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

*INTERVIEWER: Just to start, Bill, could you give us your name, your current position, your academic training, and your role in the 1970s, the start of the National Commission.*

MR. DOMMEL: Sure, I'd be pleased to. My name is Bill Dommel, F. William Dommel, Jr., and my current position is that of consultant to, an advisor to medical schools, research organizations, sometimes drug companies, in the development and enhancement of programs of protection of human subjects in research. And I come from a background of on-the-job training and absorption of medicine and research by being employed at NIH from 1965 until 1998.

My formal education is in political science and the law. I graduated from American University Law School, but my graduation occurred while I was working for NIH and, in fact, while I was doing some work with the National Commission and some of my very early activities at NIH involving other than automatic data processing, because I had begun my career in automatic data processing in the government, and then when I was about to graduate from law school, I had an opportunity to work as what was called a program analyst in the Federal Government at NIH, and some of my first work was with the National Commission. And I still use that work today in my current assignments in my own business.

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

MR. DOMMEL: The Commission--in 1974, I was approached by Dr. Charles McCarthy, who was working with the National Commission as a consultant; even though he was a federal employee, he was doing some work with the Commission. And at that time, the Commission was assessing the use of fetuses in research, which was truly its first assignment from Congress. And the greatest ethicists of the time assessed the status of fetal research in the country and made determinations from their points of view of what research with fetuses could and could not, should and should not be done at the request of the National Commission.

They were asked to keep their reports to about ten pages, and they each averaged about 30 pages. And then the Commission had a need to have these 30 pages reduced to one paragraph for each ethicist. And that was the project that I first worked on for the National

Commission, was reducing these great works to paragraphs that I'm sure did not come near to doing them justice so that they could fit into the publication.

*INTERVIEWER: Could you tell us a little bit about the political climate at the time?*

MR. DOMMEL: At the very beginning of the Commission's work, the political climate was volatile. There had been hearings in Congress about the study conducted by the Public Health Service in Tuskegee, Alabama, involving rural, poor black males who had syphilis and were being assessed but really not treated in a study that went on for nearly 40 years. And Congress had taken up this rather abusive study, this activity conducted by the Public Health Service itself, as well as other breaches of ethics carried out during research involving human subjects, and had public hearings on them in the context of developing legislation creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and assigning to that Commission a number of evaluations of vulnerable populations and creation of the Belmont study as well.

*INTERVIEWER: Since you brought up the Tuskegee study, do you think a study like that could happen today?*

MR. DOMMEL: I don't--well, yes, it could, but not by the U.S. Public Health Service, not by a federal agency, although we do have an Animal Welfare Act that applies to all research that involves animals, as well as many other things involving animals, but provides for the general welfare and care of laboratory animals, regardless of the source of funding for the activity.

In human subjects, we only have protections at a federal level that emerge from the funding or the conduct of the research by a federal agency. And so I think with the establishment of Institutional Review Boards, what we all call IRBs, we know that such a study as Tuskegee could never pass any IRB. It would just be recognized far too quickly. So--and the conduct of a study of that size and that duration in the absence of an IRB approval at an organization that required IRB review and approval would be very unlikely, perhaps even impossible.

But outside of the regulations that protect human that emerged from the Belmont Report and other activities of the National Commission, we certainly have--I lost my train of thought.

*INTERVIEWER: You were comparing the Animal Welfare Act just covering all animals and*

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MR. DOMMEL: Right. Okay. The Animal Welfare Act provides protection for all animals that may be involved in research, protection in the form of appropriate care and use of these laboratory animals. And it applies to all research involving animals regardless--all those protected by the act, regardless of the source of funding for the research activity.

On the other hand, the provision of protections for human subjects emerges not from a statute that protects human subjects, but from regulations established by the individual agencies, the federal agencies that provide a basic core of regulations protecting humans that are involved in research, but only if that research involves federal funding. And in the absence of federal funding, perhaps you could have a study like Tuskegee today because you wouldn't have the requirement for Institutional Review Board--IRB--review and approval, and such a study like Tuskegee could never pass an IRB doing its duties. And I think someone who were--was attempting to avoid the IRB review and approval deceitfully at an institution that was under the federal regulations would be unlikely to succeed in carrying out a study of this magnitude and duration.

So I think, no--in brief, no, it couldn't occur today at a federally funded agency or institution. But, yes, I think it could occur at an institution where there are no protections of human subjects by federal law.
*INTERVIEWER: Today, some people think that the Commission's work is represented by the Belmont Report. Is that how you saw it at the time?*

MR. DOMMEL: I didn't see it at the time because the Belmont--the publication of the Belmont Report came subsequent to much of the other work of the Commission. So what I saw emerging from the Commission and what I was involved in myself in the work of the Commission was much of the detail of protection of human subjects that later, when the Belmont Report emerged, we could see fit nicely into these overall principles established by the Belmont Report, set forth in Belmont.

So, but once published in the late '70s, in 1979, I saw the Belmont Report as a magnificent document that would withstand the test of time, that didn't have the detail of regulatory description that would make it be obsolete after 5, 10, 20, 30 years. I can see something like Belmont lasting for a century as a set of principles that would withstand the test of time because it contains the flexibility to do so.

*INTERVIEWER: And was that insightful perception shared by a lot of people at the time?*

MR. DOMMEL: Oh, I think not. I think we--we had people working very, very hard, people who were dedicated to the protection of human subjects, often as lifetime pursuits, who saw and recognized an opportunity to make a contribution that could have an immediate effect. And certainly they wished to design something that would work not just today but tomorrow. But I'm certain that they could not have imagined that it was as magnificent as it has turned out to be. And I'm sure that they're joyful that it has.

*INTERVIEWER: As you look back on your experience with the Commission, what stands out in your memory?*

MR. DOMMEL: Oh, many things. The--in my own memory, the first--the opportunity to work with such an august body, and I certainly recognized it as such immediately. And then to work with, on my first assignment, the evaluation of the statements relative to fetal research put forth by the greatest biomedical ethicists of the day was heady wine, if you will, for a young man about to graduate from law school. And so that stands out in my mind that I could even contribute one or two sentences, and I actually contributed significantly to many paragraphs in the fetal report.

But I guess what stands out almost as much is the translation of the important work of the National Commission in its establishment of recommendations and principles, translation of these into regulations, which became my responsibility subsequently. And at the time that I was doing my early work with the Commission, I didn't know my role would be to translate to regulations subsequently, but indeed it turned out to be an assignment that I was honored with and value to this day. And so to this day, I still use the work of the Commission and the translation of that work into regulations in assisting institutions throughout the country in enhancing or developing programs to protect human subjects and to establish their IRB reviews and approvals.

*INTERVIEWER: What topic or topics generated the most discussion among the Commissioners?*

MR. DOMMEL: I think those that even today would be seen as the most politically turbulent did bring about the greatest discussion and debate among the Commissioners, for example, research involving fetuses, research involving vulnerable populations, research involving *in vivo* fertilization and embryos and pregnant women, and indeed whether

pregnant women were vulnerable populations as defined by the statute. That indeed was a point of major debate because I think by virtue of being a woman and being pregnant does not make one vulnerable in the sense of the other vulnerable populations identified--children, mentally infirm, prisoners who were not allowed to exercise their autonomy. Pregnant women really aren't vulnerable populations, but indeed they require special consideration because of their pregnancy.

So debates about the nomenclature at the time were--were stimulating, to say the least.

*INTERVIEWER: And was that–did the staff have similar debates on similar topics?*

MR. DOMMEL: I would think it was almost mirror-like, that what we being discussed by the Commissioners you would see exactly the same thing discussed, sometimes beforehand, by the staff because the staff would recognize what would be of major concern to the Commission and to individual Commissioners in the staff's attempt to provide sufficient information for Commissioners to carry out these discussions thoroughly and to have the resources available they needed at that point.

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

MR. DOMMEL: My own most valuable contributions I would think would be the two that I have mentioned, and that is, the work that I did evaluating the reports of the ethicists on fetal research, the reports on fetal research, and developing summaries that were published by the National Commission and found satisfactory by the Commission to provide the sufficient information on the positions of these ethicists. And I worked closely with Dr. Charles McCarthy on that project, and that was my introduction.

And then, subsequently, my tangential work to that of the Commission in that my responsibility became take the recommendations of the Commission, translate this work into regulations using my legal training, and publish in the manner required by federal agencies' proposed rulemaking and evaluating public comment in light of the comment of the public on the National Commission's reports and the comment of the public on the proposed regulations, merging all of this into a set of regulations which have withstood the test of time, not quite as well as Belmont has, I think, and certainly won't in the future to the extent that Belmont will, in my own opinion, but that have served, I think, well to protect human subjects in federally funded research.

*INTERVIEWER: Having spent such a large part of your professional career right in the heart of human subject protections, as you look back at the work of the Commission, is there anything you think it would be useful to do differently?*

MR. DOMMEL: I don't think I would choose something to point to and say the Commission might have done this differently because I think the work they did and the outcome of all of their hard work has been of such extraordinary value that it's the kind of thing that I wouldn't suggest tinkering with. Even if I had the ability to go back in time and tinker with it, I hope I would have the reservation not to because the outcome is just so fine, it is so magnificent, and in an area that I view as so important and so much so that I dedicate my career to it. So I wouldn't touch what they've done. I would perhaps suggest that others who look at the work of the Commission revisit some of their recommendations and say in-- in light of our experience subsequent to the reports of the Commission, perhaps the Commission was more wise than we recognized when they said that the Congress should by statute require that these protections apply to all human subjects in this country and not just to those in federally funded or regulated research.

And one other that I think I might revisit, not the Commission's work but the translation in regulation, would be when one establishes minimal criteria for the membership and actions of an Institutional Review Board, an IRB, one should be cautious that the minimum doesn't become the standard. And the minimum, I believe, has become the standard in many circumstances, and I would offer as an example the requirement that at least one member be not affiliated with the institution.

I do not think that in its recommendations the Commission was looking for IRBs to only have one member not otherwise affiliated with the institution other than their membership on the IRB.

And yet often the case is there's one member not affiliated and an alternate for that member, so that someone else could be present.

Similarly, the requirement that at least one person whose primary focus is not in science be a member, and the standard perhaps is to make sure there is at least one member, and one member who meets this requirement present, because that requirement flows even to approval and that you may not approve a project unless there is someone who is not a scientists, if you will, present at that meeting in the review and approval.

So I think that I would as a federal regulatory agent present those requirements in a different way and make sure that we recognize that the minimum should not become the standard and do what would be required to see that that didn't happen.

*INTERVIEWER: At the time of the Commission, were there any ideas or issues that you felt should have been addressed in the Commission's work but weren't?*

MR. DOMMEL: I would like to have seen the Commission address with--with more detail the requirement for compensation of injured research subjects. And what the Commission decided to do was to pass that on to a subsequent commission that might emerge, and one did, the President's Commission for the Protection of Human--let's see. The President's Commission for--wow, I forget it now.

*INTERVIEWER: Everyone just says the President's--*

MR. DOMMEL: Right, because that's the one that includes medicine as well as research, unlike the National Commission. But the President--the subsequent commission, the President's Commission, addressed compensation and sort of passed that on to the federal agencies to pick up on. And the federal agencies were not in a position to--to bring such an enormous project to fruition. And so although attempts went on and I was involved in those for more than a dozen years, they were never successful. And although recommendations went forward to our Secretary, my Secretary, Department of Health and Human Services, other agencies did not even reach that point. And the recommendations of a task force that I worked with regarding provision of compensation in the event of injury simply did not get full attention of any of the Secretaries at the time that they went forward.

So I would like--if this National Commission was so effective that if it had taken that topic up with the thoroughness that it did its others, I think that it would have provided a program that would be in place today.

*INTERVIEWER: Even the 2002 Institute of Medicine on the protection of human subjects took up the topic yet once again.*

MR. DOMMEL: Yes, a good point. Thank you.

*INTERVIEWER: What impact do you feel that your work on the Commission has had on the rest of your life?*

MR. DOMMEL: Oh, I couldn't overstate the enormity. It really was the beginning of my career. From a personal standpoint, I came to work for the Federal Government at the age of 17 as a--as a clerk typist, and I was a Grade 3 and a Grade 2, and then I was able to find a position as a trainee in automatic data processing. And then I went into the Navy for four years around the time of Vietnam, and we won't get into discussions about my Vietnam role in the service because too many others are under discussion today. But we'll let mine pass.

But I did get an honorable discharge after four years and then returned to the Federal Government in automatic data processing, and then using my veteran's benefits and while working for the National Institutes of Health, I was able to proceed through college and law school. And about the end of my law school years, somewhere near my third or fourth year--because I went part-time to law school, so I had four years--I was tapped by Dr. Charles McCarthy to work on two projects: one, the fetal research, and another, a task force on compensation for injuries in research, human.

And at that time I was searching for a role. I had always wanted to be a lawyer, but I was now 15 years in the Federal Government and I didn't see a role as a lawyer in the Federal Government that I really desired strongly. Most of what I wished to do in the law at that time was outside of the Federal Government. But given my commitment to a federal career at that point with 15 years, I was exploring opportunities, and my opportunity came in an area that I wasn't familiar with at all--the protection of human subjects--right at the time the Commission was beginning its work.

And so blessed by my selection by Dr. Charles McCarthy and timing, that I was available when the Commission had a need, we were sort of--my professional career and the work of the Commission and the Federal Government in addressing thoroughly the protection of human subjects occurred at about the same time, in the mid-'70s.

*INTERVIEWER: Because you have spent your life, professional life, so much in the heart of this issue, what changes have you seen in human subject protections over time since then?*

MR. DOMMEL: I've seen the development of a profession similar to my own, a profession occupied by individuals who devote careers to the protection of human subjects in research, something which in 1975 very few ethicists even addressed biomedical and behavioral research ethics. Those that did, few, very few had a total career based on just the biomedical and behavioral research. And certainly there weren't individuals in other professions--law,

the analyst, Federal Government analyst profession--where programs were evaluated for with an eye toward meeting Federal Government needs, that there weren't those who focused on the protection of human subjects. But, indeed, with what came forth from the National Commission, a whole profession, if you will, of those with this dedication emerged. And today we have--there were a few Bill Dommel's in the mid-'70s, and now there are thousands who are much better and much more highly trained and far more qualified and brighter and who meet the needs of the Federal Government in--in whatever arm the Federal Government uses, whether establishments of its own commissions or requests to the Institute of Medicine for further evaluations of protection of human subjects. Now there are many who are available who are well qualified and can hit the ground running, if you will, on these very types of activities that at the time of the National Commission everyone was sort of a novice, and today we have really, really highly qualified and trained professionals who can contribute, and do enormously. It's a big change.

*INTERVIEWER: You just [inaudible] the field.*

MR. DOMMEL: I was there.

*INTERVIEWER: As the Commission defined the three ethical principles for the protection of human research subjects, was more weight given to one principle over the others?*

MR. DOMMEL: Always. There was always more weight giving to one--given to one principle over the others. But what's amazing, what's wonderful about the Commission's work and its recommendations and its establishments of the principles of beneficence and respect for persons and justice is that, as needed, you may apply different weights to these principles. And it's been my experience--and I don't recall offhand if the Commission spoke precisely to the point. But there always seems to be an equal distribution that shifts among the three. So if you said, well, each has 33 percent, but if you give away the 40 percent to one under a given circumstance, you will have to take something away from the others.

More positively spoken, anytime you must diminish your--your focus on one of the principles by a particular need, for example, then you should enhance your focus on another of the principles so that you come forward with a 100-percent ethics assessment, if you will, applying these three. So indeed they do shift, and they shift, I think, rather successfully. And one major occurrence which could be--could be properly--I'd like to stop here for a second because what I want to talk about at this point...

For example, in the 1980s, when those who spoke most loudly for those affected by AIDS, those who spoke most loudly were demanding access to research drugs that were not yet deemed as safe and efficacious and were still under research. But the research protocols themselves were generally closed to much of this population that was in need of access to new drugs or viewed themselves as being in need of access to these new drugs. And at that time, little treatment of HIV/AIDS was available outside of research. So the cry went forward: We're willing to take the risk, let us decide the risks.

Well, much of what had happened and was seen as abuse of human subjects had occurred under circumstances where someone thought that the need was so great that attention to the principles set forth in Belmont could be superseded by this need to provide for treatment for life-threatening diseases.

Well, in the absence of Belmont, perhaps one would just unilaterally begin to try these experiments on individuals while doing research. And this was not acceptable. What was assigned to the National Commission was seen as a search for answers to circumstances such as this where the need was great, we needed to do the research, people had serious illnesses, but we needed to protect their rights as well. And what could we do, how could we--how could we accomplish that?

Well, if you looked to Belmont and you say, well, you have a principle of beneficence, that risks must be reasonable in light of anticipated benefits, that you maximize benefits and minimize risks.

Well, if you don't know what the benefits are and you aren't even sure what all the risks are, how can you allow someone to go forward into such an activity without limiting greatly the activity? And that's what we do in our research protocols, and we have IRBs approve them. But when you had many who couldn't get into these studies and they said, "We want access, anyway," what could you turn to that was recommended by the National Commission to provide adequate protection? And you could turn to the Belmont principles, and you could say we will heavy-up, if you will, on the principle of respect for persons and autonomy and informed consent and the exercise of autonomy, and say in circumstances where we're unable to determine the risk and benefit but where many are in need of some sort of new treatment or they will die before a new treatment that is deemed safe and efficacious comes forward, that in that circumstances if we fully explain that to the individuals and we say we don't know what the risks and benefits are here, we're still studying it, but because of this great need if you completely understand this, consider all of the information which is

provided in greater detail than in any other kinds of research study, then we think that it would be ethical to go forward with this.

And so Belmont, the recommendations of the National Commission, and the principles set forth by the National Commission lent themselves well to this new demand and provided an opportunity for access to research at a point where there really hadn't been such access previously. And it could be done in a way that I would see as ethical.

*INTERVIEWER: Excellent. Do you think the HHS regulations, 45 CFR 46, appropriately embodied the three ethical principles--principles identified in the Belmont Report? (Respect for persons, justice, beneficence)*

MR. DOMMEL: Yes, I do. I think the--the recommendations of the Commission that actually led to all of 45 CFR 46, the regulations protecting humans, that those recommendations really are embodied in a living way in the regulations. However, regulations are regulations, and regulations leave not a great--a great deal of room for change, for--they're far more inflexible than the recommendations of the National Commission. The National--the National Commission could speak in terms of "should's," "it would be best if," and appropriately so. But when developing regulations, one must be very cautious in leaving that sort of flexibility.

But these regulations probably, in my opinion, have more "should's" or "ought to's" than most any other regulation I know that came from a federal agency. And the trick to doing it was to provide for the autonomy of IRBs. Institutional Review Boards could be presented with regulations that said "should" because we knew we had a body of individuals that brought forth a number of views that recognized an extraordinary responsibility, and when assessing a "should" really did assess it rather than dismissing it as being not a requirement.

So earlier in our discussion, I criticized the--inherently I think it's the institutions for adopting the minimalist approach to representation on IRBs. Contrarily, I think IRBs do not take on a minimalist role in making decisions about "should's."

I think they feel a "should" is a "really ought to be" unless there's a good reason not to. And since IRBs do, in my opinion, act that responsibly, then I think the "should's" and the "ought to's" in the 45 CFR 46 actually work in a way that they probably wouldn't in other statutes and regulations.

*INTERVIEWER: How interestingly put. This goes a little bit back to your answer a couple of moments ago. Over time, some feel that the focus has shifted from protecting human subjects from risk and toward permitting access to innovations that may be helpful. Do you agree with that?*

MR. DOMMEL: Yes, I think that this shift occurs at times, and at times it shifts back, and that the changing needs of those who benefit most from research and those who carry out research will--will cause an emphasis that might be greater at times than was previously the case. And so I think that in the '70s, when we established regulations that provided enormously strict requirements for vulnerable populations, that subsequently a concern for not involving in a sufficient way a number of these individuals deemed as vulnerable came--came to result in the detriment--resulted in a detriment to these protected groups. And so one could look to the regulations and the exceptions permitted in the regulations and say, How can we involved children, for example, in--in research when the restrictions on the involvement--involvement of children are so great as to make outcomes not very valuable? And--and that still the risks occur to children in or outside of research, depending on when an experimental drug is introduced into the population of children, for example, but that if we turn to these regulations and the recommendations of the Commission, we're sort of stuck. We're stuck with this very protective body of rules and guidelines that came forth in a period where those--where the abuses were such that these stringent rules and guidelines were appropriate.

I think today they aren't needed quite as much, that there are other mechanisms that are used to open opportunities to do research with vulnerable populations that an interpretation of the rules in the '70s might not have permitted, but that an interpretation today might; that, yes, the change has occurred. I don't view that change as inappropriate. I think that there is a balance shift here, and that if one looks at the overall protection and provides adjustments in the circumstance of limiting ethical provisions in one area but enhancing in another, that the system works. And I think that it works well.

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

MR. DOMMEL: No, I don't think the research environment is overly restrictive at all. I think that it's underregulated when federal funds are not involved and that the extent to which this occurs is--I would speculate is significant, that there is a great deal of research going on not receiving any federal funding; therefore, not subject to the federal regulations; and if not stringently assessed, perhaps not subject to FDA's regulations, because licensing

may not be involved, introduction of new products might not be involved; and that great risks are there. And I think you might find this more in behavioral research than in others.

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

MR. DOMMEL: I think I wouldn't want to--to--to suggest one way or another in--in that regard. I think that, in general, subjects are appropriately protected. The extent to which they were inadequately protected in the '70s, they were inadequately protected in the '70s to a significant degree. However, today, there are far more experimental products available, and so the--the opportunities for abuse are perhaps far greater, at least in numbers, and the amount of money that is available to carry forward such research might suggest that--that the opportunity for abuse is greater today.

But I wouldn't want to suggest that--that subjects are not adequately protected today simply because I might say that the difference between today and the '70s is such to suggest that. So I would rather say I think subjects are adequately protected and can be protected far better.

*INTERVIEWER: Are there any changes you feel would be needed or possible in today's human subject protections environment?*

MR. DOMMEL: I think there is an opportunity for the establishment of a commission similar to the National Commission that we've been discussing that would serve the public well if the Commission were assigned the review of protections provided individuals who are in some way compromised, either by virtue of their economic status, their mental capacity, the seriousness of their disease, which so many serious diseases have treatment only in--or in the majority of the cases in a research setting that we almost forget at times to focus on their vulnerability by virtue of the disease from which they are suffering.

And so I would like to see a commission of the stature of the National Commission that would be presented with the opportunity to evaluate in a deliberate fashion the adequacy of employing the guidelines set forward by the National Commission and the subsequent regulations, and assessing their effectiveness today with a special eye toward those who are vulnerable and with a particular focus on those who suffer from the most serious diseases and their ability to consent, to fully understand that to which they are consenting. I would love to see that assessed today.

*INTERVIEWER: Do you think a second edition of the Belmont Report is needed?*

MR. DOMMEL: No. I think--to repeat myself on something that I'm delighted to repeat myself on, I think Belmont is a masterpiece and a treasure, if you will. And if--if one were to develop ethical principles that supplemented Belmont, they ought to have a name other than Belmont so that Belmont can stand for what it is, for its thoroughness, for its capacity to function well in guiding individuals 25 years later in times that have changed in an extraordinary fashion where research today is--is--the enormity of that which is occurring in the name of research today is just--you can hardly compare it to what was going on in the '70s. And yet here is a set of principles that function as well today for this enormous project that occurs in the name of research as well today as it did in the '70s, and in the '70s and '80s it just--it fit the bill and today it fits the bill just as well.

So I think the changes that would occur would be outside of the principles. It would be how better to employ the principles, how better to write the regulations, how better to establish and provide for the proper functioning of our Institutional Review Boards, IRBs. But I think we got the principles right.

*INTERVIEWER: At the time the Belmont Report was written, the prevailing view was that vulnerable individuals such as children should be protected from research. However, currently there are requirements, such as the Children's Health Act, to conduct more research involving children. What are your thoughts about this?*

MR. DOMMEL: I think this is an expression of--I think that this is an expression of the natural tendencies for the--the weights applied to the principles in Belmont to shift this natural tension that exists among these principles. And so we have a principle that says an individual must be permitted to exercise their autonomy, to the extent that they can. "Informed consent" we call it. And in children, we attempt to get an informed consent that we call "assent" in the regulatory world, as well as a legally binding consent from a legally authorized representative of--representative of the child, usually the parents.

However, we have needs for children to benefit from the successes in our research projects, but to translate research which is only carried out in adult populations to treatment of children outside of a research context is extremely difficult to do. So it was recognized that because there were stringent rules involving the conduct of research that included children, that fewer and fewer children were involved in research.

And, indeed, the outcomes of research with adults was carried forward to little adults called children. And so the weight's different, let's decrease the amount of the experimental product, which, of course, doesn't take into consideration metabolism differences that might call for just the opposite, that you would use more of a product in a little person, a young child, than you would in adults.

So there indeed was a great danger to children occurring because of the stringency of the regulations protecting children. And what was needed in order to encourage those in the research enterprise was a benefit to including children in your research activities. And I think the act you designate was one attempt at doing this. I think there are other means, that the regulations provided those means for carrying out the research involving children, but really didn't bring forward a benefit and--to the organization for including children.

Well, if you say your benefit is going to be that you will be able to identify this product for children and you won't be able to if you don't include children in the project, or you will be able to receive federal funding to help you carry out this research but you won't receive that federal funding if you don't involve children is a move in the right direction.

In the absence of IRBs, I wouldn't want to see that move at all, but understanding that IRBs take their "should's" even more seriously when they recognize that there's a pressure on researchers to include children, where they might really not even wish to, makes their research more difficult to do.

And so IRBs say, well, with that pressure going on, we need to give special attention to this, and I think that works [inaudible].

*INTERVIEWER: Do you think there's a need to make any changes to the regulatory protection for vulnerable populations?*

MR. DOMMEL: I'm sure there are. I haven't thought about ones that I might wish to identify as in some sort of urgent need. But--but certainly the--the provisions of the regulations that limit the conduct of research with pregnant women are still in need of special assessment. And because they are a political firecracker, it's very difficult to go through an alteration of these regulations. I actually chaired the Public Health Service committee that developed the most recent revision of Subpart B, I believe it is, protection of pregnant women and fetuses and embryos. And w knew at the time that we could only go so far in our recommendations, that there were other areas that we would like to provide

suggestions to the Secretary and others for modification that would have killed the revision if we had addressed them. And so we had to be reserved.

But we were federal employees. I think other bodies can take this on with greater success, not easily, because there will always be--anything that mentions fetuses, embryos, will be subject to a great deal of attention and always a great deal of misunderstanding about what they're doing. But I think they are in need of attention, and I think the other regulations are, too. And I think the prisoner regulations are really outdated. I think they're rather restrictive in their opportunity for prisoners to participate in research. I think greater participation in federal prisons could and should be occurring, but only with special protections that would be in place. And they're so stringent now that prisoners are generally excluded.

*INTERVIEWER: Many would also agree with you on that. Do you think additional protections are needed for other populations, such as the decisionally impaired?*

MR. DOMMEL: I do. I think that IRBs and institutions are not provided with adequate federal guidance on the inclusion of those who are decisionally impaired, mentally disabled. The National Commission's terminology was "mentally infirm." And the Federal Government, when attempting to issue regulations, changed that to "institutionalized as mentally disabled," which was a much larger population then than today, because most who are--are challenged in this way are not institutionalized. So even the proposed rule, which some institutions say we used the proposed "institutionalized as mentally disabled" as our guidance for the conduct of research with decisionally impair individuals, well, it doesn't really serve that because it only addresses those who are institutionalized.

So I think there are many who could benefit from an addressing of this--the needs of this special group again.

*INTERVIEWER: Excellent. How do you think the ethical standards that were designed for this country apply in international settings?*

MR. DOMMEL: I think sometimes they apply very well, and in terms of numbers, most of the time they don't work. We rely very heavily on a rather complex informed consent process that, as a part of it, must be in writing considering that most of our population can read or have access to individuals who can read and help them understand what it says; and that in other cultures these capabilities may not exist or they may not be recognized as being

as important as they are in our culture. In some cultures, decisions are not made by individuals. They're made at a group level, and this indeed is how that society functions. And to enter that society and say, well, we need individual informed consent when nothing else in that society calls for individual consent is something that won't really work. You need to translate that into something else. And our regulations don't really provide an opportunity for that except in the form of a rather complex waiver of informed consent, which isn't really what we want to do. What we want to do is adapt the consent process to the cultural design, if you will, of another society and how they go through a consenting.

And so we aren't able to change our consent in that way, or we don't know how to, to meet what would be the traditions and the mandates of another society. So often our regulations, although required by law in foreign societies where our dollar is involved or our researchers are involved, it's really not working in--in practice. And so I think a thorough review of this with perhaps the United States taking a lead role but with an emphasis on meeting the needs of other countries, we could then be the mediator and the designer, having the needs expressed to us, and because of our experience in translating this to principles, guidelines, and regulations, we could be of great assistance to other countries.

*INTERVIEWER: Excellent. Do you think that the Belmont principles are absolutes that override all other considerations? Or are they factors to be used in balancing the risk of harm to individual subjects against the societal benefits of increased knowledge?*

MR. DOMMEL: It sounds like a trick question because I think absolutely we must consider the principles of--of Belmont. But as I mentioned several times, the principles are flexible and they permit providing a greater weight to one over the other. But to fail to properly assess them I think should be absolutely prohibited. And to properly assess them will be to apply them, I think, in every circumstance.

And so perhaps in some national emergency one might conclude that the only way you can save the nation is to go forward with something that violates the principles, well, if you assess the principles thoroughly and with an eye toward we'll make these principles work in this emergency situation, and if the principles simply can't be applied, then does the emergency outweigh it? Does the national need? Does the potential wiping out of the entire country by some virulent virus that's spreading rapidly that such emergency circumstances might call for ignoring the principles in order to save the nation? But to ignore them should only occur after an attempt to--to apply them.

*INTERVIEWER: Excellent. Do you think the regulatory approach to vulnerability should continue to be based on vulnerable populations rather than the types of vulnerability that are applicable to individual subjects?*

MR. DOMMEL: I think not. I think to identify the vulnerable populations that we did in the '70s was appropriate at the time because these were populations that we--where we saw abuses occurring. And as I mentioned earlier, I believe, I think there are other vulnerabilities that are even more important to focus on today. They're mentioned in the regulations.

They're mentioned at Belmont. But the seriousness of a disease and the inability--and the extraordinary ability of humans to deny things so that when presented with evidence of a rapidly approaching death, we often can't hear it. And so we go into denial and come back to revisit that later when we think we can handle it. So we may have been told that we're going to die soon, but we can't accept it.

Similarly, and more--more applicable to--to research would be we've accepted that we're going to die soon and we're told someone wants to do research on us that might help other people in similar circumstances in the future but won't help us. And we may not hear the "won't help us." And so we enter into the research under a misunderstanding. And I think that to identify the needs for communicating this information adequately, sufficiently to this particularly vulnerable group with life-threatening diseases is worthy of special assessment today, whether you categorize that and say Subpart F, to provide additional protections and assessments for persons suffering from life-threatening diseases which often include a denial on the part of individuals in assessing informed consent, no, I think not. I think what we do is we take provisions that we already have in the regulations and in the guidance, and we bone up on them. We begin to focus on them more and find better ways to advise our IRBs, our institutions on how to provide information in a way where it will be adequately understood before a consent occurs, for example, and many other valuable outcomes, I think, of focusing on the needs of today. Where are our problems in research today? And I think we've spoken about a couple of them, and they aren't so much in the case of violation of the rights of children.

I think children are--it's worth--I think it would be a worthwhile pursuit if we were to spend the money and the time of this vast field of professionals that exists today and of which there were so few, I think, in the '70s. And we got all the great ones and put them on our commissions then. And we have great ones today. And to ask a group of these

individuals to assess the--the use of the term even, "vulnerable populations," and special subsections protecting children and pregnant women and prisoners and whether there's a need for institutionalized mentally disabled or mentally challenged individuals having special protections, to assess all of these categories with a focus on the special category of those who really are challenged in the consent process because of inability to fully comprehend, not always because of intelligence or knowledge but perhaps because of our very nature as humans that we deny things for periods of time that we can't handle at that moment, information that we just simply don't choose to believe at that time or to absorb. To assess the needs of all of these groups today in terms of our experiences over the last quarter century would be a worthwhile endeavor. I would recommend it.

*INTERVIEWER: Is there anything else that you would like to add?*

MR. DOMMEL: Very little I would add. I would take that open opportunity to refer to Belmont as a masterpiece again, to--to stand in awe of the work of the National Commission as just an extraordinary achievement that even the regulations are deserving of some praise for translating adequately, I think, pretty close to adequately the recommendations of the National Commission and keeping those regulations within the principles of the Belmont are all worthy of commendation.

And then institutions who carry out our research today and the IRBs who play the critical role of protecting humans and assisting our investigators in protecting humans in an adequate and perhaps specially honorable way are all worthy of commendation of their achievements over the last 25 years. And I think, sure, there's room for improvement. There are opportunities for improvement and enhancement, and I don't think that we would have much objection to that if we came forward with revisions that would improve the system. But the system works.

INTERVIEWER: Excellent. Thank you so much, Bill.

MR. DOMMEL: You're welcome. Thank you very much for inviting me.

– END OF INTERVIEW –