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

Interview with

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Belmont Oral History Project

Interview

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

INTERVIEWER: To start us out, would you please give us your complete name and your current position and your academic background?

DR. BEAUCHAMP: I'm Tom Lamar Beauchamp. I teach at Georgetown University, where I am a Senior Research Scholar at the Kennedy Institute and a professor of philosophy in the Philosophy Department and my background is in philosophy.

INTERVIEWER: When the work of the Commission began, what was your role as part of the Commission?

DR. BEAUCHAMP: When the Commission began, I didn't have a role because I was not, at the time, on the staff. I joined the staff after they had the Belmont Retreat. So, at the beginning, I had no role. Which is just to say, I wasn't there from the start.

INTERVIEWER: But, then as you joined the Commission at work, what was your role? How did that come about?

DR. BEAUCHAMP: My role was to write the Belmont Report. That was my staff assignment and that's what I did, the entire time I was there, which was two years.

INTERVIEWER: If you joined the Commission after they had already started to discuss their work, and you were brought on to author the Belmont Report, which the document that became known as the Belmont Report, how did you get caught up on all their discussions and become aware of their thinking to capture it in the report itself?

DR. BEAUCHAMP: Actually, I didn't in any sense inquire into the nature of the discussions, except to talk to Michael Yesley, the Staff Director about it. And the long and short of that conversation went something like this: The Commission, at its retreat, identified these three principles. And I said, what do these three principles mean? And he said, I'm really not sure and I'm not sure the Commission is sure, but it's your job to find out.

So, rather than suggesting that I take a retrospective view, he was suggesting that I take a prospective view and figure out by talking to Commissioners and other members of the staff what they thought these principles meant. And, then, to reflect on the body of a document that I was to write what that was.

He did say, at the time, there exists a staff document, but he said, I wouldn't expect too much from it or some words to that effect. That document, I've given you, that is to say, the existing state of the Belmont Report, as it was in late 1976.
So I just used--I used that document and then I talked with people on the staff and the Commissioners.

INTERVIEWER: At the time you started writing the document, how much agreement was there among the members of the Commission in their own thinking about the principles?

DR. BEAUCHAMP: There was complete agreement on categories. Think about it in terms of three words: There was complete agreement on these three words and there was agreement that that should be the structure of the Commission's thinking. And though we several times, afterwards, discussed whether or not that might be revised, in fact, it never was.

In part because the head of the Commission, Ken Ryan, was insistent that they not be change; that that would take us into a whole new discussion. So the question was not: would we change these words. There was never any disagreement about that, really, but, rather, what did it mean and how did the three principles relate to one another.

INTERVIEWER: Were there any other principles that were discussed?

DR. BEAUCHAMP: No, not after the time I joined the staff. I understand from talking to the various people that there were, as many as seven discussed. And the list got pared down at the Belmont Retreat itself. But that was not something that I ever experienced.

INTERVIEWER: When you completed your draft version of the report, it, presumably, went to the Commission members.

DR. BEAUCHAMP: That's right.

INTERVIEWER: How did they like it?

DR. BEAUCHAMP: They thought it was too philosophical.

INTERVIEWER: So, then how did they--

INTERVIEWER: I mean, it's not that they disliked the basic discussion of the principles; respect for persons, and beneficence and justice and so on. They that was, you know, a nice start and so on, but they thought the document was too philosophical; had to be pared back so that someone who was not a philosopher would be able to sustain interest. And it would be readable by, say, people who worked on IRPs.

So, they proceeded to tell me to take a lot of the philosophy out of it. Omit any reference that might be made to great classical philosophers, like Kant or Mill or something like that, which I did. So, a tremendous amount of stuff that I had written hit the cutting room floor, at that point.

INTERVIEWER: What one of the strengths of the report is its shortness.

DR. BEAUCHAMP: Yes.

INTERVIEWER: How difficult was it to get it to a short document, but still contain the information that the Commissioners wanted--also a document that you were happy with?

DR. BEAUCHAMP: I think it was, primarily, a process, not of addition but of deletion. Well, think of it as a process of deletion and, then, wordsmithing. You delete all those parts that you think you really don't need or that are duplicative or whatever in my drafts. So, we get rid of all that. Then we get down to what everybody's pretty much agreed is the essence of the matter and then you begin to wordsmith each sentence. Be sure it says just what you want it to say.

I think that's the way the process went. Because I'm simplifying what occurred over almost two years, by the time we had the final draft ready.

INTERVIEWER: Can you tell us a little more of that iterative process of going through the various versions and how it had finally evolved to one that you said, this is it?

DR. BEAUCHAMP: Yeah, what would happen is: A lot of this was hidden from view of the Commissioners, because the Commissioners were never in the offices, right? I mean, there was just staff in the office. So, I would write stuff and Michael Yesley and I would talk about it every day. There was just hardly ever a day that we wouldn't go over stuff.

And he would be the primary feedback person, at least, orally, he was the primary feedback person. Quite frequently Barbara Mishkin would read it and she would suggest--not things orally--but would suggest it in written forms--they just operated in somewhat different ways.

They were my two primary feedback people on the staff. So a lot of stuff got cut out at that level by suggestions from Michael or from Barbara and the Commissioners never even saw it.

Then we tried to get a draft that we could all agree was ready for the Commissioners to look at and then it would be sent out in the meeting books. And it, you know, be only one thing among a number of items that would be on the agenda for that particular meeting.

The Commissioners would read it. Sometimes they would call in evaluations. They might call me or, since they were used to calling Barbara, they might call Barbara and she would pass on something to me that they wanted change. Most of the changes came from Commission deliberation.

However, if you go back and look at the transcripts, the Commission, actually, deliberated relatively little. I think the whole of the Commission deliberations, in session, on the Belmont Report would be less than 100 pages. And, you know, it doesn't take much discussion to make up 100 pages of a transcript of a meeting.

So, there was not a huge amount of time devoted to this in meetings. Still, it was the chief point for the suggestion of any significant change in the document. And it was the only language we knew whether all the Commissioners agreed on that.

There was one other part of the process: When we got right down to the end--all of this was already done, everybody was, generally, happy with the structure, they said, okay, we need somebody to put it in final wordsmithing form before the very last meeting, so that we can all agree on that wording. And they assigned that job to me and Steven Tolman and Al Johnson, jointly. We met one day in a meeting room at NIH and we worked all day, going through every word, making sure that the three of us agreed on every word. And I believe that's what constituted the final document. I don't think there were any changes at the final Commission meeting after that.

INTERVIEWER: Did you anticipate that the document that you had completed would still be as widely read and used as it is today?

DR. BEAUCHAMP: No, I think it was unimaginable, absolutely unimaginable that that would occur. The document had only one purpose: it was really to explain the frame work principles that the Commission operated on in delivering what we all thought would be the most important thing we were doing, which is the other 16 volumes, or so. That is to say, those volumes that were on very specific matters that we all knew could be weighty, because they would pass through the Office of DHEW and then into law, either that or some reason had to be given for them not passing into law.

So, we all knew that was a very weighty consideration. Basically, we thought of Belmont as a kind of background consideration.

In fact, when Michael first assigned the job to me to write the Belmont Report, I thought it was because I was the new kid-on-the-block on the staff. And I was getting the dregs of the assignment. Because it was what nobody else wanted to do.

INTERVIEWER: You have to feel good about it today.

DR. BEAUCHAMP: Well, yeah, it worked out well, exactly.

INTERVIEWER: Did you expect that the report would be translated as the basis for regulations to the extent that it was?

DR. BEAUCHAMP: No, it is a surprise to me, today, that that happened and that it continues to sustain the kind of interest that it sustained.

INTERVIEWER: Well, how was it picked up as the basis by those people who wrote the regulations? I mean, it's pretty clearly the basis for the regulations?

DR. BEAUCHAMP: Yeah.

INTERVIEWER: Who made sure that those three principles were as evident in the regulations as they became?

DR. BEAUCHAMP: I don't actually know the answer. I'm not a historian of what transpired in those offices. I would think, though, that those offices thought about this document much as the Commission did. It's a very quick access and way of explaining the fundamentals of what you should think through in order to protect human subjects, without going into hundreds and hundreds of pages of suggested arguments, recommendations, the deliberations that led you to those conclusions and so on. So, it's kind of a convenient tool. It's almost like a capsuled summary of the considerations that you have to take account of without getting into the nitty-gritty of any particular issue, like an issue pertaining to prisoners or those institutionalized as mentally inform or the fetus or whatever.

INTERVIEWER: Did you discuss at that time, the desirability of having more of those details in the Belmont Report and then take them out?

DR. BEAUCHAMP: No, I think we were all agreed that that should not happen; that it would be hopeless. On the other hand, you wanted to be sure that you didn't have any inconsistencies between what you put in the Belmont Report and the way in which you had

actually reasoned and the conclusions that you had reached in all of your other reports. So, I would constantly go back to those reports and check to be sure that there weren't inconsistencies that were appearing with what we'd said previously.

INTERVIEWER: Were there people who were prominent in ethics and philosophy at that time who thought the Belmont Report was not on the right track?

DR. BEAUCHAMP: This is, I guess means shortly after publication, is that right?

INTERVIEWER: Yeah.

DR. BEAUCHAMP: I think if you look at the publishing record, it's pretty thin. Very few scholars paid much attention to it. And those who did, I think, paid just fairly perfunctory attention. There were a few articles--but a very few--that tried to express some level of criticism, which is, basically, what a scholarly article is going to do is to say the Commission would have been better off had it argued this way or this kind of reasoning leads to a certain kind of contradiction, and so on. I don't think, though, that you're going to find that there were more than five or six articles within the first five or six years of publication.

INTERVIEWER: Were you prominent as an author in other writings, other documents of the Commission?

DR. BEAUCHAMP: Yeah, well, as a staff, we all read all the documents that we produced. But somebody was assigned to be the primary author. My own experience is that, for me, anyway--but, I think, for other members of the staff, too--it worked something like this: On written documents, Barbara Michkin was vetting them and often writing larger parts of them than anybody else. It sort of became her job. It's like, she became a drafts person. And she stayed very close in contact with the Commissioners.

Michael Yesley would, then, read it with a--would read everything with a very critical eye and give her feedback on changes, detailed changes that had to be made. The rest of us, because we had some primary assignment, wouldn't read it quite as carefully as Michael, but we would give her feedback; maybe write a section that we think should be inserted at a certain point. And, so, we just sort of kind of jogged along in that way. Nothing was ever written, just written/written and not revised many times over.

INTERVIEWER: Was there a social climate or a political climate that time that had to do with peoples' rights that affected the writing of the Report?

DR. BEAUCHAMP: Oh, absolutely, this is historically a follow-through of the civil rights movement. The civil rights movement broadly construed the rights of individuals and the

rush to those kinds of considerations. I don't think there's anyway question, if there hadn't been that prior history, I rather doubt that we would have seen this history of the National Commission.

Of course, there are a lot of other historical foundations, too, like Tuskegee, but, yes, the answer to the question is, yes.

INTERVIEWER: Then, what effect did the Tuskegee experiments have on the thinking and the drive to a product that you had?

DR. BEAUCHAMP: I don't think that Tuskegee had, itself, the actual details of the case and what was concluded by the ad hoc committee that evaluated it--I don't think had that much impact on the Commission, except to serve as a background to say: you may find more things like this in the areas in which you are looking, which is children and the like. You should be prepared for it and you should be sure that these kinds of things never occur. It was just a big red flag that we all knew was there.

INTERVIEWER: But it wasn't the gauge against which the composition of the report was judged?

DR. BEAUCHAMP: I don't think so. I think there was very little discussion of that. Of course, as is still true today, there's a constant reference to Tuskegee-this and Tuskegee-that about what was questionable and what was clearly bad and so on. But I don't, really, think that the Tuskegee case helped the Commission decide all that much what should happen to fetuses or children or prisoners or whatever. Yes, there was a link of vulnerable populations, for sure. But I think that's different.

INTERVIEWER: Do you think we could get into a situation of Tuskegee-type experiment today?

DR. BEAUCHAMP: Could it ever happen again? Could it happen now? I think that, maybe, we should think about that issue in a slightly different way because you don't know exactly what the points of analogy are between Tuskegee and the present time. Are we very likely to see a case as serious as Tuskegee? I wouldn't think so. Are we likely, though, to still see serious cases where there are lapses of judgments; people authorizing things that should not be authorized; significant consequences, such as death and suing? Yes. Yeah, as is obviously so from some recent deaths by medical experimentation at some of our best institutions. In some of those cases, I believe that with more careful scrutiny and awareness of what was going on, those events could have been prevented. In other cases, I don't think they could have.

INTERVIEWER: In retrospect, now, of having had years of thinking about it and looking at today's climate, are there things that you wish you had put in the Belmont Report to cover some of the situations that we have today?

DR. BEAUCHAMP: Not really, I don't think about revisions needed in Belmont in that way. Maybe in some of the other Commission documents. For sure, if you're going to go to Commission documents, like prisoners, for example. I was never in favor of the prisoner report, I didn't like it then and I don't like it now. And I don't think that the present rules about prisoners are the kind of system that we should have. So, I would significantly rethink that volume.

So far as Belmont itself is concerned, though, what I wish the Commissioners had done is to keep the differences between the three principles straighter than they did. In particular, I thought the first principle--the principle of respect for persons--was a kind of mishmash of considerations of beneficence and non-maleficence rolled into respect for persons and they should have kept that separate. So, I would have liked to see those principles rewritten and restructured in certain ways, but I argued that at the time and other people argued that at the time and we didn't prevail. That's the way it goes in a national commission.

INTERVIEWER: What are the other issues of today that are not adequately being taken care of? And I'm thinking of things like conflict-of-interest– situations where the report was actually silent on conflict-of-interest?

DR. BEAUCHAMP: It is silent on conflict-of-interest, which is, very often, thought of today in terms of financial conflict-of-interest.

INTERVIEWER: Ah.

DR. BEAUCHAMP: There's now a huge discussion at many medical schools and research establishments about financial conflicts-of-interest, probably not an adequate discussion, yet, but a large discussion. What's still largely undiscussed and the documents are extremely poor in every institution I know of--I don't know of a single exception and that's nonfinancial conflicts-of-interest, if you're interested in conflicts-of-interest per se.

It wasn't until relatively recently, I think that people even got onto the idea that there might be something important there. And I think times just haven't caught up. Certainly, there was nothing like that with the Commission. This was not a central category. It's not only, though, that there are other problems like this that might be bothersome in the world of research involving human subjects. It's a way in which, sometimes, all these problems get rolled together in the full weight of responsibility for attending to them is shoved off on IRBs. So, IRBs are supposed to look at conflict-of-interest. They're supposed to look at the

specifically ethical dimensions of research protocols. They're supposed to look at whether it's good science and so on.

i think that it's a very confusing world as to whether an IRB is supposed to do; what's on-limits and what's off-limits in an IRB. Yeah, I think there are a lot of things like that that we need to tidy up in the system.

INTERVIEWER: What was your thinking, primarily, as it related to research in the U.S. or were you thinking of the international scale, as well?

DR. BEAUCHAMP: The Commission?

INTERVIEWER: Yes.

DR. BEAUCHAMP: I think that that ought to be distinguished between the Belmont Report and any other reports of the Commission. That is to say, the theoretical frame work, which is what Belmont is. And then the practical guidelines that are put out in the other documents. I don't think we ever thought of the practical guidelines as being guidelines for anybody other than citizens and investigators of the United States. That is to say, that that is what we were writing for, that was the audience, that's what it was intended for.

I do think, though, in the case of the Belmont Report, that was always thought of as something that was an expression values and, therefore, was applicable to anyone in any circumstance who conducts human research as it is to people who are either Americans doing research here or others doing research in America or Americans doing research abroad, would apply equally to any--in other words, the idea is, any responsible research investigator or any responsible research committee would take account of these considerations. Otherwise, if they didn't they would be acting unethically.

INTERVIEWER: Universal also in the sense of medical research as well as social and behavioral?

DR. BEAUCHAMP: Yeah, well, that's a tough one. The truth is as--I don't know if you've interviewed Brad Gray or not--but, as Brad Gray often argued in our staff meetings and, sometimes, in front of the Commission, the truth is, very, very little attention was paid to social science and behavioral research. Very little that we wrote pertained to that. Very few of the models pertained to it and so on.

Nonetheless, your question is: Would we have thought of the Belmont Report as universally applying to those areas as well? Yes, the answer is, yes.

INTERVIEWER: There's a gray area between the practice of medicine and research in terms of how you would apply ethics and how you would apply regulations. Do you think the Belmont Report gave adequate attention to the distinction between research and the practice of medicine?

DR. BEAUCHAMP: No. No, the early part of the Belmont Report, these four pages or so, were written by Bob Levine. I did not, myself, write--I think they're very good. That's--it was under my authority, as it were, to revise them if I wanted, but I never did revise them very much. I thought they were quite good. They paid a lot of attention to the boundary between research and practice. But that's different, because that's a conceptual distinction between research and practice. And I understand you to be talking about matters of practice, right? No, I don't think that was well-addressed in Belmont, but I don't think it was intended to be addressed.

INTERVIEWER: Do you believe that's an areas, today, where, perhaps, we need to think how we work in that gray area?

DR. BEAUCHAMP: Yes, yeah, the biggest failure, I think, at the present time, in the research system is making people who actually are involved in the practice of research--not the practice of medicine, but the practice of research--in understanding something like the moral frame work of Belmont, that is to say, a basic statement of responsibilities, then to understand what federal regulations or, perhaps, institutional regulations, as well, require of them and how you translate that into practice. That's the biggest gap in the system.

In other words, it's not that we don't have an adequate theoretical frame work in something like Belmont. That's fine, but it's workable. It's not as though the Code of Federal Regulations needs to be revised to get everything into it. It's fine the way it is, but that's, then, got to filter down into practice so that people understand what the implications are of those rules and guidelines. That's where I think there's the biggest failure in the system.

INTERVIEWER: As the three principles of the ethics were considered, were they considered to be of equal importance or does one trump another one?

DR. BEAUCHAMP: There's no trumping criterion or condition whatsoever in the Belmont Report. And it was written specifically on that model. There's not supposed to be a trumping consideration. They say justice is not supposed to outweigh autonomy or autonomy outweigh justice, something of that sort. And it's set up, specifically, in terms of prima facie principles. That is to say, those that, coming into a particular deliberation, each of them have equal weight.

That's well and good as a theoretical matter. Does it work out that way, practically, as the Commission begins its deliberation? I think the answer is, no--for a couple of reasons. One, I think justice is severely downplayed. There's very little discussion of justice. The main application has to do with the selection of subjects, the just selection of subjects. Very little attention is given to that problem, either in the deliberations of the Commission--it does come up from time to time--very little time. So, justice becomes a distant third consideration.

Second matter: I think that respect for persons, actually, is the most important principle. And for this reason: It becomes a kind of threshold condition. If you don't have adequate informed-consent, either of a first-party or a third-party, you can't proceed with the research. So, it has a kind of priority position in terms of telling you what can be done and what can't be done.
The next-most important principle, by far, is the principle of beneficence and justice, then, is sort of a trailing third. So, for both of those reasons, I think there is a kind of structured, though quite implicit set of--it's not trumping considerations and it's not quite hierarchical, it's a matter of which weight you think one of the principles has in going into any given discussion.

INTERVIEWER: As IRBs do their job today, if you were to advice them on the considerations, would you put them in that same order that you just put them?

DR. BEAUCHAMP: That is really a hard question. I think what I would try to do is teach them the great importance of each of these principles and how to spot when something falls under one of the principles. You could have a case coming in front of your in which virtually all of the considerations had to do with justice, there really were very few considerations in terms of respect for persons or beneficence. And on the other hand, you could have a clear case in which everything--as a lot of cases do--everything turns on whether or not you've got adequate informed consent. So, I'd hate to say one way or the other about that.

I do think, though, that most cases that IRBs see, don't have that much to do with problems of justice. And, to that extent, what they really need to understand are the importance of principles of respect for persons, particularly informed consent. And how to weigh harms and benefits.

INTERVIEWER: Switch for a second from the thought of what IRBs are doing to how investigators are trained to be investigators. Do you think there's adequate training about ethics, as young physicians are trained or young scientists are trained about how to do research involving humans?

DR. BEAUCHAMP: No, I don't think so. We're speaking quite generally. Obviously, in some cases, and in some institutions, the training would be quite good, I think, in general, no.

And I think that's also true of people who are going in to service on IRBs. They're not adequately trained prior to getting there, so they have to sort of get their learning up while they're part of the committee. And about the time they really understand what's going on, they rotate off of the committee. So, yes, I think that's a serious problem.

INTERVIEWER: How many of the medical schools have a course on ethics that would train investigators on how to think about ethics, as opposed to think of their specialty in medicine?

DR. BEAUCHAMP: Yeah, I think it's not so much how many of the 120-or-so medical schools that we have in this country, actually teach something like that. Rather, they'd structure it in terms of a continuum. There are some institutions, some medical schools, where there's nothing at all, absolute zero. Maybe the most that we've transmitted is you're expected to know certain kinds of things in order to be board certified, right? But they don't--we don't teach you that.

Right up to institutions that have a rather large ethics faculty, like the University of Texas at Galveston, where you're got, maybe, ten people running a pretty significant ethics shop, in house and everything in-between. So, I think of it in terms of a continuum.

Is the training adequate? No, doubt it's not. On the other hand, no doubt, some of the training is inadequate in some other areas that they're preparing for as research investigators, as well. It becomes a matter, I think, in these institutions of balancing what it is that you need to know. And ethics often gets balanced out as a distant second.

INTERVIEWER: Can you share some thoughts with us about the leadership of the Commission and how the various groups of people work together?

DR. BEAUCHAMP: Yeah, we had two clear leaders: Ken Ryan, who was elected to be head from the Commissioners' perspective. And then you had the staff director, Michael Yesley. Both of them were excellent leaders. Both of them spent a lot of time in figuring out where we should go; what should be in the next meeting; what have we left behind. Even considerations that none of the rest of us, I think, even knew anything about, such as budgetary considerations; how we're using the budget and so on.

Both, I think, handled themselves very well. They worked together seamlessly and beautifully. And it led to a situation, roughly, like this: The main dimensions of where the Commission would be headed were set out in Commission meeting. So, to that extent everybody was a leader; that is to say, everybody had a chance to say something.

Then the staff would pick up the pieces after that. A lot of things would happen in, say, a 30-day period-or-so of staff working. The staff would know what's happening there the

Commissioners wouldn't, except what was sent out to them in a book. And then, behind the scenes of the staff work, itself, would be meetings between Michael and Ken. So, a lot was happening that Commissioners never actually saw. Now, presumably they were informed about the more important dimensions of it.

But, when you think about it, most of the hours of what happened in the history of the Commission were not what happened in its deliberations, but, then, how things were picked up and moved in a certain direction, either by the staff or by the leader.

INTERVIEWER: There are a lot of people who feel that we're not handling the conflict-of-interest process well, today, yet; despite how important it is and how much discussion there's been. Why are we still having a hard time knowing whether or not, as we inform subjects, that we actually have them understand what the risks and benefits are and understand the research. And that when we deal with achieving consent, that we have people who actually understand what the research is about. And that the consent process, really, is working?

DR. BEAUCHAMP: Is the question: Is the consent process working?

INTERVIEWER: Are we, in fact, achieving, through the consent process, what you had hoped we would when you talked about it?

DR. BEAUCHAMP: No, I don't think so. I think of the consent process--to use the same analogy I used a minute ago to a continuum--I think there are people who are conducting research in this country who are not getting something even close to an informed consent. There would be some minimum disclosure of information on a sheet of paper and that would be it. Then people would be expected to sign a sheet waiving, in effect, waiving their rights. There is a lot of protection of institutions. Risk management is the dignified word for it in some categories. It's not really informed consent at all. It's an attempt to get a document that's called an informed-consent document or form, but it, actually, does much more to protect the institution.

There's that kind of think all the way up to the highest levels of getting informed consent for research, where people really know what they're doing. And I think there's everything in-between.

The general problem, I think, to down lower on the continuum, let us say those cases where we say we're getting informed consent, but we're not actually getting informed consent has to do with not having adequate monitoring facilities, on the one hand and having inadequately trained people getting those consents in the first place. I think that's what's wrong with the system.

You start out with conflict-of-interest. Let me make a contrast between conflict-of-interest questions and informed-consent questions. Informed consent, I think, I readily understand, why, when it fails in the system, it fails. It has to do with inadequate training. People just not having time; it gets a ready explanation.

Conflict-of-interest, I must say, baffles me. I do not understand why virtually the whole world of universities and corporations and IRBs don't get it about conflict-of-interest. They have a tendency to say conflict-of-interest may be a perceived conflict, but it may not be a real conflict. You, yourself, have to decide as a research investigator or as somebody who has a financial investment for whatever.

Whether you have an actual conflict, and then, if you do have an actual conflict to disclose it. And then, people who are in those conflict situations, often don't see--as somebody who has some distance from the situation--that they really are conflicted. And this seems to occur over and over and over again. To put it in stark terms, virtually anybody who's an external observer to that situation is going to see they're in a conflict-of-interest situation. They don't see themselves as in a conflict-of-interest situation.

As long as we leave a system in tact in which you declare not having a conflict, you are the person who decides whether to recuse yourself in the circumstances or whatever the rules are. We're going to go on with the problem of conflict-of-interest. It baffles me that institutions don't see better that that's a problem they have to address. They have sort of gotten it when it comes to financial conflict-of-interest. They haven't gotten it elsewhere.

INTERVIEWER: Do you think we've taken on financial instead of the institutional and the professional conflicts because you can assign a number to it and it's a little easier to get your hands around?

DR. BEAUCHAMP: I don't know. I, honestly, don't know. It's probably multi-causal or a number of different considerations in the explanation. It seems to have been the one that the press has been most interested in. For example, certain kinds of financial conflicts. It seems to have been the ones that are most apparent in institutions. It's obviously the one you see when you have Wall Street-kinds of problems. So, it's gotten a prominence and a cache and a number of concerns have gone into that area that the other areas just haven't had that's a non-financial conflicts-of-interest.

INTERVIEWER: Our system for protecting human subjects is largely built on trust. We trust the IRBs; we trust the investigators; we trust the institutions; we trust the government, but, still, when there's a lot of attention paid to a tragedy that happens, there is a tendency to think that more things should be regulated; things should be mandatory, like dealing with conflicts-of-interest–and training. But, then, the research community says that the burdens

are so great that we can't do research anymore. How do we work with this system based on trust and get the research done, but still protect the subjects?

DR. BEAUCHAMP: That's a really complicated question, because that asks, in effect, about why is the system failing us in certain respects and what do we need to do to systemically repair it? And I--there's just a ton of things that can be said there. You need people to be trained a lot better than they are in terms of what they should be looking out for. I think that's one of the most significant considerations. You need to cut down--it's not so much a matter of providing better federal regulations, as you need to cut down on the number of assignments given to a committee.

Take an IRB, if an IRB is really supposed to look at all ethical dimensions of the research enterprise in, let's say, a significant research institution, maybe it runs 60 protocols a month or something like that past a committee; and it's supposed to look at conflict-of-interest; it's supposed to assure that it's good science; it's supposed to apply ethical principles and so on. It becomes very difficult to do that. So I think a big part of what needs to happen is to have discrete functions. Don't have that committee looking at conflict-of-interest, have another committee or an office or whatever, which is committed to the responsibility of looking at conflict-of-interest problems. Okay, that's one thing, dividing the tasks and making sure that people are not overburdened.

Do regulations or requirements or whatever, in themselves, in some cases need to be overhauled? Well, I think I've already said, I think they do in the case of something of like non-financial conflicts-of-interest, but that's not necessarily true in every arena.

To me, what your question asks is: Do we have systemic problems that weigh us down so that we're inadequately protecting human subjects? Answer, yes, some are more important than others and we need to identify which ones and try to tackle those problems one-by-one.

INTERVIEWER: If you were to pick one or two of those that are of much more importance than the others in terms of protecting human subjects, what would they be?

DR. BEAUCHAMP: I think training of people in research ethics, which is not just perfunctory, but one where they actually can understand what their responsibilities are and they have the time to go about being sure that those responsibilities are engaged in the system. I think that's the single most important consideration.

There's a kind of side consideration that has interested me from time to time in the last 25 years. And that's: Is the system to weighted toward science investigators? In other words, most of the people--it's a variant of the problem of conflict-of-interest--most of the people who staff and run the system--I don't mean secretaries in offices--but I mean, people who

actually run the enterprise are somehow in the research enterprise and many of them are, themselves, research investigators.

When we then ask for their protocols or their work to be evaluated, it's research investigators who are evaluating their work. They don't evaluate their own work, they pass it on to another body of research scientists. That means there's relatively few people from the outside and, in particular, people who are well-trained in ethics who are part of the system.

But the problem that's been around for a long time is, do we then get judgments that are weighted in favor of the interests of those who are in what could negatively be called the scientific establishment or, less negatively, just the research enterprise, itself? And I think the answer to that is, undoubtedly, yes. That is to say, we have a system, which because of the way in which it's constructed, certain considerations become magnified in importance; particularly those that are important to scientists themselves, and ethical considerations often get downplayed.

If you want an extreme example of this--more so, I think, in research regarding human subjects--look at research involving animal subjects where there's very, very little input from people with professional training in ethics and the people who are doing the evaluation are by-and-large always research scientists. That's the best example, but you can find examples, I think, throughout the system.

INTERVIEWER: As you wrote the Belmont Report, there was a lot of attention paid to vulnerable subjects, vulnerable groups of people, in the sense that they needed to be protected. But, today, we have regulations and we have things that encourage that women participate in research; that children are subjects of research. Are we moving in the wrong direction compared to what you thought was the right thing when you wrote the Belmont Report?

DR. BEAUCHAMP: No, I think it's a balance in consideration. I think we've moved in the right direction. Think of it as a two-phase movement: We moved in the direction of providing adequate protections, increased protections to vulnerable populations. It's not as though the idea of protecting vulnerable populations had never occurred to us, until the Tuskegee ad hoc report or the report of the National Commission, of course it has.

But we decided to increase protections in the system and I think there was, undoubtedly in the National Commission, and this deserves underlining, undoubtedly a conception of a research subject as somebody who is being burdened. I mean, you can find hundreds and hundreds of lines in Commission reports and in the transcripts of the meetings, in which exactly that is suggested. Being a research subject is a burden. I don't think there was ever a positive spin on the idea of being a research subject that it was not just a burden to the

individual, but was actually considered a benefit. Or, if not a benefit, then potentially a benefit for a class of persons that that person represented.

AIDS activism and the aftermath in the scientific community, I think changed all of that in the direction of, as you see a lot of people, thinking--people that are interested in juvenile diabetes, or whatever--thinking that research is the answer and wanting actually enroll subjects and conduct trials and the like. Both are right, we need to adequately protect vulnerable people. We also need to do more research because research, after all, protects people, as well. That's the whole point of research is to protect people against injury and disease and the like. so it becomes a balancing consideration.

I think the Commission was lopsided, yes. Maybe some people who want expedited trials at the FDA have a lopsided notion in the other direction. Maybe they want it to be too expedited. So, what we need to find is a balance between the two.

INTERVIEWER: Out of that balance is also the fact that while we want to encourage protection of human subjects, but there's a new emphasis today on bringing new products to market. And the only way we can do that is to have people volunteer to participate in research. Are we being too non-conservative as we allow studies to be improved people taking risks?

DR. BEAUCHAMP: I don't know the answer to that. I don't know, I think you'd have to look at how many studies are approved that have that kind of problem attached to them. I mean, I'm sure there are some; whether there are a large number I don't know.

INTERVIEWER: As the regulations are being used today to manage the enterprise, do you think we have the right emphasis on the three principles?

DR. BEAUCHAMP: Does something like the Code of Federal Regulation, appropriately or properly incorporate these notions? I don't think that the Code of Federal Regulations or anything else for that matter--and I'm talking about not just government regulations, I'm talking about scholarly writings--ever adequately address these questions of justice that we were talking about earlier--the just selection of subjects. I think it's muddled and confused and it doesn't seem to address questions of justice to say, well, we only take volunteer subjects. That's more a question of consent than it is anything else. It's not a question about who we ask to be a subject or who we will allow to be a subject or payments to subjects or any of these kinds of questions of justice. I think it's muddled and confused and I think it really needs to be reconsidered at almost all levels of the system.

The problem with informed consent, I think, is not what's said about informed consent, but actually getting informed consents. And the problem about beneficence is that nobody quite

knows how to balance risks and benefits. We know a lot about what risks are. We know a lot about what benefits are, we just don't know how to balance them real well. That's the way I think--because you're asking about problems that might be present. If they're not appropriately recognized in the Code of Federal Regulations, right?

INTERVIEWER: Yes.
DR. BEAUCHAMP: Yeah.

INTERVIEWER: If we were to try and improve the protection of subjects today, as well as to protect the enterprise so that we continue the conduct of research involving humans, do you think the emphasis should be on coming up with better regulations or do we start back with a new Belmont Report-kind of activity to start at the beginnings, again?

DR. BEAUCHAMP: Neither. I think Belmont's okay as it exists. And I think federal regulations are, by and large, okay as they exist. It's how you implement them. The training of people and what the meaning of these documents is and how you actually do what they require you to do.

INTERVIEWER: Coming back to the issue of vulnerability of people versus vulnerability of populations. There is a lot of protection paid to protecting vulnerable groups independent of their health condition or their age or whether they're male or female.

DR. BEAUCHAMP: Yes.

INTERVIEWER: Do you think we should be protecting people or protecting populations?

DR. BEAUCHAMP: A little of both. It's not an either/or situation, although it might be an either/or in terms of emphasis. Take an issue, for example, that the National Commission was not concerned with. But that I've been concerned with in some of my work, which is the homeless.

The homeless, I assume, are, by most definitions, a vulnerable population. And there are some people who are homeless who are extremely vulnerable individuals. There are others who are not. They're homeless by choice; it's a lifestyle consideration and they're actually not all that vulnerable.

So, if you're concerned about people who are homeless, as a lot of people are, you're concerned about them as a vulnerable population, best to be concerned in any regulations or guidelines or shelters that you create or whatever about those members of that population that are actually vulnerable.

This, of course, involves you in trying to define what it is to be vulnerable; what the conditions of vulnerability are. For example, is mental illness a vulnerability? If so, if that's a condition that's both necessary and sufficient, let's not make it necessary, let's just make it sufficient, if that's sufficient for making somebody vulnerable, then they're an awful lot of vulnerable people. And maybe, even, that would define a vulnerable class--those who are mentally ill. Well, there are a lot of people out there who are homeless and have some form of mental illness. Is that what makes them vulnerable or is it something else that makes them vulnerable and so on.

You asked earlier about questions that might be addressed. That's a question that is not, in my judgment, very well addressed in the literature on vulnerable populations. You say what are the necessary and sufficient conditions of vulnerability? And once you identify that, what percentage of or which particular people within those populations actually are vulnerable under the definition?

INTERVIEWER: Research, as it's being proposed today, is much more complicated than the research that was proposed 20 years ago, just the nature of the science; in the development of questions; in the development of new products, products are more complicated. Has that eroded our protection of people by virtue of these things becoming just much more complex than they were and it's harder to identify who is a vulnerable population?

DR. BEAUCHAMP: I think I'd go back to the earlier comments as protocols--let's just take protocols for a minute, which is something we can get our finger on. As protocols become much more complicated to understand the science and what's going on. It's meant that we needed more time to deliberate. First of all about whether it's good science, but that I take as a study section-type question. But then, secondly, about the ethics about what's going on in these circumstances, because we had to understand what the science is and what was actually going to be done to people in order to find out a particular scientific question.

The point of this is, I think it's created a wait in the system. You need more time to deliberate about these more-complicated matters. And I think what's happened in the system is, rather, than affording more time, it's actually afforded less time, because there's also more of it. It's not only that it's more complicated, but there's more of it.

INTERVIEWER: As you think back on your time in bringing the Belmont Report into reality, are there things that were particularly exciting moments of success that you--or breakthroughs in getting to where you wanted to be? Or were there moments where particularly frustrating, where you thought this wasn't going where you wanted it to go?

DR. BEAUCHAMP: I guess from my perspective, this is supposed to be a personal question for me, not , for say, the staff or the whole Commission or something like that. The most

exciting time and the biggest breakthrough was after I did the first draft, because I had virtually nothing to go on from prior documents and I'd thrown away huge amounts of stuff that had been drafted for this, that or the other reason in and around Belmont. I just said, it doesn't have anything to do with these principles, so I threw it away.

And when I got positive feedback from the staff and the Commissioners on the document, I suppose that was a big sigh of relief came at that point, because until I did it, until I actually wrote it out, I didn't know if people were going to accept it or not. They might say, well, that's a hair-brained idea and reject the whole thing.

INTERVIEWER: Any particular moments of frustration?

DR. BEAUCHAMP: I referred to one earlier. I tried to convince staff and Commissioners that these principles were never rightly conceived; that there was too much confusion between what it is to respect persons and what it is to provide them with a benefit or to protect them against a harm, particularly when it came to the class of incompetent persons.

I thought that was the problem. Because it looked like sometimes they applied the first principle, respect for persons; sometimes the principle of beneficence. For basically the same reason to the same problem of incompetent individuals. And most of the people that we were talking about were incompetent, right? Those were most of the classes of individuals that we were talking about.

So, I felt this was really a significant problem. But, basically, Ken Ryan didn't want to discuss this at all. He didn't want, at that point, to revise what was in the Commissioners' heads about respect for persons and beneficence. So, it just never got attended to. And the consequence is, I think there's a sloppy delineation within the Belmont Report of what respect for persons is and commit yourselves to it and how many people it covers. Because persons covers everything. Incompetence and competence are covered equally under that principle. And then how the principles of beneficence and non-maleficence are just beneficence in the Commission Report are to be handled. That was the one thing that I found a little depressing.

INTERVIEWER: There are very few of us who have something as large as authoring the Belmont Report at an early stage of our career.

DR. BEAUCHAMP: Yes, I was quite young at the time, that's certainly true.

INTERVIEWER: How did that affect how the rest of your career unfolded?

DR. BEAUCHAMP: There's a mythical interpretation of it that appears in a number of scholarly writings. What they say is that Jim Childress and I wrote out book "The Principles of Biomedical Ethics," out of the model of the National Commission. That's actually false. However, to qualify it. I try to qualify it and set it historically right and then answer your question. Childress had already been writing our book for about a year when I was hired on the staff of the Commission. So, I already had all that background.

What happened is the two grew up together. I would learn things from the Commission. I would go talk to Childress about them. We would build them into the book, but we also had the book there, the manuscript and stuff we were thinking about. I would then take that to the Commission. So the two documents actually grew up simultaneously.

They started almost at the same time, they matured at the same time, and they were published--well, they went to the publishers, is the way to put it--at the same time.

That was by far and away the best-known publication that I ever published, let us say under my own name, "The Principles of Biomedical Ethics." So, to that extent, what happened in the Commission was enormously influential on what happened in my career.

The side that I'm trying to bring out is that it's not as though Childress and I took the model of the Commission, it's that the two models were developed together and in interaction. I should say, I suppose, as a footnote, I'm really indebted to Jim Childress for a lot of ideas that the Commissioners might never have appreciated were coming from him through our conversations that found their way into the Belmont Report. Because he was a great inspiration and source of ideas to me at the time.

He and Michael Yesley were the people who really attended carefully to what I was doing and helped me correct my own thinking and, therefore, the way in which I authored these drafts at the time.

–END OF INTERVIEW–