



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

Interview with
Albert R. Jonsen, Ph.D.
Professor of Medical Ethics
University of California at San Francisco Medical School
San Francisco, CA

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Belmont Oral History Project

The Tower Building • 1101 Wootton Parkway • Suite 200 • Rockville, Maryland 20852 •
(301) 496-7005

INTERVIEW WITH DR. ALBERT JONSEN

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

DR. JONSEN: My name is Albert Jonsen. I'm a Ph.D. in religious studies from Yale, and I have taught medical ethics, first at the University of California-San Francisco for a number of years, and then at the University of Washington School of Medicine until my recent retirement.

INTERVIEWER: What was it about your background 30 years ago that accounted for you being brought into the National Commission?

DR. JONSEN: At the time the National Commission was formed I was in my second year as the professor of medical ethics at the University of California-San Francisco School of Medicine. There were only two people in the United States at that time who held such positions. And it has been my assumption that that was one reason I was chosen. It's a prestigious school of medicine and professors of ethics were rare birds.

And, secondly, I was at the time a Roman Catholic priest, and I assume that that sort of expertise was desired on this commission. And at the same time, my graduate education was at Yale, which is unusual for a Catholic theologian--it was at that time.

So those, I assume, were issues that made me a viable candidate.

INTERVIEWER: Sometimes commissions discuss for a long period of time about what their understanding of the charge really is. How long did it take the National Commission to get on one track for what the charge was to the Commission?

DR. JONSEN: We got to our commission and to the work of the Commission very rapidly, because the legislation actually made us do so. The legislation specifically required this commission to present a report to the Secretary of Health, Education and Welfare on the question of research with the human fetus, within, I think, 90 days of the Commission's first meeting. I'm not sure of that, but it was a very short, and quite

specified, period of time.

So we had to go to work right away on that task. And so we didn't have time to wonder what we were supposed to do. We simply went to work.

The very first meeting had to do with the specific tasks that had to be accomplished in order to get that going; in other words, we had to commission several studies of what was actually going on in fetal research around the world, and we did that, and then we were off and running.

INTERVIEWER: But the Commission itself went on for several years, and how long in that series of meetings did it take for you to realize that what you were going to end up with was a small number of principles?

DR. JONSEN: Oh, we didn't end up with a small number of principles. We ended up with 15 very long reports. And the primary work of the Commission was to recommend to the Secretary how the rights and welfare of human subjects of research could be protected.

So our task was to make recommendations to the Secretary, and the Commission's mandate, set by Congress, very definitely set the areas in which those recommendations were to be made: research with children, research with institutionalized mentally infirm, research with prisoners. There was a special study to be made of psychosurgery. There was a study of the IRB system, which was just beginning around the country. And, finally, there was something called "The Special Study," which was the impact of biomedical technology on society.

Those were all mandated in the Congress's legislation. And so we fairly rapidly had to move into them. The one area that we now refer to as "The Belmont Report" was the recommendation to do a comprehensive study to identify the basic ethical principles underlying research with human subjects. We started to plan how we would go about that fairly early in the Commission's life. About halfway through the Commission's life we had a four-day retreat of the Commissioners to intensively focus on that, and in the second two years of the Commission's life we went over and over drafts of the document that had been first sketched out at the Belmont retreat.

So that was just a small piece of the overall work of the Commission. And in order to really understand the Commission's work, one has to read through all of those

recommendations--most of which eventually became regulations in the Federal code of regulations. Several did not, but most of them did--and, also, the background documents which were created for each of those specific tasks.

INTERVIEWER: When you were finished with what came to be the Belmont Report, did you think it would have the impact that it has, and the recognition of one of the best commission reports that's ever been written by any commission?

DR. JONSEN: I, personally, did not think that it would have that kind of impact. I was quite satisfied with it. I thought it was a concise and crisp and clearly stated. I thought it covered the essential issues as we saw them at the time.

But I didn't think much attention would be paid to it. I thought it might have been a little too abstract, a little too theoretical for the people we were communicating with.

So, to me, it was not a major contribution at the time. It was simply kind of secondary to our principal work, which was the recommendation of regulations. So I was pleasantly surprised that within a few years it had been so widely praised and used.

INTERVIEWER: Even though you were doing this at the request of Congress--or the directive of Congress--did you intend the Congress as the audience for these reports, or were there other audiences--like the public or investigators--who might have been the audience?

DR. JONSEN: The real audience for these reports was the Secretary of the Department of Health and Human Services. However all of the reports were sent to the [Congressional] leadership, and were sent to the White House.

But the intended audience was much wider. We tried to write reports that we felt would reach the research community much more largely. So people who were working with research with children, for example, that they would be helped and enlightened and elucidated by the way the report was written, so that each report contained not just the recommendations--which was really for the reading of the Secretary--but fairly long explanatory chapters as to why we reached those recommendations, and what the general issues were-- say, what do you do with informed consent when you're dealing with a person who has diminished capacity--was explained in language that we thought would be open and clear to people who were working in that field.

INTERVIEWER: One of the notable features of the Belmont Report is its shortness. Would it have been easier to write a much larger document that had more information in it that might have detracted from its importance?

DR. JONSEN: I guess it would have been easier, but several of the Commissioners were very insistent that a statement of principles should be short and sweet. There was never any temptation to write a long report. There were a number of iterations of the draft. As I said, there were really two years between the time of the discussion and the draft and the final approval. And during those iterations it got shorter. We did a lot of cutting and trying to make things more concise, tighter and so forth.

The final event in that cutting was in my own home. There were several Commissioners in San Francisco, together with the Commission chairman--it was Mr. Yesley and Dr. Brady and Dr. Lebacqz and Dr. Toulmin, myself--and we took all the previous drafts, and I sat at my typewriter as we went through those previous drafts, and tried to type a tight, concise document.

We didn't do anything very original that day, it was mostly an editing effort. But it was that conciseness that we were going for.

INTERVIEWER: How well was the report received when it was released?

DR. JONSEN: That's not an easy question for me to answer. I don't really know. I don't know that there were news articles about it. I just don't remember how it was received. It seemed to me it kind of slipped into the world of research, and its acclaim seems to have come later, as this world of IRB activity and so forth matured.

Certainly, one of the reasons why the Belmont Report attained some significant wide acceptance was that Beauchamp and Childress picked up the essential framework--that is the three principles--and they actually made it four, because they broke beneficence down into beneficence and non-maleficence--so they took those principles as the structure of their book on bioethics, generally. So, outside the field of research, the interest was growing in bioethics as a general field within the world of medicine, and by using that framework of Belmont, they essentially promoted Belmont, which was really written just for the field of research. And also both of those authors had been part of the Commission's development of those ideas. So they weren't stealing anything by any means. They were, in fact, contributors to the report itself.

INTERVIEWER: Having just come through the time of the Tuskegee experiments, what impact did that have on the thinking of the Commissioners and the nature of the discussions?

DR. JONSEN: Well, Tuskegee had broken in the news in 1970. So that was really four years before the Commission's life. It was certainly a strong motivation in Congressional action. We were right in the center of the civil rights issues, and there was clearly the impetus to move something ahead.

There had been a special commission to deal with Tuskegee, appointed by the President. And it was a very distinguished commission, it came up with specific recommendations with regard to the Tuskegee study. So, although some people think of this commission as being formed in order to deal with Tuskegee, that was not the case. Tuskegee had been dealt with.

But there's no question that it was a primary example of the problems that research ethics has to deal with. It dealt with the problem of respect for persons. There was no consent. It had a problem with beneficence: there was no benefit whatsoever to the subjects. And it clearly was a problem of justice, because it was dealing with an already badly deprived minority population who were exploited.

So, as we thought through those things, Tuskegee was a constant echo that informed the way in which we viewed research ethics.

INTERVIEWER: Do you think another Tuskegee situation could develop in the research community today?

DR. JONSEN: I would doubt very much that another Tuskegee situation could arise in the research community. Research is now a much more visible enterprise than it was, certainly, in 1930, when Tuskegee started. The whole IRB system, for one thing, plus press, media--their awareness of the kinds of issues that can arise; and particularly with regard to large populations, I would think that it would be very unlikely that we will ever see another Tuskegee.

I think that the research abuses that we are likely to see are those that will arise much more within smaller designs of clinical research. It will be much more questions with individual subjects. It will be much more questions of conflict of interest, in which

researchers have dual motivations that may affect the subjects.

There's no question that--in my mind--that a large-scale abuse of that sort could take place today.

There are interesting things even in the design of Tuskegee that--as a research design, it's naive. It's not well-designed research in the first place. No researcher would take such an approach to the problem today that those researchers did; the selection of subjects was flawed in many ways, not just the problem of injustice, but they were unable to sort out the subjects in ways that avoided contamination of the cohort. There were already treated subjects that were put in there, as well as non-treated ones. So there were a number of things of that sort that were just bad research design, that would never pass muster today, much less the ethical problem.

INTERVIEWER: Are there important issues of research involving humans today that you wish you had dealt with, or that you had dealt with to a greater extent in the Belmont Report?

DR. JONSEN: Well, the Belmont Report has a funny feature that limits its applicability. While respect for persons is a very broadly defined principle and it has as its practical application informed consent, which is also a very broad practice in research ethics, the second and the third principles--namely, beneficence and justice--are defined quite narrowly in Belmont. We talk about "beneficence" in a relatively general way as bringing some benefit to the subject, and the question of benefit to the subject and benefit to society, but then we immediately make the practical application of risk-benefit assessment. So that's only one issue in the broad beneficence area.

And, similarly, "justice" is very tightly limited to only one topic: namely, the selection of subjects for research, because that's where we had seen the abuse--the use of captive populations, the use of minority populations, the use of the sick-poor and the old wards for the sick-poor, and so forth. So selection of subjects was the only issue of justice that we actually focused upon.

So, there is no question that both beneficence and justice could do with a much broader viewpoint. And I suggest, for example, not that we change Belmont itself, but that we think about writing a new section under each of the principles called "Frontiers," in which we talk about the kinds of questions that are now arising within science, within the sponsorship of research, etcetera, and ask how these principles ought to be thought

of in a wider sense.

They're all susceptible of broader interpretation. We don't want to make it so broad that they lose their punch. That's one of the problems. You don't want to say, "Well, research should be just." Well, you know, what's "just" mean? It's just a big vague idea.

I think we still have to keep a focused idea of justice, but at the time look at its broader application.

INTERVIEWER: How much of the focus of Belmont was on the medical research versus behavioral and social research?

DR. JONSEN: One ought not to be able to discern any difference in various kinds of research when reading Belmont. There is a section in Belmont which explicitly has to do with the distinction between medical practice and research.

But other than that section, Belmont should read as if it applies to all research--that is, the use of persons in almost any way--it's simply not defined any more specifically--the use of persons to develop generalizable knowledge in a protocol--that is, in a methodologically designed study to generate generalizable information. And that ought to apply to all kinds of research.

And I don't think that people who look at Belmont read it just as a medical, or just as a sociological. I think it's applicable everywhere.

Clearly, the Commission had a major question going all through its four years of life. And there was an overemphasis on the medical. And the overemphasis came from the fact that all of us were quite aware that by this time in medical research, we had moved to a fairly sophisticated form of research design. The randomized control trial was research par excellence. Outside of medicine, that's not true.

And so as long as that model dominated our thinking--and I think it really did--the Commission's report tended to be medical more than behavioral.

INTERVIEWER: The Belmont Report doesn't specifically mention conflict of interest as an ethical issue. In the context of how important it is today, how do you see conflicts of interest being covered in the wording of the report?

DR. JONSEN: The Belmont Report does not mention conflict of interest as a major issue--that's true. It's a little bizarre that it doesn't, because in the early years of discussion about research ethics, the conflict of interest question was raised. It was a different conflict of interest issue than we raise today. It was the conflict of interest that arises when a clinician is caring for a patient and is, at the same time, using that patient as a research subject.

That was almost a standard formulation of the research problem in the 1960s, in the earlier literature. One important figure in that early debate was Dr. Otto Guttentag, who was at UCSF, who used to say that if a clinician is a researcher he should wear a red coat instead of a white coat to distinguish himself.

So that was the problem of conflict of interest. It had been recognized at NIH in the early years of the research regulations, where clinicians--the matter was discussed, because at the Magnusen Clinical Center, clinicians were all researchers. And that was recognized as a problem.

It's probably an issue that would be a "frontier" issue, even though it was an old issue. It would be a "Frontier" issue because now the question, I think, has to do with researchers' affiliation with commercial enterprises and with the opportunity of the clinician to get patents--or the researcher to get patents to profit by the work that he or she is doing. And at the time the Commission was working, researchers rarely even thought of profiting from anything that they might produce. That's what they did, and it became a public good.

But today the issue would be there, and I think it probably could be mentioned under all three principles; that is, it's a matter of informing persons--therefore, respect; it's a matter of beneficence, because one of the problems in conflict of interest is what benefit is motivating this work, and who gets that benefit; and it's a question of justice--equally.

So I think some creative thinking would put conflict of interest in under all three.

INTERVIEWER: There's more international research going on today than there was 30 years ago, bringing research into other cultures throughout the world. How much emphasis was there on that possibility, that the principles would be used in cultures other than what we have in the U.S.?

DR. JONSEN: It's an interesting question. In one sense, the question has been answered, insofar as the Federal regulations are used now in other cultures for any American researcher that's going to be working in other cultures, and therefore the Belmont Report has to be implemented there.

But a question of how those principles apply within other cultures, again is certainly is a question of respect for persons. And it is a question of respect for persons which sees persons not simply as isolated individuals, but as members of communities. In some cultures, that link of the individual and the community is much more powerful than it is within our culture. Well, it's hard to say what our culture is but--certainly, even in minority cultures within our culture, it's much more powerful; in the Hispanic communities, for example, there is a much greater sense of identity of individuals with their community.

So it's a question of respect for persons. And it is a question of beneficence, insofar as you have to be aware of the danger of exploiting communities that are culturally different, and you also have to seek to benefit communities. International research now works with the fairly general principle that researchers that come to take something out of a community should bring something back to a community--perhaps in the form of health care, or whatever. So beneficence is clearly a principle.

And, finally, again, it's a principle of justice--well, basically for the same reason; that you--the benefits--the place where you get your benefits from should be the recipients of benefits, as well, which is the general way we've defined justice within Belmont.

So, as a "frontier" issue, cultural research is very important. I think it's of interest that the Federal regulations, and the Belmont Report, have basically served as a model for research ethics everywhere in the world.

And the additional work done--the Helsinki Declaration, the CIOMS work and so forth, does add the international dimension much more explicitly than Belmont. But I think Belmont--if it took this "frontier" idea--would clearly move in that direction. There's nothing incompatible.

What's incompatible is an interpretation of the principle of respect for persons as individualistic. And that's not really necessary.

INTERVIEWER: In arriving at agreement on the three primary principles, did the Commission intend that they would be considered independently of each other, or sequentially, with the possibility that one might trump another one?

DR. JONSEN: It's an interesting question. We have three principles, and the question is: are they simply sequential or are they in any way in an order of priority?

They clearly were not intended to be priority. There's nothing in the report that suggests that they are listed in any way in priority. But--against the general background of the research ethics debates of the time--it's fairly obvious that the respect for persons is perhaps the most significant of the principles. And the reason for that is that in the early literature about research ethics, there is a very strong attempt to repudiate the kind of crude social utilitarianism that seemed--that was frequently used to justify research, that deprived human subjects of some of their rights. And certain important authors--such as Hans Jonass, whose work was very well known to the Commission, and Jay Katz--were very strong--and Paul Ramsey, as well--very strong on repudiating the utilitarian justification. And the repudiation of that is, of course, the primacy of the individual as a research volunteer.

So, that jumps right up in front. So, while it's not listed as a priority list, that has a kind of a pride of place that's unquestionable.

And it's also the case that both the beneficence sections and the justice sections are somewhat underdeveloped. They could be written more powerfully. I think many people feel that in some way the importance of community should be stressed, and one place to stress it is in the justice section. But, if you really strengthen the justice section, you are in danger of, once again, falling back into a situation where the justification for research becomes a community good. And that is a slippery slope.

So I think that there's an effort to say: whenever you look at research as asking ethical questions of it, you simply ask these three questions. And if you ask them and you find that there are conflicts, then the conflicts must be resolved--in that case.

It's very much like case law, or Constitutional law. The Bill of Rights is not set out in terms of priorities. We don't prioritize the Bill of Rights. But when a conflict arises between rights stated in one section of the Bill of Rights and another, or within one

section itself, we adjudicate it. It goes to the courts--it goes to the Supreme Court.

And you resolve conflict between the principles of Belmont, really, when you see the circumstances of the case; when you see precisely what that case--what's going on in that case.

I'll give you the most striking example in the Commission's work; that is in the report on research with children. The Commission comes to a dead-end, almost, when it has to look at research which poses no direct benefit to the child-subject, and which may be of more than minimum risk, and which appears to be justified by some extremely urgent situation--for example, the research relative to the cure--prevention of polio. That's a kind of a perfect model.

The Commission doesn't have an answer to that, because it really goes against all of our principles--it appears to, rather. And we say, you've got to wait until the situation arises. And when you see that--how urgent is the situation? Precisely what are the probabilities of risk, benefit and so forth? You've got to know it in the concrete in order to be able to say: "This is something that does, in fact, meet our understanding of the ethics of the case." That might be a situation where justice, in fact, prevails over the rights of individual subjects.

INTERVIEWER: During these few decades since the report and the development of the report, there has been a shift away from protecting human subjects from risks, towards permitting access to potentially beneficial medical products. Is that consistent with the principles?

DR. JONSEN: That clearly was a shift that took place--historically--at the time the HIV-AIDS epidemic appeared. The demand for treatment of a condition for which we knew no positive treatment was available at all had to be met by saying, well, the only way you can get that treatment is to be a research subject, because we're working on various anti-virals that may be beneficial. And it was generally agreed that that was acceptable; that people should be admitted into research on those grounds.

As it moves away from questions of urgency such as the AIDS epidemic, and of life-and-death situations--which it clearly was then--into a more general sort of "Here's something new coming down the pike, maybe you'd want to be one of the first to get a chance--to get in on it"--I think it's much more questionable. And I guess that's what's happening as research is done more and more by pharmaceutical companies. They

seem to advertise that way for research subject.

I think that's deceptive. And it's deceptive largely because--unless it's a "me too" drug where, you know, we already really know the risks and benefits--it's deceptive because people do not understand that if they're randomized their risk of not getting the drug is 50-50 with their risk of getting it, and that even if they do get it, the probabilities of benefit may be quite remote.

So, if that's the kind of research that we're thinking about, and the kind of solicitation of people for research, I think it verges on the unethical.

INTERVIEWER: It ties together with the idea that more and more of the research to develop new medical products is being done outside the U.S., in cultures other than ours. And the principles were not explicit in dealing with questions about research outside the U.S.

DR. JONSEN: Yes, more and more medical products are being developed in cultures outside the U.S., where the benefit is much more likely to flow back into wealthier societies, and more developed societies, not in the cultures where the research is being done. And if that's the case, Belmont says--really says nothing directly to that.

The principle of justice is applicable to it, however. And I think that the CIOMS regulations take it into account as a question of justice, that there must, in some way, be a compensation for what's taken out of the culture in terms of knowledge, it must go back into a culture.

Also, much of that research--particularly in the area of AIDS--does have potential benefit within those cultures, and some of the very controversial research of recent years has been precisely of that sort, where research may not appear to be culturally insensitive, but rather appear to be an exploitation of the culture in terms of the research design. But the argument of changes in research design was precisely that this change in research design does, in fact, meet the needs of people within this culture.

So, I think, while Belmont says nothing directly about it, we have moved that issue ahead a long ways within the international sphere of research.

INTERVIEWER: The Declaration of Helsinki has been tinkered with in terms of a few paragraphs, but there are some people who think the Declaration of Helsinki needs to be rewritten. If that happened, do you think it would bring the Belmont Report and the new

Declaration thinking closer together, or might it become more divergent?

DR. JONSEN: The question of whether the Helsinki report should be rewritten to meet contemporary standards is an interesting question. Helsinki has been rewritten many times. I don't know how many iterations there have been of Helsinki since it was first stated. And some of the more problematic stuff has disappeared. I think one of the great problems of early Helsinki was that it was very unclear and squishy about informed consent, largely because they had a distinction between therapeutic research, where consent was of less significance in their minds. And I think that's been written out. There was nothing in early Helsinki that had to do with review, and review is now in there.

I haven't followed that debate about rewriting Helsinki enough to be able to say whether that would bring--whether a rewriting would bring Helsinki more into conformity with Belmont, because I think informed consent is now where it should be in Helsinki--I believe. And review is there. And in Belmont, risk-benefit is discussed as the beneficence application, and that's basically the question of review.

So I don't know whether a rewriting would bring more conformity or not at this point in time. It's clearly the case that some advanced nations, such as Britain, really take Helsinki as their guide, and therefore to the extent that we would like to have fairly clear international standards, it probably would be a good thing if both Belmont and Helsinki basically said the same thing.

INTERVIEWER: Do you think there's a need to revise or rewrite the Belmont Report?

DR. JONSEN: I don't think that there's a need to rewrite or revise the Belmont Report. My suggestion is--first of all, there may be some rewriting that's useful, but it should be stylistic. I look back with a certain amount of embarrassment, as one of the authors, on some of the style questions. I would like to see it cleaned up. But that doesn't go to the question of substance.

My suggestion is that Belmont remain, and that it be expanded by a series of sections, which I have named--just for convenience--"frontiers;" that is, how do these principles apply to the new sorts of issues that have arisen, not necessarily given the answer to that question, but by saying questions of justice now have to be thought of in a broader way because of international research, *et cetera, et cetera*.

So I'd like to see a "frontiers" section, or something of that sort, that keeps this document projected into the future, but doesn't lose its essential stress. Because I think its essential stress is what I believe to have been the thrust--the most fundamental reform of research ethics thinking--namely, the rejection of what I called crass social utilitarianism. And I wouldn't want to see that lost.

INTERVIEWER: Was the Belmont Report put together with a full expectation that it would be translated into regulations?

DR. JONSEN: No, it was not intended to be transformed into regulations, but it was intended to be a preface, as it were, to the regulations. We thought it would give some breadth of thinking to the regulations--which always tend to be quite narrow and quite specific, and cut down to meet the kind of needs of regulators. And so our conception was--or at least my conception was--that this would be a preface. That's one reason why we wanted it to be short, so that anybody who went to the code of regulations could see a two- or three-page statement of the generalities before they dug into these very precise and oftentimes confusion regulations. It's to lift the mind. [Laughs.]

INTERVIEWER: Do you think the FDA regulations and the HHS regulations to protect human subjects adequately reflect the principles of the Belmont Report?

DR. JONSEN: Do the HHS regulations and the FDA regulations reflect the principles of the Belmont Report? Yes, I think they do.

But again, "reflect" is a word that always is open to interpretation. Any regulation is written from a regulator's point of view. It's got to be written in a certain style. It's got to, you know, cover certain points that the regulator wants to get over. And it may be that the tone and the general feeling of Belmont somewhat disappears, but I think the substance of Belmont is in the regulations. I believe that.

INTERVIEWER: Do we have adequate clarification today of the distinction between the practice of medicine and research?

DR. JONSEN: One of the sections in Belmont is the distinction between research and practice. And it can be asked whether that section answers the question that it poses.

The document behind that section is perhaps one of the most elaborate documents in the whole library of the Commission's work. It's a very, very long and complex analysis of that, done by Dr. Levine. And so when we ended up with a couple of paragraphs out of all of that, we've lost a lot of the subtlety and a lot of the kind of nice distinctions that he originally made.

I think it still works today, but it has to be understood again--has to be interpreted again--in terms of the variety of things that go into the practice of medicine. We were thinking in terms basically of innovative practices. Innovative practices is a category that, in our minds, applied very largely to surgery. I mean, when I think of "innovative practice," I usually think of a surgeon who's already in somebody's abdomen and sees something--a move that he or she might make that's a little different way of dealing with the anomaly that has been revealed. So you can go run to the IRB and say, "Can I do this?" you know. And surgery has generally been a place where there's been a dearth of research--of well-designed research, for a number of quite good reasons.

But outside of the practice of surgery, we clearly, in medicine, have such things as off-label usage, that now has expanded greatly. Commercialism is pushing off-label usage in subtle ways. Patients are pushing off-label uses in more explicit ways.

And so the practice of medicine is becoming much more--I don't want to use "experimental" here, I want to use--there's another word that we use--it'll come back to me--but to see a whole variety of practices that develop kind of subtly and very widespread ways, that need--that are clearly new and different, and have not been evaluated very appropriately. They're the kinds of things that come up frequently to insurers, that say, "Here's a new practice that we're seeing; a new diagnostic procedure that's appearing; a new form of treatment that's appearing--and people are asking us, 'Should this be covered?' And since we don't cover experimental procedures, what should we do with this?"

Well, that's clearly a place where a better and cleaner distinction. On the other hand, there may not be a better way to make a better and cleaner distinction.

But we ended up with a definition of research that largely depended upon the ability to design a protocol; that is, to bring to bear the methods of research that will allow valid and generalizable new knowledge. And so a lot of new things are being tried in areas where it doesn't appear to people possible to develop such a protocol. You can't get

control groups, for example; or you can't deprive a patient of a possibility of treatment, because it's a lethal situation and so forth.

So there are all of these things that are happening, that mess up our nice little clean distinction. That's fine. What we want, I think, out of Belmont is the opportunity to keep asking the question: how should we think about practice? What is practice? And that's going to be changing. It's going to float.

INTERVIEWER: The Belmont Report gave a lot of attention to protecting vulnerable subjects, vulnerable populations. But still today we find there are more women in research than there are men, as research subjects; there's strong encouragement, even through regulations, to conduct more research in children on therapeutic agents. There's a fair amount of research in prisoners. How does that wash with what concern there was by the authors of the Belmont Report for protecting vulnerable populations?

DR. JONSEN: Yes, the question of protecting vulnerable populations remains still a very important major question. It was the question posed to the Commission. The Commission, after all, was named for "protection of human subjects."

Well, when you bring up the question of protection, you always immediately raise the question of vulnerable people, because you don't "protect" powerful people. They protect themselves. So every research subject, however--in our view--was vulnerable. There's always the possibility of exploiting persons in the research situation--particularly persons who are ill or sick. And we recognized that.

But then we had a special category of vulnerable populations, where the vulnerability really arose from their socio-economic setting. And those, I think, were--in some case the setting was institutionalization. And the Congress actually wrote the study on the persons with mental disease as "institutionalized mentally disabled." Congress did that. It's because the scandals had been in institutions for the retarded--as we used to call them--and it was thought to be institutionalization that was the major question, rather than mental deficit. I mean, clearly, we were concerned with mental deficit, but if you read the report, the report is really about institutional structures and its effect on the persons who live within them.

The subsequent reports deal not with that, but with the problem of mental disease as an impediment to consent. The NBAC [National Bioethics Advisory Commission] Report views it that way, and it takes out the institutionalization.

So the question of vulnerability remains a consistent question. We're going to be dealing with children--that's a standard category. With women, I think we recognize that research was not being done with women in many settings, where the diseases were such that women were affected. For example, heart disease was mainly male research, whereas more women suffer from heart disease than men. And, in particular, the problem of effect upon pregnancy had driven researchers away from women as research subjects.

So now we have mandated research with women and with children. It's got to be done or you've got to justify why you don't include them.

And women, I do not think of as a "vulnerable population," except in that broadest sense of anybody who's in research is vulnerable.

I don't think of them as a vulnerable population. I think they stand as "normal" research subjects.

Children, clearly so. Prisoners are another problem. They are certainly vulnerable to coercion. But in the Commissions experience with people in prisons, we found that they were very often--that their form of coercion was very different than what we'd imagined it to be. It's not that they're stood up against a wall and made to be research subjects. It's that they have--there is an inner coercion within the structures of the prisoner population itself, which has to do with their passing out favors to friends and punishing enemies within that population. That's what the prisoners do to each other; and that research had gotten caught up in that world, so that the coercion to pull out research oftentimes pulled something out from a very complex social structure where it was beginning to serve a very definite purpose within the coercive inner life of the prison.

I think that prisons today are probably a lot different than they were 30 years ago. And certainly the most problematic kind of research in those prisons was the drug research. Social research--or research regarding diseases that are particularly prison-related--I think probably can be done without--well, I guess I have to go back and say: are they a vulnerable population when you're doing that kind of research? I wonder. I think that probably needs to be looked at again.

INTERVIEWER: You and the other Commissioners invested a huge amount of your own experience, your own personal time, your knowledge, into writing all of the documents of the Commission. Were there some parts of this that were especially exciting, or especially frustrating, as you look back on it?

DR. JONSEN: Well, we spent a lot of time writing. I think one of the unique features of the National Commission was that the reports were actually written by the Commissioners. That's pretty rare in Federal commissions--committees--that's usually done by staff.

Now, on the President's Commission for the Study of Ethical Problems in Medicine, which followed the National Commission--on which I also served--all the reports were written by staff. We didn't do--the commissioners didn't write.

On the National Commission, we wrote it. And we went--you know, people were assigned sections to draft, and then they were criticized and redrafted. So--I remember times when I sat with maybe one or another Commissioners in the hall, in Building 10 at NIH, and pounded things out on the typewriter so they could go back into the Commission.

INTERVIEWER: It's interesting--when you do that kind of work do you find some parts of it more exciting more than others? Some parts of it more frustrating?

I personally found it almost always exciting. I like to craft language. I like to try to get clarity into ideas. And it's especially exciting when it's been the result of a good argument. And that's what we had. We had lots of good arguments.

Frustration? If there was frustration, it didn't come from the writing part of things. It came from the occasional situation where we had some bureaucratic interference. And we did have that several times and, in fact, had to take some quite definitive action with regard to that, after which it disappeared. That's where the frustrations came from. Somebody from the bureaucratic side trying to tell the Commission which way to go, or which way not to go. And once our chairman took effective action, that stopped.

And I never found the Commission's work frustrating. It was burdensome, but not frustrating.

INTERVIEWER: Well, the real test of a product that we write is its life-span. And because this has lasted so well for all these decades, there must be a large amount of pride among the Commissioners that this has been so.

DR. JONSEN: Well, I'm certainly proud of it. I would actually like to see other pieces of the Commission's work more available. LeRoy Walters and Bob Veatch and I published a book about five years ago called Sourcebook for Bioethics, which takes big hunks of the Commission's work in other areas--not the regulations, as such, but the chapters which explain the background. So, in the children's report, we pulled out the chapter on ethical principles and we published all of that, because it's, of course, in the public domain. And so we have made that available.

But, generally, there's some splendid sections in the Commission's larger reports which I believe are still worthwhile, and ought to be read. I'm very proud of them.

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