would have as much impact as it has?

DR. TOULMIN: In spite of the 15 years that I was involved, from the late '60s on, I haven't been very closely or deeply concerned with medical ethics in subsequent years. But I do think it's worth noting--or there are points that are worth noting about the Belmont Report, and in particular this idea of principles, which have a much longer history.

I mean, to give you just one example, for instance, the first well-known person who contributed deeply to our understanding of the nature of moral principles was Aristotle. Aristotle himself came from a medical family. His father was a physician, he himself was the physician to Alexander the Great, and his philosophical lectures were, in a sense, a byproduct of the experience that he had as a physician. And this led him, in particular--if I may take a subject that Dr. Seldin is particularly concerned with--it is in particular made him sensitive of the importance of context; the importance of looking at the ways in which particular moral problems arise in relation to the actual human details of the situation in which that problem had to be faced.

And he saw quite clearly that small changes in the context could result in radical changes in the way in which the balance of our judgment tilted between the different kinds of considerations that arise.

INTERVIEWER: When you were working on the report, did you anticipate that the report would be translated into regulations?

DR. TOULMIN: Indeed, if you look at the Congressional procedures which led to the establishment of the Commission, its very purpose was to provide guidance to the Secretary of Health and Human Services, as it now is--it was then called the Secretary of Health, Education and Welfare. Its very purpose was to provide guidance to the government in deciding how the funds that they were providing for research could be acceptably spent. And they wanted to avoid situations in which the activities of the government and the ways in which they were spending the taxpayers' money could be challenged and said to have been illegitimate.

INTERVIEWER: Do you think the regulations, as we use them in this country today, accurately reflect what you intended with the principles?

DR. TOULMIN: That's a difficult question. I mean, in any activity, you get a spectrum of people, some of whom are too casual, others of whom are too scrupulous and restrictive. And one needs to look at--one needs to look at the particular case in order to arrive at a properly considered judgment.

It's interesting to look at the history of the word "scrupulous." In the middle ages, one of the primary sins was what was called "scrupulosity." And scrupulosity meant blaming yourself needlessly for things that you should, from the moral point of view, be more relaxed about.

And we all know from our own personal experience that there are physicians who we feel

are drawing lines too tightly and are not prepared to allow procedures which seem to us to be perfectly reasonable and in very much the kinds of things that individual patients, their relatives and advisors, should be allowed to decide, even if it meant rejecting and declining-- or declining the advice of the physicians in question.

INTERVIEWER: What was the response of the community to the release of the report?

DR. TOULMIN: Well, I don't have to tell you that most people don't read government reports. I mean, on the other hand, the people who were most profoundly concerned, or those directly concerned, I think were very happy to have a well thought-out statement of the considerations that they should bear in mind in deciding on particular medical procedures, whether they should be accepted or not. And this depended, again, very much, as I say, on the details of the particular situation, on whether the patients or their relatives were--accepted blood transfusions, or were bitterly opposed to the use of blood transfusions or the like.

INTERVIEWER: How much of an impact did the Tuskegee experiments have on the thinking of the day of the Commissioners and on the discussions?

DR. TOULMIN: Well, like Dr. Seldin, I think this was something which everybody took for granted. I mean, this was part of the historical background against which the establishment of the Commission needed to be seen. Nobody would defend the kinds of procedures which had been adopted in this--I don't hesitate to say--wicked series of experiments on the liability of African American patients to injections of cancerous substances into their blood systems.

But just because this provided us with, so to say, an undoubtedly wicked and undoubtedly unacceptable example of procedures, it gave the Commissioners a backstop against which they could compare the more serious and relevant issues that were their concern.

INTERVIEWER: Are there issues about human subject protection that we are facing today that you think weren't anticipated when the Belmont Report principles were being discussed?

DR. TOULMIN: Oh, yes indeed. I mean, to revert to this question of stem cell research, which was one of the topics nobody had yet got to the point of understanding, it was very interesting a couple of days ago, to see Mrs. Reagan appealing to the President to relax the restrictions on stem cell research because of her hope that nobody in the future would be left in the condition that Ronald Reagan, in his own advanced stage of Alzheimer's disease was subject to. And it will be very interesting to see how the appeal of the wife of one

Republican President affects the activities of another Republican President.

INTERVIEWER: How much of the discussion in the Belmont Report was based on biomedical research, as opposed to social and behavioral research?

DR. TOULMIN: I would say about two-thirds of it was biological and medical, and one-third was concerned with psychology.

One of my favorite memories of the Commission was a public hearing at which a young lawyer came down from New York and denounced the whole idea of conducting any kind of research on young children as quite unacceptable, after which the Commissioners, in discussions, were heard to say, "Well, now we must find some way of decriminalizing Piaget."

And it's clear that there's a great deal of psychological research which is very helpful, and very much contributes to the development of our ideas about human development and, in particular, the development of human ways of thinking and acting that are not only acceptable but highly desirable. And in this respect, the whole field of what they would call cognitive sciences--cognitive psychology--is a field that has great importance for us in relation to our understanding of the needs of education and so on.

INTERVIEWER: Various conflicts of interest are major problems in research today; financial conflicts of interest, professional, institutional conflicts of interest. The Belmont Report didn't mention conflict of interest by name. How much was it discussed? Do you wish you had mentioned it in the Belmont Report?

DR. TOULMIN: Well, I certainly wish it had been mentioned. There was a good deal of discussion, usually informal--not in the actual meetings of the Commissioners, but in their personal conversations around the meetings. And I think we all understood--certainly, Albert Johnson and I, who were led to write a book about casuistry, as it's called, as a result of our joint experience with the Commission, and certainly we were very, very much concerned with the ways in which different--if you call them principles, different weights attached to different kinds of historical in our dealing with our human problems.

I think we all of us know how, when our friends find themselves in quandaries, we sit around--I'm tempted to say young women in particular are very good at sitting around and discussing, in detail, how one could arrive at a way of acting which was acceptable to all the people concerned. And this, I'm tempted to say, would be a very Aristotelian insight, very much a proper concern with the detailed contextual context, or detailed situation, in which

the people concerned were apparently trapped.

INTERVIEWER: There has been a fair amount of discussion since the Belmont Report was written about whether the three principles are independent of each other, or would be used in a more sequential manner; or the possibility that, for example, respect for persons would trump the importance of the other two principles. How much agreement was there among the Commissioners about how the principles should actually be applied?

DR. TOULMIN: I don't think they sufficiently considered this. I think that they were too easily satisfied with the formulation of these basic ideas, and that the actual practical problem of balancing them off against one another in particular situations was one that they did not sufficiently examine or reflect on. That's why, I think, we have as much to learn from--say, from novelists, people--storytellers--who construct situations in which we can feel on our pulses the ways in which the claims of different peoples, or the different kinds of claims that different people have, need to be taken into account.

INTERVIEWER: Do you think the Belmont Report, and the principles need to be rewritten to get the protections that we need today?

DR. TOULMIN: It doesn't seem to me that the principles themselves need to be changed. I mean, they all of them express general features of human life and human action that have lasted for several thousand years, and are not obviously going to change in general abstract formulation.

How they're going to apply, what kind of situations are going to arise, this is something we can hardly predict--as I think we can all understand. I mean, when the American Constitution was written, people had no idea that there was going to be such a thing as radio. And it has been the task of the United States Supreme Court to reapply, or to arrive at a proper, an acceptable, reformulation of the ways in which these general terms of the Constitution are applied in the light of new technological changes; the development of railroads and automobiles, the development of flying machines and now the development of rockets and the rest.

This is something--these are things which Franklin and Jefferson and George Washington could not possibly have thought of, could not possibly have foreseen, but whose application, I believe, they would have understood if we had only been able to explain to them the technological innovations that were going to occur in the next 200 years.

INTERVIEWER: Research involving humans has much more international dimension today than it did 30 years ago. But did the Commission work primarily on domestic concerns, or

was it international?

DR. TOULMIN: Well, the business that the Commission was given had to do with the needs of the United States Congress and the United States Administration. But it was clear to the Commissioners that there was something to be learned from considering the activities of other countries. In fact, I remember we had visitors from Holland, which is a country which has been very, very thoughtful in its ways of dealing with these problems, so that the Commissioners and the staff, of which I was a member, we all felt that there was, indeed, something to be learned from the ways in which issues of this kind were dealt with in other countries.

And, I think, it's certainly right to say that this is increasingly the case. As Dr. Seldin said, the extent to which research projects which we would not tolerate in this country are translated to India or Africa or other countries, this is something about which we should feel deep concern.

INTERVIEWER: Over the past 25 years we have seen a shift away from the focus being on protecting subjects from risk, towards permitting access to potentially helpful new drugs, devices, biologics. Do you think that's consistent with the principles of the report?

DR. TOULMIN: Oh, certainly. In fact, when you look at the origin of those principles, it's very interesting to notice that there was much more agreement between the different Commissioners about the kinds of research which were morally acceptable or unacceptable than there was about the ways in which the reasons for their consensus were to be justified.

At the end of each period of discussion, for instance, about young children, about prisoners, about the mentally impaired and the rest, they would find that of the 11 Commissioners, there were perhaps two who disagreed with the general tenor of the rest of the Commission. But the ways in which they expressed the reasons for their agreement or disagreement were very different from the formulation of the terms on which they were very largely agreed.

In fact, one might say that the Protestants agreed for Protestant reasons, the Catholics agreed for Catholic reasons, the Jews for Jewish reasons, and so on. It was a matter of reconciling their human insights with their religious or intellectual commitments that determined the exact words that they chose to express the reasons for their consensus or disagreement.

INTERVIEWER: The report has a very thoughtful piece on the distinction between research and medical practice. Do you think we are adequately distinguishing research from medical practice today?

DR. TOULMIN: That's a difficult question, and there are indeed reasons why physicians who work for particular drug companies may be tempted to present conclusions which are in the interests of that particular industrial corporation.

But to the extent that the arguments that they present are published--and, by and large, it's an essential part of scientific procedure that we accept only those conclusions which have been presented for public consideration and criticism--to that extent I think we have some kind of a political and social protection against the crazies.

To reformulate slightly the way in which these points are put, I'm a little unhappy about the word "paternalism." I would prefer, myself, reflecting the relationship between mothers and fathers, or brothers and sisters, I'd prefer to talk about "parentalism." I mean, it's not a matter of gender, it's a matter of humanity which is at issue in this kind of situation. And to that extent, however much the technological situation may change, however much our medical procedures become subtler and more discriminating, it's essential to formulate them in a way which is gender-neutral and to that extent of broader human application.

INTERVIEWER: The report mentioned the need to protect vulnerable populations, or vulnerable individuals. But today we have more women in research than men. We have a need to do testing in children; to develop better drugs and better knowledge of how to use the drugs. We have a fair amount of, at least, social and behavioral research going on in prisons--but not so much biomedical research. Do you think we are adequately protecting these vulnerable populations, as you had in mind with the Belmont Report?

DR. TOULMIN: Well, that, again, is a question which is very hard to answer in general terms. I mean, there's a well-known saying in journalism that bad news is news, good news is not worth mentioning. And to that extent what we'd read in the newspapers is nearly always--has to do with objectionable actions, objectionable developments.

And the fact that a lot of doctors, a lot of soldiers, a lot of psychologists are treating the people that they're concerned with in an acceptable--indeed, even an admirable--way, this is not the kind of thing that makes headlines. On the contrary, it's what we hope and, to some extent, believe is the case.

INTERVIEWER: Do you think we adequately protect those people who are impaired in being able to make decisions?

DR. TOULMIN: I think we have to be very sensitive to the ways in which these inadequacies

can be remedied. I mean, Dr. Seldin himself said, we need to have an adequate procedure for substituted judgment for people--who may be relatives, who may be other physicians, who may be spiritual advisors and the rest. We need to have mechanisms by which what they have to contribute to the discussion is taken sufficiently into account.

I remember, for instance, when I worked at the University of Chicago on the problems that arise in the case of medical research, we very often found young physicians who regarded any patient's dying as a terrible failure, as a reflection on themselves. They talked as though they could be expected to keep all their patients alive indefinitely. It was necessary for them to come to understand that at a certain point the hope of curing a terminally ill patient's condition was vain, and one had to make the transition from curing to caring, to make sure, as people try hard to make sure in hospices, that their passing can be made as painless as is humanly feasible.

To that extent, I think we've all come, in the last 30 years, to understand much better that our lives reach a point at which we can be grateful, we can hope that our relatives and physicians and other people with whom we're concerned will be as humane and comforting as is possible. Being in my 80s myself, I certainly trust that this is going to be the case for me.

INTERVIEWER: If you think back to the years of hard work that you put into helping with the writing of the report, are there some things that are particularly exciting memories, or things that are particularly frustrating?

DR. TOULMIN: Well, there was one particular episode--we went up to San Francisco, and the proceedings of the Commission were disrupted by a party of people breaking in and objecting very vociferously to any kind of brain surgery. I mean, this was the only time in which I remember Ken Ryan, who was the excellent chairman of the Commission, who has, alas, himself passed on-- it was the only time I saw him unable to control the proceedings, and the meeting had to disperse because it was clear that nothing more could be achieved in the face of this eruption--"eruption."

INTERVIEWER: Did it every happen after that?

DR. TOULMIN: That was the only time--that was the only time I remember anything spectacular happening in the activities of the Commission.

INTERVIEWER: The report itself was spectacular.

DR. TOULMIN: I'm glad you feel that way. I think it was a well thought out and very well expressed, but necessarily very general, account of the ways in which medicine—the activities of physicians, and activities of research physicians—give rise to situations in which moral quandaries face us and have to be resolved.

INTERVIEWER: It's general in nature, but the foundation that it provided, is one of the reasons why it has survived so well in 25 years.

DR. TOULMIN: Indeed. I think anyone who takes the trouble to re-read the report at this stage will see how much care, how much thought, how much literary subtlety went into its production. And to that extent, I think it has a permanent place in the literature, not only of the medical profession, but of the social and personal impact of medicine and psychotherapy on our ways of life.

INTERVIEWER: It must be exciting to have contributed to that.

DR. TOULMIN: Indeed. I can say quite honestly that those three years had a permanent effect on my ways of thinking, and on all the work that I've done since then. And to that extent, I'm extremely grateful for the opportunities which the Commission gave me to engage in and participate in and make contributions to their activities.

INTERVIEWER: The rest of us are the beneficiaries.

DR. TOULMIN: Thank you.

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