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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August 19, 2004

Belmont Oral History Project

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INTERVIEW

Interviewer: Patricia C. El-Hinnawy, Office for Human Research Protections staff

INTERVIEWER: Michael, could you give us your name and your degrees and your job or jobs?

MR. YESLEY: Well, I'll give you a few of them. I'm Michael Yesley. I'm an attorney by profession. I have an undergraduate degree in philosophy, of course a law degree, and some graduate training in economics as well. I have worked as a regulatory attorney in the Federal Government. I have, since the, since 1974, when I got off of the Commission, I've been involved in bioethics in a variety of positions for the last 30 years or so. And I've also continued to practice law in various capacities, and to write in the field of bioethics.

As far as a formal position, the one I might mention is that for several years I ran the Department of Energy's ethics program related to the Human Genome Project during the 1990s.

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

MR. YESLEY: I started out as a staff director and was the Commission staff director during its entire four-year term of office.

INTERVIEWER: Could you tell us a little bit of the background of why the Commission was formed?

MR. YESLEY: Well, it was formed in response to a number of sort of egregious stories that came up, it seemed, one after another. It was perhaps first the Tuskegee research, which itself was the subject of sort of a mini-Commission before ours, and then there were many stories that were related intentionally before the Subcommittee on Health that was headed by Senator Kennedy.

And at the same time also there were some influences in the literature. There was Dr. Beecher's book documenting a large number of at least suspect research enterprises, medical research enterprises. And so there was a climate of concern about the conduct of research with human subjects, both because of these anecdotal, if you will, stories, and because of a

more systematic effort by Dr. Beecher, Dr. Katz from Yale.

It seemed that this was a field that needed looking into, and the legislators and administrators needed some guidance on what action if any they should take to assure that human experimentation was conducted appropriately in the future.

INTERVIEWER: And so what was the impact of that political climate on the Commission's work?

MR. YESLEY: Well, there was a lot of interest in what the Commission was looking at. The topics, such as fetal research and research with prisoners, were very much in the news, and particularly on the fetal research report which came out toward the beginning of the Commission's term. There was very substantial press interest.

MR. YESLEY: And so I would say that there was a lot of concern. The political climate wasn't pushing the Commission in any one direction or another. What the political climate was, was saying, we've got a problem here and we need to have some experts look at this issue or look at these issues and come up with a way of resolving them and assure that appropriate protections are afforded to people who get involved in medical research.

INTERVIEWER: And what was the pathway that led you specifically to come to work at the Commission?

MR. YESLEY: Well, my pathway was sort of abrupt. I got a phone call from the general counsel of what was then the Department of Health, Education and Welfare. He told me that there was this Commission being formed. It had been established by act of Congress. It was about to hold its first meeting in the next several weeks or a month or two, that NIH wished to have a lawyer as the staff director, and therefore had come to him. And I had worked for him in the past. He had a good opinion of my efforts, and thought it appropriate to recommend me for the job, and his recommendation carried, carried some weight. And so I was selected by the NIH to be the staff director.

The Commission itself didn't hire me, and in fact, didn't hire anyone. The hiring was all done either by me acting as an arm of NIH or by NIH itself.

So in any event, I had a background in regulatory law. That was the, perhaps the area that was thought to give me some, some relevance in my, in my experience, but in terms of background in bioethics, nada.

INTERVIEWER: The staff director has a very impressive ring to it. What was your job as staff director?

MR. YESLEY: Well, I considered that the job was about one half administrative and one half substantive. On the administrative side it was doing a lot of logistics, both arranging meetings, arranging special meetings, field trips, hiring, firing, overseeing people in their assignments, contractors, consultants. There was an awful lot of work just to--behind the scenes, making sure that the efforts that the Commission needed as inputs to its deliberations were carried out.

On the substantive side, I did a lot of the preliminary drafting of the Commission's recommendations. I translated the Commission's requests into action items for the staff or outside consultants. I was the final editor of virtually every document that the Commission produced. On some documents, my editing was pretty light, and other documents I was more involved in their, in their production, and I wrote a few of the legal chapters.

INTERVIEWER: For some people today the Commission's work is mostly represented by the Belmont Report. Is that how it looked in '74 to '79?

MR. YESLEY: Well, definitely not. I think that some members of the Commission, particularly the philosophers, might have considered it to be an important or perhaps the most important document, but for others of us, including myself, it was sort of an add-on. We considered our major work to be investigating what was going on in the conduct of research with certain subject populations, and we considered the Belmont Report to be sort of an abstract exercise that might be of academic interest, but probably would not have any practical import such as our reports and recommendations on special populations would have.

INTERVIEWER: And why do you think the Belmont Commission has ended up having such visibility over time?

MR. YESLEY: The Belmont Report?

INTERVIEWER: Yes.

MR. YESLEY: The visibility of the report sort of surprised me. When I realized a few years after the end of the Commission that some of its reports had just been laid on the shelf and were gathering dust. Other reports had been integrated into regulations, the ones involving research with prisoners, for example, or with children. But it seemed to me that the report referred to as the Belmont Report was the, was the report that continued to resonate.

It had neither been ignored nor adopted, but it was the one document that appeared in the field of bioethics to have a continuing influence, or at least people were continuing to refer to it, and clearly, in the literature it was a continuing subject of analysis. And it turned out perhaps that the more abstract document had the greater practical importance in terms of influencing the way people thought in this area.

INTERVIEWER: As you look back on your experience with the Commission, what is it about that that stands out in your memory?

MR. YESLEY: Well, I think that it would be interesting to me to hear what the other Commissioners and staff members have responded to that question. But my own feeling, and I'm sure that most of them hit on this, was that the Commission was a great experience in collegiality. There really was a tremendous amount of loyalty going in both directions.

The Commission, at its meetings, was up in Conference Room 6 of Building 31, I guess, and that conference room has an enormous conference table. The Commission always sat with all of its staff at the table and everyone spoke. And so it was in a sense a classless society. So it was a good deal of intellectual ferment, but it involved at least two dozen people or more, without consultants, not just the 11 members of the Commission. And so that's not something substantive that I can say stood out, but I have rarely seen a group that large work so well together, and I think that that's one of the reasons that this Commission could come out with a large number of reports, some of which even had some influence.

INTERVIEWER: What was the topic or topics that generated the most discussion among the Commissioners and the staff?

MR. YESLEY: Well, this is not a particular topic, but a type of topic. The Commission would say, say in a given area such as research with prisoners, the Commission would decide that it wanted a number of factual and opinion inputs, and so they would say we need to learn this about what's going on here, about what's going on there, where are people doing this, what have some penal sociologists learned about this? What do philosophers think about this? They needed a lot of inputs. When they got those inputs, they would then digest them, discuss them, and come up with a set of recommendations for regulatory action that would protect the given group of human subjects.

The thing that stands out is that they could come up with those conclusions, and then when it came time because the Commission thought both to gain credibility and also to be

intellectually honest, they wanted to provide a rationale for these conclusions. The rationale was generally far more difficult to arrive at than the actual conclusions themselves, and I think this drove everyone crazy, both the Commission and especially the staff. And I can remember many meetings with skilled philosophers trying to figure out what would provide a meaningful rationale? It wasn't that there wasn't a rationale for the conclusions, but it was much harder to get agreement amongst all the Commissioners on what the rationale was than to actually get the conclusions themselves.

INTERVIEWER: What do you believe was your most important contribution to the work of the Commission?

MR. YESLEY: Well, my own contribution was sort of pervasive, and by that I don't mean it was substantial, but just that it was all over the place. And I just think that I helped in terms of making it into a smooth functioning machine and assuring that the reports read reasonably well.

INTERVIEWER: Michael, could you tell us what you feel was the Commission's most important contribution to human subject protections?

MR. YESLEY: Well, I think it probably was the Belmont Report in that that product of the Commission sort of boiled down societal concern and societal guidelines, and provided I think an accessible document that people could refer to to know what sorts of standards they were hoping to comply with.

The Belmont Report is not a formula to arrive at conclusions about research. But if one reads through it and careful reading can't take more than 45 minutes or--it really a fairly terse document--if one reads through it, one comes out of that brief experience with a good knowledge of important concerns to bear in mind when reviewing the appropriateness and the conditions under which research with human subjects is conducted.

INTERVIEWER: Go back in time to the Commission. Is there anything you think you should do differently or should have been done differently?

MR. YESLEY: Well, there are some problems with some of the research that we contracted out, not major problems but we could have tweaked the assignments. Perhaps half the Commission's budget was devoted to outside work. Most of that work was very important and was folded into the Commission's discussions and into its results. We might have made it a little more useful if we'd, in hindsight, known which direction we were going in.

But by and large, when you have a group that size that is resonating with each other, that reflects a lot of different concerns, there aren't too many ways that--and the product was an intellectually honest product that came out of the back and forth of discussions with Commissioners, with Commissioners and staff as well. There aren't many ways to improve on that.

You can say 20 years or 30 years later that certain things weren't covered, but on the other hand, we covered what we needed to cover at the time. And one of the concerns of our chairman was that we not undertake tasks for which we were not suited or which would place impossible demands on our resources. So we looked at our assignment, we interpreted it in a moderate fashion, not expansively, and we provided the responses that were requested from the Commission, and I don't think there was much that could have improved on what we did, not that it was perfect, but given the time, given the circumstances and the resources, it was a darn good job.

INTERVIEWER: Were there any issues or ideas that you felt should have been addressed during the time of the Commission but you didn't have a chance to or--

MR. YESLEY: Well, I would say at some point perhaps in the middle of the Commission's four-year term, or perhaps it was toward closer to the end, we were asked if we would look into this new biotechnology stuff that was coming along. Obviously, that's very important and a lot of attention is being paid to that right now and rightfully so.

We could have gotten our feet wet, but I remember the chairman of the Commission, Ken Ryan, saying, "We've got to get our first job done. We can't just start looking for other things to wade into." And so that's an important area. We had an opportunity to get into it. I think Chairman Ryan was quite correct in limiting our focus though.

INTERVIEWER: Your work has kept you in the field of human subject protections for a very long time. Since the time of the Commission's work what changes have you seen in the field?

MR. YESLEY: Well, this is a field that started out with a handful of people, perhaps in right across Puget Sound here in Seattle, and the issues of the field were seen to be broader than just the concern of what to do with a limited number of kidney dialysis machines. So the field grew and it grew fairly fast, starting in the late '60s and then with our Commission in the '70s, and then there was a big burgeoning, and now there are literally thousands of people involved, whereas at the outset there was a handful, and at the time of my Commission, perhaps two or three hundred people involved.

And at the outset I think that our Commission did some ground-breaking work, some good basic laying down of fundamentals, of which of course the Belmont Report is a good example.

What has happened in 25 or 30 years since that time is a routinization, to use a vabarian [ph] term, is a routinization of the field where the regulations have become increasingly detailed and increasingly voluminous, and satisfying the regulations has come to be seen as an end in itself rather than doing appropriate research.

And so I see reflected in the literature and in the online discussion groups, I see a concern with the minutiae of protecting human subjects, and people who raise questions about whether some practice might be ethical or not, and then other people weigh in by referring to such and such a regulation, saying, "I think that you can do this under that, or isn't that forbidden by that regulation?" I never see anyone stepping back and saying, "Well, that's not fair," or "Why wouldn't that be fair? No one uses these fundamental ethical principles any more. They've become too interested in fly-specking.

And so that's what I've seen--what I see has happened in the field of human subject protections. It's become sort of over-regulated, but in a sense at the same time, under-regulated, in that we're no longer doing the broad goal, and what we're doing is, again, the minutiae of regulatory compliance.

INTERVIEWER: So do you see a way of changing that?

MR. YESLEY: Well, I don't think there's a simple way to change it. I think for various reasons we've settled on peer review for--to assure ethical conduct of research. There is not an easy solution to the problems of IRBs.

There are dramatic solutions, but I'm not sure if the time is right to make substantial changes. There are a lot of people who are invested in the IRB movement, whether or not it accomplishes what it's supposed to accomplish, or whether or not it accomplishes its goals efficiently or effectively.

And so I would hesitate to come up with a grand scheme to replace what we have, but I do think that we're expending a lot of time and effort on a system that is not highly effective.

INTERVIEWER: You said in another venue that your work on the Commission changed your life. Could you explain a little about that?

MR. YESLEY: Well, at the outset of the Commission, when I was asked to come in as the

staff director, I had no background at all in bioethics. I had an undergraduate degree in philosophy for what that was worth, and certainly I was a practicing attorney for what that was worth, but in terms of focusing specifically on bioethics issues--I had never done that before--and of course, nowadays if you placed a neophyte such as I was in a relatively important position in bioethics, there would be a hew and cry about political favoritism or just making the wrong appointment.

And so I came from nowhere, and it was an unusual--it would be unusual if it happened now, but at the time there were so few people in the field that you basically had to say, "Well, he'll do a good job once he's exposed to the issues," and I hope that that's what turned out.

MR. YESLEY: And so coming from perhaps a relevant background but no actual contact with bioethics issues into this job, I thought at the end of it that perhaps I would go on to the next interesting thing, but as it has turned out, I've kept my hand in bioethics ever since.

I have been involved in bioethics issues, bioethics administration ever since the Commission's time. I've run another ethics program more recently in the field of genetics. I've been on hospital committees. I've been on IRBs, chaired some of these committees, done some writing in the academic literature, and mainly now in the time of semi-retirement my sole professional interest is in bioethics and that's the area that I continue to stay up to date on and to do some writing and speaking on.

So it changed my life because I had never heard of it before the Commission came along, and now it's the only professional interest I have.

INTERVIEWER: At the time of the Commission the prevailing view was that vulnerable individuals such as children should be protected from research. Now, however, there are requirements such as the Children's Health Act to conduct more research involving children. What are your thought about this?

MR. YESLEY: Well, I think that children were, all children were sort of orphans, and still are to a certain extent, in terms of whether medical treatments, proven effective for adults, might be effective for children as well. And so I'm not opposed to conducting research with children.

The idea of conducting more research with children does not strike me as being unfair, but probably would be to their overall benefit. The only issue is the circumstances under which the research is conducted, and whether it is appropriate in light of the usual concerns with risks and benefits, and informed consent, and selection of certain groups of children.

As long as those concerns that were highlighted in the Belmont Report are responded to and are satisfied, the idea of calling for more research, to me, is a positive.

INTERVIEWER: Again, over time, some people feel that the focus has shifted away from protecting human subjects from risk and toward permitting access to innovations that might be helpful. Is this a position that you would agree with?

MR. YESLEY: Well, it's interesting. In the field of genetics, for example, there are some who have called the whole field of bioethics, where it intersects with genetics, as sort of a stocking horse to enable the scientists to carry out the research that they want to carry out. And in fact, bioethics is, I think, a fairly pragmatic discipline. And being pragmatic, it tends toward--I wouldn't call it permissiveness, but it tends toward enabling research to be conducted, hopefully under appropriate conditions. Rather than saying this research is bad or it's going in a bad direction, it shouldn't be done at all.

And so to a certain extent it is true that the field of bioethics is an enabler of the conduct of research, but hopefully, at its best at least, it will enable research to be conducted in appropriate fashion.

INTERVIEWER: Do you think that today's research environment is overly restrictive?

MR. YESLEY: Well, there's certainly a lot of hoops that people have to go through, and I'm not sure that those, making people go through all those hoops is actually making research any more ethical or more appropriate. So I would have to say that it seems overly restrictive in terms of the bureaucratic maze that's been imposed on the field.

In terms of whether important research is hampered--of course, a lot of people say we couldn't do this nowadays because of the ethics regulations. Well, when I hear that argument it tends to be research that shouldn't have been conducted in those days either, as well as these days.

And I think if anything, getting through the maze is not an insurmountable barrier. Research that should be conducted, gets conducted. It's not turned off by the human subject regulations, and probably too much research is still conducted because IRBs, given their institutional setting and their membership, I think it's very difficult for them to say no to senior researchers wanting to conduct research.

And so, yes, there's a lot of hoops and a lot of bureaucratese that you have to go through, but, no, I think probably research is not in the end unduly hampered and perhaps there is still

research going on. Certainly, some of the genetic research that's had some adverse consequences, a death even, should not have been conducted in the way in which it happened, but you've got a senior researcher there, and it was hard to say no. And that's probably carries through in a lot of instances.

INTERVIEWER: Do you think subjects are more at risk today than they were 25 years ago?

MR. YESLEY: I think that that's an empirical question that would be difficult to answer. Certainly there are more speculative risks, such as what might come from certain types of genetic research that at least has been proposed if not actually conducted to date. But greater risk? Probably not. Probably the same amount. But as I said, that's basically an empirical question that I don't have a good feel to answer.

INTERVIEWER: Do you think that a study like Tuskegee could occur again today?

MR. YESLEY: Well, in different guises it is occurring. I mean, in that there are people who are research subjects who do not receive accepted treatments. Now it comes up in a totally different environment. It comes up in the international area where researchers would claim that they're not altering people's natural state, they're just coming in, doing their research, then going back with the research results.

But in fact, they are interacting with human subjects. There is an accepted treatment. They're not providing the accepted treatment. So--and I'm not saying that given the context and the practical considerations that that's something that's unethical or inappropriate. But to say that Tuskegee couldn't occur, I think you're just--it's just a failure of imagination, because the notion of interacting with human subjects where there is something, an accepted way to treat them, and not providing that accepted treatment, people come up with all sorts of rationalizations for doing research under those circumstances. So it could happen. It wouldn't happen in exactly the same way, but it could happen.

INTERVIEWER: Do you feel that the Commission's ethical framework functions in an international setting?

MR. YESLEY: Well, the Belmont Report is a reflection of western or perhaps you might say the United States or American--Canadians will forgive this--American social concerns. And as such, when people from America want to conduct research elsewhere, they can't leave their society's concerns behind.

On the other hand, other societies, be it in Asia or Africa or wherever, may have social

concerns that aren't reflected in a document such as the Belmont Report, and those too have to be adhered to.

So basically when you, when you are conducting research internationally, there is more at issue than just the Belmont, but the Belmont doesn't cease to be relevant, but it has to be tempered, perhaps contradicted even, by whatever social standards and social conditions might be relevant to the conduct of research abroad.

INTERVIEWER: Are there any changes you think that would help improve that situation in international research?

MR. YESLEY: I think that you've always got to be suspicious of people who study down, who look to a convenient population that might be--that might--that might provide an opportunity to conduct research that won't necessarily inhere to their benefit.

Beyond that, I think that it makes sense to require that research conducted abroad be research about something that might affect the future lives of those who are human subjects, if not then, in people in their society or their descendants. And so if the research could be conducted domestically, it should be conducted domestically. If it's research specifically about people abroad, then clearly, you want to conduct it on those people who are affected by that research.

But you shouldn't cross the line and do research abroad because opportunistically it's cheaper or you can take advantage of people.

INTERVIEWER: Do you think that the HHS regulations appropriately embody the three ethical principles of the Belmont Report?

MR. YESLEY: In a sense it's like trying to get people to be honest. And does, does studying the notion of honesty make people any more honest?

The Belmont Report sets up some principles that reflect social concerns and social notions of what might be appropriate, not in any particular way, but as a general matter. The regulations, in a sense, treat the Belmont Report as you might treat a general law, and try to implement it with a lot of detail.

The detail may be practically necessary or it may not satisfy that criterion. It doesn't necessarily ensure that people will achieve the ends of the Belmont Report or the ends of the Belmont principles.

The regulations affect certain elements of behavior. Often they have perverse consequences in that if you regulate one thing and people want to do it anyway, it pops up in a different guise. So I think that the HHS regs are a good effort to implement the Belmont Report, but are not necessarily effective in getting people to see what the goals of the Belmont principles are, and to integrate those and comply with them so that research is appropriate whether or not you've dotted all the "i's" and crossed the "t's" of the, of the bureaucracy.

INTERVIEWER: Are there changes you think that would help lead us more toward that situation?

MR. YESLEY: Well, I think that the whole IRB mechanism is an unproven but demanding effort that uses up a lot of resources, that may or may not accomplish its goals, certainly does it inefficiently. The changes? Well, you know, one alternative at one extreme is to rely on self-regulation, to tell investigators that they're responsible for the appropriate conduct of research, and to indicate something broadly like the Belmont Report, that those are the principles that should guide investigators in determining whether their research is appropriate.

And at the other end you would have a centralized regulatory mechanism, either state by state, or located in Washington, that would oversee research that crossed a certain threshold to make it subject to this regulatory scheme.

And peer review is considered to be something in between those two extremes, and also to reflect an extension of peer review that's already employed in medicine in terms of determining effectiveness and avoiding mistakes. I think that it probably is misdirected, reviews too much and not deeply enough the things that it should be reviewing.

I don't have a simple fix for it, no, but I certainly would--I certainly think that the mechanism needs sharpening.

INTERVIEWER: Do you think the Belmont principles are absolutes that override all other considerations, or are they factors to be used in balancing the risk of harm against the societal benefits of knowledge?

MR. YESLEY: Well, I can't imagine that anyone insisted that Belmont, that the Belmont principles were absolutes, although we might have thought so at the time when we were drafting them.

But clearly, the--to me, and I think to most others--and I certainly see this reflected in, say, Beecham and Childress's work--the Belmont principles reflect social norms, and as such, they don't provide answers, but they provide considerations that should be--that must be taken into account in deciding whether something is appropriate or not.

I like the term "appropriate" much better than the term "ethical." I'm not sure what "ethical" means, but "appropriate," while it's not a fixed term, to me is a more significant term, because "ethical" usually is misused. What's ethical is what I think is right. "Appropriate" at least indicates that we're talking about something that's not fixed. Different people may, may have different opinions. I'll leave it at that.

INTERVIEWER: Is there any other topic or issue that you would like to address here?

MR. YESLEY: I wanted to make a point about the operation of an advisory Commission in this area or in a similar area. It seems to be that while this Commission and similar commissions and the whole field is often called an ethics commission, or this is a field that's concerned with ethics. In fact, to me a more appropriate term is that these commissions and this field are better described as policy fields, and that what the goal of the effort is, is establishing and then implementing an appropriate policy, not making something ethical, but having a policy that reflects social concerns and social goals.

And to this end it seems to me that when an area raises questions of appropriateness or ethics, if you insist, that the response should come not solely from people expressing their opinions of what's right and wrong, but first and probably foremost, from a close investigation of the facts involving the particular situation that has come up.

You can't make policy in a factual vacuum. I think one of the advantages of our Commission was that the Department of Health, Education and Welfare made a fairly liberal budget available to the Commission. The Commission was enabled to do the investigations that it thought were necessary and appropriate to its work. Those inputs were very important.

When you get together a commission of so-called experts who believe that they can resolve a social dilemma or a social issue on, on an abstract level solely from their powers of concentration, solely from their beliefs and opinions, that to me is the makings of a suspect policy. Any policy-making group has to look at the facts, and if the facts aren't available, it has to figure out ways to generate relevant facts. You can't make policy in a vacuum.

So one of the values of the National Commission, and one reason that its results gained some credibility is that people saw the process, they saw that the Commission was gathering

information and that it was using that information to reach pragmatic conclusions. I think that that's a good model for other commissions to follow.

When I see commissions of 10 or 15 members that have a staff of 3 or 4, I know what the results are going to be. The results are going to be the opinions of the commissioners, not the results of careful investigation and generation of factual information.

As far as the IRB mechanism is concerned, I think all would agree that improvement is in order. I would suggest that probably a radical change is in order. Unfortunately, I don't have the radical change to recommend to you, but I do feel that this is a substantial effort that is disproportionate to what it's accomplishing, not that the field doesn't require some assurance that people involved as participants in research are not put to undue risk or treated unfairly, or treated without their voluntariness, but I do feel that we have imposed a mechanism that is not justified by what it's accomplishing.

Finally, in terms of the current day attitude toward Belmont, clearly Belmont doesn't reflect eternal verities. And also even here and now Belmont principles don't provide answers in difficult cases. They just provide considerations that should be taken into account.

I think that the approach to the Belmont principles should be that they are relevant, that they require continuing analysis. I think that the several editions of the Beecham and Childress volume are one good example of a continuing analysis of this sort of guidance. To me, it has been very helpful. I've gone back to look at ethical analysis as a general field, and I find it very helpful to ask where the authority comes from, what are the influences that led us to certain conclusions?

I think Belmont needs to be continually pulsed, analyzed, questioned, but that at least for the foreseeable future it remains relevant.

INTERVIEWER: Excellent.

MR. YESLEY: That's a few little addenda there.

INTERVIEWER: Can I ask you one follow-up question?

MR. YESLEY: Sure.

INTERVIEWER: I think that what you said about international research was very eloquent, among the most interesting of the responses we've had to that question. Are there any--

MR. YESLEY: That was on the fly too. I hadn't really thought about that.

INTERVIEWER: Are there any examples that come to mind of groups that you feel are not benefiting directly from the research that are involved in the research?

MR. YESLEY: Well, I think that probably, you know, there is some international research that, for example, looks at whether you can provide HIV treatment in a deprived setting where you can't afford the full treatment. Clearly, that's relevant to people because it's a given fact that you are not going to be able to provide the full, the full bore treatment that's available in, in the United States, for example, or in Western Europe. It's relevant.

This doesn't mean that the research and the way it was conducted and all that are appropriate, but that would be an example of something that's relevant.

But the drug company that goes to China or Thailand or Burma or wherever, to test a drug that's not particularly relevant to those subjects, but it's cheaper to do it over there, I think that's an example of outsourcing, if you will, that raises questions of taking advantage of a population that is in a--I hesitate to use the word--but sort of an inherently coercive atmosphere.

INTERVIEWER: And it seems to me that that makes something of a parallel with the situation of prisoners.

MR. YESLEY: Yeah. One of the things that the Commission did, as I recall, in the prison report, is that it clearly carved out for approval research that was specially relevant to the prisoners, which I won't try to figure out just what that research is.

But on the other hand, there is a dilemma with prison research that I think the Commission recognized, and it was a close question, because what they were in part concentrating on was Phase I drug testing, which on the one hand uses prisoners, or it used to use prisoners opportunistically, but on the other hand, as far as I can tell from what I've been told, presents very little risk. And so it becomes sort of a big hullabaloo about something that, okay, on the one hand you're taking advantage of this situation, but you aren't presenting very much risk to them.

So--and this is part of the radical overhaul of the review of research. If you can assure that research with fairly low risk, that people aren't going to take advantage of that category, we should get the heck out of the--there should be--you know, we have a thing called expedited

review. It seems to me that the bureaucrats have made it so that there's now an expedited review to determine if you're entitled to expedited review.

There should be a threshold that's higher than expedited review that is self-enforcing, and that eliminates a great deal of research from review by IRBs on the basis that while you could, if you wanted to, speculate, imagine that say a certain population is being taken advantage of. If they're being taken advantage of in some minor way that doesn't expose them to risk, then let's not try to develop a social mechanism to take care of every possible insult in this world. Let's focus on the serious ones.

INTERVIEWER: Is there anything else?

MR. YESLEY: Do you have anything else?

INTERVIEWER: No, no, no. That was wonderful. That's it.

MR. YESLEY: Well, good.

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