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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INTERVIEW

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

INTERVIEWER: Charley, thank you so much for letting us come. Just for convenience, instead of saying The National Commission for the Protection of Human Subjects as biomedically indicated on research, we will refer to it as The Commission, if that's okay.

DR. McCARTHY: That's fine.

INTERVIEWER: Could you tell us a little bit about the circumstances when the Commission was formed.

DR. McCARTHY: I'm Charley McCarthy. I studied mathematics out in St. Paul, then I studied law. Then I came to Washington, D.C. and studied theology, philosophy and theology for about seven years and finally went to the University of Toronto where I got a double doctorate in politics and philosophy, and came back to Washington - then thinking I would spend my life as a teacher of political science, political theory and philosophy. And I did that for close to 12 years between the years of 1960 and '72. And then I--but, increasingly, I was getting interested in active politics. I was ordained a priest in 1956, and in 1971 I left the active priesthood, I married my wife Estelle, I moved to the National Institutes of Health into their Legislative Development Office, and as it turned out, 1971 was, and 1972, were big years for the formation or for the events that led to the formation of The National Commission.

So I happened to be in the Legislative Development Office at the time that all those events fell into place, and they played out for four years. My initial job was just to cover all the health legislation introduced into each Congress. And as you may know about, in the typical Congress, about 115 to 120 health fields are introduced; in a typical Congress about five bills are actually enacted dealing with health matters. So we tracked all those bills not knowing in the beginning which ones might have a future and which ones would be abandoned. And, in fact, the ones that do survive usually incorporate features from the ones that don't.

So we have to track them all and try to figure out the impact on the health system of the

United States and particularly the research end of the health system at NIH. So that was the job I took on, and that meant that I spent about half my time on the Hill going to hearings. I got to know a lot of congressional staff. I got to know a number of congressmen and senators, and began to figure or, or to learn very slowly, how the system actually worked as against the theoretical background that I had already learned how it was supposed to work.

In those years--that was the first years that Senator Kennedy was elected to the Senate, so Kennedy was quickly named the Chair of the Senate Health Subcommittee.

And so I attended many, maybe all, of the hearings that he held through those years. The Kennedy family--a little background on them--have had at least one retarded child, and they created what came to be known as The Kennedy Foundation for Handicapped Children, and it included both cognitively-impaired children and children with physical disabilities.

And sometimes many of the children in the Kennedy Foundation had both kinds of difficulties. So the Kennedy family was very interested in finding ways to do research in this particular vulnerable population. And Senator Kennedy began to hold hearings, which he called "ethics hearings." Sometimes they were just about the health care delivery system and how it affected handicapped people; sometimes it wandered far afield and dealt with such matters as giving testing contraceptives in women who did not speak English and were told that they were taking a contraceptive, but half of them were taking a placebo. And so in a number of those studies a number of women, thinking that they were protected by contraceptives, all got pregnant.

And Kennedy held hearings exposing some of those injustices. He also held hearings on sterilization of handicapped persons, even though the federal government was not directly involved in any of that. That was left to the state governments.

And I now live in Virginia where, finally in this last state legislature, the state has apologized to women who were handicapped and who were sterilized. But there was a long tradition of sterilizing cognitively-impaired women in this state that's only recently been overcome.

So I attended all those hearings. Many of them had some bearing on NIH; many of them had little bearing, but the Kennedy family was interested in figuring out what kind of

research is ethical and what sorts of research is not. So they also put some money into the Kennedy Institute at Georgetown University, and Andre Helligers (ph) was the first director, and his first hire was a very close friend of mine, recently at that time graduated from Yale University, Leroy Walters. And Leroy and I attended lots of those hearings together. We prepared lots of testimony for the government witnesses and worked together along with other staff members at NIH to present the government position on the bills that were introduced and the abuses that were uncovered by the Kennedy hearings. He held about four sets of hearings. Each one lasted about a week and about four a year.

And so it quickly came to my responsibility to write the government testimony for all of those hearings. And we supported some of the suggestions and opposed some of them. And it was largely seen in terms of how they would affect the party in power.

And, of course, in those days the Congress was predominantly democratic, very different from today's climate, and the administration was, alternately, democratic or republican.

In 1972, The New York Times--I don't think it was the first to break the story, but it featured the story on the Tuskegee--so-called Tuskegee Syphilis Study. And that was front-page news for a very long time. I think it was a newspaper in the West that first broke the story, so a couple of days before The Times got the story my boss came in, dropped about 20 pounds of paper on my desk and said, "Write the government defense for this research." I had never heard of the research at that time, but it was the so-called Tuskegee Study that is the syphilis study that involved some 400 black syphilitic males from Nathan County, Alabama, all of whom were systematically denied treatment for their syphilis. There were about 200 controls also involved in that study who were black, illiterate and did not have syphilis, but they were used as a control to compare the development of the disease of those who did have syphilis with those who did not. The government promised them health care and delivered health care except for treatment of syphilis for close to 40 years, and they followed those men. They intended to follow them all till they died.

But the story broke, and, of course, these men had never been told what the diagnosis was, their syphilis was untreated, and in the beginning that may not have been such a bad thing because the standard treatment at that time for syphilis was compounds of arsenic and mercury, and the idea was to poison the disease and poison the person with

the disease in hopes that the disease would die before the person did. So it was a very horrendous kind of treatment, and they were spared that.

But in 1943, of course, penicillin was discovered, and by 1944 it was plentiful. And from '44 until '72 these men were deprived of any treatment for syphilis which would be the drug of choice for the disease.

Anyway, I read through the whole study. It took me a couple of days because the study was, at that time, some 30 years old, and all of the data and all of that had been collected. And then I wrote a very short memo saying, in effect, there can be no government defense for this study. No consent was obtained in the beginning from any of the participants; their rights were systemically denied or overcome and, as a consequence, the only stand the government can take is to say: We will take steps to make sure that this never happens again.

Now, this study did not come out, as it now sometimes appears in our history books, in isolation from a lot of other lesser abuses that had also been conducted, and I mentioned some of those: whole body radiation was another one of the hearings that Kennedy held where the government radiated the entire body of persons with cancer in hopes of replacing their bone marrow and saving them. But the rescue technique never worked so that all of those subjects died. And it may, although it was much less publicized, may have been as serious a violation of rights as the Tuskegee study itself.

But in any case, I wrote a memo that was about a half-page long and said the government cannot defend itself other than to say it will take steps to see this does not happen again. For reasons that I've never understood, that memo went right through the system up to the Secretary. Now, if you understand what it's like to be a Grade 12 federal employee and write a memorandum, you know that before it ever gets to somebody who's high enough to do anything about it, it's ordinarily revised six, seven, eight, ten, twelve times. So that it was the one and only time in my life that I ever wrote a memorandum that went unchanged from my desk to the Secretary of HEW, the predecessor to HHS, and that person was Elliot Richardson, who was and is much better known for his later activity in standing up to Richard Nixon and refusing to fire the special prosecutor associated with the Watergate scandal.

But at that time Richardson was the Secretary, HEW, and I was called to his office. He asked me a few questions, was satisfied that the Tuskegee study could not be defended,

asked us to write the testimony, and he presented it before a hearing in the Kennedy subcommittee. Most of those hearings were not well attended, but, of course, it was standing room only that day, and even lined up way up and down the corridor because by that time the press had picked up the story, and it was front page news for two or three months at least.
After the hearing--and it was kind of interesting--Richardson read that testimony the night before he made a couple of minor editorial changes, and he took his hearing book with all kinds of background information to the witness stand or desk in the hearing room and never opened it. And he gave that testimony word-for-word as it was written. And he must have had a photographic memory because as far as I know he read it through only once and was able to repeat it about nine or ten pages of testimony without so much as hesitation.

He also did another thing that was interesting. The administration was just being killed by the press, and so not only was Senator Kennedy there but congressmen and senators from both parties were prepared to pepper him with questions. And the idea was since it was a democratic congress was, at least in part, to embarrass the republican administration. Richardson presented that whole testimony in a monotone. He never raised his voice, he never inflected a word. He just droned on reading everything--reading it off the back of his mind, I guess--in such a way that after 10 or 15 minutes, I looked around that hearing room, people were falling asleep, their eyes were drooping. It was very soporific, and he took all the fire out of that hearing, which I--and I later talked to his son who said it was a technique he learned for diffusing really hot issues when the press and the Congress were attacking it.

So that I found very interesting. I never knew that he was going to do that. I never saw anybody else do that in all my years in government. So he made it, as he took a very hot subject and transformed it into a boring topic. On the other hand, he read with some vigor the very, or pronounced with some vigor--the very final part of that testimony was that the government would take action.

After the hearing, we were invited back to his office, those few of us from the legislative office at NIH, and he simply turned to us and said,

I don't know how to do this, but make it happen. Make those promises come true." And so in a sense that was--that changed my career at NIH.

So I continued in the legislative office for a while, but I got very close to Dr. Don Chalkley, who was then the Director of the Office for Protection from Research Risks. And we began to talk about how that office which has become and even was at that time was the--what was it called?--the Institutional Relations Branch, and it consisted of four people over in the Division of Research Branch. And it had many other duties besides protecting human subjects. So it was, for practical purposes, ineffective. And we began to talk about how we could strengthen that office and turn it into a force that would truly offer genuine protection for human subjects.

Chalkley's original idea was to create committee which has since come to be called the Institutional Review Boards, but that name came two or three years later. But what he wanted was those committees to be--to review each piece of research, and a member of each committee would be assigned to be a prosecutor, and another member would be assigned to be the defendant. And the committee would serve as a jury so that the research would be attacked and defended. The jury would decide whether there was enough merit in the research to go forward, and the full of that would be documented, and he wanted to get West Publishing, the publisher's legal opinions, into the process so that when you argued a case for or against a certain research protocol, you would argue from precedent. And he wanted to build the whole system as a kind of paralegal system that paralleled our civil court system. In fact, the medical profession had little sympathy for that. He got no support from Congress. He got no support from the medical profession, and very little support from NIH. So those ideas lasted a few months and then, like a lot of other ideas in the government, they're forgotten. But it is kind of interesting to see what the original concept of an institutional review board really was.

The idea of a committee had come from the NIH Clinical Center where Dr. Felippe Cardone (ph), Phil Cardone, who was the Deputy Director of the Clinical Center through the late '60s and early '70s, decided that, well, even though--and this was the concept at the time--even though patients were involved in the research, they were to be treated as patients, and that equated to: therefore they have no self-determination about how they will be treated. But he said he could not make the same case for normal volunteers, and so he built the system within the Clinical Center whereby normal volunteers would be presented with a protocol; it would be explained to them, and they would be given a choice of whether to participate or not.

That was a big departure for the Clinical Center because in the previous decade most of the so-called volunteers were not really volunteers, they were conscientious objectors to

serving in World War II, and so they were drafted to serve as research subjects. And they were ordered to participate as research subjects in lieu of their military service. And so there was in the medical profession a long history of telling research subjects what they should do or not do because they were often referred to as deserters, even though they were, technically, freed from military service by the courts because they were conscientious objectors. But there was such a sentiment for the war that these people were not respected, their rights were not respected, and they were treated pretty much without courtesy for a number of years.

But after the war, Cardone realized they're no longer here because they're conscientious objectors, they're here because they volunteered, and we have to treat them, we have to respect their consent before we involve them in research that offers them no chance of direct benefit. They don't need the research, they're merely volunteering for the sake of society. So it was Phil Cardone and the NIH policy that began, then, to model the first IRPs.

After the Tuskegee incident, all of NIH was buzzing, and the press was buzzing, and Walter Reed Hospital, which was doing a lot of research and other places in Washington were all buzzing with: How are we going to regulate research? And so a number of bills were introduced. I think five or six in the Congress, three or four in the Senate. The one that got the most attention was a bill that was introduced by Senator Kennedy, and his bill called for the creation of a regulatory agency that was to be patterned after the Securities and Exchange Commission, and that's where the term "commission" came from in the national commission that finally emerged. But what he wanted was, technically, a separate federal agency that would regulate the federal agencies that actually fund or conduct research.

NIH, of course, was, and HEW later HHS, were not very happy about falling under the regulatory control of another federal agency, so they began to martial forces against the passage f the Kennedy bill, and so they enlisted the aid of Congressmen Paul Rogers, who was in charge of the corresponding committee in the House of Representatives. It had a slightly different title, and I can't remember the name of the Rogers committee. We just called it the health committee, but that wasn't its full title.

In any case, Rogers then introduced a bill picking some of the language out of the Kennedy bill, but turning it into an advisory commission instead of a regulatory commission. And that was really the bill that finally was enacted by Congress.

Now, lots of stuff was going on in between. The FDA, in the meantime, had stopped the dissemination of thalidomide contrary to what happened in Canada and in England thalidomide was administered to pregnant women in hopes of preventing spontaneous abortions, and so women who in their early stages, or earlier stages of pregnancy began to have contractions, were given thalidomide, and no one understood that thalidomide would cause limb anomalies in the offspring. What that meant was that babies were born with no arms, no legs, or occasionally just little stumps.
Because television was just coming into vogue at that time, the first medical hearings I ever remember seeing on television were seeing those thalidomide babies, and they created an uproad. Frances Kelsey up at FDA had reviewed the animal research on thalidomide, and she had picked up the point that when it was administered to rats or mice--I've forgotten which it was, that some of their offspring were born in a deformed state, and she refused to approve thalidomide in this country, and FDA saved what could have been an enormous scandal in this country.

And Frances Kelsey got a presidential award and all kinds of accolades for taking a very courageous stand because she was vilified by the company that wanted to sell this. And the argument was, they're using it throughout Europe, they're using it in England, they're using it in Canada, why can't we use this drug here?

It's going to help women who are pregnant, and why are we prejudiced against women, and all that kind of stuff. Now, and then when the scandal broke and it turned out she had saved many woman, hundreds, perhaps thousands, and children from the heartache of deformity, she became a heroine overnight.

So all that was going on, and it was very interesting. In the course of that, Senator Jake Javitts, who was a republican senator from New York, had insisted that from the time of the thalidomide study on, he had forced amendments to the Food and Drug and Cosmetic Act that required all drugs that were tested to be done so only after the subjects had given informed consent. And that was a big change in the way drugs were tested in this country. I think the public was largely unaware that advancement simply went to physicians, gave them sample drugs, and paid the physicians for testing the drugs on their patients, and the patients never knew that the drugs they were taking from and were given them by their physicians, not prescribed for them through the drug chain but given to them and were actually experimental drugs. And probably most families in America were subjects of drug research and never knew it.

And that had been going on since the '30s in this country, and probably all of us who lived at that time were research subjects without knowing it because physicians never told their patients:

This drug is unproven, but I'm going to give it to you anyway, and so the physicians were double-dipping. They were getting fees in those days, mostly directly from the pockets of their patients, not through an insurance system. And they were also getting fees from the drug companies for testing the drugs, so doctors were making very handsome living conducting research and keeping the data, but it was an unmentioned secret of the whole profession in this country for many, many years. And it was Javitts who put that small amendment to the Food and Drug Administration to the laws that required consent. And all of a sudden, it upset the whole medical profession and interrupted the practice.

But FDA had the little idea how to enforce it. This was a well-established practice, and it was not then until we actually codified the regulations for research in 1974 that we required research not only to be carried out only after subjects had given informed consent, but after it had been reviewed by an institutional review board. And that that term appeared first in the Rogers bill, which was the one that was largely enacted.

A little by-play occurred in between the Kennedy bill that would have created a regulatory commission and the Rogers bill that created an advisory commission.

And Kennedy said, "I will drop my bill and support the Rogers bill if the Department of Health and Human Services--or at that time it was still HEW--if the Department will issue regulations for the protection of human subjects.

The Department had had a policy since 1966 administered by Dr. Chalkley and so on, but it had never been enforced with any rigor, and mostly it was enforced by neglect. And Dr. Chalkley's way of dealing with it was simply to write in longhand--in those days we had Selectric typewriters, but he couldn't type--he would write in longhand nasty letters to university--I shouldn't tell you about it.

As the House and the Senate were jockeying for position, it became clear that some kind of bill would be enacted.

INTERVIEWER: Could you tell us a little bit about the background of the National Research Act?

DR. McCARTHY: The National Research Act, as you well know, was public law 93-348, and it was signed into law on July 12, 1974. But it came to be, because the Senate bills that were introduced by Javitts, by Senator Mondale and others, were all being coalesced into one bill that was drafted by Senator Kennedy and his staff. The House bills were gradually being incorporated into a bill that was developed by Congressman Paul Rogers and his staff, and there were three or four other health bills that were included, one of which was by Congressman Ron Cowell (ph) from upstate New York.
Ron Cowell had somehow got hold of some rather tragic pictures and accused the NIH of carrying out research that the research was in fully-formed abortuses, They were then beheaded, and their heads were perfused, and the effort was to try to keep blood flowing through parts of the brain so that outside the uterus the development of the human brain could be observed. Ron Cowell got pictures of these heads, which were, to say the least, unedifying, and circulated them to every member of the Congress and the Senate. And the letter accompanying said: This research is being conducted by the National Institutes of Health. This is where your tax dollars are going.

Needless to say, it caused an uproar and a furor. This is about two years after Roe v. Wade, and so both sides were upset on the abortion--of the abortion question. Anyway, we finally tracked it down, and this was research actually being done by somebody in Finland; it was not funded by the NIH, but an HIH grantee had gone over to Finland, met the man and taken a couple of pictures. How they found their way to Ron Cowell, I have no idea, but as a result one of the bills was to put a ban on all federal funding for fetal research, and that, in itself, was very controversial. But that was folded into the Rogers bill along with the recommendation for a commission.

So Kennedy then went to Rogers. They were apparently pretty good friends or at least not hostile to one another. And they worked it out that Kennedy would accept the Rogers bill and drop his own if the National Institutes of Health, or HEW, would issue regulations for the protection of human subjects. NIH breathed a high sigh of relief because they did not want a regulatory agency overseeing them.

So, suddenly, I received an order along with Jane Fullerton and Charley--and I'm blocking on his name from the National Institute of Child Health and Human Development--yeah, I think it's Charley Lowe, I think. Anyway, the three of us were to

draft regulations as quickly as possible. The Secretary dropped all the usual clearances for regulations. Usually, it takes about two years for regulations to get cleared. Public comment, all the rest, the Secretary waived all that and said get those regulations out there.

And that was a very funny experience for me, because Charley Lowe and Jane Fullerton, for whatever reason--and I don't know what the reason was--wouldn't talk to each other.

So I was in a committee of three, and Jane would say, "Please tell Dr. Lowe such and such." And I would tell Dr. Lowe such and such, and he would say, "Please tell Ms. Fullerton such and such," and the three of us are supposed to be drafting a regulation, and two of them are not talking to each other. So we did produce some regulation based on the old 1971 HEW policy which was referred to as the "yellow book." It had a picture of da Vinci's man on the front and so on, and it was widely used.

It was a flawed policy, but given the conditions under which we produced it, I think it was next to a miracle. It sailed right through. Normally, a regulation would have to have sign-off from every department head. That was all by-passed and went directly to the Secretary. It was promulgated, Senator Kennedy said he was satisfied. Now, who reviewed it for him I have no idea because it was full of shortcomings, but in any case he said he was satisfied. He would support the Rogers bill, and so the regulations required by the Rogers bill actually preceded the enactment of the bill. So although the requirement came in July, the regulations were published on May 30th of that year, and in the succeeding weeks, then, the Rogers bill was enacted.

Now, that was also an exciting time because now Rogers had his commission, advisory commission to the Secretary, HEW, and all of a sudden he said, "What is this commission going to do?" And nobody had filled out the responsibilities of the commission.

So I got a call one day from Rogers' staff person, and he said, "Can you draft us some responsibilities for this commission and get them down here by close of business today?" This was around 2 o'clock in the afternoon. Well, we had been thinking about this stuff for a year or two, but we had nothing on paper. And I just sat down and scribbled out in longhand the responsibilities for the commission, sent them down, which was, technically, dubious whether the executive branch should be drafting legislation for the Congress or not, or whether that was lobbying, and we could get different opinions from

different people in the department as to whether it was legal or whether it was lobbying or whether it was simply providing technical assistance. But we liked to call it "technical assistance."

Anyway, we sent it down, and those words found their way into the bill. So I actually drafted the responsibilities that the Commission was to meet. And that--and we put them all together to look into informed consent, research involving pregnant women and human fetuses they were to look in-- and that was in response to Ron Cowell.

They were to look into such matters as psychosurgery, because in those days it was fashionable to operate on the frontal lobes, and you may remember the movie "One Flew Over the Cuckoo's Nest" was based on that. And so the public was in an uproad about how mental patients were being treated.

And some had to do with cognitively-impaired individuals and how they would be treated an so on. We drafted all those, and when I read it over I said nothing holds it together. This commission will issue a report on informed consent on cognitively impaired, on fetuses, on pregnant women, on children, and is there any common theme? And I began to think back to my own training, and I had had considerable training in moral philosophy and theology, and so I said, "It looks to me as if a common set of principles ought to underlie all these different moral issues that are facing the research community and facing the country.

And so kind of as a last minute--I remember about a quarter to 5:00, and we had this old fax machine. It took six minutes to fax a page, and so we're looking at the clock, and we have to get them down to Rogers' office, and we had about one minute left when we finished writing the language for "and there will be a study looking at the principles underlying the research ethics." And I've forgotten--I don't have them in front of me--the exact wording of that in the bill now, but that's what we put in it, and it went--it sailed right through. The bill was brought to the floor of the House the next couple of days, to the floor of the Senate. It passed, and that was the beginning of the Belmont Report.

So it came out of my head about five minutes at the end of a long, busy day working under high pressure, and I'm absolutely amazed that it survived and nobody changed a word of it. So that's where the responsibilities of the commission came from, and the bill was enacted by Congress. I forget the day they passed it, but then it was signed on July

12th.

INTERVIEWER: Today some people think that the Commission's work is mostly the Belmont Report itself. Is that how you saw it?

DR. McCARTHY: I suppose I would say the most important thing the Commission did was the Belmont, but I think perhaps it did a couple of things that go along with that that are equally important. One is simply by gathering all of the information about the ethics of research that it could find in seven different languages and gathering all that background literature, it really in many ways gave birth to, or at least gave it an enormous boost to the whole field of bioethics.

Prior to that time, bioethics was limited to a handful of scholars, and they were almost all morale theologicians, so there was virtually no secular writing about the ethics of medicine, or health care, or medical research. And the Commission almost single-handedly changed all that.

The brought every scholar in the country and many from overseas to testify, and they also did a literature search into each of the topics under consideration, and then they asked scholars to evaluate all that. So it was a great shot in the arm to the whole field of bioethics, and people still say today that the Commission saved the teaching of philosophy because, usually, this is a branch of philosophy taught in our universities. It saved the teaching of philosophy in America.

I don't know if that's true or not. I don't know how to evaluate that statement, but, certainly, it gave an enormous impetus to the whole world of ideas and principles and understandings, not just for research but for philosophy in general and a whole principled approach to guiding human life. And I think that part is probably not well appreciated, and a lot of that was picked up by the Kennedy Institute. I mentioned them earlier. They then got government grants to create the best library in the world of ethical literature.

It's funded by the National Library of Medicine, but it actually is housed at Georgetown University, and I think they now have articles in ethics in about 28 languages, and they have a wonderful set of librarians. All of that came out of the Commission. Whether they set out to do that or whether that was an unexpected by-product I can't tell you, but it did happen and I just think it's an invaluable contribution to American culture and

maybe to world culture. It's another kind of favorite theme of mine that the big contribution that America has made to world culture is in two areas: 1) jazz, and 2) in ethics and moral theology, and not in government, not in all those other things, but in these two areas I think we have led the world. And those are the things I'm most proud of to be an American.

INTERVIEWER: Did you expect the Belmont Report to have the longevity that it has in day-to-day lives of institutional review boards?

DR. McCARTHY: I don't know that the question occurred to me one way or the other. I saw so many drafts of it before it came out. I saw the final draft. I never thought about: Is this going to still be guiding people 40 years after it was written? I guess I just--the question didn't occur to me.

Later on when we -- because I moved out of legislation into the Office for Protection from Research Right Risks, which was the NIH predecessor office to the Office of Human Research Protections. When I made that move, one of the very first things we did was to take that clause in the law that requires institutions carrying out research to assure the government they will comply with the regulations. Those what we call "assurances," are really assurances of compliance with regulations, and we put in there that the institution must have a set of principles.

And, of course, what we recommended was the Belmont principles. They are free to choose Helsinki or some other set of principles, but I think there are only two or three institutions in the country that don't follow Belmont as the institutional guide. And that means for the first time we had no common set of ethics for medicine in this country prior to Belmont, and that move actually made every institution in the country first think about what are our principles; and, secondly, can we live with Belmont? And the answer to both questions was yes, we can live with Belmont and we will adopt them as our principles.

So I think OPRR actually took Belmont Report off the shelf and put it into practice, and that's been continued, of course, by OHOP (ph), but I don't think OHOP really innovated anything; they just picked up what was already in vogue.

INTERVIEWER: We left off right as the legislation for the Commission has become signed. And what was the next step?

DR. McCARTHY: Well, the next six months were really organizational. One of the--I was still at that time working in legislation, and it was customary at the time if you tracked a piece of legislation you were responsible for getting it started. So we had to find curriculum vitae of several hundred people who could possibly serve on the Commission and send them down to the Secretary's office.

We had to find--and, by the way, the bill provided no money. It's typical of the Congress to write bills saying: Thou shalt do something, but you don't have any money to do it. So we had--we found space in the old Westwood Building that was not being used. We borrowed furniture from the used furniture that was turned in by government offices when it was no longer usable, but we found we could get a little more mileage out of it, and we began, then, to dun the institutes to provide us with staff whose salaries were paid by the institutes.

So they were not very happy to give up paid employees to the service of the--but we were able to bring some pressure to the Secretary on the institutes to give up employees to serve the Commission.

So all of that kind of scurrying around with the details, I'd never done anything like that, organize a body and try to find them offices and typewriters, and staff and all of that kind of stuff. And I didn't know much what I was doing, but we got a lot of help from the Secretary's office, and we got a lot of help from the Director of NIH. And if I could go into an institute and say, "I'm from the Director's office, and the Director would like," we found we could get cooperation.

And so it ran, really without budget, for the first year until we were able to put a line item in the budget to support the Commission. NIH institutes really coughed up the money out of their discretionary funds.

So that's what we did the first six months. What I only found out recently was that Charley Lowe, who had drafted the '74 regs., and Duane Alexander and Barbara Mishkin had all been involved with the Secretary's office in making the final selection from all of the CVs that we sent down to them. And I hope you will interview them and find out what criteria they used and why they made the selections they did, because the Commission, with the exception of a couple of people, were not nationally-known figures at the time. And people thought, oh, ho-hum, they're just a bunch of also-ran

writers and teachers from around the country, and it was not thought to be a blue ribbon commission at the time. Now, when people look back, of course, they think it was the best commission ever put together. But that's hindsight. Prospectively, it was not. It was thought to be a weak commission.

INTERVIEWER: Once the commission was formed, what was your interaction with them?

DR. McCARTHY: The Secretary asked for someone to serve as a liaison to the Commission, and, I suppose because I had had a lot to do with the legislation before it tasked, I was liaisoned to the Commission. And I got very little instruction as to what that meant. Somehow you're liaison to the Commission, but what do you do? I took it as my job to alert all of the research components within the Department, and that meant predominantly, but not exclusively, NIH. At that time mental health was separate agency, so I got to know them very well, by the way, because there were so many hearings about cognitive impairment and mental health issues and the like, and so that was an education for me to get to know those folks.
In any case, I kept them all informed of what the Commission was deliberating about, what the rules were likely to be, and inviting them if they had an disagreement or if they had points they wanted to make to contact the Commission and testify. And many of them did, and so we got lots of testimony from within the Department as well as from research institutions all over the country and some--a lot from England, a little bit from the Continent, I think almost nothing from Asia, that I recall anyway.

But I attended all of the meetings in Washington. As you might guess, since you work in the bureaucracy, when the Commission traveled, I couldn't get travel money, so I missed the meetings that were held outside of Washington. Travel money didn't extend to following the Commission; it was enough that I could read the transcript of what they did then they were away; but I was present there and, occasionally, they would ask me questions.

And, occasionally, they would have social events and invited me. And Al Johnson, particularly, because he had been a Jesuit priest and I had been a Paulist priest, and we had studied the same kind of curricula together for a number of years. He and I got to be very close friends. We would often have dinner together and argue out issues, and so I suppose, indirectly, I had a small influence on the deliberations of the Commission.

Ken Ryan, the chairperson, was a very pleasant person, and always very courteous, but

he was reluctant ever to tell you what he was thinking until the meeting, so nobody knew what Kenny was going to say until he said it in meetings.

Mr. Turtle was a lawyer on the Commission, a young lawyer, and he was very suspicious of government, and so no matter what was suggested, he would try to make sure that the suggestion would--by the way, that the government would have to implement the recommendations of the Commission, and the reason it succeeded, I think, was because of the forcing clause. There's a clause that I think came from Paul Rogers himself--I'm not certain of that--but the clause said the Secretary must either accept the recommendations of the Commission or public in The Federal Register the reasons for not accepting them.

Well, no Secretary ever wants to go on record as saying, "I disagree with an ethics commission." So in the past they had buried recommendations of ethics commissions, but this time they couldn't; by this, this time they could not bury those recommendations. And I think that's what made that commission different from virtually every other advisory commission I know of. As far as I know, that clause has never appeared again, and no government agency ever wants it because they want to be free to reject and bury recommendations without having to give their reasons.

And if you look at the current news today about the 9/11 Commission and whether their recommendations are going to be buried or not, the commissioners have said, "We don't want our recommendations buried like everybody else's are, so we're going to go out and stump for them." And that will be headline news in tomorrow morning's paper.

But it was different with the National Commission. The Secretary could not.

One of the funny things that happened when the bill that created the commission was being developed was a time I was meeting with Senator Javitts' staff person, and we were meeting in an empty hearing room down in the Rayburn Building in the House of Representatives. He wanted to be as far away from the Senate as possible, and this was a secret meeting because the Secretary of Health, by then seeing this bill coming along, had told NIH to butt out and stay away from that, he was going to take it over. And, of course, NIH said yes, yes, but they paid no attention.

So we were kind of sneaking around doing this, but making sure or trying to make sure the Secretary of Health would not know about it. So I'm meeting with Javitts' assistant,

and that was the day that Richard Nixon announced that Agnew was being replaced by a new vice president. And all of a sudden a press conference took place in that conference room where we were meeting. And about 40 photographers first came in, and they were snapping pictures right and left and center, and if you go back to those pictures where Gerald Ford was announced as the new vice president, you look in the back you will see two guys with their heads in their hands hiding from the photographer. And so here we were trying to be secret, and we made the front page of The Washington Post.

So anyway, that was just a funny incident, and I just died until I saw the pictures the next day to see whether they got our faces or not, and we got away with it. Nobody ever noticed who those two vague individuals were in the back. And we couldn't get out of the room without going right by the vice president--he wasn't yet vice president, but the nominee for vice president. But anyway, that was just a funny incident that occurred, and we laughed about it many times about a private meeting where only about 40 press people and the vice president were present.

INTERVIEWER: Once the Commission was formed, what was your--you were the liaison back to NIH, but how did that fit into your work life?

DR. McCARTHY: Well, we could see the shape of what was to come. First the Commission, since the Rogers bill had put a moratorium on fetal research, the very first report the Commission addressed was fetal research. And they first investigated, they got testimony from all over the country and the world whether abuses of pregnant women were occurring in the name of the research. And they got all kinds of testimony, and finally concluded that, no, there was no serious abuse of either pregnant women or human fetuses. And the bill read in such a way that fetal research may not go forward until such time as the Commission reports.

So that was the first report they issued and, once they issued it, then I sat together with Charley Lowe and by this time Don Chalkley and Barbara Mishkin, who had joined the staff of the Commission, and we drafted the regulations for the protection of pregnant women and human fetuses and got those promulgated in August of 1975, I think. So there was a little over a year of moratorium on fetal research caused by Ron Cowell and put in the bill, and we had to meet the conditions to get that moratorium lifted.

So that is one of the things we did, and we had to pay close attention. Fortunately,

Barbara Mishkin and Charley Lowe, in their previous existence, had already outlined a set of regulations for research involving the human fetus, so we didn't quite have to start from scratch. And we monitored everything that was said in the Commission and read everything we could get our hands on. So it didn't take us very long to draft those regulations.

But what is interesting to me now, looking back on them, is just the cultural change that took place over a period of years because in there we said that decisions about whether a fetus may be subjected to research which ought to be made by the mother, the pregnant woman, and the father if available.

And we got no criticism of any of that. Later on, the women's movement, women's lib took over, and 10 or 15 years later we were getting all kinds of complaints about that clause from NOW and other women's groups that this is a woman's decision, and the father of the fetus, whether it be her husband or anyone else, has no voice in making that decision.

So we saw a big cultural shift in that 10-year period that I found very interesting, that all of a sudden we were pilloried 10 years later for something about which women were silent at the time. So it showed me a kind of evolution of authority and self-consciousness and self-responsibility in women that probably was not present in the culture--maybe in rare cases--but as a general rule at the time we published the fetal regs. And that's since been modified, by the way.

But I thought that was kind of an interesting insight.

What else we were doing, we were--I was still--the Commission went from '74 to '78. I was tracking them, I was still working in legislation, and there were lots of other interesting issues, many of them unrelated either to, directly, to research or to the Commission that I worked on. There was no question of who should have access to the information in the grant was hotly contested, and that had almost nothing to do with the Commission.

But I drafted the brief for the government position that until such time as a grant is funded, the intellectual property in the grant belongs to the applicant, not to the government and, therefore, cannot be released under the Freedom of Information Act. So I was doing stuff like that.

The staff of the legislative office was in many ways the staff of the Director, so I chaired a lot of commission of different--a lot of meetings of committees of different institute directors and the like. I was the Executive Director of the Directors Advisory Committee, and so I had a lot of other duties besides tracking the Commission. And so it was a busy time for me.

And then in '78 a number of things happened. The Commission wound up its work, and so it had extra meetings and was trying to get everything published. Don Chalkley, the head of OPRR, had a stroke and suddenly was forced to resign for medical reasons and Secretary Califano was appointed.

And it was not well known, but in a previous existence I had been Califano's confessor when he was one of MacIntyre's whiz kids in the Department of Defense. And he was known as the "enfant terrible" of the government. And so he decided to create a Secretary's Advisory Committee, Ethics Advisory Committee, and so he selected me to be the Executive Secretary of the Ethics Advisory Committee.

And the very day that he appointed me to that role was the day that I was selected to be the Director of OPRR, so I got two full-time jobs the same day. And both of them were--I was informed of both of them by Tom Malone, who was then the Deputy Director of NIH.

And I said, "Tom, you know, this is great, but I can't do two jobs, and Califano isn't going to last long, I don't want that job."

And he said, "You can't say no to the Secretary."

And I said, "What do I do," 'cause I really would like to succeed Chalkley. I'm really very interested in carrying out over the years this thing, the mandates of the Commission, and I still feel that I had promised the Secretary years before that we would make it happen."

So Tom said, "Get yourself a good deputy and take the job as Executive Director of the Secretary's Advisory Committee for a year or so, and then resign that job and go back to OPRR full time."

And that's what I did. So, actually, it was 13 months with the Secretary's Ethics Advisory Board. And we worked hand in hand then with OPRR, and so Charles McKay was the Deputy Director of OPRR, and he ran it for that year. And I used to get up there one day a week. But that was as kind of an interesting dilemma.

I was in a meeting up at FDA--I forget what that was about--and, suddenly, I was summoned by the Secretary's office, and by Malone's office, and all of the phones started to ring off the hook, and I didn't know what it was all about. And that's what it was about, so--

And then in those days we always had an excuse. We didn't have any metro at the time, and so when you get a call from the Secretary's office to be down there in 30 minutes, and there was no metro, and rush hour in Washington, I was simply able to buy some time by saying, "I can't make it, I'm caught in a traffic jam. There's no way unless he sends a helicopter, for me to get downtown." So I was able to buy overnight, and I was able to work it out with Tom Malone how I was going to take two jobs at one time.

INTERVIEWER: And during that, after the end of the Commission, was OPRR issuing regulations?

DR. McCARTHY: Well, yes and no. We created the Public Health Service Task Force to take each of the reports of the Commission and draft it into regulations. So we worked about a year. There were some 125 different recommendations of the Commission that we had to work into a redraft of the old '74 regs. that we had drafted prior to the enactment of the bill. And so we had representatives of FDA, and the FDA rules were so different from the HHS rules, HEW rules--HHS, I think, came in '83--but anyway, they were so different that we had to persuade FDA to change its rules dramatically.

And they were not mandated to do so by the bill, and so I spent half my time at FDA trying to talk them into going along, and finally was able to persuade them to put a competent, highly respected person on our drafting committee. And that was John Petruchony, (ph) who later became the director of FARMA (ph) and other things. Now he runs Cancer Research Institute out in California.

But John was part of that committee, and he happened--he helped us to bring congruency between the HEW rules and the FDA rules that we'd never had before. And he did it over people at FDA, who were kicking and screaming but finally--finally

agreed to do it. And we found every different way we could think of to put pressure on FDA to do that. Otherwise we would, all research committees, would have had two disparate rules to follow in approving research. And we knew that was--would undermine the whole system.

So Petruchony is just one of my heroes. He stood up, and after it was enacted, he was under such fire he asked for a leave of absence, and he came over and worked in OPRR for about a year until the heat was off, and then he went back and worked in the what was then the Division of Biologics.

So that was some of what we were doing, but we drafted for two years. We finally had a draft ready in December of 1980.

That was after the election but when Carter went out and Reagan came in, but before Reagan had actually taken office. And Reagan had campaigned with extravagant statements saying the government over-regulates everything in the society. "I'm going to repeal all government regulation." Well, that was--you know, nobody really thought he could do that, but everybody knew that this was not a time to try to propose a new regulation when Reagan was coming into office.

So we gave a lot of thought. We had the regs. all drafted, and Patricia Harris was going out of office. She had replaced Califano after Carter fired him--not for anything to do with human subjects or even the Ethics Advisory Committee, but because he had campaigned against smoking in both North Carolina and South Carolina in an election year. And he lost both states for Carter, and Carter was furious. So that was the sort of by-play that was going on at the time.

But we were trying to decide when is the appropriate time to get the Secretary to sign off on the new regulations? They had already been proposed, we had got comments from the public. We'd incorporated the comments. We wrote the preamble, it was ready to go. And then when is the best time, 'cause Harris could care less whether they every got published. So we talked to the transition team, and they said Reagan will never allow new regulations to see the light of day, so if you're going to get those out at all, you'd better get them out before he takes over.

So we're struggling with this problem, and the way we worked it out was that's when we wrote, overnight one night--brilliant inspiration--we wrote--everybody stayed in the

office, and we worked all night long, and we wrote the exemptions to the regulations, and we also wrote expedited review neither of which had ever been addressed by the Commission. And that's where they came from.

Then we went to the transition team, and we said would the transition team endorse regulations that are less stringent than the previous regulations? And, of course, they weren't, but they looked like they were because we wrote some exceptions. And so when we sent the package down to Harris, we said "Diminished Regulations for the Protection of Human Subjects." And that was the title. And, of course, we knew nobody down there in the last weeks of the Harris administration getting ready to leave office would actually read it. So they didn't know what all that was about, but they could read the title.

And so Secretary Harris signed that at her farewell party. She put down her glass of champagne and signed the regulations on January 19, 1980, and went out of office on the 20th. So we squeaked by. Those were some of the adventures we had that were kind of harrowing for regulators, and that's why some of the language in those exemptions is so convoluted because it was really a first draft. But it survived and it's still in there. And it makes some sense, but if we could rewrite the regulations, we would run that through three or four more drafts and make them crystal clear. They're less than elegant writing, whereas if you read the rest of the regulation, I think you'll find sub-part A is very well-written if you leave out the part about the exemptions.

So that's some of what we were doing. Does that make some sense to you?

INTERVIEWER: Absolutely. Was there a reason the Commission did not address exemptions or--I'm sorry--expedited?

DR. McCARTHY: I don't know. They were not looking to reduce or to minimize regulatory burdens on the research community because their hearings had led them to concentrate first on major invasive research. And I don't think the Commission ever fully appreciated how much research is carried out at minimal risk level. All the kinds of psychological and survey research done by sociologist and by psychology 101 students and all that, there are hundreds of projects every year that are pretty innocuous. They ask you questions like, "Is your favorite color blue, or gray, or red, or yellow," and they try to draw some kind of psychological conclusions from that stuff. But it's really minimal risk kind of stuff.

And the Commission wasn't--I think all of these were focused on fairly high-powered medical research and unaware that the regulations extended to social science research. Their mandate, if you read the bill, extended to social science research, but you cannot find a report on any of that. A couple of mentions made indirectly in the Belmont Report, but just in passing. So I think that was--the Commission did a wonderful thing, and it was a great commission. But I think it missed a major part of its mandate in dealing with social science research. And I think that's still a problem. It was a problem for OHARP (ph) and for OPRR. It is a problem for OHARP. And until we find a better way to deal with that, I think it's going to continue to be a problem

And for that I don't know whether to fault the Commission or simply say they had worked very hard for four years, and they were exhausted, and they were just not going to take on one more big issue. And so they didn't, and they didn't fulfill their mandate in that regard.

And that's why one of the first things we did when I took over at OPRR was publish a handbook on behavioral and social science research in the IRB. And we got Joanie Seebert (ph) from--I've forgotten what school she was with at the time, somewhere on the West Coast--who was the editor of that book, and we gave it wide publication to try to help people in those fields.

And we had to decide when is legal research invasive of human subjects' rights; when is historical research invasive of rights? And so we had lots of interpretation to do because the Commission never addressed those kind of questions. All of that came from within our own office, not from outside.

INTERVIEWER: One of the issues or topics that I've heard you speak about before is the part of the Commission's work as well as the subsequent regulations that dealt with prisoners. Could you tell a little bit about it?

DR. McCARTHY: Well, the report of prisoners was developed by the Commission, at least in my judgment--and others may disagree with this--but in my judgment it was the weakest of all the reports that the Commission put out. They visited Jackson Prison in Michigan before writing the report, and at Jackson Prison they found serious abuses. First of all, they found that the prisoners were malnourished, that they didn't get adequate medical attention, that they didn't get reasonable amounts of exercise, that

their sanitation was poor, that they were overcrowded in the prison environment.

Just about every kind of malpractice for running a prison that exists was there, and in that context the pharmaceutical houses came in and offered to involve the prisoners in research.

And what that meant was in most cases one or two days a week they would meet with somebody from outside, so the boredom was relieved a little bit. It also meant that the incoming researchers would complain to the prison authorities that the johns were filthy and the food was lacking in nutrition. And so they found that research was a big boon to the living conditions in Jackson Prison.

And when the commissioners went up and talked to the prisoners, that's what they told them. They said, "Do no take away research, because it is the only place that keeps us--the only thing that keeps us sane in this place." And the commissioners came back and realized that the Commission--the prison environment was coercive. Those prisoners had virtually no choice. If they wanted any kind of decent living conditions, they had to agree to research, and much of it was very invasive and dangerous, and the prisoners vied with one another to get into those research studies.

One of them I recall was the study--and it sounds innocuous enough--but it was a study on shampoos.

And so the way they studied it was simply to put together all different kinds of hair shampoos, and then they would drop it in the prisoners' eyes to see which ones--which of the soaps were so toxic that they would blind the prisoners. And a number of prisoners were blinded in those studies. That's one reason why to this day I won't use Johnson & Johnson baby shampoo because the way it was developed caused terrible blindness to a number of prisoners. And it just infuriates me when I see it on the shelf. I want to throw it in the trash because it was not necessary to do that.

But in any case, the Commission then came back and decided its mission was really to reforms prisons rather than set standards for prison research. And so they put--if you read that report, they put: No research may be done in prisons unless HHS has determined that the food is good, the sanitation is good, the exercise is good, and all those things that are outside of the jurisdiction of NIH or HHS, and, consequently, nobody could meet any of those conditions, and it said very little about the coercive

atmosphere of the prison if it was well run, if it was humanely operated.

And so it placed on the investigator a reforming role, if you want to do research in there, you've got to go reform the prison. And I think they missed the whole point about that HHS, that the Justice Department has the responsibility for federal prisons; the states have responsibility for penitentiaries, and HHS has no legal or experiential responsibility for any of that. And as a consequence they were trying to load onto research the whole--a whole prison reform movement, and the regulations couldn't possibly carry that burden.

So we drafted the regulations leaving out as much of that as we could while, nevertheless, we did invite Justice to come in and help us draft so that they would understand these guys are telling you you're running a terrible prison system, and you ought to change it. But we can't change that by writing research regulations. And so we had--that was the second set of regulations written after the pregnant women and the human fetuses.

A guy who was staff in ORPP, Norm Gulay (ph) drafted them, and I don't want to say anything negative except he had little idea what he was doing. Every office has somebody that should be put out to pasture, and in that case it should have been Norm. And why he was assigned, it was prior to Chalkley's demise, I think, because the Commission was still going. I think it was '77 when we drafted them--and weren't they published in '78?--so it was '77 when we drafted them, and why Chalkley assigned Delay to write them, I don't know.

But it was a terrible job. The Commission put pressure on us to get them out there, and what I'd like to do is retract them and rewrite them, and I would like to see a kind of mini-commission look at prisons today. The whole field has changed. HIV has changed the medical aspect of what it's like to be a prisoner, dramatically, so that we're not even dealing with the same kind of issues that we dealt with then. And I'm not quite sure what the prison regs. should be, but I know that they're nearly impossible to implement, logically and consistently, in their present form.

INTERVIEWER: Okay, I just have a few more questions about your experience with the commissioners. One of those is what topic do you remember as having generated the most discussion among the commissioners themselves?

DR. McCARTHY: Oh, I think probably the classic debate over research involving children was--was just first of all they had the best scholars in the country, and those scholars devoted major quantities of time to addressing this, and the whole issue of whether a class of citizens who are legally not competent to consent could be involved in research was hotly debated. And the background, of course, is that French, the French thing, any research involving a child is immoral, and they make no bones about criticizing us. The Germans, after World War II, were so sensitive about all the abuses of children they had conducted that they banned children's research.

Here is NIH with its Institute of Child Health and Human Development, and it was under attack. And there were several research projects that I'd have to go look them up to be sure now that were criticized that were carried out in children. So the whole notion of allowing research with children was under fire.

On the other side, Bob Cooke was one of the Commissioners, and he had been the director of the Kennedy Foundation and part of the very reason for establishing the commission was to see what kind of research could be allowed that would improve the lot of children, and especially handicapped children who were housed but not helped by any research going on. And so Cook was arguing strenuously for research with children, but he was arguing for it within the context of more animal research. And that generated all kinds of ethical--stimulated a lot of criticism from the animal activists, so the Commission was getting some fire from that side as well.

And Mr. Louisell, who is a lawyer who had practiced before the Supreme Court, took the side that children cannot consent, and parents are biased and therefore should not be able to consent on the children's behalf, and therefore, you can't do much if any research with children. He wanted to limit it only to that research where there was no standard treatment available to a child, and it appeared to be in the best interest of the child to participate. But no other research could go on unless--there was no standard treatment for anything that the children might need.

And so it was--it was hotly debated, and Dick McCormick, who was the head of the American Catholic Theological Association at the time and a Cardinal Spellman scholar, wrote an article in which he argued that it is a parental duty to introduce the children to some form of civic contribution. And one way to do that is for parents to volunteer their children for low-risk research even when there was no direct benefit for the individual child, but by learning to participate in society as a whole, children themselves would be

benefitted. And he argued that it was part of a child's education and an obligation of parents to volunteer the children to do some kind of social action and a major--and research would fulfill that obligation.

It is interesting that the Commission then came out with its recommendations. They followed everything McCormick recommended, but they left out of their report any theoretical justification, so it kind of stands there, and if you were there you'd say McCormick won that argument against very strong opposition. But you can't find it anywhere in the report.

And I can't tell you why the drafters did that.

I can guess that because it was coming out of Catholic moral theology, they decided they didn't want to take on another critic. They didn't want to get into trouble with the Protestant community in this country; they didn't want to get in trouble with the secular people who said, "You're following religious arguments," so they just left it out altogether, and there it stands, a beautifully modulated set of recommendations with no justification.

And I don't know all that went on in that debate. I know you're going to interview Bob Levine, or at least I think you are, and he did a lot of this drafting of the Children's Report for the Commission. And he, perhaps, can supply some of the rationale of that that's missing in the report. But I think it was their finest hour in terms of the result, and maybe the weakest in terms of justification of the whole Commission.
But that's my opinion, and I'm not sure it's right. And I never talked to Ken Ryan about that.

And Ken, of course, because he himself was a pediatrician, had a lot to do with that. And as you recall, Louisell and I think maybe Turtle, also --I can't remember now--but Louisell dissented and wrote his own report, but it never went anywhere.

INTERVIEWER: Were there other areas that the Commission did not touch on that you felt might have or should have?

DR. McCARTHY: Well, I mentioned the social science and behavioral science side, and that really was a disappointment to me that the Commission didn't do it, didn't address those questions. I think they did poorly with the prisoners; I think they did well with

the fetuses, particularly under that was their first report, and it was rushed, and I still think they did well. I think they failed to understand with respect to--what's the word that we used in the legislation that was popular at the time?--now it would be regarded as prejudicial--for the cognitively impaired. I think "mentally infirm" is what the legislation said.

That report failed completely to understand the deep division that existed at the time when we were coming out of the Freudian emphasis on deep psychotherapy and moving towards treating mental illness by drugs. And the field was deeply divided, I mean to the point where there were threatened fisticuffs in meetings, psychologist and psychiatrists as to which is the best way to treat the patients. And the Commission seemed--made almost no mention of that, and, as a consequence, they really didn't ever distinguish kinds of research that might be carried out with the mentally infirm, nor the climate in which the regulations would, would come out if they were published.

So we published the proposed rules that reflected the Commission's report, and they were eaten alive.

The two sides both rejected them because the regulations came out in the middle, and neither side wanted them. And so the whole--Adam taught the whole Alcohol/Drug Abuse and Mental Health Administration refused to sign off, and the Secretary said he wouldn't publish until they signed off. And so that was a standoff.

On the side, civil rights lawyers said: You haven't sufficiently protected the rights of incompetent--and they linked everybody who had a mental illness as being incompetent--incapable of consent. You're going to give them drugs, and they can't even consent for what, and you're going to abuse them. And so we had a brouhaha, and as a result, we were never able to get any Secretary to sign off on those regulations 'cause it was fatal. You would always have two or three groups against you and only one for you if you signed off, no matter what the regs. were. And I think the Commission's failed to acknowledge some truth in each of those camps and find a middle ground.

And so, as a result, we published proposed rules, and they were so controverted that they have never--the proposed rules have never been withdrawn because no Secretary even wanted to withdraw them and attract attention to them again by withdrawing and saying: We're not going to implement them. So, in fact, they're there as sort of guidance rules, but they're not implemented.

I don't know if we could do better today. We couldn't do any worse. And so I thought that that was another place where the Commission was weak.

INTERVIEWER: You were telling about just some of the broader aspects of finding humor during areas of hard work.

DR. McCARTHY: We had lots of good people in OPRR, but not all of them were good. Through the whole Reagan administration for eight years there was a freeze on federal hiring, and, consequently, when somebody left or retired or simply when--when you need to expand because research was expanding dramatically, we couldn't expand our staff. So I went around NIH, and I went to each institute director and I said, "I know you have somebody on your staff that is causing you so much trouble you would be willing to get rid of that person and give up the position." And so OPRR became known "refugium petratorum" (ph), the refuge of sinners. But if they were kicked out of every place else, and they were so bad that people would give up the position, then we would hire them.

And so we had some pretty unreliable employees there for a while, and trying to rehabilitate them and give them some responsibility of morality and morale was a real management challenge. And we accomplished a lot of that by simply fun. And, unlike OHARP today, OPRR had responsibility for laboratory animals, so nearly half our staff were laboratory animal people, and they were looking at all the demonstrations against research with animals and so on.

But what I found is that veterinarians, particularly, are among the earthiest people in the world. I suppose it's because they mostly grew up shoveling manure out of barns. But in any case, we had lots of humor going on, and Nelson Garneth (ph) and John Miller kept the office laughing all the time, and so there was--and Kay Duncan was herself a comic. She would come into the office some days dressed as a witch with the big, high black hat on. Some days she would black out every other tooth in her head so that she looked like she had somehow been in an accident. Sometimes she dressed up like a frontierswoman, and she'd come in with her little wooden gun. Today she probably couldn't get it through security, but she came in with a little wooden gun, and she would threaten people if they didn't line up. And she dressed for the season; she dressed as a sort of female Santa Claus at Christmas time and so on.

INTERVIEWER: Well, you know that all people in OHRP are going to laugh when--

DR. McCARTHY: Well, it's okay. Duncan was really a favorite. Kay also had congestive heart failure for the last 20-some years of her life, I think, and she handled most of the assurance documents, what we called in those days "general assurance documents." That's all been changed in recent years, but every time she picked up the phone she first did that kind of cardiac cough and clearing her throat. So there is not an administrator in the country who didn't call in to OPRR, and the first thing you'd hear was this loud, crashing cough in their ears and clearing of her throat, and expiration of the phlegm in her mouth, and then she would start to talk. And she was just infamous all over America for doing that to everybody she talked to--and she talked to leading people in every institutions in the country.

And so they started out by just being horrified and ended up falling in love with her because she was such a great lady. She was truly a great lady. And one of the funny things that happened, she came in my office, slammed down her purse and said, "I'm quitting. I'm not coming back."

And I said, "What happened?" We had a summer employee--that was another way we supplemented the failure to be able to hire--we had a summer employee who found out she was an M.D. So he asked her to go in the men's room with him and examine him for sexually-transmitted disease, and she was insulted and furious, and came in and quit on the spot.

And I didn't help matters very much because I laughed. But when she calmed down even she could laugh about that stuff.

But we had Helen Gordon in the office. Helen never believed that--that computers were here to stay, and as a consequence she kept a copy of every piece of paper that ever went in and out of OPRR until we had to go in there at night and clean out her office by the truckload of stuff because she would never--no piece of paper was without its value as far as Helen was concerned.

So we had some characters.

INTERVIEWER: That's wonderful. Some people feel that the focus of human subjects has shifted away from protecting from risk and towards permitting access to innovations that may be

helpful.

DR. McCARTHY: Well, I think that happened, but I think the pendulum is swinging back again. Initially, what the Commission felt needed stressed, and partly because of Tuskegee and some of the other various serious abuses that I mentioned, the commissions wanted to make sure that the informed consent stressed the risks of participating in research. And I think that was stressed to the point where the African American community in this country is still very reluctant to be engaged in research because they know the Tuskegee study and not much more, and they don't realize that in many cases research holds out marvelous benefits for them that they could not get anywhere else. So I think as far as the African American community is concerned, they've only heard half of the story.

But in 1983, the AIDS virus was isolated, and for the next three or four years there was virtually no treatment for AIDS, and, consequently, those who had HIV infection or AIDS and no place to turn but to research. And we had demonstrations demanding that we create more research projects because it was the only way they could get their disease treated or at least examined. And they could get the accompanying care even if they got very little benefit from the therapy in some of those early research projects. They could get the benefit of care, and it was paid for by the government.

So the pendulum swung away from protecting against risk to offering us the latest and best in care and service. And then I think the 13 or more institutions around the country were shut down for research abuses, mostly in the time of Gary Ellis when he was director.

And all of a sudden the risks of research began to be re-emphasized, so I think we're now kind of back in a middle ground with the opportunities to participate in research there, but also the risks are not downplayed. And I think that is a happy balance. And right now I think OHARP is playing both sides of that street very effectively and very sensibly. So I'm very pleased with the approach that looks to me as if Dr. Schwetz is taking.

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

DR. McCARTHY: No, I don't think so. I think every new generation of researchers--and typically a generation only lasts about 10 years--researchers study a long time, they get into the field, they--they have brilliant ideas, they work them out, they burn themselves

out, and then they either become administrators or go into the practice of medicine or some other distantly related to medicine or behavioral research.

So I think every new generation comes along, has to be re-educated, has to be reined in. They have brilliant ideas, they're contributing enormously to society, but unless we have a strong regulatory environment I think they're going to abuse it again. And I don't think that's ever going to stop because I think research, while people talk about it as a life-long career, in fact their productive years in dealing with sick people are often limited to five or ten years. And those are times when they're so excited that they found a cure for AIDS or for cancer, or for some other disease, they forget all about the rights of their subjects, and they feel as if no one has ever had this great insight before or ever will again, and there should be no restraints on them.

So it's my feeling that they should--that they need to be reined in, and the IRB is doing an excellent job of not killing the research but protecting the rights of the subjects.

It seems to me that medical schools in particular are--their curriculum is so full, and they're cutting corners everywhere they can to cut costs, have left out of the curriculum how to do research. And, consequently, I think the IRB has willy-nilly been drawn into the role of the teacher of how to develop a clinical trial out of conducting clinical trial, how to do good research. And so I think the IRBs have become in the academic institutions of our country the only place where a young investigator can get good training in how to do research, how to make sure the results are properly--have sufficient power, that the statistics are right--that the research is properly designed and all the rest.

And so I think the IRBs are spending more time for protocol because the young investigators are coming in and writing awful protocols. Nobody taught them how to do it right. And the IRBs, I think, are maintaining a tradition of sound research in this country that makes them invaluable, not only for protecting human subjects but for continuing sound clinical research.

INTERVIEWER: So with this new generation of young Turks in every cycle, do you think it's every possible that there would be another study like Tuskegee?

DR. McCARTHY: When I was in the government, I learned to say never say never. I hope it's impossible, but a few times I have seen people who seem to be somehow

morally indifferent to the rights of others. And that's--I see that occasionally in the highway, I see it occasionally in other parts of our society, and rarely but not--not totally absent, it's found in the research community itself. Every once in a while there's a cowboy who is lawless, and I think the research community is not totally immune from such rare individuals. Thank goodness they're rare. I'd like to see them so rare that they don't exist, but maybe that's too much to hope for.

INTERVIEWER: You mentioned in an earlier point about the changing environment for research over the past 25 years, and one of the areas is clinical trials and multicenter clinical trials and such. Could you talk a little bit about that?

DR. McCARTHY: Well, the whole system was based on the assumption that a research investigator would be in an institution would recruit subjects from the local catchment area, would conduct the research, report to the IRB, and it would all be done locally. Those days are gone for the most part. They're still a lot of small studies that are done, locally and by individuals, but the larger and the riskier studies are almost always multi-centered.

The lawyers have got into the act. They're so afraid of the institutions being sued if anything goes wrong that they insist that every institution carry out a full review of a project even though it may be conducted in up to 125 other institutions. And that's, I think, in our society with the cost of research, we cannot afford to duplicate efforts 125 times when it offers minimal return, maybe no return to the subjects. And it simply delays the research, adds to the cost, and adds nothing to the protection of subjects, but it adds legal protection to the institution.

And I think there are other ways to deal with them. I think we could create some kind of an assumption of legal innocence until the standard of proof abuse is very high and handle research violations of the rules much as OHARP does anyway by simply shutting down projects that don't meet the rules and limiting the legal liability of the institutions. And that way I think institutions would accept one another's review. We could cut down the review and have all the quick, maybe something like an expedited review of these multi-centered trials, reduce the cost and the human effort tremendously and not put subjects at any greater risk, or very little if any. So that's an area where I think we need to work, and we have to work with the legal community, not despite the legal community, which has been the tradition in the research community.

They don't want anything to do with the lawyers, and the lawyers don't want much to do with them, and the result is the lawyers have put up some constraints that make research very difficult.

INTERVIEWER: Do you think the regulations 45CFR46 appropriately embodies the three ethical principles identified in the Belmont Report?

DR. McCARTHY: Let me come back to "appropriately." But, in fact, the way they were written was simply to take each Belmont principle and then write the rules to implement the principle. So the very heart of the regulations are the Belmont principles. And when I teach them to our own IRBs, what I teach is Belmont. And I say, "Now, what are they? What is informed consent," and read out of Belmont.

And then I say, "How is that implemented in the regulations," and find the whole section of 46-116 and the sequelae there to show how this concretizes the principle of informed consent.

We do the same with the IRB responsibilities on the 46-111 for justice and also for balancing risks and benefits. So I think, yes, they embody Belmont. Whether--I think you asked the question "appropriately," and here I think the climate at the time of the Commission and the focus of the Commission itself was protecting the individual subject and protecting his or her rights. We have now moved where you can scarcely affect any subject without affecting that subject's family, without affecting that subject if the person is an adult--employment, health insurance, all the rest.

And, therefore, I think we need--and here I'm going back to something Jim Childress said at the recent symposium--I think we need to reinterpret those principles that can be read in such a way that they apply to more than just the rights of the subjects themselves and apply to the subject's families, employers, community and so on. I think it will be a major undertaking. I wish I were 25 years younger because I would--I would try to get a grant somewhere and start writing about this stuff. It excites me. It's not easy but I think it must be done, and so, yes, Belmont in some sense has gone as far as it can go in protect--

I think the task of reapplying Belmont principles to more than just the subjects is very difficult because it's hard to know if this is stopping point. If you go beyond the subjects to their families, to their communities, to their businesses, then Belmont will be used to

protect everybody. And if that occurs, it probably will protect nobody. I don't think the system can support that much.

So finding ways to make them, their application wider without making so diffuse that they're useless is going to be a major intellectual enterprise, and I wish I were younger so I could undertake it.

INTERVIEWER: Do you think that the Belmont principles are absolutes that override all other considerations? Or do you see them more as factors to be used in balancing the risk of harm?

DR. McCARTHY: I guess I would want to rephrase the question. Certainly, they're not absolutes, because even the Belmont Report itself says that sometimes they're in conflict, and the conflict has to be resolved, which means you can't follow them absolutely or you are contradicting yourself.

So they are meant to be general value guidance, and they have to be supported by reasonable understanding of factual situations, and that's the way they're to be read. And if they are read that way, I think it's very rare that they don't service well.

INTERVIEWER: There's an area that we haven't touched on, the Belmont Report's ethical framework in an international setting.

DR. McCARTHY: Because Belmont, at least superficially, looks like the work of Tom Beecham and Jim Childress, their ethical textbook, because they identified three basic principles, and their vocabulary is very close to, but not the same as Belmont. I think that book itself, although widely endorsed in this country, is controversial overseas.

When I was in Scandinavia, they used to refer to it as that the "George with contempt," as the Georgetown mantra. And, unfortunately, because of the superficial similarity, the criticism directed against Beecham and Childress, even though I happen to think their book is very good, the criticism directed against them gets directed against Belmont as well. So that's the first problem with applying Belmont overseas is that they mix it all up with Beecham and Childress, and that's unfair but it happened.

Secondly, I think the Europeans, particularly the Scandinavians and the Danes, and to some extent the British and French, have for years used Helsinki. I think Helsinki in my judgment is inferior and far less useful and much more prescriptive and less rational

than Belmont. Nevertheless, because they invested so much time, talent, energy over a period of 40 or 50 years, the Europeans are reluctant to let go of their system and adopt ours.

So I think Helsinki, we might be better off if they'd never been written, and that, itself, is a pretty controversial statement. But it's my view, and I think the Europeans are somewhat unreasonably hanging onto the Helsinki and setting it up as opposite to Belmont whereas, in fact, I think the proper way to read Helsinki is in the light of Belmont. So my view is that's why it's been slow to catch on.

The Japanese just want to please the westerners so they can get more research dollars. They'll go along with any system of ethics as long as the dollars come with it. And maybe that's too critical of the Japanese, but in any case, I don't see really sound that I think's coming out of Japan. Mostly, they're content to follow Belmont, and they could do a lot worse.

INTERVIEWER: Is there any other topic or area or issue?

DR. McCARTHY: I've been talking about two or three hours. Great. I can't imagine any other area that ought to be addressed except to say that as research changes, then I think the application of Belmont and the rethinking of ethics must be a constant process. So I don't think there is ever a point when you can say: Now we have it all figured out. Belmont is not written as if it's rigid and to be applied, but, rather, it is to guide our thinking. And as long as that thinking is creative and imaginative and concerned for the rights of others, then I don't--do not fear for the research that is to come.

But that requires sound and well-educated people to understand the spirit of Belmont and to be willing to do the intellectual hard work to make Belmont realistic instead of simply an icon.

INTERVIEWER: Tell me about stem cell research.

DR. McCARTHY: Stem cell research really involves cells that are as yet undifferentiated, and we're usually talking about stem cells that are associated with fertilized ova. So they are other kinds of stem cells, and I'm not addressing those at the moment, but these cells are so undifferentiated they have the full genetic code of a human being in them. But if you divide them you will get two human beings. If you divide them again, you

get four human beings. They are not and cannot be, by definition, unique human persons. Our whole debate about abortion is the issue of whether the use of stem cells is somehow dealing with the abortion question, and that's often defined in terms of, from a conservative point of view, that you have a living human being from the moment of conception. In fact, that cannot be true because you can take that fertilized ovum and divide it, and then you've got two living human persons.

What the debate should be about is not about whether it's human--it certainly is human--a fingernail is human, a skin graft is human, an eyebrow is human. What the question is: When is this living piece of human tissue, when does it become a living human person to which we attach rights and dignity? And no one that I know of--and I don't think there is any side to the answer can tell you when that occurs, but they can tell you when it cannot occur, and it cannot occur if you can take this embryonic cell, or set of cells up to about 16 and divide them and get twins, you cannot --it cannot be a unique human person if it can be divided. So the earliest point in the development of the embryo where you could possibly make the case that you're dealing with a unique human person is when the cells no longer can be divided and you can get surviving duplicates, identical twins.

And that point comes when they begin to differentiate, and you begin to get some kind of a nervous system. It's sometimes called the primitive streak, and eventually it will grow into a spinal column and develop a brain and other things. That's the earliest possible time. It comes about 16 days after fertilization is complete. Fertilization itself lasts about 18 hours, so there is no moment of conception. That's a misnomer.

The notion that you have a unique human person from the moment of conception makes no scientific sense, so the stem cell cannot be a unique human person. Since it has the potential of becoming one, it is not therefore worthless. It has value, but that value, it seems to me, is respected by developing it into a stem cell and using--or into a cell line and using that cell line to improve or to cure disease. And that seems much better, to me, than simply discarding stem cells and say we're doing that because we're respecting their dignity.

So the argument for not creating cell lines and not using embryos seems to me to be a very false one and scientifically untenable. Where I would, as we can find this in the old HHS, Secretary's Ethics Advisory Board, where we address the whole question way back in '79 and published a 100-page report and a thousand pages to back it up, stem

cells, embryonic stem cells, are discarded after almost every human intercourse because approximately 60 percent of fertilized ova are spontaneously aborted anyway. And if you say each of those is a unique human person, then it seems to me you're getting into a position of saying that 60 percent of the human race dies before 12 days old, and somehow that seems to me to be defiant of human reason.

So we addressed all that stuff years ago because we knew it was coming long before it was actually possible. And somehow I think the Bush administration has simply closed its eyes and its ears to the scientific facts surrounding this because they want to please the Right to Life people. But the enlightened Right to Life people don't--are not opposed to stem cell research either.

A classic example--I mentioned Dick McCormick before, the head of the American Catholic Theological Association--has supported exactly the same position that I just argued for, and so it's not a matter of religion or any of that; it is a matter of facing the facts about what a stem cell is.

And so I feel very strongly that we're simply driving this research overseas. It's cause a brain drain here. Eventually, we'll have a new administration, and we'll be starting after the rest of the world, and I think that's not a very wise public policy.

INTERVIEWER: Thank you.

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