



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

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## INTERVIEW

*Interviewer: LeRoy B. Walters, Ph.D., Professor of Christian Ethics and Professor of Philosophy, Kennedy Institute of Ethics, Georgetown University.*

MS. KING: My name is Patricia King, and I'm a professor of law at Georgetown University Law Center, and I was one of the Commissioners for the National Commission.

*INTERVIEWER: Where were you working at the time when you received the invitation to join the Commission, Pat?*

MS. KING: At the time, I was the Deputy Director of the Office for Civil Rights at HEW, and I had been the Acting Director of the Office of Civil Rights at HEW. So I was at HEW when the Tuskegee syphilis study was unveiled, and also when there was a panel set up to examine the study, and I assume that I was appointed to the National Commission because I had that civil rights background, although I had not worked on Tuskegee itself. I don't know for sure, though.

*INTERVIEWER: So it remains a little mysterious how exactly you were appointed to the Commission?*

MS. KING: I've never had anybody confirm it for me, but I had a pretty high position in the Department, so I had spent some time interacting with both the Secretary and the Under Secretary, and I was planning to leave HEW to start teaching, and all I remember is being called into Secretary Weinberger's office to say goodbye. And at that point, he asked me would I be interested in serving on this Commission, and I said, absolutely. So I jumped at it. I didn't know much about it, but I'd heard--there was a little bit in the newspapers about human subjects protection. There had been a lot about the Tuskegee study, and so I leaped at the chance.

*INTERVIEWER: Were you following the legislation as it made its way through Congress about setting up a national commission?*

MS. KING: I'm ashamed to say, no, because the civil rights issue of that day happened to have been desegregating public schools, and the initiation of affirmative action programs and higher education. Health was way down on the civil rights agenda. In fact, probably just about the same place today as it was then. So I hadn't been paying a lot of attention in terms of my official capacity with anything to do with the National Commission. I read the

newspapers every day, and I found a few things about fetal research, et cetera, that I found interesting in the sense of having to think about tough, hard issues.

*INTERVIEWER: Had you done work in biomedical ethics before you joined the Commission?*

MS. KING: No, I didn't even know the word "biomedical ethics" until I read the Commission's title. I had no prior background. I had majored in religion and philosophy in college, and of course I had a law degree, but I have always assumed that there were political reasons for having a minority and having someone who might have what others regard as a relevant background, which was civil rights, because the Tuskegee study did play a role in the establishment of the Commission, which I learned after the fact. And so I would say that probably had something to do with why I was appointed.

It's a long time ago, but it was unusual at that time to have either minorities or women involved in National Commission of any sort. So the National Commission was breaking new ground in many ways.

*INTERVIEWER: What were some of your first impressions at the early National Commission meetings?*

MS. KING: Well, if you'll recall, the act required that the Commission deal with fetal research right away, and they gave us a time limit. So we really had to hit the ground running, and so there wasn't a lot of time to understand the group dynamics in advance or understand a lot about the issues. We sort of plunged right in. But in retrospect, that was good. So my first impression is all about fetal research and an unknown, a fact that we don't talk about a lot about at the National Commission, is that it was the first national commission to operate totally in public. And if I remember the most daunting thing, it was to discuss issues like fetal research and abortion in public in the sense that you had to deliberate in public. So no behind-closed-doors and emerging with the consensus.

The consensus had to be hashed out in front of an audience, and that is quite unnerving at the time. And so I remember those two things--controversial topic, probably one of our most controversial topics of all, all in front of everybody else. It was quite astonishing, but we reached consensus.

*INTERVIEWER: Were you pretty well satisfied with the first report on fetal research as you look back or did you think it was too rushed, the process?*

MS. KING: Well, in retrospect, I think having a deadline pushed us towards reaching a consensus. In retrospect, I think that it is actually amazing that we did given the fact that we had both pro-choice and pro-life avowedly pro-choice and pro-life members of the National Commission. Certainly, in the beginning, it seemed that we would never, could never reach agreement about fetal research.

I, personally, thought we were fairly conservative in our agreement and the consensus that we reached. On the other hand, the fact that we did reach a consensus established I think an extraordinarily good precedent, and it was important to reach consensus, and I think most national bodies, bioethics bodies or otherwise since then, have learned the importance of being able to do so, in terms of thinking about the clout that your report might have. The 9/11 Commission, for example, comes to mind.

*INTERVIEWER: You did have a consensus, but you did have some dissenting opinions expressed at the end of that report?*

MS. KING: Well, tell you the truth, Leroy, who remembers the dissenting opinions except those of us who struggled with the report. The message that went out, and it was an important message was that a group of diverse people with different value orientations had reached agreement about something that could become a federal regulation that would govern research, and I think that that was really important. It wasn't the only report where we had dissents, but you're the first person to ask about those dissents in a very long time.

*INTERVIEWER: I just remember that David Lewis would not have been likely to accept the majority view, but he expressed his minority viewpoint in such a respectful and articulate way that I think his participation in that whole process was very important.*

MS. KING: It was very important because if you compare the National Commission to some of the other policy bodies, bioethics policy bodies that have dealt with fetuses and embryos, it has been much more difficult. It has not always been--people have not always been so gracious to each other and so respectful in dissent as with the National Commission.

And if I recall correctly, and I didn't look this up again, I'm not sure that the votes were cast, whether he dissented without actually casting a formal no vote. Perhaps he did with respect to one recommendation, but overall it was really very mild, and for the National Commission, it was a good precedent. I'm not sure it had stayed that way with subsequent groups.

One of the things to think about with respect to the National Commission is, although I didn't

have a biomedical ethics background in any way, I learned that people were very skeptical that establishing a National Commission to think through issues of research on human subjects was a valuable activity. I'm told that at least in the medical community that the medical community thought it was a really fairly foolish idea, and so there was trouble establishing the Commission. But that was a downside.

The upside was we were able to operate, even with very controversial issues, and in public, without anybody thinking we had power, and that is wonderful because you're allowed to deliberate and think through issues without advocacy groups, lobbying efforts, political machinations, in terms of who was appointed and who's not appointed, and how you stack a group versus not stacking a group. And I attribute a great deal of the success of the Commission to the fact that we operated under the radar, at least the Washington "inside beltway" radar, and that worked to our advantage.

*INTERVIEWER: How important do you think it was that the Secretary of Health, Education and Welfare had to respond to your recommendations within a certain period of time?*

MS. KING: Critical. I think those of us who care about how policy is formulated know that that was a hidden power available to the Commission. Whatever we did would generate a response, and I think the fact that so many of our recommendations became regulations is due to that. Now, not all our recommendations became regulations, but there were reasons that were expressed, particularly with the mentally impaired on why our recommendations were not being adopted. But the fact that the--just imagine what we could do today with making a Cabinet official respond to something that you're doing, have to go on record in terms of your work, it was a critical aspect of the legislation.

*INTERVIEWER: On the whole, which of the reports did you find the most satisfying, intellectually or in terms of its impact?*

MS. KING: Well, I suppose, with all of its flaws, it was the report on children. Even then it was clear that children were not little adults and that we really needed to have information about children, and it was one of those shifting periods where you reexamine your principles or your values, and you try to give them a new interpretation or understanding in light of changed circumstances.

Now, that's not something that lawyers have a problem with. I'm not sure that philosophers and others approach it the same way, but lawyers have an experience of taking a Constitution and watching a document grow, change, shift, emerge over time as circumstances require. I

think of the children's report as that sort of experience, where you were taking a hard look at a hard issue and weighing and balancing the implications, trying to find ways to ethically include children in research not for their direct benefit, and to put in safeguards and procedures that might protect them.

It really wasn't perfect, but it got us all started, and I think it was a major breakthrough, and for parents, in particular, whose children suffered from diseases or illnesses, I am sure that they were particularly grateful. So I'm proudest I think of the children's report. It was the one that was the most contested, but I think overall we did a pretty good job.

*INTERVIEWER: Do you mean it was contested within the Commission or after it came out or both?*

MS. KING: Both, because, of course, it was a question of whether you could consent to research that didn't directly benefit or was not likely to directly benefit children. There still are questions about the limits, if any, of parental consent to involvement of children in research if it's not for their benefit, direct benefit. The whole prospect of reviewing research for children and thinking about additional safeguards, with new, when advocates might be required.

As a person who teaches family law, the Commission's work on ascent, which was to give a position that allowed us to give children a role, if they were mature enough, in determining whether they would participate in research is a major breakthrough in allowing, particularly adolescents to have any say in what happened to them.

So I think it was new ground, and that doesn't mean it was good for all time, but I'm proud of that report.

*INTERVIEWER: Do you think that the notion of a minor increment over minimal risk is a useful concept. Were you happy with it at the time?*

MS. KING: I was happy with it at the time because I can't think of anything better. I mean, it is slicing the apple very finely, but you had to try to figure out a way to balance risk and potential benefits, and it was a way of walking a very fine line down the middle. Remember, this was all new. So you weren't going to just go wide open in one direction or the other.

As I said, I'm a lawyer. Lawyers work with standards that have to be applied in specific circumstances. So while it can be tough sometimes, it's not an insurmountable object. I don't quarrel what people who are still trying to look for a better standard because I think having

20, 25 years experience with the standard should provide lessons that may help you to articulate a better standard. So I'm not suggesting that--what I'm suggesting that I am quite comfortable with it as an initial step in a direction that I thought it was important to go into.

*INTERVIEWER: Which of the reports did you find most frustrating or were you least-well satisfied with at the end?*

MS. KING: The report on prisoners. And the reason I found it least satisfactory is because it raised issues pretty clearly that we just didn't know how to become, even begin to grapple with. The prisoner report raised questions about both justice and autonomy. And as you know, the Commission came down pretty heavily on the side of looking at the autonomy questions--the question of consent and coerced consent. But the prisoner report raised questions of distributing burdens and benefits of research that we talked a lot about. I remember being in a lot of fierce arguments, but ultimately we didn't have a clue about how to understand medicine in a broader social context because that's what the prisoner report required that we do.

And I think we were, as Commissioners, unprepared for the fact that prisoners who participated in research thought of us, to some extent, as meddling liberals because, inside of a prison, what constituted a burden and what constituted a benefit was not necessarily the same thing in the outside world. That was a really difficult report, and nothing legally ever really came of the prisoner report except to close down research in prisons, and some would argue that was a very important and powerful thing to do. But we just didn't--we weren't able to work through some of these justice issues, and that's actually my problem with a lot of the work of the Commission, and that is that we were terrific at understanding autonomy, informed consent, and pretty good at dealing with questions of beneficence. We just didn't have too much of a clue about what to do with this principle of justice, although it is to our credit that we included it, so that there is still an opportunity to have it evolve as a principle in bioethics issues, and it's beginning to do that. It's beginning to happen, but that was my big disappointment.

And we had a now-forgotten report on minority health care, which was our effort to think about Tuskegee a little bit, but we, and I put myself in this group of "we" pretty strongly, didn't know how to tackle that either, so we turned it over to another group to have a conference. And like all conferences, if you don't have papers, if you don't have things prepared, then you have a conference, and you listen to the people, you write up something, and it goes away, and that's what happened to the minority--you can't even find a copy of the minority health report. You probably have it at the Kennedy Institute of Ethics because you



have everything.

*INTERVIEWER: We do. We have everything, yes.*

MS. KING: But it is--people just didn't even keep it. I mean, it's, you know, it's very hard to come by. And what I'm really saying is we just didn't follow through on the issues that the Tuskegee syphilis study raised. Now, in retrospect, I think we probably didn't because we had so much work to do, and the Tuskegee syphilis study had its own group to examine it. There was a task force.

So, to go back and redo what had just been done the year before or two years before, surely seemed like a bad allocation of resources. And I also think that, in 1974, we were only 10 years post-civil rights legislation, desegregating health facilities, period. And we were in this--a little bit euphoria about ending the Tuskegee-type problems in health care. Those are plausible explanations I think for why we didn't go beyond thinking about informed consent in Tuskegee without thinking about what informed consent really means in a situation in which the men in Tuskegee found themselves, but we didn't. And so all of the Commission's report that might arguably--reports--that might arguably have raised some of those justice issues, didn't, and that is my major disappointment.

*INTERVIEWER: The Commission worked on a lot of reports on particular topics, and then as it neared the end of its work, it tried to put everything together. And out of that process came some ethical principles. Do you think that was a good way to approach things--to work inductively?*

MS. KING: Well, it wasn't quite like that. We actually started trying to do what became the Belmont Report about halfway through the Commission's life--four years. So, what was really important, I think, was that we did it both ways. We worked on specific problems and then had a Belmont meeting where we talked about principles--

MS. KING: I've got to get my days straight. Belmont is '78?

*INTERVIEWER: Yeah.*

MS. KING: But the meeting at Belmont was--Belmont is '79. The meeting at Belmont was much earlier.

*INTERVIEWER: Was it?*

MS. KING: Maybe two years earlier, yeah.

*INTERVIEWER: Maybe '76, '77. The Commission began by dealing with very specific issues and then tried to move toward formulating some general ethical principles. Do you think that was a good approach to start with specifics and then move to general principles?*

MS. KING: I knew, particularly if you have some people in your group who had no experience with the issues or topics under discussion, and that was certainly true of me, and I believe it was true of people like Dorothy Height, and David Loiselle, and Bob Turtle. In other words, we were all immersed in our own professions and sort of hadn't thought about this interdisciplinary area. And to have started trying to work on a framework I think would have been not doable actually and a little daunting.

But once we had started to talk about specific issues and the lines of disagreement or the focus of disagreement had started to emerge, then we were interested in trying to understand why we were having differences or, in some cases, consensus, and we actually had the meeting at Belmont long before, of course, the Belmont Report came out. And just having the meeting made an enormous difference in the way we deliberated and talked to each other.

My memory is very poor, but Al Johnson tells me or at least he put it in his book that I reportedly said, when Belmont, the meeting itself was over, that it had helped enormously in helping the media understand what we'd been doing because I didn't have that sort of framework.

So I think, in this kind of environment, interdisciplinary, people coming from different places, different backgrounds, it helps to have both facts and framework and have them interact with each other, attempt to have a framework. And I thought it worked quite well, as a matter of fact.

*INTERVIEWER: Were you pretty well satisfied with the three principles that emerged? Do you think there should have been more or could one of the three had been skipped?*

MS. KING: I really don't think any of the three could have been skipped, actually. You know, there's a lot of controversy about the Belmont report, but my view is you start somewhere. You know, sort of think about the Founding Fathers who sat down and try to figure out what they were going to put in their declaration or the Constitution. It's not a perfect document. There are all these things that you can add later, but you need to start with someplace, and you want to start with a formulation that is broad enough to be able to

evolve over time, and lawyers would say even a framework that was susceptible to amendment or additions.

Unlike the Constitution, we haven't done that with Belmont, and I'm not sure we ever could because we don't have a process for doing it. So the fact that it is very broad and general I think is a good one, and it certainly captures the prevailing norms, both in our political life, and in our moral and philosophical life. So, in that sense, it was satisfactory.

And of course it permits people now to debate so many things about whether principles are the way to go or whether the formulation of each principle was a good formulation, and it generated its own literature, which I think is a good thing as a part of the debate.

We were only going to get a framework that the people who were members of the Commission could generate. And when you take a look at us, I think we did a pretty good job. We didn't have any idea that Belmont would have the impact that it has. It's a convenient document, tight, because it says everything and says nothing. But it helps people to really think, to develop lines of argument or understanding, and it provides a way for people across disciplines to be able to talk to each other. I mean, you sort of get where you are in this wavelength, I think, with the assistance of Belmont.

*INTERVIEWER: Is there one of the principles that you think is especially important in the American context?*

MS. KING: Well, in the American context, the principle of autonomy is the most, and the idea of individualism, of course, is the most important principle.

And I think, given the time in which Belmont emerged, one would expect that because, after all, we were in context too. We were a part of the culture, at that particular time, with a great deal of emphasis on individualism. But I think of Belmont as having three principles of equal weight, equal importance, and specific situations might, and the facts of specific situations, might cause one to be highlighted more than others.

One of the, I think--and I've said this before--unfortunate aspects of thinking about that principles is that we've spent subsequently so much time talking about autonomy and informed consent without spending what we probably need to do, a great deal of time, on both beneficence and justice, in part, I think that if we had had economists on the National Commission, we might have reached the utility questions inherent in the beneficence principle much more readily, but we didn't, and so we formulated them in terms of traditional medical ethics, in terms of thinking about their doing no harm. And we talked

about burden--not burdensome benefits. We talked about maleficence and beneficences. They are now structured. But we couldn't do much more with it because those kinds of assessments are not easily done outside of the context of a specific problem.

*INTERVIEWER: We've talked a little bit about respect for persons and beneficence in the Belmont Report. What about justice?*

MS. KING: Well, it's my view that, though we stated a principle of justice, that it's the forgotten principle. It was not a principle that played a major role in the deliberations of the Commission, except in the context of the prisoner report, where the issue, of course, did arise.

And even though social justice questions were a major part of the times, I mean, we had after all just finished the civil rights movement, and we were just talking about equality, we'd just come through Tuskegee, we just did not pay a great deal of attention to it beyond recruiting subjects to make sure that you didn't use vulnerable populations in research which resulted, of course, in not using African Americans in research.

But I think we are now in a period, almost a quarter of a century later, where people go back to Belmont, and they think about the justice questions raised, and they go beyond, actually, what we talked about--selection of subjects in Belmont--and we hear a great deal more discussion about distributive principles and what is fairness and what's equality in health and in areas of medicine. So we're getting there. So it's there, and that's the good part. The fact that we didn't use it very much 25 years ago is the bad part, but I hope we are correcting that. There are many people working on health care issues, for example, that sort of go back to thinking about Belmont and other philosophers as well and thinking about those issues.

*INTERVIEWER: For a while, it seems as if the concern was to protect minorities and poor people against being exploited in research. And maybe we overreacted and later on we needed to come back to the idea of including minorities and poor people in research?*

MS. KING: Well, I think you're right, LeRoy, that we were--that's what Tuskegee did, and that's what all of the outrageous examples of bad research, for instance, in children did for us, and we went very far one direction, perhaps too far. But I also should say that it may be that we just didn't understand how to include fairly either.

We all know that HHS has still not issued guidelines for conducting research on vulnerable populations that don't fall into the category of children or women or prisoners, vulnerable populations in terms of educationally disadvantaged or economically disadvantaged. I don't

think that's for lack of thinking that it's an important thing to do. I think that we just haven't been able to figure out yet how to include people without putting them at more risk than we want to put them, without creating greater risks than necessary.

And subsequent efforts to include minorities, and women, and children have encountered that problem because we still think of all three categories as being vulnerable, in some sense, although perhaps a different sense from each other. And to strike a good balance between inclusion and protection is just not so easy to attain.

We haven't debated this so much with respect to minorities, in part, because we still have trouble recruiting minorities into research, but--

*INTERVIEWER: We were talking about the tension between inclusion and protection.*

MS. KING: I think, frankly, to repeat myself, that it would have been difficult--it still is difficult--for the Commission to strike a good balance between inclusion and protection, and it was just easier to protect.

And I think the subsequent years demonstrate all too well the difficulty, particularly today with children, for example, as we are convinced that we need to include them in research, and we struggle to figure out ways to do that that are acceptable and don't put children at too much risk.

We are still struggling with ways of including minorities in research not so much in terms of the inclusion protection balance, in terms of physical risk to minorities, although that exists, but how to include minorities in research without fostering or promoting stigma or biological understandings of race or conceptualizations of race.

So the harm is different. It's a quite significant harm, but it's a social harm, in some cases, a psychological harm. But we still worry that, since participation in research is a benefit to many, that minorities, like other Americans, should have that opportunity, and we also worry that perhaps there are differences between minorities and nonminorities that are medically significant.

So we want to make sure we've covered that base as well, but all the while we really risk perpetuating risk, social risk, that we would like to see go away, and of course all of the work with the genome project is really bringing to the fore this hard question of inclusion and how to include because we were worried about doing harm.

So, while I wish the Commission had made some initial efforts at striking a balance between inclusion and protection, I recognize how difficult it was then, and even now how difficult it is.

*INTERVIEWER: Some people have proposed that there should be a principle of solidarity added to the Big Three that the National Commission included in its report. What do you think about that?*

MS. KING: What do you mean, LeRoy, by principle of solidarity?

*INTERVIEWER: Somehow expressing the notion that we're in society together. We ought to care for each other. We have some mutual obligations to each other. What do you think about that?*

MS. KING: It's a notion that I'm quite sympathetic to. And when I say I'm sympathetic to, I see it as somewhat of a counter to our very heavy emphasis on individualism and essentially every tub on its own bottom in the society as well as in biomedical research.

I think there is a role for groups or communities, as some people use the term. It's not clear to me yet, however, just how we will go about doing that. I'm not so sure we need a principle of solidarity, as we need the same kind of group that the National Commission represented, to debate how you add that as an additional principle. It is particularly important in international research, I think.

However, the issues for international research are also issues of domestic research, and that is how to do benefit sharing, how to involve communities in the consent process, what obligations are owed to groups, as well as individuals, are all the kinds of questions I think that deserve the same kind of attention that the first three principles received, in part, because we may be in a period of correcting our earlier emphasis or swinging back a little bit on that earlier emphasis on what I call excessive individualism that also crept into biomedical research.

*INTERVIEWER: Some people in bioethics have suggested that a fourth principle should be added to the Big Three--respect for persons, beneficence and justice--and that would be a principle of solidarity, some notion that we're all connected to each other and that we ought to help each other and support each other.*

MS. KING: Well, I don't know exactly how to describe it as a principle, and I'm not sure I

would agree with all of the formulations that come out, but I do think that it would be important to point to a--or to have a principle that would point us in the direction of the collective that we are linked, that a good formulation is the Golden Rule formulation--"Do unto others, as you would have others do unto you"--somehow to show our connection to each other and that we are not isolated individuals, a reaction, I think, to what I consider excessive individualism.

But I think it's important not only to show that we live in families, groups, communities, tribes, and what the relationships, those sorts of relationships, the impact of those sorts of relationships. It may be worth, I think it rather is, the--composing a group to just deliberate how you might think through some of those issues of the statue of the original group.

I think it may be particularly important, in terms of genetic research. I think it was particularly important in international research to start thinking about some of those issues. But I'm the first to say that the issues of international research are also the issues that are here, in terms of benefit sharing, for example, and we really don't have any good way to get at some of those issues now, and I think they're very important.

*INTERVIEWER: Did your work with the Commission have a major impact on your life between the '70s and now?*

MS. KING: Well, it had an enormous impact because I started life as a civil rights lawyer, and I became a bioethics--I refuse to say ethicist--but I became a biomedical ethics expert I guess. All of my writing, my teaching, is connected in some way or another with bioethics. I'm a co-author on the textbook on "Law, Science and Medicine," which is getting ready to go into its third edition. This was the first legal textbook in the country that dealt with those issues of the relationship between law, science and medicine.

I would not have done any of those things if I had not been a member of the National Commission. And, lord knows, I have served on more public policy bodies and committees, most of which have been absolutely wonderful to do, and it just wouldn't have been possible if I hadn't been this young, naive lawyer, asked to join this National Commission, who ended up four years later convinced that this was the way to go. If I hadn't been so old, I would have gone back to school and gotten another degree in public health or in philosophy.

*INTERVIEWER: So it did open up an area of interest for your further research and teaching that hadn't been there, although you had studied the liberal arts, and you had majored in religious studies as an undergraduate, so that part of your life was always there?*

MS. KING: Well, I reconnected with that part of my life, and I never would have imagined that I would have done that. I just--civil rights law was where I thought that I was going to be. And it's very interesting, the bioethics part is not perhaps as interesting or unusual as ending up in family law because family law and tort law were the two areas of the law that most closely connected with bioethics, those parts that deal with death and dying or reproduction, et cetera. So it really had an enormous impact. It just turned me all around.

*INTERVIEWER: What do you think were the major keys to the success of the National Commission? Was it the staff? Was it the Commission members? Was it action-enforcing power that you had or some combination of all of those and other factors?*

MS. KING: Gee, that's really hard to answer because I can think of a number of factors that, if they had not been present, I think that the Commission would have totally gone awry. I've mentioned some already about the Secretary having to answer us, the fact that we got off on such a good start with consensus, the fact that we were proceeding under the radar. But, you know, the Chairman of the Commission was an extraordinary man, and he kept an often fractious and unwieldy group all marching in the same direction. And you tend to forget those things over the years, but during the four years that the Commission met, we always said to each other--and you know we met a lot, once a month every month for four years, with very few exceptions, sometimes twice a month--and we all commented that it would not have been doable if Ken hadn't been there.

He didn't really crack a whip, but he was firm, and he kept us marching forward, rather than allowing us to dissipate and scatter our energy. And he set the tone. He was respectful. He lost his temper every now and then, but not too often, but we were difficult sometimes. He was respectful of our views. He listened to everybody's views. He kept his own inclinations firmly in check as long as he was acting as Chair. And I think that the product of the Commission's work is, as much as anything else, attributable to his leadership. And I feel pretty strongly about that.

And I'd like to think that all of the other things in the ingredients just helped him to do that job very well, but I think of him as being indispensable.

*INTERVIEWER: So the Commission worked in the late '70s, and it's now early in the 21st century. I'll ask you a hard question, and that is, on balance, do you think human subjects in research are better off today than they were in, say, the late '60s or early '70s?*

MS. KING: Well, I don't know what measure to use to tell me whether we are better off. I



like to think that we are, although there are problems now in our system that we just didn't anticipate or think very much about 25 years ago.

What I think I would like to see is something that's already beginning--some careful assessment of how the system actually operates. We do a fair amount with informed consent, for example, but I'm not sure that we have a sense of what studies are approved, and why, and how harm is assessed, for example. I'm not sure that we have an empirical base for assessing how IRB's operate. We've got a lot of ideas about processes and procedures that might make functioning better, and I'm not suggesting such as accreditation, for example. I mean, there are lots of ideas about what to do, including changing the regulations, but I'm struck by the fact that we may not know a great deal about actual functioning. And before I thought we were in a better place, I'd like to know exactly how we were functioning.

We clearly spend more money. We clearly have pulled more kinds of research, even with our remaining assumptions under a review process and umbrella, but I think we don't have a good base on which to make the kind of judgment that you're asking. In fact, I think it might be a good question to debate whether, given the amount of resources going into the system, whether all of the resources that are being used are really important, in terms of keeping the lid on risks coming about or whether we would be just about where we were before, in terms of harm to people, if we had a less-elaborate structure. I don't know. I'm sure that quite a good deal of money is flowing into the system.

That said, there are of course big gaps that still remain, and I appreciate that, but I don't know how I feel about that. What I think we have done is increased the confidence of people that the system is operating just about, not right, but is operating well, and that's important so there's some trust in the system. But I don't know. I'm not sure I can make that evaluation. You always like to think your work was for something good, and so I'd like to think that we're better off, but I'm not sure.

*INTERVIEWER: One factor that the National Commission didn't have to deal with in the same way as we do today, in research ethics, is the huge amount of private money going to universities and to research organizations. That's a qualitative change.*

MS. KING: It's a qualitative change, and it is a change that we have been reluctant to take account of. For a long time, if you could impose regulation on government-funded research, you could accomplish a great deal, all sorts of government-funded research. and that, I would agree with you, is no longer the issue. And the real question will be whether we're willing to impose a system of protection on everybody because, unlike government, private industry is very cost-conscious in terms of the value to be obtained from imposing a stringent system of

oversight and monitoring.

So I don't know, but it certainly is the big issue, and I think that, interestingly enough, one of the major side elements of the stem cell research controversy, as well as our concern about reproductive technologies and what happens to subjects in--well, they're not called subjects--but what happens to people involved in reproductive technology development may propel us in a direction of finally making some--Congress finally passing statutes that would apply more broadly.

They've been surely reluctant to do it in the past because they don't want to infringe basically on what they've seen, a scientific endeavor, which was good, but maybe we are at the point where we will have to consider a broader focus than we were willing to do in the past.

*INTERVIEWER: So, if you were President, would you be urging the Congress to enact a single high standard for all research regardless of how it's funded?*

MS. KING: Well, I don't think they can enact a standard. What they would enact would be a process, and the question would be whether the process would have to apply to all. You might have some substantive standards, don't mis--we already have a little bit of that in embryo research, and fetal tissue research, et cetera, but what you basically want to have accomplished, I think, is to have some oversight mechanism that would apply to private research, as well as publicly funded research because that's actually what is the most valuable thing about the publicly funded research, that there is monitoring, and oversight, and an opportunity to impose substantive guidelines.

But if you take a look at the regulations carefully, many of them are just guides, in which the review process occurs. But I wouldn't be surprised, in the next 20 years, that we actually got a broader coverage of research, particularly human subject research, because government is playing a decreasing role.

*INTERVIEWER: Yes. So a single standard, regardless of whether it's FDA regulated or federally funded or even privately funded--*

MS. KING: I didn't say that.

*INTERVIEWER: --and intrastate.*

MS. KING: I didn't say that.

*INTERVIEWER: Okay.*

MS. KING: What I said was that you might get review processes enacted. I don't think it would necessarily be appropriate to have FDA regulation look like NIH regulations. I don't know But to think about it as a generic matter, should there be oversight of private research, as we were contemplating with recombinant DNA research, for example, that question is the question that I think we may start to deal with. Because informal mechanisms are just not working for some areas of research, and it's much more likely, I would think, that FDA is the inappropriate place to lodge not in the new regulation because not all of it is going to be safety regulation or safety regulation may not be extensive enough to accomplish what you would like.

*INTERVIEWER: So maybe this brings you full circle in your career. You started out being interested in civil rights, and maybe there's a civil right or should be a civil right to be protected as a research subject no matter in what context you participate?*

MS. KING: Well, I don't know if we will call it a civil right. It is likely to be called a human right because that's the new terminology, but I think that it's an actually important topic that a woman who participates in research, with respect to reproductive technology, is treated and subject to protections that, as far as we know, are only in terms of what the institute or the physician is willing to impose, while a woman who is in a clinical research protocol at NIH or involved in drug research understands and can appreciate that the research was reviewed.

It's not so much the informed consent I worry about. It is the research proposal and protocol itself and how to assess the risks and benefits and the protocol. And the fact that the two are different makes no sense. The safety issues in that case, for example, are the same.

*INTERVIEWER: So what was that last thought you were expressing about a human right to be protected in research no matter what the funding is--*

MS. KING: Irrespective, right.

*INTERVIEWER: --and so forth.*

MS. KING: The funding should, the funding...the funding stream for research should not be the determinative factor in terms of whether or not potential subjects are adequately protected in the sense that their research is adequately reviewed or monitored and that informed consent is obtained in a proper manner.

*INTERVIEWER: And I think you're also concerned about the question of risk--in certain context as well as the consent issue.*

MS. KING: It seems to me that, in both the setting of experimentation, and reproductive technology and fertility work, as well as when participating in a drug study or participating in a clinical trial, that, from the woman's perspective, the question is the same, and that is has this research been adequately reviewed, do I understand the risks, have all the risks been thought through in terms of the research?

And the answers to that question ought not depend on the particular, the stream of funding for the research, and if we get a bad incident in privately funded research, I am sure that this table will, this question will be foremost. It is already emerging in areas like reproductive technologies. Should we ever get stem-cell research and applications it will be a question there too if there is not government funding.

Well, thank you, LeRoy. It is always a privilege to have a conversation with you, especially about such serious matters.

Thank you.

–END OF INTERVIEW–