



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

Interview with
Hon. Paul Rogers
Congressman
Washington, D.C.

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Belmont Oral History Project

INTERVIEW

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

INTERVIEWER: Would you please identify yourself and tell us what your degrees are and what your current affiliation is?

MR. ROGERS: I'm Paul Rogers, Paul G. Rogers. I am a member of the firm, law firm of Hogan & Hartson in Washington, D.C. I have a degree, a B.A. degree and a J.D., Doctor of Jurisprudence in law. And, as a lawyer now, I am currently practicing law. But I am also doing a lot of nonprofit work with nonprofit organizations, in the health field particularly.

I was a Member of Congress for 24 years and I chaired the committee, subcommittee on Health and Environment, where we handled most of the health laws of the nation and the environmental laws, which was an interesting area of activity, particularly at the time I was in the Congress because the public was in a supportive effort of doing health laws. And, interestingly enough, environmental laws at that time.

We did the, for instance the clean air, safe-drinking one, those types of bills, where Muskie did them in the Senate. We did most of the health laws that even now are on the books; the Cancer Act, heart, lung, blood medical device bill all sorts of health legislation. So, it made for a very interesting time to be in the Congress.

INTERVIEWER: So, you were not a member of the National Commission, but you were instrumental in helping to form the National Commission. Will you talk about that further a bit?

MR. ROGERS: Yes, I was not a member of the Commission, as you say, but I was on the committee that handled the legislation in the House on the National Research Act, which held hearings and provided the establishment of the Commission, the National Commission on Human Subjects.

And the Senate bill was passed, too. And Senator Kennedy, Ted Kennedy, chaired that committee at the time and really was the main driver, I think in this particular arena that you're interested in.

INTERVIEWER: Was it easy to convince your colleagues in Congress that the Act that helped to form the National Commission was something that had to be done?

MR. ROGERS: I think, after the publicity that was pretty well spread around the country from some of the experiments that had been carried out, like the Tuskegee, where they'd gone in with not very many ethical considerations and just gave syphilis to people; not take care of them and so forth sufficiently.

There are others where they injected cancer cells into people, without any real ethical considerations at all. There were enough of those, where I think we were able to convince them it should be done.

Now, as I recall, and my memory is not as good as it should be, probably, since that's a good while ago. But, as I recall, on the House side, we had a lot of concerns expressed to us about establishing a permanent Commission to set rules and regulations. I think the Senate side felt it should be permanent. It would be good to go on and get it started and have a permanent commission.

But the expressions of concern from scientists, because they weren't quite sure how this was going to operate. As you know, the individual investigator, used to be the one to decide whether it was all right to do his experiment. So, all of the publicity of incidence--it really was shocking to the public and shocking to the committee, laid the foundation for us to bring this legislation out of committee and through the floor.

So, I don't think we had, really, any hard determined opposition, because people were not quite sure, even those who might have opposed shifting from the individual investigator and the local institution, to allow a national body to come in and set some standards. At least call for the standards and see if they could get them established.

Even they felt that it was not feasible, I think, to really object, strenuously. So, as I recall, we did not have an extended floor debate or difficulties in passing this legislation in the House.

INTERVIEWER: And was that true in the Senate, as well, then?

MR. ROGERS: I think so. I don't recall the details on the Senate side, but I think that was probably true.

INTERVIEWER: Thinking about your constituents back home in Florida, was this issue of protecting research-- the subjects in research, was that a high-priority issue for the people back home, as well as up here in Washington?

MR. ROGERS: Well, I think, if you would bring it to their attention, I don't know that they would have just automatically said, you know, do something right off.

But once it was brought to their attention, if I were to discuss it, you would find strong support for doing something to correct the, really, the evils of the system there.

INTERVIEWER: When the Commission was formed and began to have meetings and write reports, were you happy with what they were doing in response to your actions?

MR. ROGERS: Yes, I thought they were carrying out their duties quite well, "The Belmont Report," where they set forth the basic concerns that people should have. And then we wanted to change the structure where the individual investigator who would be getting the funds to do a research project didn't make all of the determinations himself, because of the obvious conflict that he would have, too; with selecting patients; with how it was carried out; what about damages; suppose a person were injured; so many considerations.

So, I think we were satisfied that it was needed and I think it's proved that that's been true.

INTERVIEWER: Did you anticipate that the reports of the National Commission would become the basis for regulations? Was that your goal?

MR. ROGERS: I did think that, because we, you know, put in the law, rather than writing any particular provision in the law at the time we took up the bill, we felt it should be studied more; that we, really, should have greater background, because, as Members of Congress, there were many items that the members would never be exposed to, basically, that the scientists and people of medicine have to deal with.

And, so, I think everyone felt that's why we needed the Commission to do the study, to be on top of it, to develop those--and point up those areas where there are abuses, which they did. And what are the concerns that must be addressed before research is undertaken or permitted or funded. And what are the conflicts in the funding? Who participates? How is it done? For whom is the benefit to come? And so forth.

INTERVIEWER: In forming the National Commission, it was kind of--it must have been anticipated that there would be a length of time that would have to pass as the Commission met before there would be regulations -- as opposed to the choice of not forming the Commission and getting right to work writing regulations.

MR. ROGERS: Well, I think--that's true, but I think the correct determination was made, because you don't want to go in and write laws that are not correct. And that are

destructive rather than constructive and helpful and bring about the results that the public should have.

If we just ran in and wrote a few regulations, we would have missed some, we would have overdone some, I'm sure. But with proper advice, I think you know, the regulations could be appropriately addressed.

INTERVIEWER: A goal of yours was to have proper regulations in place. Do you think that was the outcome of the reports of the National Commission?

MR. ROGERS: Yes, not that all of them have been answered, necessarily, because new ones crop up often, all the time, I think. But, I think, for the most part, it was. For instance, the establishment of the institutional review boards; the peer review before you let someone start a project in an institution.

It had to pass that scrutiny. Other people who had no particular personal advantage in seeing research go forward on that particular subject or funded for that particular subject; they could take a more rational view of what the ethical concerns were; what considerations should be given, as, for instance, who was it that should be involved in the experiment; what people; what persons, so many questions.

So the Institutional Review Board gave an outside, critical look. I don't mean it as criticized, but I mean a very thorough look at what was proposed; what would be done; and what you might expect as an outcome.

INTERVIEWER: As you think of how humans have been involved in research studies now for the last 10 years or so, that the regulations have been in place for 10, 20 years. In the last years, as someone who helped to start this whole process of providing protections for humans in research, are you comfortable with how the subjects of research have been protected in the last few years?

MR. ROGERS: I think there are many items, as has been shown in other reports, need to be addressed still. And not all of them have been addressed by any means. We just had an instance within the last year at the University of Pennsylvania; conflicts of interests; that I don't think were given as much attention, probably, in the original consideration as should be given. And that's been borne out, I think, by what's happened. We need to do more there.

And this is developing rather rapidly, I think and I believe you will see some resolution of those particular concerns soon. They have already been addressed in some areas, but still to

go, I think, a considerable amount.

INTERVIEWER: When you formed the Commission and tracked what they were working on for the first few years, was the concern primarily research in the U.S.? There is a larger amount of research that's being done outside the U.S. today, where it's difficult to oversee the protection of subjects. Were your thoughts primarily the domestic or the international, as well?

MR. ROGERS: Well, I think, when we passed the National Research Act, it really was domestic. I think that was the main thrust of what we were trying to do; clean up the research done in this nation, so our people who might be involved, would be protected. I think that was the thrust of our concerns.

And, of course, we're concerned about what happens--and, particularly, if it's American citizens overseas or others or with the research that might be done overseas where they use that research data as a justification, then, to bring drugs or whatever it may be into this country. There would be a concern on that. And that's difficult to do though and the agencies, Food and Drug, they do go out and inspect plants and that sort of thing. NIH has some efforts. So, it is--and I expect that will be expanded.

Because, as we get more and more into global health and global health concerns, which we are moving to more and more rapidly all the time, then I think you will see those concerns expand.

I think it will be that we will try to set some standard here which we would encourage people to use, just like we feel that Food and Drug is, probably, the best agency in the world on the safety and efficacy of drugs.

And our procedures are generally pretty good and that we think if other nations can match that, that that would be good, not only for us, but we think, for their own people, too. But that's their judgment, of course.

INTERVIEWER: The experiments that brought a lot of attention; the syphilis experiments at Tuskegee and the Nazi war--the medical experiments--those experiments were, primarily medical in nature, as opposed to the social and behavioral research that we also worry more about today.

MR. ROGERS: Today, yes.

INTERVIEWER: When you were thinking of the need for regulations, were you thinking

of the social and behavioral or just the medical?

MR. ROGERS: Well, I think, probably, we started out thinking more specifically medical. But I think the Commission helped develop the idea of the social, too, behavioral. So, I think that was a natural development in the consideration of the whole subject of human research.

INTERVIEWER: As you started out, you mentioned some of the legislation that you were heavily involved in helping to bring forward – otherwise, you've done a lot or we wouldn't know you as "Mr. Health."

MR. ROGERS: Well, that's kind.

INTERVIEWER: Based on the experience that you've had in helping to support the development of bills to protect the health of people, together with that, you have also been an advocate for research – through the years. Has it ever created a problem that you are advocating for research, but you also are very concerned about protecting subjects? Is there a potential conflict there?

MR. ROGERS: No, I think that goes hand-in-hand. In other words, if you want to promote research, you want to promote research that's going to be done ethically and correctly. And you would support any effort to assure that the research that you might advocate and try to obtain support and money for, that it's going to be done correctly. So, I think it goes hand-in-hand, not in an opposite direction.

INTERVIEWER: So, the two of them need to be considered together –

MR. ROGERS: Yes, they do.

INTERVIEWER: – not separately?

MR. ROGERS: Yes.

INTERVIEWER: One of the things that the National Commission struggled with was differentiating between research and the practice of medicine. And, sometimes, there's a gray area between when physicians are practicing medicine, but gathering information in a way that it becomes research. Did you have in mind that that was something that the National Commission should focus on specifically, so that we had a clear distinction and guidance for the practice of medicine versus the ethics of doing research?

MR. ROGERS: Yes, I think we did feel that, right from the beginning, because we did not want to infringe on the proper practice of medicine. And, so, that was a consideration, I think from the beginning. Now we did not--and we can understand how sometimes it's hard to draw a line, because a doctor has a great deal of leeway. For instance, you know, he can--Food and Drug even lets him prescribe drugs that are not particularly approved for a particular malady that he may be prescribing that medicine for. As long as he's a doctor and has that judgment.

So, we did think of that. But we also felt that by putting basic tenets of protection, ethically stated, would get to that problem, so that research would have to stand on its own and pass the ethical test there.

Now, if a doctor said that this is not research, this is, you know, this is my way of improving the health of this patient, then that got to the question that they looked at of compensation, I guess. And you get sued if you're not going to do what's right and maybe pay something. So, that was another protection that helps keep that division, I think, too.

INTERVIEWER: When the reports of the National Commission were used to write the regulations and the Common Rule was written and the subparts that protect women; protect fetuses; protect children; protect prisoners--special attention was given to protecting vulnerable groups.

MR. ROGERS: That's right, the minority groups.

INTERVIEWER: But, today, or in the last few years, we have been encouraging women to participate in research. We have been--we now have regulations that encourage children to be involved in research, to develop new drugs for children. Do you think we have overreached and we're compromising the protection of vulnerable groups?

MR. ROGERS: I that might happen in an occasion or so, but I think, generally, the feeling has been that we were letting medicines be prescribed to children without really knowing how they would react on children. And that's not very safe. So, I think with very strictly controlled, and carefully monitored research protocols that might involve some children, it would improve the application and the practice of medicine to children, as well as women.

Now, you've got to be careful that you've got to follow it very closely. But that's another reason we needed to have the IRBs and overlook the individual scientists.

INTERVIEWER: Minorities are still under-represented in research today. How strongly do you think we should encourage minority members to volunteer to participate in research?

MR. ROGERS: Well, I think anything that can lead to the improvement of health in a segment of our population, it's wise to try to involve them in whatever research is necessary to bring about that improvement. And many felt that they have not been adequately researched, that many things had not been adequately researched for particular groups that needed to be. And I think they probably were correct. But there has to be a reasonable approach. And I think one that you could explain and stand behind. And by having them adhere to the basic rules that have been established in ethical requirements, I think that will come about.

INTERVIEWER: When you started the process of developing the legislation that formed the Commission and led to the regulations and now you look at where we are today, are you satisfied with how we have played this out?

MR. ROGERS: Well, I think it's a beginning. I'm satisfied that we got established fairly quickly, the IRBs – the Institutional Review Boards – which is very important. So that you've got a peer-review group looking at all of the research in that institution before it can go forward. I think I've been fairly pleased to see that. Now, of course, there are areas in research that are cropping up every now and then, where they have not been handled properly. And we still need to do other things to bring about protections there. And we just had recent examples. And, particularly as we move into genetic use of medicine, as we get into nanotechnology, which is just beginning, we're going to have to be very careful and have the review and, hopefully, this review can be ongoing, which I think it should be.

INTERVIEWER: Do you think the regulations that we have in place today will protect us when you consider all of the potential wonderful parts that will come out of nanotechnology and knowing the human genome?

MR. ROGERS: I'm not sure that we've thought all of them through yet. You know, in nanotechnology, for instance, we're just beginning – although, some have been doing it for some time – but we're just beginning. And we're not sure – in fact, we don't even have a proper wordage, yet, to identify what's being done. We don't – we need a language, even. We don't know how to call what, yet, but it's started.

So, I think you'll find that we're going to need to devote some time to looking at that very carefully, that whole field of nanotechnology and we may need additional protections set up and agreed to, in order to do research that will naturally be called for.

INTERVIEWER: The complexity of the technology today is even more difficult for those of us who are involved in it firsthand than the technology of 20 years ago.

MR. ROGERS: Yes.

INTERVIEWER: How do we educate the public so that they understand better what the risks and benefits are of being involved in this kind of complicated research?

MR. ROGERS: Well, I think that is a significant problem. But I think it can be done, just as now, if we had the proper information; informed consent. I think it can be done. It won't be easy in some instances, but I think it can be done. And I think it will be required to be done.

Otherwise, you will end up with people who didn't know what was going to happen. And that can get us into multiple problems.

INTERVIEWER: Would you have anticipated, when the National Commission was formed and began to start reports, that the Belmont Report would still be seen as a premier document in guiding human subject protection questions 25 years later?

MR. ROGERS: Well, you know, I thought it was kind of broad enough, the way we had classified things that it would stand up pretty well. And I thought there were enough areas of flexibility in those items that they centered on, that it could be a document that would be useful for many years.

I think they felt that they had pretty well covered the field by doing broad things, too, so that they weren't so limiting in their definitions. So that they tried to make them broad, that that would cover the field fairly well, and it has, fairly well. But there are now new things cropping up and, you know, we really need to look at them, more closely. And I think this will be done. Well, it's already being done.

INTERVIEWER: After the National Commission was formed and the people were identified who were going to work on the National Commission and they started their work, were there times when you had second thoughts about whether or not the right people were picked and whether they were working on the right issues?

MR. ROGERS: Might have happened in a couple of cases, but, generally, I thought they picked good people and they did a good job.

And I know one person, Barbara Mishkin, who was on the Commission – and, incidentally, who is now with my law firm, our law firm, she staffed that some and did a great job, really. So they had good people and they tried hard and worked hard. So, I was generally pleased

on that.

INTERVIEWER: As the Commission did its work and the work, the products got translated into regulations, were there...as you watched that process unfold, were there things that you were excited about that were really exactly what you had in mind and were there disappointments?

MR. ROGERS: I don't recall identifying any real disappointments during that stage. I felt they had made an honest effort to try to address the problems for which they were constituted to do. And I think the report was well received by the scientific community. They knew something had to be done. Scientists, generally, don't like a lot of looking over the shoulder, which I can understand. But a certain amount of it has to be done to assure the public of safety and so forth. So, generally, I felt they did a pretty good job in the beginning.

INTERVIEWER: Were there any things that happened as they worked that you saw as the breakthrough of the time, that you really knew that this was going to succeed?

MR. ROGERS: Well, I, as I said, I was very pleased that they established the IRBs. I think that's getting down right to where decisions need to be made quickly to give some protection in every research institution in the country. That's the way it should be.

Now, if there are other problems, they may have to go up a little more, but at least you have a mechanism which we were very interested in trying to assure safety to the public. And ethical concerns that should be considered whenever any human being is subjected to research.

INTERVIEWER: As you look at how research is going today, research that involves human subjects, do you feel a need to have a new start to develop a new Commission, a new regulation to protect human subjects?

MR. ROGERS: You know, I think it would not be a bad idea to form a Commission – just to do a study to bring us to date – to let them look at examples that slipped through what had been planned to protect the public and where they had difficulty doing that. That ought to be looked at and steps taken.

Now, a lot – some of that's already been done. Of course, they do that as it goes along, to a certain extent. But I think it would not hurt to have another Commission do that. And, particularly, with so much of the new technology being developed so quickly, it would be good to, at least, to have thought through some of the areas that should raise ethical

concerns, as we apply the very newest research that we are having, as we mentioned, with, you know, the genome and nanotechnology and science in that nature.

INTERVIEWER: If we were to form a new Commission today, do you think it should, again, be made up of people from ethics and philosophy and medicine and law kinds of backgrounds?

MR. ROGERS: Yes, I do, all the way around.

INTERVIEWER: Even though the issues are new, today, do you think those...

MR. ROGERS: Well, you're going to have to some, too, that have technical knowledge, I think of, you know, the genome, you would want someone who really has an understanding of how that's going to be applied; what's the best way; how are we using it currently; what are the concerns. And, particularly as nanotechnology develops, what should we look for to protect the public, as that may be applied to them in the delivery of medicines or going, just to the single cell. What are the considerations that might arise that may cause concern for the public's well being.

INTERVIEWER: The development and the research that it takes to get a new medical product approved today, that research has to involve human subjects, for the most part. Do you see that we will ever be able to get away from having that dependency on humans to develop new products?

MR. ROGERS: It might be possible, but not, I think, in the very near future. It's going to take a little while, I think. Well, I think I recall, even, Martin Clone [ph], saying that he thought, you know, you could go into literature and, perhaps, do some things.

I'm not sure I'd be satisfied in that, but I think from practical experiences that were done or have been done, we might gain enough knowledge where you wouldn't have to have extended human trial and do a follow-up as they're currently beginning to do now, to follow a drug, what happens to it, and if corrections need made they can take action very quickly.

INTERVIEWER: So, you're suggesting that the tracking of new products, how they perform among users after they are approved, is part of that research process as well?

MR. ROGERS: Yeah, I think it could be used effectively and might, also, reduce the costs of development, which are astronomical now. And by having such broad extensive clinical trials that are so expensive, you might reduce them some, if you have a good follow-up program. So, that, as soon as you see any problem develop, you could take action. And we

may have to move in that because of the cost.

INTERVIEWER: But that brings us back to that question of the interface between research and the practice of medicine.

MR. ROGERS: Yes.

INTERVIEWER: And if we depend very heavily on the practice of medicine to gather the data that would, otherwise, have been developed in research, you get into questions about informed consent. Will we have to have people buying approved drugs, give informed consent to take them?

MR. ROGERS: Well, I don't think you would let them out until you feel they are safe – the drug is safe and, hopefully, effective.

But it may be on the effectiveness. I don't think they'll let any drug out unless you did require informed consent of them as safe. I don't think the public would approve that.

Now, we added effectiveness during the, I think it was the Kefauver/Harris legislation, Oron Harris chaired the committee when I first went to the Committee on Health. And I was on that conference committee between Kefauver in the Senate and Oron on our side where we put into the law the requirement that not only must drugs be safe, but they must be effective. And I think that's been a very sound movement.

Now, how we show that, people, as Mark said, you can look at it different ways. Maybe have a shorter test to prove safety of a drug and then a follow-up on effectiveness, so long as the drug is safe.

INTERVIEWER: I don't think I have anymore questions, but I certainly want to thank you for the insight to form the legislation that ended up with the Commission and all of the protection that we have had since then. Thank you very much for your insight.

MR. ROGERS: Thank very much, doctor, it's a pleasure to visit with you. And, as I said, I was very interested in when we got this legislation out, I think it's been very worthwhile, as I said. But I want to give Ted Kennedy due credit on this. He really was a pusher for this.

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