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.

INTERVIEWER: To get us started, would you tell us your name and your current position and your academic training?

DR. WALTERS: I'm LeRoy Walters. I am a senior research scholar at the Kennedy Institute of Ethics. And I'm also the Joseph P, Kennedy, Sr., Professor of Christian Ethics at Georgetown University. I did my Ph.D. work at Yale University and wrote my dissertation on the just war theory. I took no formal courses in medical ethics. At the time there weren't courses offered in this field.

INTERVIEWER: How did you come to be asked to be a consultant to the National Commission?

DR. WALTERS: I had written an article on the topic of fetal research, and I think that--as that topic became a topic for the National Commission, they turned to me, among several other people, and asked me to write a position paper on the topic.

Later, the Commission was looking at the general ethic principles underlying biomedical and behavioral research and asked a number of philosophers and theologians, including me, to write papers on that topic. Those were the backdrop for the Belmont Report.

INTERVIEWER: The concern or the interest in research in fetuses, was that driven by political concerns or medical concerns or societal concerns?

DR. WALTERS: I would say that shortly after the Roe v. Wade decision was handed down by the U.S. Supreme Court, the issue of fetal research became a very lively topic in the United States. NIH denied that it was involved with the funding of any fetal research. However--do you want me to change something?

INTERVIEWER: Was fetal research being paid attention to at that time because of political concerns or medical concerns or social concerns?

DR. WALTERS: After the Roe v. Wade decision by the U.S. Supreme Court early in '73, I

think people were considering the abortion question in new ways. Rumors started to float that NIH was funding some research involving living fetuses, and though NIH denied it, I think over the course of that year it became quite clear that NIH was indeed funding such research.

Then there were also reports found in the medical literature of quite grisly experiments involving the decapitation of live fetuses after they had been delivered through hysterotomy. So I would say it became both an ethical issue and a political issue. It was one of the political issues that led to the formation of the National Commission.

INTERVIEWER: As you worked with the National Commission, did you feel that you were free to work on the basis of what your thoughts were, or were you driven by political concerns or pressures from other circumstances?

DR. WALTERS: I felt totally free as an academic person to call matters as I saw them. I'll never forget the special committee that was chaired by Maurice Mahoney at Yale that did a study of the worldwide literature on fetal research. During the winter of '74-'75, we would frequently fly to Chicago for a one-day meeting, and in that committee, I felt that we honestly tried to find out exactly what kinds of research were being done. We wanted to face the facts.

And as I then wrote a position paper on the topic, I felt totally free. I thought that the Commissioners wanted to hear my best thoughts about what the issues were and what would be an ethically acceptable approach to live fetus research.

The two kinds of fetal research that were of special concern were research on pregnant women in anticipation of abortion, and in that case, drugs or radioisotopes were often given to pregnant women, thinking that the fetus would only be in utero for a few more days and that there would be no damage to a future person. The other kind of live fetus research concerned fetuses that were accidentally delivered alive and intact, and the Scandinavian study with the decapitation of fetuses was, I think, the most striking example of that kind of research.

INTERVIEWER: We've all had the opportunity to read and reread the Belmont Report, but it was just a few of you who were actually the Belmont Conference Center when the thinking went on that led to the development of the report. What was it like during the meeting at Belmont?

DR. WALTERS: We really didn't have a sense that this was a historic day or a historic

meeting. We met as a large group at this conference center between Washington and Baltimore at the beginning of the day, and then we broke up into smaller groups. Our group, at least, was charged with trying to come up with a short list of the ethical principles that should underlie biomedical and behavioral research.

I recall that in the literature, the philosophical literature of the time, there was quite a bit of discussion of the principle of beneficence or concern about good and bad consequences and the principle of justice. There wasn't as much discussion of a notion like respect for persons. However, the consultants who had written background papers really did a superb job of outlining some major ethical principles, and as the day wore on, at least within our small group, people almost came up with kind of a litany--beneficence, justice, and respect for persons. And that actually then anchored the Belmont Report.

I must say that much more work needed to be done over the next two years to flesh out those principles, but I think the three principles have stood up very well over time.
INTERVIEWER: Were the Commissioners and the rest of you of pretty much good agreement during the meeting, or was there a lot of contentiousness between the members? Were there a lot of issues that caused a lot of discussion?

DR. WALTERS: It was almost too early to know whether beneficence, justice, and respect for persons would be adequate. And since the Belmont Report was published, people have proposed other principles like solidarity, or they've worried that respect for persons maybe covers too many different topics. But I think by the end of the day at the Belmont Conference, people were convinced that this was a pretty good provisional list and we should take the matter further and try to flesh out the principles.

INTERVIEWER: Were there other principles on the list that day that subsequently didn't make it into the Belmont Report?

DR. WALTERS: I can't recall other specific principles that were discussed during that day in the paper by Tris Engelhart. In particular, there was a lot of discussion of respect for autonomy as a central notion in moral philosophy and bioethics. I think the Commissioners preferred to go with the broader notion of respect for persons. Probably Al Jonsen and Karen Lebacqz played a key role there. There was a very excellent book on respect for persons by a British moral philosopher that I think had played a role in their own thinking and perhaps their own teaching.

INTERVIEWER: Several of you who worked with the Commission and writing of the documents were theologians, are still theologians.

DR. WALTERS: May I come back and elaborate on that point a little bit?

In the time since Belmont, I would say in the book by Beecham and Childress, for example, respect for the autonomy of persons has replaced respect for persons in the Belmont trilogy. And I think that's okay if one makes respect for persons kind of a fundamental principle that underlies the whole ethics enterprise.

You don't care at all about respect for autonomy of persons or justice or beneficence unless you start with a mind-set that you are going to respect human beings. And in that sense, I think respect for persons was a good concept. I think Beecham and Childress contributed a clarification by focusing on respect for the autonomy of persons. But I think respect for persons is just the most fundamental principle of all of morality.

INTERVIEWER: Is that another way of saying that not all of the principles are of equal importance, that perhaps one is more important than the others, and if that one isn't met, the other two are less important?

DR. WALTERS: The way I look at the Belmont principles is that all of the three are necessary conditions for morally right action. Each one of them is necessary, and together they're sufficient. If a particular study or a particular public policy respects the autonomy of persons and provides good benefits but doesn't take justice into consideration, I think it's a defective policy and needs to take justice into account.

So I think they're all necessary. I would not want to give priority to any of the three principles. I would say that within the history of Western moral and political thought, respect for the autonomy of persons is the newest principle.

Thomas Aquinas and Aristotle would not have known what this notion was. Aquinas did talk about the importance of conscience and behaving in accordance with one's conscience. But I think it was someone like John Locke in political theory who started to develop the notion of individual rights and political autonomy, and then Immanuel Kant and John Stuart Mill did a lot more with the notion of the autonomous person. It's a very important notion. It's closely connected to the notion of human rights. And so I think it's a good complement to the kind of ethics that Aristotle and Thomas Aquinas have bequeathed to the Western tradition.

INTERVIEWER: To what extent was the thinking of the Commissioners and the rest of you driven by the desire to protect people's rights as opposed to protect people from harm that might happen as they were involved in research?

DR. WALTERS: People knew about the abuse of human subjects in the United States in the 1960s and earlier through Henry Beecher's 1966 article in the New England Journal of Medicine. Then Tuskegee came on the scene in 1972, and so people were very concerned about harms to human subjects. But this was also the time of the civil rights movement. So I think it's hard to distinguish between rights and harms. There had been clearly very risky experiments done in subjects in the '50s and '60s in the United States who had not been adequately informed, if they had been informed at all.

But the other concern exemplified by Tuskegee was that these men were never told that they were participating in an experiment. And even if you could say, well, most of the harm that occurred to them occurred because of their underlying disease, still the notion that for so many years they were misled about what as happening to them, what they were being asked to do, was a gross violation of the rights of those men. They were not informed properly, even if the experiment itself did not do great harm to them.

INTERVIEWER: Was the Tuskegee syphilis experiment a dominant feature of the thinking--did it dominate the thinking of the Commissioners and the rest of you? Or was it something that was in the background and you proceeded with that simply in the background?

DR. WALTERS: Senator Walter--I'll start again. Senator Walter Mondale deserves a great deal of credit for having provided the early impetus that led to the creation of the National Commission. In the late '60s, he was arguing that the U.S. should set up a National Commission on Health Science and Society. He was concerned about genetic intervention questions. He was concerned about the definition of death and the updated definition in the light of the desire to transplant organs from people who had just died. So his concerns were much broader.

I think that Tuskegee did actually provide the final push, so that when Senator Kennedy held hearings in 1973 on Tuskegee and broader issues in research with human subjects, Senator Mondale's ideas from the late '60s actually finally cleared the hurdle of being accepted by the Congress and enacted into law.

INTERVIEWER: Do you think there could be a situation today where there would be another Tuskegee experiment that would surface?

DR. WALTERS: I hope that we've made so much progress in the protection of research subjects that another Tuskegee experiment would not be likely to occur in the United States. I feel less confident about contexts in the Third World where the research protection system

is probably not as well developed as it is in the United States and where companies or academic researchers might have the temptation to cut corners in a setting where the oversight system is not so strong.

INTERVIEWER: As you developed the Belmont Report and other reports of the National Commission, were you thinking of research in the domestic sense or globally?

DR. WALTERS: International research was not so visible a topic in the early '70s as it is early in the 21st century. I think the primary focus was on the U.S. domestic situation, our own history, and how the Institutional Review Board system was set up in the United States, how well it was functioning.

One of the great contributions of the National Commission was actually to provide us with the first snapshot of how IRBs actually function in the United States, what their workloads are like, and what issues they see as the most important issues in reviewing human subjects research.

There was a massive study of IRBs led by a social scientist, Brad Gray, that I think is often overlooked as one of the major contributions of the National Commission.

INTERVIEWER: Did the discussion focus primarily on biomedical research, or was there also a discussion of the social and behavioral science kinds of research?

DR. WALTERS: The Commissioners did their very best to live up to their title that they were to study biomedical and behavioral research. And several social scientists were, in fact, asked to submit papers to the Commission. In its findings and recommendations, the Commission always tried to be aware of social science research, but I think it's fair to say that social scientists were not well represented on the Commission or the Commission staff, apart from this empirical study of IRBs. And I think a great deal of work remained to be done by others on social science research after the National Commission concluded its work.

INTERVIEWER: If we were to convene a Commission today and ask the question how do we protect subjects not only in the U.S. but outside the U.S. involved in research, and we protect subjects in biomedical as well as social and behavioral research, do you think the principles, the ethical principles would be any different?

DR. WALTERS: I think that the three Belmont principles, with a bit of elaboration and interpretation, do help us to think about some of the most important issues in biomedical and behavioral research. Some of the applications of those principles I think also stand up very

well. Informed consent is important in research. A concern about the selection of subjects is very important.

We've changed our paradigm somewhat from the early '70s. At that time people were primarily concerned to protect subjects against the risks of research. Now we've sort of looked at the other side of the justice question, and we've said we don't want any group to be excluded from the possibility of participating in research either. So we want research to invite women and African Americans and Hispanics and people of other heritages to participate in research and to feel as if they're entitled to take part in research that might be particularly useful to members of their own group.

I do think that some kind of a notion like solidarity would be a useful addition to the three principles of the Belmont Report. I know that some philosophers who like to economize say why add a fourth principle when you can probably cover the same ground with three; perhaps justice can cover what you're concerned about with the notion of solidarity, or perhaps beneficence can cover it.

But what I have in mind is the notion that we're all in this world together, that there are certain things that we can do to try to respect each other and to help each other. We're surrounded by the problem of disease and accidents and premature death--often premature death from cancer or heart disease that's accompanied by a great deal of suffering. And so if we sense that we're all in this together, I think that really does layer on each of us the responsibility to think of what we can do as individuals to take part in research and to do what we can on behalf of people who really are suffering and dying prematurely.

INTERVIEWER: The public at large to some extent and for certain some parts of the public are still very aware of the harm that was done to people even in more recent years than Tuskegee, where subsets of the population were taken advantage of in terms of being research subjects. So while solidarity is an important concept, there still is a great reluctance on the part of many people to volunteer to be part of research. How do we convince them to become part for the good of our culture?

DR. WALTERS: Looking at the question of solidarity and justice solely through biomedical and behavioral research won't work. For those questions, we really have to look at other issues like access to health care, access to a decent minimum of family income per year, access to good schools. I think that if we work on those problems and if poor people in particular feel that they have a stake in the society, that the society cares about them as people, it's going to make a much different context, it's going to create a much different context for inviting them to take part in biomedical or behavioral research.

If I were a poor person and had very limited access to health care, but when I had to go to a hospital and perhaps throw myself on the mercy of the emergency room, if I were then invited to take part in biomedical research, I'd wonder, Why are they asking me? I mean, what have--what has the society done for me in general lately? And is this some kind of exploitation of me? I think I would be quite distrustful of an invitation to take part in biomedical research if the society were saying in so many other ways that it didn't really care about me.

INTERVIEWER: Were those factors such as the availability of health care taken into account as you talked about the three principles?

DR. WALTERS: There was a small study done by the National Commission on differential access to health care. It was done late in the Commission process. It didn't receive a great deal of attention. When a new Commission was set up in the early 1980s, the President's Commission on Bioethics, it specifically included a focus on medicine and biomedical and behavioral research. And that broadened focus allowed the second Commission, the President's Commission on Bioethics, to deal with topics like access to health care, like the extension of life through extraordinary means, and the definition and determination of death.

So I think that the Commission's focus was actually quite narrow and quite limited. It wasn't asked to look into what was, even in the early '70s, a serious social problem, namely, differences in access to health care. Its focus was primarily driven by NIH-funded and FDA-regulated research.

INTERVIEWER: When the Belmont Report was eventually published and became available to the community, what was the reception? Were there people who were happy to see that it was published? What was the reaction within the research community or in the public?

DR. WALTERS: It's hard for me to go back and reconstruct how people were thinking and feeling in the late '70s. The Belmont Report came out just about the time the National Commission was completing its work and closing up shop.

Probably the major impact came in the revision of the research regulations, and that revision was indeed carried through in light of the Belmont principles. So the way the Belmont principles got translated into the practice of researchers and IRBs is through the research regulations, which in a way--

The way the Belmont principles were translated into practice was through the research

regulations of the Department of Health and--Health, Education and Welfare initially and then the Department of Health and Human Services. Those regulations really are a kind of making very specific the Belmont principles of respect for persons, beneficence, and justice, and some of the specific questions outlined in the Belmont Report are almost repeated verbatim in the research regulations.

So Belmont was translated into something operational for local IRBs and for researchers to think about as they planned their research and as they reviewed research.

INTERVIEWER: While you were working on the Belmont Report, did you have the expectation that it would be translated into regulation by the government?

DR. WALTERS: One of the beautiful parts of the National Commission legislation was that it required action, some kind of response from the Secretary of Health, Education and Welfare within 180 days of the Commission's formulating recommendations to the department. That action-forcing requirement meant that Commission reports didn't simply get put on shelves and gather dust. There had to be some kind of response.

The Secretary did not have to agree with what the Commission recommended, but if he or she disagreed, the Secretary had to provide reasons for disagreeing with the Commission's recommendations.

So here you had a group of academic people and citizens making recommendations to government and requiring a response. I think it's a wonderful model for accountability in government, and I worry that many Commissions fail because there isn't a similar requirement of some kind of formal response by the government within a specific time limit.

INTERVIEWER: As the Commission produced its reports, was it constrained by the knowledge that these would be translated into regulations?

DR. WALTERS: I think the Commissioners called matters as they saw them. They were not primarily concerned about whether the government would agree with their recommendations or not. In fact, behind the scenes early on, particularly on the matter of fetal research, there was a vigorous struggle--I won't say a bitter struggle, but it was vigorous--about whether the Commissioners and their views or the views of NIH would prevail going forward to the Secretary of HEW. And the Commissioners stood their ground and prevailed. So it was their views being put forward to the government for a response.

INTERVIEWER: Do you think the thoughts and the conclusions of the Commission were

actually captured in the regulations with good fidelity?

DR. WALTERS: You'd have to look at specific reports and specific regulations. The fetal research regulations were, I think, quite an accurate reflection of the majority recommendations of the Commission. The children's research regulations were also, I think, quite an accurate reflection of the Commission's report. The Commissioners were not quite sure what to do with research involving prisoners, and there never has been a set of regulations put out on the prisoner research issue. So it varied with the topic.

INTERVIEWER: Was there a lot of media attention when the Belmont Report came out that would have let the public know that something was being done to protect them?

DR. WALTERS: The Commission meetings were quite well attended by the public, and they were quite well attended by the media. The fact that the Commission had a very short time frame on the fetal research report and the fact that this topic was so much in the news I think gave a focus and a momentum to the Commission's work. Major newspapers, Science, and Nature covered the Commission meetings. So I think it was a very interesting experiment in conducting public policy in the biomedical arena and probably educated many citizens for the first time about what was possible in terms of thoughtful, scholarly work on very controversial issues.

I think it also was instructive that the Commission brought a more academic approach to these topics than was possible through congressional hearings, which sometimes were stacked and in any case were often very brief. The Commission's discussions certainly were more thoughtful than many of the speeches that are given on the floor of the House or the Senate because they were perceived to be--and I think they really were--less politically driven and more searching for answers to difficult issues, trying to take as scholarly and academic an approach, trying to take advantage of thinking on these topics that had gone on around the world.

INTERVIEWER: Science and technology is much more complicated today than it was back in the '70s in terms of improvements to medical procedures, new product developments, new tech--new techniques, for example, in the area of genetics. Gene transfer is a newer issue than what would have been the basis of thinking in the '70s, in the early '70s, knowledge of the human genome. Does the Belmont Report and the ethical principles cover the situation where we have complex technology today?

DR. WALTERS: In the mid-1980s, human gene therapy or human gene transfer research was a very hot topic in the United States. I had the privilege of helping to formulate guidelines for the conduct of this research in '84 and '85. I can tell you that the Belmont principles, the existing research regulations, and a report of the President's Commission on Bioethics called "Splicing Life" were really our guides as we formulated the points to consider in conducting human gene transfer studies.

I think for all biomedical and behavioral research, regardless of technology, these principles and the research regulations that have emanated from them are very applicable and very appropriate.

INTERVIEWER: Twenty-five years ago, when the Belmont Report was released, would you have thought at that time that the document would have the power and the impact that it still has today all these years later?

DR. WALTERS: I think it's very likely that there's been a mutually reinforcing relationship between the Belmont Report on the one hand and the book by Tom Beecham and Jim Childress entitled "Principles of Biomedical Ethics." There's a lot of parallelism in terms of the principles selected for treatment, and I think that the Principles book has been very successful, both in the United States and around the world, in giving us a list of topics to think about, a kind of set of guides, at least for our initial consideration of research involving human subjects.

So the book helps to remind us of the Belmont Report. The Belmont Report in many ways points forward to and anticipates the book, "Principles of Biomedical Ethics." And I think together the Belmont Report and the Principles book have had a major impact, so much so that around the world people ask themselves, Are these distinctively American principles? Are there Asian principles or European principles that should be used to supplement the Belmont principles or the Beecham and Childress principles?

I think, if anything, people abroad have worried that in American bioethics respect for the autonomy of persons is elevated to a supreme status and that we tend to neglect particularly justice and sometimes we don't worry enough about the harms and benefits of research. Europeans also have a greater sense of solidarity, social solidarity, much better systems than we do for taking care of the most vulnerable members of society. And so I think a principle like solidarity would appeal to Europeans, even if it hasn't joined the canon in the United States.

INTERVIEWER: One of the strengths of the Belmont Report is its shortness. How did you reach--how did you ever agree to a document that was short and avoided the details that you must have wanted to put in it that would have dated the report?

DR. WALTERS: There was a great deal of give and take between the Commissioners on the one hand and Tom Beauchamp, the staff person for the Commission, in the writing of the Belmont Report. Steven Toulmin, another philosopher, had been involved in the very early stages of writing up the principles, but I think the credit has to go to Tom for being the principal staff person who authored the final version of the Belmont Report. Tom has a gift for conciseness, and I suspect that he had a great deal to do with pruning down the text, making it a manageable document, one that people could easily read and from which they could gain guidance.

INTERVIEWER: We still have issues today that involve the distinction between practice of medicine and research. Does the report give us sufficient guidance on how to know the difference between research and changes to the practice of medicine?

DR. WALTERS: There is an attempt in the report to distinguish between research and the practice of medicine, and the key issue is whether the goal of the activity or the procedure is to gain generalizable knowledge, in part or in whole, or whether the procedure is directed totally to the benefit of this particular person with no desire to gain any information that would affect other people.
I think that that distinction holds up well, has held up well over time, but how to apply it in particular situations I think is still a challenge. In cases of doubt, I think we ought to err on the side of assuming that it's research and provide people with all of the protections that should be accorded to research subjects.

INTERVIEWER: Are there any ethical issues today that weren't adequately anticipated by those of you who wrote the Belmont Report, for example, issues involving conflict of interest and also gene therapy, new genetic technology?

DR. WALTERS: I can think of several issues that are new since the late '70s when the Belmont Report was published. One is what kind of oversight system needs to be developed for clinical research that goes beyond the simple system that we had for academic research in the late '70s. There's much more private money from private companies and private, nonprofit corporations going in--I'm going to stop.

There are several questions that it would have been difficult to anticipate at the time the National Commission did its work. One is can we devise an even better oversight system for research involving human beings. One topic that's been discussed quite a bit recently is whether all clinical trials should be a matter of public record. For example, should there be a public record of all clinical research that's conducted in the United States regardless of the source of funding? I think that that would be an improvement in the transparency of biomedical research. I hope it will happen. It would also improve the reporting on research results because we would know much better how many studies have been done. We wouldn't have such a skewed impression of how successful a particular drug or a particular intervention was. So that's a topic that the Commissioners could hardly have anticipated in the '70s but that we are discussing early in the 21st century.

There's much more private money going into biomedical and behavioral research today than there was in the late '70s. Universities I think are in a much more perilous situation vis-a-vis large amounts of private money from pharmaceutical or biotechnology corporations. The administrators of universities very much want to get the grants to keep their research enterprise going, and I think there are questions about conflict of interest or compromise of the academic mission of academic institutions that the Commissioners didn't see early on that we see more clearly today.

There are also concerns about conflicts of interest of individual researchers and whether they have a vested interest in the outcome of clinical studies if they own stock in that particular company that's manufacturing a drug that's under study.

Another kind of issue that the Commission only dealt with in one study that we need to look at is what--how do we envision the future of the human race? What kinds of changes is technology going to make possible? And here I'm thinking primarily of genetics on the one hand and nanotechnology on the other. I think that there will be possibilities for enhancing the performance of human beings, for improving our capabilities, and we'll face decisions about how many of these possibilities we actually want to implement.

It would be good to have anticipatory public discussion of those kinds of topics rather than reacting to them when they're right on our doorstep. And so I think a new Commission to look ahead to those kinds of questions would be very helpful. The current President's Council on Bioethics is trying to look at issues in the neurosciences, and I think that that's an example of the kind of anticipatory work that public advisory Commissions can do.

INTERVIEWER: Do we need Commissions or committees to deal with specific ethical situations? Or do we need to have a Commission that would go back and revisit the ethical bases for doing research?

DR. WALTERS: I think topic-oriented Commissions or advisory committees are often very helpful. In the United States at the present moment, I think it would be quite helpful to have a public advisory committee or Commission on human embryonic stem cell research, for example. But I would imagine that that committee could complete its work in two or three years and submit a final report.

I think it's also useful to have a general advisory commission on biomedical and behavioral research in place at all times. One of my concerns is that some of the later Commissions had pretty much of a political cast, either a liberal cast or a conservative cast. I think the National Commission, to its credit, was perceived to be quite neutral politically. I don't think that there was a litmus test for the views of the Commissioners when they were appointed. And I'm not quite sure how to deal with this politicization of the commission phenomenon that I think we've seen in the Clinton and Bush administrations. Perhaps something on the model of the British system of having the Nuffield Foundation fund a--privately, a commission, the Nuffield Council on Bioethics, would be a solution that wouldn't be so susceptible to the various political winds. That council then is able to choose its topics, and it's not suspected of being either liberal or conservative.

INTERVIEWER: Several of you who worked in developing the reports of the National Commission were from a theology background, so you had theologians who were working with people from the ethics and philosophy background. How do those three different areas come together to develop principles of ethical conduct of research? How does the background differ between the three of those groups?

DR. WALTERS: There were two theologians appointed to the National Commission: Al Jonsen and Karen Lebacqz. At the time the Commission was established, there were only a handful of philosophers who were interested in bioethics, so I think it was a reasonable choice to appoint two theologians. Theologians had been involved in biomedical ethics since at least the late '60s. Paul Ramsey's book "The Patient as a Person" had come out in 1970. So I think it was reasonable to have theologians.
If you look at the lists of consultants, there were many theologians, very few philosophers. That changed a bit over time.

Steven Toulmin and Tom Beauchamp did join the staff as philosophers by the latter part of the Commission's work, and that fact reflected the growing interest of philosophers in bioethics.

DR. WALTERS: When Al Jonsen and Karen Lebacqz participated in the discussions of the Commission, I think that they did so primarily as philosophers. They were educated in moral philosophy. They used philosophical arguments. You did not hear Al Jonsen talking about the views of the Catholic Church or Karen Lebacqz talking about the views of Protestant theologians. They were entering into a discussion based on secular ethical principles, and I think that that's the way a National Commission needs to function, on the basis of arguments and theories that are able to be supported by any conscientious person.

Even in the position papers drawn up by consultants who were theologians, I think you found a very conscious attempt to find common moral ground with people of good will from a variety of religious and non-religious traditions.

So, in fact, I don't think that you saw a strong impact of theological arguments on the National Commission even though two of the Commissioners were definitely trained primarily in theology.

INTERVIEWER: If we were to form a new Commission today to look at ethics surrounding humans and research, do you think theologians would be as well represented, and would they be there as theologians or as ethicists or philosophers?

DR. WALTERS: Since the late '70s, the philosophers have found how popular bioethics is and how exciting the field is. And, conversely, I think too many theologians have lost interest in the field of bioethics and have turned to other topics. There are historical reasons for that. I think the strong criticism that the Vatican has leveled against some Catholic theologians working in bioethics has had a chilling effect and has been a deterrent to young theologians going into this field.

DR. WALTERS: Today there are many more moral philosophers than theologians interested in bioethics and teaching bioethics. That's partly because of the popularity of bioethics courses on college campuses and the intrinsic interest of the field to philosophers. I'm not quite sure why theologians aren't as actively involved as they were in the '70s. I think it's an exciting and very interesting field.

In any new commission, I would hope that theological questions would be considered, but there's a variety of ways to consider theological questions. The National Bioethics Advisory Committee under the Clinton administration actually invited representatives of various religious traditions to talk to the committee about their religious tradition and its views on human embryonic stem cell research or human embryo research in general. So I think that there are ways to--to find out what various religious and theological traditions think about topics and accept their thinking as input into a process. But if it's a public advisory committee or commission, I think that ultimately its conclusions and recommendations have to rest on secular moral arguments and have to begin on a foundation like respect for persons rather than any particular theological beliefs.

INTERVIEWER: Do you think young scientists and physicians starting a career in research involving humans today have enough training in ethics?

DR. WALTERS: My personal view is that all of us, regardless of our profession or academic field, need to become involved with ethical questions, at least from the time of high school education forward. So I guess my hope is that high school students can be sensitized to discussions of bioethical topics, that they can carry this interest into their college education and develop expertise, real expertise on research ethics and other areas of bioethics during their college careers. And then I think they'll be hungry for continuing that kind of education in professional school and as they go into their academic or professional careers.

We have seen also the emergence of people with dual degrees, perhaps an M.D. degree and a Ph.D. in philosophy with a concentration in bioethics, and I think those bridge people are also very helpful. However, they have to make a choice about which field they will give preference to in their academic careers. So I don't see any alternative to teamwork among people of good will in philosophy, theology, biology, and medicine. We can only keep up well in a very limited area, but we can learn a great deal by talking to other people with a common interest in the highest standards of research ethics.

INTERVIEWER: There are very few of us who have the opportunity to be involved in something as important as the National Commission and developing a document like the Belmont Report. What impact did that have on you as a young person in your career? How did it impact how your career unfolded?

DR. WALTERS: It was very gratifying as a young academic person to be invited to submit

two position papers to this National Commission for the Protection of Human Subjects and to participate in the Belmont Conference. I think it was also gratifying to see that the work of the Commission was not neglected, that its work was translated into regulations.

I do want to give credit to people in the Federal Government, especially at NIH, who were involved for many years in the trenches after the Commission completed its work. They are the ones who had the job of implementing the regulations that grew out of the Belmont Report, and without their good will and their determination, and in some cases their courage, I think that the Commission's recommendations and the Belmont principles would have remained purely theoretical and abstract.

INTERVIEWER: How much involvement did you and other consultants or other Commission members have as some of those other government people proceeded to translate the documents into regulations?

DR. WALTERS: There was an informal network that existed in the '70s and '80s so that consultants to the Commission and Commission members would often be called by civil servants and asked for their advice about specific points in the development of regulations. Sometimes we would hold joint seminars. So there was a network of people who actually remained in very close touch with each other. Often it was informal. Sometimes it was very confidential and very much on a background basis. But there was a process of consultation based on mutual respect and appreciation that I think really did help in the improvement of research ethics during those years.

INTERVIEWER: As you think back on the activities that went on with the Commission meetings and writing the documents, are there some things in particular that stand out in your mind as having been milestones of great importance in getting the job done? Were there things that ended up being disappointments?

DR. WALTERS: The first milestone was completing the report on research involving fetuses, doing that within a very short time. It seemed like an impossible time frame, doing, I think, a very creditable job with a document that everyone could be proud of at that time and that still stands up well to review so many years later. So that was a momentum builder.

I think the Chair of the Commission, Ken Ryan, was eminently fair. He was well organized. He was articulate. He was genuinely interested in learning more about ethics. The Commissioners themselves I think were a very wonderful group of people, a mixture of

academic people and public citizens. A great deal of mutual respect developed among them over time. They would have meals together, and they really seemed to respect each other as people. They didn't agree on some issues, but they wrote respectful dissents, which I think are also instructive as we read the Commission's reports.

And then I think this action-forcing provision so that the government couldn't just ignore what the Commissioners recommended, but had to respond either by accepting the recommendations or giving reasons for not accepting them was a key to the Commission's success.

As far as what it didn't do so well, well, it wasn't assigned to look at access to health care and issues of justice in access to health care. And so it didn't do that, and I think that was an important job left undone in the '70s. In some ways, even though the President's Council on Bioethics worked on this topic in the '80s, it's still left undone.

I better stop before the 12 strikes.

What did the Commission not accomplish? It wasn't asked to look at problems in access to health care, so it gave very little attention to this topic. And that topic remains a serious problem in the 21st century. The President's Committee on Bioethics in the early '80s dealt with the topic in a report entitled "Securing Access to Health Care," but that work really needs to be done again in the light of new circumstances today.

I think the National Commission did not do nearly as well on behavioral research as it did on biomedical research. Questions of how to administer surveys, how to observe public behavior were not nearly as well addressed as traditional biomedical research.

Also, whatever the Commission did on technology assessment, looking at new biomedical technologies and their likely impact, was done almost as an afterthought. There was a special study on that topic, but it really was not central to the Commission's work, and it, I think, did not anticipate problems that we see today in genetic engineering or nanotechnology, which could really quite profoundly affect the future of human evolution.

INTERVIEWER: One of the important thrusts of the documents of the Commission had to do with protecting vulnerable subjects. But today we have legislation that encourages that research be done in children, and we have been pushing that there are more women involved in research studies. Are you comfortable that we're now encouraging more vulnerable

populations to be involved in research in consideration of the fact that you were trying to protect them when you wrote these reports?

DR. WALTERS: On research involving children, I think we do face a genuine moral dilemma, and it's very difficult to resolve it, at least in my mind, other than by using an argument about the consequences of not involving children in research that's not directly related to their care.

I do think it's important that therapies that are developed be tested in children, and I think not in every case can those new interventions, those new drugs be tested in a way that's solely directed toward the care of the children. And so I come back to some kind of a notion of solidarity, that we're all in this together. And adults as a group really, I think, should feel a moral obligation to participate in research for the good of all. And I think in the case of children, we as adults make a judgment that for the sake of children now and children in the future, some children will be asked to undertake risks not directly related to their own care for the good of the whole. It sounds very utilitarian. It's very scary. I think the limits have to be very strict. But I would use the same argument in other situations, for example, with pregnant women. We simply will not know what we need to know unless some pregnant women take part in research that may not be directly related to their health or the health of the fetus that they're carrying.

INTERVIEWER: Thank you. That's all the questions I have.

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