



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: Dr. Alexander, to begin, could you give us your name and your degrees, and the current title that you have?

DR. ALEXANDER: I'm Dr. Duane Alexander. I'm the Director of the National Institute of Child Health and Human Development at the National Institutes of Health in Bethesda, Maryland. My degree is an M.D.

To start off, could you tell us why the Commission was formed?

DR. ALEXANDER: The Commission was established by Congress, I think, in large part to get the debate on biomedical ethics issues off the floor of the Congress and provide a cooling-off time while the Commission could deliberate the issues in public but without the political pressures the Congress was having placed on them.

At the time, they were dealing with the issues of the Tuskegee syphilis study, psychosurgery, research with prisoners, research with people who had mental impairment, and then the crowning blow was fetal research...research on the human fetus after abortion.

And there was so much time being taken up in discussion and debate on the floor of both the House and Senate on these issues that they needed to try to get a resolution off the floor and move this to a commission for discussion – fact-finding – rather than legislating in haste to put bans on all kinds of things, which we were facing, that could have been harmful in the long run.

So the Commission was the perfect solution. It got these issues off the floor of the Congress. It got them into the realm of a commission of people with expertise in the area; respected scientists and civilians and ethicists who could deliberate these in public, but without the political pressures on them that the members of the Congress felt, and come up with recommendations.

The other thing that was going on at the time was the Department acting to develop regulations for the protection of human subjects. And they were proceeding, also, very hastily under the pressure of these things happening on

the floor of the Congress. And by requiring the Department to respond to recommendations from the Commission, with either regulations or saying why they were not going to do these things for each topic to be studied by the Commission, this also took some of the pressure off the Department for its regulatory process for the subgroups of human subjects.

So that combination of trying to get the debate off the floor of the Congress and trying to allow the development of regulations by the Department to proceed in a more orderly fashion, I think was the impetus for establishing the Commission and I think, really, it was a very, very wise move.

What was your role--how did you come to be a part of the Commission?

DR. ALEXANDER: When issues first arose, they focused really on the NIH. And as they focused on children and then on fetal research, they came to the National Institute of Child Health and Human Development for a response.

And I was, at the time, the assistant to the Scientific Director of the NICHD, Dr. Charles Lowe, who got the assignment of preparing NIH responses to issues of fetal research, and then research on children, and then, broader issues of protection to human subjects.

We had worked with the scientific and ethics community to get advice in how we might best respond...and were working in this area when the Commission got established. The Department then came to NIH and to Dr. Lowe and asked him to be the first Executive Director of the Commission. And he asked me to come with him in this role to work on the staff as the physician on the staff.

Because we'd been working on this together and because I had a very special interest in the issues of research with children and research on the human fetus, in particular, I agreed to do that enthusiastically.

And what brought about your interest in research with children and research on the fetus?

DR. ALEXANDER: I'm a pediatrician, so, obviously, I had a vested interest in the issue of research on children. I had spent several years here at NICHD

involved in research of various types...and was very keenly professionally and personally committed to making sure that research with children would not get banned, that it would be allowed to go forward in an ethically acceptable way so that we could gain the knowledge we needed so badly to improve their health and development and well-being.

There was great concern at the time that impediments could be placed in the way of getting this research on children done, to the detriment of children. Sometimes we protect people to their harm. And there was a very real risk that this could have happened with children; with other population groups; particularly, others that couldn't give consent.

And I was committed to trying to do what I could to provide information to people who were in decision-making positions that would try to make the case for the importance of this research going ahead.

You mentioned this slightly, about the political climate or the political environment at the time that the Commission was formed. Could you tell us a little bit about that?

DR. ALEXANDER: Biomedical ethics had rarely received the attention from the public and from the Congress ever before that it was receiving at the time the Commission was established. This came about because of revelations of some kinds of research that had been published claiming some research had proceeded unethically – research on prisoners, research on dying patients, research on persons with mental retardation or mental disability, and then, particularly, research on the African-American men from the Tuskegee syphilis study.

But the crowning blow, really, was the issue of research on the aborted fetus. This took on a very special significance because it came just after the *Roe v. Wade* Supreme Court decision on abortion. And opponents of that decision and opponents of abortion looked for any ways they could to cast abortion in a worse – even worse – light.

And one of those things that happened to provide fuel for that fire was the report of a study conducted in Scandinavia in which fetuses after abortion had their heads severed and were used for research on brain metabolism.

This was a study that was distasteful to just about anybody and could be used maximally to create a distaste in the public, as well as the Congress for this kind of research and to further the concern about trying to put an end to this research.

So there were calls for bans on research on children, calls for bans on research on the fetus after abortion, calls for banning research on prisoners...all these coming together.

So, this was a highly charged political issue. Then getting it off the floor of the Congress and into the hands of a commission that was to deliberate, initially, for two years and then for four years as they got extended, was a very wise move that I think helped to prevent a significant amount of that research from being stopped permanently.

As it was, we had a moratorium on research on the human fetus after abortion for four months or until the Commission had made its report, which it did in five [months]. But after that report was issued, that moratorium was lifted and that research, under the regulations that the Department developed, was allowed to go ahead.

Do you think that studies like the ones you've cited could happen today?

DR. ALEXANDER: I think the likelihood of studies like the Tuskegee syphilis study or the research – some of the research on patients without them even knowing they are research subjects, or research like some of the fetal research after abortion – is highly unlikely to be able to get done today...not just in the United States, but virtually anywhere in the world.

Times have changed considerably, partly because of the work of this Commission; partly because of the work of other bodies in Europe and under the auspices of the World Health Organization, World Medical Association, and others, that I think make it highly unlikely that we will again see abuses of human subjects in research like we had seen in the past.

We'll step back in time a little bit to the Commission. Today, some people think of the Commission's work as being represented entirely by the Belmont Report. Is that how it looked in 1974 to 1979?

DR. ALEXANDER: The Commission's work is represented by far more than just the Belmont Report. The Belmont was one thing, almost a sidelight, at the time that the legislation was put together compared to their major tasks, which were to produce recommendations for how research on human subjects should be conducted in general and then how it should be conducted on sub-populations who were at particular risk or were particularly unable to give consent for themselves...children, persons with mental illness or retardation, and other groups, the fetus.

And so those were really the key reports on which the Department was required to develop regulations...either accepting *in toto* the recommendations of the Commission or saying why they weren't going to and developing some regulations, instead.

And that was another beautiful part of the legislation that created the Commission – that it was not a report or a series of reports from a Commission that could just get received and people say thank you and put it on a shelf.

By law, the Secretary had to respond within a certain number of days, I think it was 180 days by either issuing regulations, putting into place the recommendations of the Commission saying why they weren't going to do that.

And so those things that got translated into regulation actually had more direct impact than the Belmont Report itself did. The Belmont Report was sort of overarching guidelines and principles on which these other regulations really relied for their fundamental principles.

But the immediate impact of the Commission's recommendations in these other areas was really greater than the Belmont Report. So the public probably associates the Belmont Report with the Commission more than anything else. But we shouldn't forget that every regulation that exists for research on the fetus, research on children, research on prisoners, research on people in general....all that had its origin with the recommendations from the Commission.

A very powerful responsibility, then?

DR. ALEXANDER: Yes.

As you look back on your experience with the Commission, is there any part that stands out more in your memory than others?

DR. ALEXANDER: I guess the part that stands out most for me was the work on the report on the fetus. That's the one that I had the most extensive involvement on, probably because I had been working in this area at NIH, before I went with the Commission, completely. And second, because it was done with such enormous visibility and under such an incredibly tight timeframe.

The law gave the Commission four months from the time they were established to come up with a report on recommendations on the fetus...and imposed a moratorium on that research until the report of the Commission was delivered. And the Department would act on it.

So, we had a very, very incredibly short timeframe, in order to gather the information for the Commission. And we worked very quickly, we worked as fast as federal regulations and rules would allow us to do, to form several different groups that provided information on various aspects of the topic: literature reviews on what research on the fetus had been done and reported in the world literature and descriptions of those various categories.

Another group had looked at survivability and viability – what was the lowest birth rate and the lowest gestational age at which a fetus had ever been born and survived. And another review of world literature and hospital experiences was done by this group...and then ethical issues with regard to our research on the fetus.

All these were put in place and done and reports delivered to the Commission in record short time. And we worked very, very hard to get that done. The Commission worked very, very hard to get it done; and they didn't quite do it in four months, but they did it in five. And they delivered the report and the Department responded, also, extremely rapidly. Basically, right after they got the report, they had regulations developed and published and the moratorium lifted. So, it happened very, very quickly.

It was an exciting time. It was a high-pressure time, the stakes were big here.

And the Commission responded beautifully based on the information that they got. They took into account, you know, some of the emotional overlay and concern, as well...and recognized the kind of importance of the public policy that they were representing with their recommendations. But they also paid attention to the facts; believing, as Ken Ryan [ph], their chairman often said, good ethics begins with good science and good facts.

And they were determined that they were going to make their report recommendations consistent with the scientific information and the ethics advice that they got. And they did a really good job.

That was an exciting time and probably the thing that I remember most about the Commission.

Which of the topics generated the most discussion among the Commissioners and the staff?

DR. ALEXANDER: Well, this was a discussing commission. There's not much that they didn't discuss pretty extensively. But they were very, very thorough. They were extremely conscientious.

They took their jobs very, very seriously. They met every month, flying in from all over the country for these two, sometimes two and a-half, three-day meetings. And they really pursued every issue in depth.

They wanted to be sure that they got the science; that they got the ethics opinions and the full range of ethics opinions and that there was not a source of information that went untapped to get them what they needed.

And then they discussed, deliberated with each other in depth. So there really wasn't anything that got neglected. As to what they probably spent the most time on, they spent a lot of time on the fetus. They probably would have spent more time had they not been under such a short deadline.

They had a real hard time grappling with the issue of prisoner research. There was a lot of division there. Not so much when they started as when they came to debate at the end because of the information that they had gotten from site visits

to a prison where research was being done, from site visits to a different kind of a set-up that used a reward system for good behavior in a particular way, to other information that they had gotten in interviews with prisoners with drug company officials, and so forth.

And they really had a hard time grappling with that one. But every issue that they dealt with, they did in depth. They discussed it thoroughly and they worked extra hard, trying to reach consensus.

As, Ken Ryan said, right at the outset, as chairman, if we issue a report that has five different dissenting opinions among 11 Commission members, nobody's going to pay attention to it. And so that kind of set the stage for a very conscientious effort on the part of the members to try and understand where each other was coming from, to understand and reason together the various principles on which any recommendations would be made, to understand the science as well as the ethical issues and concerns...and to try and – by reasoning together – reach a consensus to the fullest extent possible. And they really succeeded in doing that in just about everything.

The report on children has a couple of dissenting comments from several members, but that's the only one that has anything in terms of any extensive dissent, other than, maybe the one on the report on the fetus. But they really did a good job of reaching consensus.

It would be hard to imagine something like that today?

DR. ALEXANDER: Well, it's still possible. The other thing that they did was – they got to know each other socially and individually. Every meeting, a different Commission staff member would host a dinner or a reception in the evening that went on into the night for the members and the staff. And we really got to know each other and respect each other very much.

Our Commission members would go to an ice hockey game together or a basketball game. When we would be in other cities, one of the Commission members, if they happened to live in the area, would host a Commission reception at their home.

Ken Ryan, when we were visiting the **Frenault** [?] State School, an institution for mentally retarded individuals near Boston, had the whole Commission to his home for a dinner that evening. Some of the Commission members would host an event for the other when we were in their area.

So people got to know each other socially. They respected each other's views and all that worked together to create a very positive working atmosphere among these eleven individuals, that they really wanted to get consensus to the fullest extent possible. And it worked.

As a Commission staffer, what did you feel was your most important contribution to the work of the Commission?

DR. ALEXANDER: Well, I think probably what I would consider my most important contribution was helping get the report on the research on the fetus done within the timeframe that the Congress had set out.

Getting that information to the Commission and really, by those actions, helping to set the tone for future reports that we were going to get them every bit of information they would like to have, to the extent that was possible, so that they would be able to make their recommendations based on the best information possible...and have it a fact-finding Commission and a factual basis action Commission.

So I think that was important, partly because of the content and partly because it kind of set the tone for the approaches that we would take with future reports and topics.

I think that was important. I think the work on children--the children's report -- was important. And I think those were the major contributions.

All this was done before the Internet and e-mail?

DR. ALEXANDER: And before typewriters that you didn't have to use WhiteOut and CorrectType for. That was--that was how we did it. We had one of the first computer-based typewriters at NIH, helping to get the work of the Commission done, when they were just coming into use.

If you could go back in time to the Commission is there anything you would do differently?

DR. ALEXANDER: That's an interesting question. You know, I can't think offhand of anything we would have done differently because we had time. If we had been held to two years, as the original legislation proposed, the Commission's work would have been far less thorough and professional. But extending it to give that Cassure that the products were sound, well-thought out, well reasoned and, really excellent, in terms of their quality. So that helped a lot.

Maybe giving it four years at the outset would have been useful, maybe giving six months instead of four months for the fetal research report might have been helpful. I don't think the outcomes would have been different, it might just have been a little less hectic. But all in all I think the Commission did its job well. I'm not sure what I would have done different.

I think the membership on the Commission was terrific. It was a very representative, balanced group of people who really cared about what they were sent out to do as their task.

And do you know how the Commission members were selected?

DR. ALEXANDER: The final decision was with the Secretary who was Casper Weinberger, at the time. NIH had the task – the lead task – in putting together a slate and we contacted a wide variety of organizations, professional societies in medicine, in ethics, in other areas, as well as, you know, the National Academy of Sciences. We got many recommendations from members in Congress. And then these were vetted at the NIH and within the Department and a slate of possible people went to the Secretary, who made the final decisions.

But there was a very broad effort made to tap a very representative group. The law prescribed that the majority of the Commission be non-scientists, so we had three medical scientists and two behavioral scientists and the others were from law, ethics areas and public policy. And so it was a minority of scientists prescribed by law. And it worked out very, very well.

Good lesson.

DR. ALEXANDER: Yes.

Were there any issues or ideas that you felt the Commission could have addressed but didn't?

DR. ALEXANDER: I think the tasks set out for the Commission by the legislation were pretty comprehensive. I don't think that they needed any other topics to address. I don't think they asked for anything else to address.

One thing that did come up right at the end of their tenure was the birth of Louise Brown through *in vitro* fertilization (IVF). So that came to a subsequent body, a successor body to the Commission to deal with – with recommendations with regard to *in vitro* fertilization. The Commission never really dealt with that one because efforts were being made but had not yet been achieved for a successful human IVF. I think people knew it was bound to come but since it had not occurred yet the Commission didn't deal with that. They had plenty of other things to do.

And so, their successor body the President's Commission dealt with that issue.

In a somewhat broader sense, since the time of the Commission's work, what changes have you seen in human subject protections?

DR. ALEXANDER: The changes that have occurred have really been minimal. Even though groups have been set up to look at the regulations, very little has been recommended in terms of change. Sometimes interpretations have been required. A particular case in point involved the children's regulations, where the issue of what constitutes minimum risk and minor increase over minimum risk was interpreted differently by different groups.

Mainly, it revolved around whether minimum risk was an absolute or a sliding scale, such that minimal risk for a very sick child might be a greater risk than minimal risk for a well child. This was never the intent of the Commission, but some people started interpreting it as a sliding scale.

And the actions that have been taken since that time by the advisory groups that

have been asked to look at it have re-enforced the original concept of the Commission that this is an absolute – that we mean minimal risk for a healthy child and it does not change what minimum risk is if you're really sick.

So, that, I think has been clarified. The only real change in the regulations themselves, that was Subpart B – Research on Pregnant Women and the Fetus – and the wording has been changed there just a little bit but not a whole lot, with the subsequent revised Subpart B.

And I think that the change that we have seen really relate to people being more comfortable with extending research to people, perhaps with less capacity to consent or with, perhaps, some greater risk, than was envisioned that was possible, really, at the time the Commission did its work. And I credit the Commission's work and the regulations that were put into place as reassuring an anxious public that research was going to be done in an ethically accepted way, that there were standards in place, that the ethical principles from the Belmont Report were guiding this research, that there were regulations that were providing for protection, that there was an institutional review board wherever research was done that was looking at research – each individual project – and passing on whether it was acceptable to do as proposed or needed to be modified.

With this reassurance of an anxious public, I think that the general perception of research gradually changed from something that posed great risk to people and a burden to be avoided, to a benefit to be desired. And the actual reflection of that change took place, I think, first with the AIDS epidemic. And as AIDS appeared and spread, people recognized that the only way that there was going to be any development of treatment, of prevention or cure was going to be through research. And that research, even if you were dealing with some vulnerable people or not, needed to be done.

And holding back research for people was doing far more harm to them as individuals and groups, than offering research far more broadly.

And I think it was, in my perception, it was the onset of the AIDS epidemic and the people who were the leaders in the AIDS movement to recognize research as their only potential salvation; and as a benefit eagerly to be sought, rather than

avoided, did help to start the real swing of the pendulum from extreme protectionism to a more liberal approach to enrolling subjects in research.

That was followed by the women's health movement. And we saw women clamoring to be included in research. Men were in the studies, women need to be included, too. And so women, again, as a group saw research as a good, rather than a risk to be avoided.

The same thing happened with minority populations. The African-American population, said, hey, we have disparities in our health. We're not doing as well as the white population in this country. We need to know why and we need to have our people eligible to participate in research and encouraged to participate in research for the benefits that accrue to them from research. Directly as individuals and as a group.

And so when minority populations, who had felt so threatened because of the Tuskegee revelations – even there – we began to see research viewed in a positive light, rather than a negative one.

And then, the last to join in this group – and it came after Congress passed legislation requiring NIH to include women and minority groups in our clinical research studies – children, then, came to be included, as well. And the pressure came here, as well.

You can protect children to their harm, if you protect them from conservatism on institutional review boards and people being unwilling to give approval to projects without enormous information being given to people in the consent process. But that's not based on the regulations.

Where that comes up is in terms of institutional protection, rather than subject protection. And I think what happens sometimes is that institutions get so concerned about protecting themselves against claims of inappropriate research conduct or whatever, from subjects, that they go to extremes in requiring what people must be told or how they may be selected, or whatever, as a condition for approval for the project to go ahead.

This is just intrinsic to a system. Any time you have groups assigned to do these

kinds of tasks, there is a risk of them becoming excessively protective of the institution or their role as individuals, rather than mainly assuring that people get the essential information that they need.

So this is the main concern that I think we see raised by people who have complaints about the system being excessively restrictive. And it's not the regulations themselves. It's not the ethical principles themselves, it's how these may be carried out in various institutional settings that go, perhaps, beyond the letter and the intent of the regulations themselves and forget who the primary group is to protect, which is the subject.

Do you feel the subjects are at any greater risk today than they were 25 years ago?

DR. ALEXANDER: I think subjects are at far less risk today than they were 25 years ago, because of what's in place to provide assurance of their protection.

First is the knowledge and awareness of investigators of what has to be done to make sure the subjects understand that they are in research and what that research involves and that they have a choice in whether or not to participate, and the precautions that have to be taken during the course of research. And I think subjects themselves are more aware of research and what it requires and what it doesn't require...and how they can act to protect themselves, by asking questions, by getting information and they have the authority to withdraw at any time.

The system of institutional review boards that we have in place adds to this protection which starts with the investigator and the subject.

But then we have the institutional processes involved, as well, that enhance that protection. So I think that subjects are at far less risk today...both because these are in place and because we monitor their participation in research and we monitor the impact of any interventions that we do, much more closely than we did 25 years ago.

We're going to take a slight side step. When we look at children's research in international settings, how do you think the ethical standards that were developed for this country apply in those international settings?

DR. ALEXANDER: Countries vary greatly in their inclusion of children in research and in the protections and oversight they provide when children do participate in research. And this variation is within Europe, it's within developing countries as well.

Many countries are much less permissive than the U.S. is, when it comes to involving children in research. Many do not do it at all. Many do it with only for what we would call highly therapeutic research, when it's highly likely that that individual subject is intended to benefit but not at all for research where there is not that benefit to the child, regardless of risk.

But most of them have protections in place comparable to what we do in terms of the principles of informed consent, of permission of parents, of institutional review board equivalence, whatever.

In developing countries, the situation is quite different. Many of them are still developing the concepts of what is research, what does it mean to participate in research, is there an IRB, is there only one for a whole country?

And so, in developing countries, the situation there varies widely, but the reach of the United States roles for what we support, goes wherever the researcher goes and wherever the U.S. dollar goes that supports that research...so that, if we are going to conduct research in a developing country, there must be that kind of process, an institutional review board process, or whatever.

We're involved in research in a developing country at the present time within NICHD in a global network for maternal and child health, where we're studying ways to improve the process of labor and delivery to make them safer.

Research is a foreign concept – women having any say about what they do themselves, rather than their husbands having the control – is a totally foreign concept, yet we have to find a way to get review of that research in that country... to get some acceptable means about informing the women about what's going to be done and that it is research and that they have a decision role to play in whether they participate in that or not.

So, even in the most underdeveloped of developing countries, if the U.S. is involved in that research, our rules pertain. And while they may not have the sophisticated IRB that we have here or they may not have subjects who are as sophisticated about a consent process, the elements of an ethics review in that country and the elements of telling people what they're going through and that they have a choice whether to do it or not, still apply.

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

DR. ALEXANDER: I think that the regulations really reflect and are built upon the basic principles for research in the Belmont Report. They find their expression in the concept of informed consent; in the concept of balancing research risks and benefits; and in subject selection. All the three cardinal principles of the Belmont Report for Research. So they embody those, but they go beyond those and extend to cover other ethical principles, as well. But the foundation is still those three.

I'd like to ask you how your work with the Commission has impacted the rest of your career since then?

DR. ALEXANDER: Well, the work with the Commission is one of the most enjoyable things that I have ever done professionally. It was a wonderful group of people to work with. It was a very significant task to be engaged in with the government and the public sector.

It was, I think, an important contribution to medical research in this country and the world. And to improving the health of people worldwide because we facilitated the continuation of research being done in an ethically acceptable way, rather than putting such prohibitions on it that we couldn't gather the knowledge we needed to improve people's health.

So, I just look back on it with very fond memories of what the contributions were and of the pleasure that we had in working with the Commission members and the other staff members. All of whom brought special skill sets and special personalities and wisdom to this subject.

Since that time, I've continued to be involved in ethical issues, particularly with regard to research with children and research during pregnancy.

What I learned as a result of that experience has stood me in incredibly good stead as director of the Institute of Child Health and Human Development, that deals more than any other with issues of research in pregnant women; research in women's health; research in children's health; research on the fetus; research on the embryo.

All these issues, are particularly significant and have their own nuances. And the understanding and the depth of knowledge that I gained as a consequence of my experience with the Commission, have been very, very valuable to me in dealing with these issues that the institute has had to deal with.

In addition to that, it's been my privilege during the last 10 or so years to be the representative from the United States to the Council of Europe's Committee on Bioethics, which is dealing, for the European countries with the same issues in biomedical research and practice that we have dealt with here in the United States.

We're dealing with the same things contemporaneously now in Europe and in the United States. And it's been a very interesting process to see how members of this committee have worked through trying to come up to solutions to the very same ethical issues that the Commission grappled with and that we're grappling with now, in contemporary biomedical ethics. So that has been an opportunity that I would not have had without my involvement with the Commission.

I've also continued to be involved with the evolution of the Department's regulations, participating in revisions of Subpart-B, as well as taking the lead responsibility when the issue of the inclusion of children at NIH research came to the fore. That was handed to me as a lead person and gathered, again, following the Commission model, gathered information on what was happening with inclusion and exclusion of children in the clinical research that came to the NIH; putting a group of people together for a conference to address this issue and come up with recommendations and then come up with finalizing the NIH guidelines for this.

So, that was another activity that I got responsibility for where the experience with the Commission was extremely valuable.

Is there anything else you would like to add?

DR. ALEXANDER: One of the best things about the Commission was the interactions that we had with the commission members themselves and with the staff.

This was an extraordinary group of people who were on the Commission and the staff members. They came from vastly different backgrounds, but they all had their own expertise, their own ideas, their own commitments to bring to the issues that they were to address.

So, it was just such a pleasure to have the opportunity to interact with them in this four-year period. And since the dedication and commitment that they brought to this issue and I think their sense of public service in trying to help the U.S. government, the U.S. behavioral research community, deal with this in a way that would assured a worried public that research was going to be done in an ethically acceptable way that was going to provide benefit to them and not ut them at undue risk of harm.

And the fact that the work of the Commission has really stood the test of time and that those basic principles from the Belmont Report are still the basic principles, that the regulations that the Department issued based on the recommendations of the Commission have stayed almost unchanged during that period of time – I think is a pretty good tribute to the good work that the Commission did.

Dr. Alexander, thank you very much.

DR. ALEXANDER: Thank you, my pleasure.

– END OF INTERVIEW –