November 9, 1999. Interview with Charles R. McCarthy, PhD, Senior Research Fellow, Kennedy Institute of Ethics, and former Director, Office for Protection from Research Risks, NIH. The interview is being conducted by Judith P. Swazey, PhD, at the Clarion Hampshire Hotel, Washington, DC.

Swazey: Can we start with a little bit about your family background? What your parents did? I know you were born in St. Paul.

McCarthy: I think our family was almost like a novel. My mother was second generation from England. Her father migrated to Minnesota where he developed better methods of churning cream into butter. He worked in a dairy; eventually he came to own the dairy and over time, developed a monopoly on the dairy business in Minnesota and Wisconsin, the two biggest dairy states in the country. So my mother belonged to one of the wealthiest families in Minnesota, maybe in the whole Midwest. She grew up in opulence. Her childhood home is now long gone, but the St. Paul Cathedral sits on the site. It’s one of the choicest pieces of real estate in Minnesota, overlooking St. Paul, and overlooking the capital building. So that’s my mother...her family was very unusual. Her family owned the first car in Minnesota. Her brother owned his own car at about age fifteen; you didn’t need licenses in those days. He got so interested in careening around in that car that he got into racing. He won the Indianapolis Speedway Race a couple of times, and held the world land speed record. He and his brother both became
engineers and invented all kinds of stuff. They were very creative, but looking back, I would say they were spoiled brats! They were looking for anything that was new, exciting, and different.

My father was a tough Irish kid from the West side of St. Paul; that was the Irish community in those days. I think it’s mostly Hispanic today. He put himself through college and then studied law by apprenticing himself to a lawyer. So he read the law but he didn’t go to law school. My parents met at some kind of a high school dance. Mother’s family wanted nothing to do with Catholics; my dad’s family wanted nothing to do with Protestants. They courted for a couple of years and wanted to be married. Both families said “no.” They broke off their relationship a couple of times but eventually they were married. My mother chose to study and become a Catholic; like a lot of converts, she became more Catholic than the Pope! Her family felt so strongly opposed that they didn’t come to her wedding. She was largely ostracized, but they gave her a big dowry. My father was very proud and very proper. He invested her dowry for her, but wouldn’t touch a dime. Eventually the Milton Dairy business failed. In the 1929 stock market crash my mother lost every penny of her dowry. My father became the attorney for the St. Paul Street Railway, that was the local streetcar company at the time. He was relatively affluent during the depression. He contributed to the support of my mother’s family during the depression, even though her family
would scarcely speak to him.

Swazey: That must’ve been a bitter pill to swallow.

McCarthy: That made the tensions between the two families only more intense. They hated to accept his largesse, but they were also pretty desperate and had never before functioned without having plenty of money. As a child, I heard a lot of talk about the “damn Protestants” coupled with the “damn English”, my mother being of English descent, because my father was very sympathetic to the Republican cause of unification and freedom of Ireland. Late at night when I was supposed to be sleeping I would hear him, gathered with his Irish cronies, and they would whisper and whisper. What I think they were doing was raising money for the IRA at the time, though I don’t know that as a fact. Then they would end up singing Irish songs at the top of their lungs expecting the kids to sleep through this.

Swazey: How many kids?

McCarthy: There were eight children in my family, which I think was also a bone of contention. The Protestant side of our family made the usual comments about, “those damn Catholics don’t do anything but breed!” My father went out of his
way to take every occasion to show his pride in the size of his family. Such
bickering produced a kind of tension which I gradually came to hate. I was the
sixth out of eight, four boys and four girls. I went through Catholic grade school,
high school, and college. My father had carefully chosen our residence in order to
be within walking distance of all three. I am the only person I know who walked
to grade school, walked to high school, walked to college, and lived at home
through the whole period. I never even had to have a car to get to school. I was a
day student living at home until I entered the seminary. So I led a fairly sheltered
Catholic life. Minnesota has a Scandinavian, German, Protestant population with
the exception of Catholic St. Paul which is where I grew up. After the Civil War
Archbishop Ireland had been appointed as the administrator of the land grant
program. He got J.J. Hill, who owned the Great Northern Railway, to buy him a
ship and it plied back and forth between Ireland and the U.S. bringing in Irish
immigrants and settling them along the right of way of the Great Northern and the
Northern Pacific Railways (twenty acres and a mule). I’ve come to believe,
although I can’t prove it, that the Irish potato famine was largely caused by the
fact that the Irish were such terrible farmers. They came over here not knowing
how to farm either. They eventually sold their land to the Germans and the
Scandinavians and they moved to the railroad centers. About 90% of the
employees who work on the railroad are of Irish decent. St. Paul was a big
railway center, so the Irish migrated to St. Paul which used to be called “Little
Boston.” We used to think we were going into enemy territory when we crossed
the Mississippi river into Minneapolis, which was predominantly Scandinavian. I
remember seeing signs in the windows in Minneapolis, “Help wanted: Catholics
need not apply.” From my earliest memories, I hated religious controversy. I
think that really shaped me in many ways.

When I got through college where I studied physics, and majored in
mathematics I started law school at the University of Minnesota. This was 1948.
Up till then I had never been schooled outside of a Catholic educational
institution. At law school there was a tradition that every day after class,
somebody would stand at the top of the law school steps and give a speech.
Students would stand around and jeer, or cheer, or argue with, or defend the
speaker. A lot of students defended Communism in 1948. One day a guy got up
on the law school steps who was a professed Communist and an atheist. He
attacked the Catholic Church. I got so angry that I went up to the top of those
steps--to this day I don’t remember what I said -- I was just yelling and hollering
and ready to punch him out. It was the first time I ever felt so strongly about my
own religion. Previously I never thought to defend it because I had never been in
any hostile environment outside my extended family. Why should I have to feel
like I should defend my religion? I remembered my mother’s tears and I
remembered the days, in the middle thirties, when Father Charles Coughlin used
to talk on the radio; I’m sure you know he was the anti-Jewish Catholic leader
who preached a lot of hateful things about the Jews. His talks were supportive of
what was going on in Nazi Germany at the time. My father was loyal to the
clergy. It’s hard to recapture the attitude that: “if a priest said it, it’s like it’s
directed from God.” The whole family was required to sit around an old Philco
radio every Sunday evening and listen to Father Coughlin. As soon as the
broadcast was over my mother would denounce Coughlin, and my father would
defend him. The family just about blew apart every Sunday night. I was about
nine or ten years old and I didn’t really understand a lot of what Coughlin was
saying until much later. I had to go back and read Church history to find out what
he was really talking about. He declared that Jewish bankers were taking over the
country and gradually reducing the rest of us to second class citizens.

Swazey: The Ayn Rand conspiracy theory of history.

McCarthy: Right. I didn’t realize that at the time, but I realized that religious controversy can
just tear you up! So after that day when I tried to defend the church on the steps
of the law school, I went over to St. Lawrence church, which was operated by the
Paulist Fathers. I had heard of them but I really hadn’t dealt with them much.
The Paulist Fathers were dedicated to religious ecumenism long before Vatican II. I was so taken with their desire to heal religious division, particularly among Christians, that meeting them seemed to me like finding something I had searched for all my life. I quit law school after one year to join the Paulist Fathers and went to the novitiate in New Jersey and then went to their seminary in Washington, DC. I was in the novitiate in 1949 and part of 1950 and in the seminary from 1950 to 1956.

Swazey: Had you had any thoughts before then about the priesthood?

McCarthy: You could not avoid those thoughts if you were raised in Catholic school. When I was in grade school the pastor used to come to the grade school every quarter to hand out report cards. To each boy who came up to get his report card, if he got C’s or better, he would say, “Young man have you given serious thought to becoming a priest?” It was just like the air you breathed. I had been an altar boy since fourth grade. I was the head altar boy for a couple of years. That meant I had to assign all the other kids to serve at all the masses and all marriages, funerals and the special devotions. I had to make sure they were there. So I hung around priests a lot. I grew up thinking priests were good buddies. I admired the young priests in the parish. At that time there was no shortage of priests.
Swazey: But apart from the fact that it was in the air and you were constantly asked if you
had given it serious thought, did you give it serious thought?

McCarthy: My decision to go to the seminary was largely unpremeditated. I still, after all
these years, can’t evaluate the reasons. In college I dated a very attractive young
woman pretty seriously and got to the point where we at least had some
conversation about marriage. She was a couple of years younger than I, and she
was, at least at that time, not interested in marriage. At the time I thought no other
female will ever measure up to her. So that probably influenced me. What I
cannot tell you, because I can’t answer the question myself, is how much it
influenced me. All that I can say is that, given all the other things that were going
on in my life, coping with the death of my brother and my father, and suddenly
finding the Paulist Fathers who stood for everything I thought the church ought to
be doing and standing for, contributed to my decision. The official initials of the
Paulists were CSP, Congregation of St. Paul, but they are popularly known as the
Congregation of Semi-Protestants. They have very few parishes, very few
Catholic institutions. They’re found on secular campuses, in secular education
centers, they’re found in academia trying to bring a Catholic perspective to a
secular culture. To me, that seemed like what a believing Catholic ought to be
doing. Not mingling church and state but trying to influence the culture. Isaac
Hecker and the four other original founders of the Paulist Fathers were all converts from Protestantism.

Swazey: It seems like something directed you to the St. Lawrence church about that time.

McCarthy: The Paulists seemed like a breath of fresh air to me. I entered the Paulists Novitiate and was trained in the Paulist seminary at Catholic University in Washington, DC. In 1950 I picked up a case of tuberculosis. In those days there was only one drug that was known to be effective against tuberculosis: streptomycin. Up to that time I'd had little experience of being sick. I had a kind of a “galloping” TB which was pneumonic in character. The Paulists found a good Irish doctor named Dr. Tom Kinsella. He was a surgeon. His colleague was a physician named Dr. Cohen, who was Jewish. They were two wonderful doctors.

I was in a TB sanatorium for about nineteen months, give or take a month or so; I can’t remember the exact date I went in and the date I came out. The treatment at that time required total bed rest. For all that period of time I wasn’t allowed to go even a few steps to the bathroom; not allowed to have a pillow on my bed; because patients were required to lie flat. I was in a long ward at the “T” end of a corridor with private rooms on each side. There were six of us in that porch room at the end of the corridor and we didn’t even have curtains around our beds. We
had no privacy whatsoever. The private rooms on the 7th floor were reserved for
dying patients. There was a saying around the hospital, “If you get transferred to
the seventh floor, your next step is the mortuary.”

Swazey: It must’ve been a long nineteen months.

McCarthy: Well, it was and it wasn’t. When I look back on it I forget the down side, but a
number of things happened. One: when I was finally released, Dr. Cohen said to
me very proudly, “You didn’t know it, but all the time you were here you were on
streptomycin in a study that was funded by Merck corporation. You had about
three-quarters of the streptomycin dose that was then the standard dose.” The side
effects of streptomycin were loss of hearing, which is one reason why I don’t have
great hearing, and injury to some of the cranial nerves. Dr. Cohen very proudly
said, “We got as good results using about three-quarters of the standard dose as
others did using a standard dose. You have less side effects.” I was mad as hell.
Nobody had ever told me I was involved in research. I remember the shock on his
face when I said, “Why didn’t you tell me?!”. Now when I look back I think the
research was a blessing, but I understood very clearly that all those decisions were
made without my knowledge, and it infuriated me. I didn’t know anything about
medical ethics, but I knew that I should have been informed. Dr. Cohen thought I
was ungrateful. He and I had become good friends. His wife was the dietician
and so we got to know her very well. I thought the world of this man, and
suddenly this hero of mine who had saved my life had clay feet. Not in his
professional knowledge, because everybody in the hospital recognized him as the
best expert and the kindest, warmest physician in the whole place. I felt so lucky
to have him as my physician. Then I found out he didn’t feel that he should tell
me that I was a research subject.

Swazey: At the time it never occurred to him?

McCarthy: His assistant, whose name I’ve now forgotten, was a female doctor, which in itself
was very unusual, and she was hurt because I was mad and did not understand
why a patient shouldn’t just be grateful for what they did for me. In many ways I
was grateful. I had really come to believe I was part of the health care team and
finding out I was an uninformed subject was a downer for me. I repeated the
mistake one time when I was teaching. I was teaching a psychology class in the
seminary, and I got a couple of students to function as confederates and started an
argument and simulated a fight; it was all pre-rehearsed. On cue, I ordered them
out of class. Then I told the rest of the class to write down what they had seen and
heard. I wanted them to report the incident as accurately as possible. The class
were guinea pigs. When I told them afterwards that the event was a hoax, they
were furious!

Swazey: They didn’t like deception research.

McCarthy: And I thought, “How could I have done that when I was furious with Dr. Cohen a
few years before for not informing me?” I think the stakes weren’t as high, but
the principle was the same. The students didn’t trust me for a very long time, and
felt that I had breached some kind of tacit covenant of the teacher-pupil
relationship.

Swazey: That’s a fascinating sequence.

McCarthy: So I can hardly point at Dr. Cohen, who is now deceased, and say, “I’m purer than
you are.” I think all of that played into my later life.

Swazey: When you went off to get your PhD what field was it in?

McCarthy: I studied philosophy for two years in the seminary, and theology for four years.
Then I was allowed to do graduate work in philosophy and political science. The
Paulists decided they wanted me to come back and teach in the seminary, after ordination. Their first thought was to send me to Louvaine, Belgium where, at least at the time, it was thought you could get the best post-graduate theological and philosophical training. A Paulist who was a colleague a couple of years ahead of me had received his STD over there. He came back and described the drafty living conditions, damp, cold, difficult to keep from freezing while you’re studying and so on. So because I’d only recently had TB they decided not to send me to Louvaine and they said, “Can you find a place in the country that’s really attractive to you?” By this time I was fascinated with philosophy and I still was interested in law and public policy, so what I tried to do was combine philosophy and normative political theory. I wanted to learn about standards for measuring the success or the failure of a socio-legal system. At that time positivist political theory was taught almost everywhere in the United States. How do you measure trends? How do you predict what’s going to happen? How do you do voter sampling, and establish voting trends? The climate was a predecessor to the polling that is common today. A politician can simply look at the polls and decide what is popular. I knew at the time that I wasn’t interested in politics by polling or by predicting, but trying to find standards to judge the quality of the political culture and the wisdom of broad trends in the law, if not particular legal proposals. The only place I could find in North America that taught that approach
swazey

was the University of Toronto, so that’s where I went. Partly I studied at the
Medieval Institute, and partly at University College. The Canadian system is a
little more like the British system than it is like the US system. The colleges are
quite independent. My degree came from University College but I was entitled to
take courses at St. Michael’s Catholic College, at the Medieval Institute and at
Trinity Episcopal College. I sampled courses all over the University. The faculty-
student meeting place was the big dining hall. They called it the “Great Hall.” It
had two levels, the students ate on the lower level -- there were only about four
inches difference -- and the faculty ate on the upper level. The day that a faculty
member invited a student to come up and eat with him or her was a mark of
transition. Your first year you were never invited, the second year you might get
one or two invitations, but by your last year you knew quite a few faculty
members and they often invited you. It clearly was a way of establishing an
educational class distinction and gradually letting you into the “club.”

swazey: What kind of philosophy or philosophies did you study?

mccarthy: The Paulists wanted me to study modern philosophy, so I studied Descartes
through Hegel. I wrote my masters thesis on Descartes’ theory that God somehow
causes Himself: “Causa Sui.” I was critical of his theory, and I was critical in the
light of much more traditional Catholic philosophy and theology, particularly St. Thomas Aquinas, and Aquinas’ arguments for the existence of God. If you do believe in God these arguments are likely to offer you a rationale for the fact that it is reasonable to do so. The assertion that God exists is not stupid or contradictory. If you do not believe in God, the arguments may not be entirely satisfactory. That’s how I was interpreting Aquinas. I got into analysis of the different kinds of causality. I don’t think it was a very good thesis, but it was fun and challenged me.

Swazey: You probably learned a lot doing it.

McCarthy: I learned more about how to do academic research than I did about Descartes. We had all the original works of Descartes in the University library. They’re not so difficult to translate; they are mostly in Latin but the script was that old German-type lettering. I had a difficult time reading the script itself. So I relied heavily on translations that I compared with original texts. I learned that I didn’t enjoy functioning as a scholar who goes back to original sources. That kind of research didn’t interest me. What interested me were the conclusions reached by seminal thinkers, and whether they had any meaning for today’s world.

On the political side of the university Professor Roscoe Brady fascinated
me. He developed a couple of theories that I think are very important. One is that he was very concerned even in those days about whether French Canadians would separate from the rest of Canada. He began to analyze the arguments in terms of trying to determine what are the central values held by the English speaking society and what are the central values held by the French? Is there enough overlap so that they can ever truly be one nation? He predicted that they were going to break apart (this was back in the late '50's). Everybody writing at the time thought he was wrong. In fact the Quebequois haven’t quite broken, but they are certainly not integrated. Brady argued that Canada is one country but two nations. His methods seemed to me to be the right way to think about politics. What are the basic values in the culture? How do those values affect the way a society organizes itself?

I wrote my doctoral dissertation on the work of Orestes Brownson. Brownson was a New England Transcendentalist who was self educated. He taught himself to read seven languages. For thirty-five years he published Brownson's Quarterly Review. In the Journal, written almost exclusively by himself, he reviewed most of the books written in Europe and America in his time. Typically his reviews ran between twenty and thirty pages of print. In his day he was as well known as Ralph Waldo Emerson, but he has faded from the pages of American history. Joseph Schlesigner wrote his PhD thesis on
Brownson’s early days. I concentrated mostly on Brownson’s later work after 1844 when he rejected the transcendentalism. He rejected Unitarianism (he had been a Unitarian Minister) and became a Catholic. He wrote one major book entitled *The American Republic*. Woodrow Wilson called it the greatest work of its kind ever published.

I spent a year in Boston, living at the Paulist Chapel on Park Street where I did pastoral work as well as research at the Atheneum library. I finished my dissertation at the Paulist seminary in Washington, St. Paul’s College, which is affiliated with The Catholic University of America, and began teaching students who were candidates for ordination within the Paulist Fathers community. I introduced political theory into the curriculum of the seminary, and soon was invited to split my time between the seminary and the Catholic University of America.

As a beginning teacher in the University’s Political Science Department, I was assigned to teach survey courses because no one else in the Department wanted to teach them. Survey teachers were expected to teach a little about the Greek political system, a little about Roman system, the French system, the German and the English systems. Most of the faculty thought of it as “dabbling” rather than teaching at the university level. But I loved teaching those courses. I developed a theory that if you read the seminal literature of each different culture
about what it means to be human, you can see almost a one-to-one correlation
between the view of what it is to be human, and the government that reflected that
view. I looked at Newtonian physics, the Copernican Revolution, the Darwinian
Revolution, and their effects on the notion of what it means to be human. As the
concept of humanity changed, so did the forms of government change.

Swazey: I hope the students appreciated the kind of survey course they were getting. That’s
not your normal Rome to Roosevelt survey course, that’s for sure!

McCarthy: It certainly wasn’t giving them a list of dates and asking them to memorize what
happened. But I found that if students read the great literature of the different
cultures, they would find that a lot of it centered on the question “what does it
mean to be human?” I think we’re still struggling with an evolving concept of the
meaning of “human.” I suspect that part of our superficiality today is related to
the biological revolution that we’re in now. People don’t know if they’re just a
pile of DNA -- randomly organized -- or maybe even organized according to some
internal principle. I just rotated off the ILAR council where I served for six years.
At almost every meeting someone restated the fact that a typical human shares
close to 98% of the DNA of a non-human primate. In fact, we have more than
80% of the same DNA as an earthworm or a fruit fly.
Primates most people can take, but earthworms might upset them.

And you probably could go all the way down to fruit flies.

ILAR stands for?

The Institute for Laboratory Animal Research, within the National Academy of Sciences. These people, all of whom defend research involving animals, were having a hard time trying to articulate the fact that humans are superior to animals. I think if you go about it statistically in terms of DNA, you can’t demonstrate superiority unless you say, “The genes I have that an animal doesn’t have are all important.” I think those are fruitless arguments. I remember one day ILAR asked me to write a paper justifying using animals for human purposes. The scientists couldn’t think of any way to look at animals except in terms of comparing biological composition and structure. That didn’t offer much of a basis for using animals in research. I started comparing animal values and human values. I said, “The value systems are what distinguish us.” Animals have rudimentary language but we have abstract terms, they have rudimentary tools, we are constantly inventing new tools. They nurture their young, we try to do the same but we’re always trying to figure out a better way to do it. We’re never
satisfied with the way our parents reared us, whereas, the animals rear their young
the same way generation after generation. Animals don’t have any observable or
measurable aesthetic appreciation. Animals may be taught to obey, but they have
no sense of right or wrong, no ability to laugh, no worry about the past (no sense
of shame) and no worry about the future. Those are some of the things that
distinguish humans from animals. I believe that humans, despite all their
shortcomings, are superior to animals, not only in degree, but in kind.

Swazey: Tell me about your move to NIH in 1971. How did that come about?

McCarthy: In 1967, a fellow priest named Bill Greenspun, invited me to an ecumenical
conference. His mother was Catholic and his father was Jewish. He was a Paulist
Father for a lot of the same reasons I was, and he was appointed to the ecumenical
desk of the U.S. Catholic Conference, the central office of the Bishops of the U.S.
Following Vatican II, Protestants invited Catholics to share in training programs
for church personnel of every type, everything from pastors to teachers of religion,
church administrators, sextons -- the whole works. Most of the mainline
Protestant churches bought into shared training and invited the Catholics to join
them. That was considered to be a big step forward in ecumenism. The Catholic
bishops were very skeptical about joining, so they asked Bill Greenspun to
represent them at a program held in Green Lake, Wisconsin and write a report. As it happened, Bill said there was room for two Catholic observers so he invited me to go along. At the last minute he got the flu. So there I was, a lone Catholic priest among 350 Protestant leaders. I put a little notice on the conference bulletin board, it was just a little 3x5 as I recall, saying that I would be offering mass on Sunday if anyone wanted to come. The response was astonishing! Nearly everybody in that place wanted to come to mass.

Swazey: Ecumenicism.

McCarthy: Ecumenicism was in the air at the time. So all of a sudden I had some organizing to do. The conference had broken up into small groups and I was assigned to a small group that included an attractive woman with a lovely voice and southern accent who turned out to be Estelle Rountree. Estelle was and is an active member of the Presbyterian Church (U.S.A.). She has held many positions in that church and is considered to be one of their outstanding educators. She agreed to pull together some friends and turn them into a choir. I asked an Episcopalian priest to concelebrate with me, and that blew his mind. He never thought he would concelebrate with a Roman Catholic priest. We asked other ministers from different groups to participate, and to help with communion. We planned a
dialogue sermon where the celebrant just said a few words and asked if anyone else wanted to add any comments. The sermon and discussion went on several hours; people were very emotional talking about our divided Christian family, and how we've got to overcome divisions. Anyway, Estelle and I worked together to prepare the music and ceremony. Obviously we were very attracted to each other. So when the conference was over, my head was really spinning. We had a very frank talk and I said, “I am very attracted to you, but this relationship just can’t work out.” So we broke off. This was 1967.

In 1967 Father Charles Curran was fired by The Catholic University of America although he was a tenured professor. The whole university went out on strike in protest. I believed then, and still believe, that the church exceeded its authority by trying to limit the views of a moral theologian and what he could write about. Although I wasn’t a student of Curran’s, I learned a lot about what he was teaching. He and I became close friends and I came to agree with virtually all that he was saying. Because of Charlie Curran, I became more acutely aware of excessive use of authority by Catholic Bishops. Then Father Dan McGuire, another moral theologian at Catholic University, left the active priesthood and was married. Although he was tenured, the University fired him. I was outraged, and I headed up the faculty committee that protested his firing and made myself a general nuisance to the administration at the University. I was angry with the
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bishops and their misuse of church authority. I was angry at the way the
principles of Vatican II were ignored.

One day in 1968 Estelle called me from National Airport. I met Estelle
out there at a lunch counter. A lot of thoughts coalesced...That was the same year
that the Encyclical *Humanae Vitae*, against contraception, was published. Despite
the fact that most respected theologians in the world had informed the Pope, “Do
not try to ban contraception!” the Pope banned contraception. I joined the group
that was demonstrating in Washington, D.C. against the Encyclical and the
bishops who supported it. After more time passed I finally decided: “I cannot
continue to wear the Roman collar, although I am a loyal Catholic. I believe that
what I stand for is more in line with the best Catholic traditions than the current
leadership in the church.” However, if you wear the collar you are in effect saying
publicly, “I stand for everything that the official church stands for.” It was very
clear to me by that time that I didn’t and couldn’t support *Humanae Vitae*. I
remember after the Encyclical was issued, I felt like I had to leave the active
priesthood. It took me several years to act that out, but I think I knew at that time.
I began to correspond with Estelle. I don’t know how much of my decision to
leave the active priesthood was based on my strong attraction to my future wife,
and how much was rejection in principle of the church leadership at the time. All
of that was occurring at once.
In the period of controversy over Dan McGuire, a Catholic lady, whose name I've long since forgotten, invited me to a cocktail party at her home. I didn’t really want to go. I didn’t know her very well. Her hidden motive was that she was going to invite all her “lax” Catholic friends, and I was supposed to “convert” them. That was a plan she didn’t share with me. I went to this party and she introduced me as the priest who favored retaining Dan McGuire and who supported academic freedom for moral theologians. As it turned out I was largely alone in my view except for one short fellow at the party who agreed with me and supported me. I thought he was very cogent. He only came up to my shoulder. He had a deep voice and salty vocabulary. “The trouble with you sons of bitches is...!” But I liked him very much. I never heard his last name. His first name was, “Tom”. The cocktail party was a disaster because everybody left in an angry mood. I never heard from that lady again. About three weeks later my telephone rang and I heard a deep voice on the phone. It was Tom Kennedy. Tom said, “I’ve been trying to find out how to get in touch with you since the cocktail party. Do you want a job?” “Well, yes”, I said, “as a matter of fact I’ll be leaving the active priesthood in the spring.” That was February or March of 1971. He said, “I guessed as much from what you said. You ought to come over and have an interview. I think we can find a place for you at NIH.” So although I sent my resume all over the country I never applied for the NIH job. I had to go through
all the civil service placement tests, but I had the job before I was even eligible to
take it.

Swazey: What was his position at the time?

McCarthy: Tom Kennedy was the Associate Director for Program Planning and Evaluation at
NIH under the Director, Dr. Robert Marston. It soon became clear to me that
Marston relied more on two people than anyone else for advice: John Sherman,
the Deputy Director, and Tom Kennedy. That triumvirate was running NIH at the
time. Tom had responsibility for planning, but he also supervised the legislative
liaison office. I was hired as a legislative analyst. Tom said, “You need a broader
education about how this place works.” So he made me the Executive Secretary
of the Director’s Advisory Committee. Over the next seven years I dealt with
virtually every major issue at NIH. I also dealt with many of the leading political
people. In 1972, the year the Tuskegee scandal broke, Ray Wolmerdorf, who was
my immediate boss, dropped a packet of stuff on my desk including a lot of news
releases about the scandal of the so-called Tuskegee study. He said, “Write the
government’s defense.” I’d never heard of Tuskegee, I didn’t know anything
about this syphilis study. I spent a couple of days wading through that packet. I
wrote about a half page memo to Dr. Marston, the Director of NIH, but he
forwarded it to the Secretary of HEW, who was at that time Elliot Richardson. What I said, in effect, was that there can be no defense for what happened in the Tuskegee trial; the only stance the government can take is to make sure that nothing like this will ever happen again. Richardson bought that position hook, line, and sinker. He was, as best I can tell, a decent, honest man. I regard him as a hero. By the way, his son is now at the Kennedy Institute of Ethics and is himself, a first-class ethics scholar. I drafted the testimony that Richardson delivered before Sen. Ted Kennedy’s Senate Health subcommittee. Richardson gave the testimony that I wrote word for word. He never even looked at the paper. He had a photographic memory. I was very impressed with him. He not only did the right thing, but he also defused tensions in the hearing because he delivered the testimony in a soft monotone. He tended to put his listeners to sleep. He calmed everybody down. I thought: This guy is a master! I’d never seen anybody deal with such a difficult issue so well. Through the Kennedy hearings, I came to work closely with Senator Kennedy’s staff and with Rep. Paul Roger’s staff. Over time I collaborated more with Paul Rogers, a Democrat from Florida, than with Kennedy. Tuskegee prompted a series of Congressional hearings chaired by Senator Kennedy that dealt with all kinds of ethics issues; including the sterilization of cognitively impaired persons in Virginia, and the state imposed sterilization of two retarded teenagers in Mississippi. This was part of the Jim
Crowe residue in the South. Senator Kennedy also dealt with contraceptive research issues (Depo Provera), in which some women were given placebos and not informed of the fact, whole body radiation of war veterans without their consent, and psychosurgery dramatized in the movie “One Flew over the Cuckoo’s Nest.” I got interested in all those subjects, and for three or four years I drafted much of the testimony delivered by officials of HEW to the Kennedy and Rogers subcommittees. By that time Eunice Shriver Kennedy, Ted Kennedy’s sister, had started the Kennedy Foundation for handicapped persons. A lot of ethical issues began to arise as to what sort of research such handicapped people could be involved in. When were research investigators exploiting them? When were they helping them? Those were difficult, very tough issues; they are still tough issues. We’ve extended protections to people with various kinds of vulnerabilities as a result of those discussions. The Shrivers decided they needed a better academic rationale for the kinds of research they wanted to do in and for the Kennedy Foundation. So they created the Kennedy Institute of Ethics over at Georgetown University. They funded it with a bolus of money in the beginning. Each year the Institute was to become a little more financially independent. Around 1980 the Kennedy money ran out. But the Kennedy name survives and the Institute is now self-supporting. The first director was Dr. Andre Hellegers, and the first person he hired was Dr. LeRoy Walters. Walters came to
Washington, a new PhD from Yale, in 1971 the same year I began work at NIH.

The Kennedy Center for the performing arts showed a movie that year about a family that refused treatment for a Down’s Syndrome baby at John Hopkins University.

Swazey: “The Jamboree.”

Right. I don’t remember why I was invited, but it was there that I met LeRoy Walters. Charlie Curran had told me about him, and had told him about me.

Curran wanted us to work together. We formed one of the closest friendships I’ve ever had with any human being, other than Estelle.

That was the year that I read Eric Tofler’s, *Future Shock*. Tofler said that you can avoid futureshock if you don’t change every aspect of your life at once. I left the active priesthood, I left the Paulists, I changed my residence, my job, my marital status, my lifestyle. I changed everything I could change about my life....I waited for lightning to strike. Futureshock seemed inevitable.

And you were in complete equilibrium, right?

I’d say to myself: “When am I going to be struck by lightning?” But anyway,
LeRoy had just left the ivory tower at Yale where he studied under Professor Jim
Gustafson. LeRoy was the first person hired by the Director of the Kennedy
Institute, Andre Hellegers. At that time both of us were finding our way in a new
world. Even though LeRoy is about fifteen years younger than I, I think we were
equally naive about what we had gotten into.

LeRoy and Andre Hellegers showed up at my office one day. I have no
recollection of their making an appointment. We had a discussion lasting an hour
or two. We lamented the fact that researchers mistrusted ethicists, because
ethicists seldom said anything to researchers until the research was completed.
The research community didn’t want anything to do with the ethics community,
and the ethics community chose to critique researchers after the fact. We decided
that we would initiate a seminar series at NIH. Our purpose was to persuade
scientists and ethicists to plan research together. Andre and LeRoy agreed to
recruit somebody from the ethics community every other month. In the alternate
months, I would recruit a scientist from NIH to talk about why the work he or she
was doing was ethical. For the first seminar we staged, we made all kinds of
announcements. We didn’t have e-mail or web pages in those days where you
could tell everybody by way of the LAN (Local Area Network) what you were
doing. We placed posters everywhere -- but only four people showed up, and one
of the four was the lecturer. That was in 1972, I think. By the time we
discontinued the seminars in 1979 we couldn’t get an auditorium big enough to hold all who wished to attend. All of a sudden scientists at NIH were talking about ethics. The seminars grew to the point that people began demanding money to present. We had no money for this purpose. We couldn’t even pay for the speakers’ transportation. We finally decided maybe the seminar program had achieved what we set out to achieve. We stopped the seminars, but by that time many other science/ethics forums had begun to function.

In the middle seventies a funny thing happened. Do you know Don Chalkley?

Swazey: Yes.

McCarthy: I don’t know if you know some of his characteristics. Don ran the old Institutional Relations Branch of the Division of Research Grants at NIH that was gradually transformed after 1966, before I got to NIH, into the office responsible for the protection of human subjects. Don was very much taken with Jay Katz. In a previous existence Don had taught ethics at Notre Dame. His father was a very famous researcher. I never knew his father or what he did, but clearly Don was in awe of research. He also wanted research to be ethical. He ran that office by looking at things people were doing, just reviewing grants more or less on his
own. When he would find something he thought was unethical he would sit down
and write a long-hand letter to the investigator with a copy to the president of the
institution saying, “You’re violating subjects’ rights!” Those letters would “take
the hide” off people. I thought many of them were very funny. Dr. Marston kept
getting complaints about Chalkley’s letters telling scientists and administrators
they are unethical people who are violating the rights of subjects and that they
ought to be ashamed of themselves. Chalkley’s letters were very personal, very
pointed letters. Dr. Lamont-Havers, the Associate Director for Extramural
Research, called me into his office one day and said, “I’ve got a little extra job for
you. I want you to edit Don Chalkley’s letters.” I had received a couple of
memos from Don so I knew what he was talking about. I said, “I can’t do that! I
don’t work under him or for him. His office is outside of legislative channels, his
letters don’t go through our office.” I was still in legislative affairs. Our office
was called the Division of Legislative Analysis. Dr. Lamont-Havers said, “I’ve
talked to Dr. Chalkley, he realizes that he’s creating a lot of problems for this
agency, but he says his temper won’t allow him to do anything else. He’s quite
willing to have you edit his letters. I want every letter he writes to be submitted to
you and I want you to rewrite it in such a way that you tell recipients in a polite
way that they’re not performing properly. And I don’t want the Director of NIH
to continue to get complaints and threats that recipients are going to go to their
congressman or senator. I want you to be the middleman.” Chalkley could not
have been more gracious. I began to find out a lot about what his office was doing
and how he viewed his responsibilities. Then I would go talk to him and ask him,
“why do you have this or that in the letter?” He had a vision for the governance of
research that was based on the common law court system. He expected the IRB to
be a lower court. Anybody who didn’t like an IRB’s decision could appeal it to a
higher court, and ultimately there would be a supreme court of ethics. Every IRB
would record its findings, and findings would be published more or less like West
Publishing House publishes legal decisions. So when you wanted to do a
particular kind of research you would go study the ethics analogs of legal cases,
you would study the ethics cases, and make your case. It was based on an
adversarial model. The IRB would be the court, and the investigator would be the
plaintiff. A member of the IRB would argue against the research. Only if an
investigator won the trial could he or she go ahead with the research.

Swazey: I don’t like the adversarial system but I sure wish we had that kind of
documentary record.

McCarthy: Wouldn’t it have been great! We didn’t have the money or technology at the time
to do it. If we had had computers and enough vision, it might have been feasible.
Initially I bought into Chalkley's idea: then I realized he had too much adversarial process. IRB colleagues in the investigator's own institution cannot play the adversarial role. Chalkley gradually came to agree. We began to shift the system to one in which the IRB could approve, approve with modifications, or disapprove research protocols. About 4% of the research protocols are disapproved, and between 50% and 60% are modified by IRBs.

Parts of the Kennedy hearings regarding the so-called Tuskegee research were televised. As far as I recall, the only Congressional hearings that had been televised prior to the Kennedy hearings were the Sen. Joe McCarthy's unAmerican activity hearings. After Tuskegee, the Kennedy hearings were held about four times a year. They dealt with many topics. I attended most of those hearings. After a day in the hearing room, I would see snippets and sound bytes from those hearings on the evening news. Because of the publicity they exercised more influence than many other hearings that were going on in the Congress at the time. Of course the Kennedys had a knack for getting their views out in the public. They knew everybody in the media, they were attractive to the media, they made sure the media were there to cover all these hearings. In 1973 Sen. Kennedy introduced a bill to create a National Bioethics Commission. He used the Securities and Exchange Commission as a model for the National Commission. I think he consulted Jay Katz about this approach. Kennedy proposed a separate
federal agency that would have had authority to regulate human subjects research
to make sure that it was ethical. The bill was a bit naive in that it presumed that
any trained inspector could easily tell which research is ethical and which is not.
It assumed that if you got trained people to look at something they could quickly
tell you “yes” or “no”.

By that time, I was working very closely with Rep. Paul Rogers’ staff on a
variety of health research legislative initiatives. Over time legislative liaison
personnel get to know Congressional staff pretty well. NIH made it clear they
wanted the Kennedy bill softened. Rep. Rogers agreed. He held his own series of
hearings. I worked with Rogers’ staff to write Title II of Public Law 93-348
which created the National Commission for the Protection of Human Subjects of
Biomedical and Behavioral Research. I wrote most of the text of Title II of the
Rogers bill. It was illegal for the Executive Branch personnel to lobby the
Congressional branch. But it was legitimate to provide “technical assistance.”
That is what I did. The Kennedy bill passed in the Senate, and the Rogers bill
passed in the House. Kennedy said, “If HEW will issue regulations for the
protection of human subjects that I find satisfactory, I will scrap most of what’s in
my bill and accept the Rogers’ version.” The part that he didn’t compromise on
is the part that Senator Walter Mondale had been advocating for five years or
more: Mondale wanted a National Commission to evaluate the impact of scientific
progress on society. Kennedy and Mondale wanted a kind of early warning system. When is a major breakthrough going to come in science or medicine that will have a profound effect on society? How do we prepare for it?

Swazey: The Special Scholarly Study. I was a member of it and it never got out of the file drawer.

McCarthy: That mandate was introduced by Sen. Mondale as SJ Res. 75. It bore different numbers in different Congresses because he introduced it four or five times before Sen. Kennedy incorporated it into his bill.

I wrote a speech that Sen. Kennedy delivered on the Senate floor in support of the National Heart Act. I was involved in lots of other Congressional initiatives as well.

Swazey: You were very busy helping out the legislative branch, weren’t you? Technically assisting them!

McCarthy: We gave Congress a lot of “technical assistance.” Most of that material was (off the record) checked by LeRoy Walters, for ethical acceptability. NIH operated like a family grocery store at that time. Tom Kennedy called it management by
“swarming.” Anybody who had an idea about any issue was allowed to get involved.

Swazey: In some ways it’s a shame that was lost.

McCarthy: It was a wonderful climate to work in! I could’ve worked 24 hours a day because I’d go to Tom and say, “You know I’d like to work on this or that.” “Go for it!,” he’d say, “and I’ll back you up!”

Swazey: It was so recent, but it seems so long ago.

McCarthy: I idolized Tom Kennedy. I thought he was the best boss a person could have. He motivated me. Sometimes he verbally beat the daylights out of me if he thought I had done something shoddy. But I never felt humiliated. I remember him yelling at me, “What shit-for-brains idiot wrote this?!” I’d say, “I did.” He would go on and rant for a while, and I would laugh. He would say, “Why are you laughing?” I would say, “Because if I close my eyes, I can hear my Irish father scolding me.” And I said, “It brings back happy memories.” He didn’t know how to deal with the fact that I gradually learned not to be afraid of him, and that I loved working with him. He scared the daylights out of almost everybody else, but he was a
good man, and a kindly man. The female employees at NIH created an award for
the administrator who was fairest to women, and he won that award; there wasn’t
even a close second. He promoted all kinds of smart women, and arranged for
increased pay for secretaries. NIH had a reputation for having the best secretaries
of any part of the government, the best secretaries in Washington. When the glass
ceiling finally shattered many of those women who had been doing their bosses’
work for years got senior administrative jobs. A lot of them jumped from grade 6
or 7 government jobs to grades 14, 15, 16. Before they were promoted, they often
seemed to run the agency as secretaries. They were doing everything including
their assigned secretarial work. They finally got recognized. I lived through that
time and it was really exciting to see people move from the outer office where
they answered the phone and covered for their bosses, and typed memos about
what the boss was supposed to have done but seldom did, to actually taking
responsibility for major decisions. Tom Kennedy was responsible for a lot of
upward mobility. It was a great transition.

Swazey: Can you tell me how the human subjects regulations got drafted?

McCarthy: The regulations were drafted in direct response to the conflict between the
Kennedy bill, which called for something like a Securities and Exchange
Commission, and the Rogers bill, which called for an Advisory Commission.

Senator Kennedy, after a conference with Rogers, said that he would accept most
of the Rogers version if HHS, (then HEW) would produce regulations that he
found satisfactory. Consequently NIH created a three-person committee to draft
those regulations. We produced them in about three weeks, they were forwarded
to the Secretary and skipped most of the clearance process, and were published on
May 30, 1974. Senator Kennedy took several weeks to look them over and
pronounced himself satisfied. On July 12, 1974 Title II of the National Research
Act was enacted, and that created the National Commission for the Protection of
Human Subjects of Biomedical and Behavioral Research. The Rogers bill, with
Kennedy’s endorsement, became law.

Swazey: Who was involved in drafting them?

McCarthy: I was involved, and Dr. Charlie Lowe from the National Institute of Child Health
and Human Development. The third person was a young woman named Jane
Fullerton who was from the planning office. She had some post-graduate training
in ethics. The three of us drafted them and we consulted a lot with Don Chalkley.
In essence, the regulations codified the 1971 HEW Policy for the Protection of
Human Subjects. It was a strange, and strained Committee because Charlie Lowe
and Jane Fullerton barely spoke to each other. They communicated through me.

It was like a sitcom caricature of government work.

A lot of other stuff was going on in that same period. In 1972 Dr. Marston, the Director of NIH, was asked to give a talk for the graduation ceremony of nurses at the University of Virginia. Dr. Marston thought it would be a good idea -- where he got the idea I do not know -- to address the ethics of research. Marston did a couple of things. He took the old Institutional Relations Branch, renamed it the Office for Protection from Research Risks (OPRR), and moved it out of the Division of Research Grants up to the NIH Director’s office so that it answered to him through his Deputy Director. The talk that he gave in Charlottesville was actually written by a very interesting man named Storm Whaley. Storm had been a professor of ethics at the University of Arkansas in the 1960's. When Arkansas students staged demonstrations against the Vietnam War, the president of the University of Arkansas resigned. As a temporary measure Storm Whaley was named Acting President of the University. I think he spent about a year and a half in that role. Where he took his training or how he came to be an ethics professor in that university, I have no idea. When a permanent president was appointed he resigned from the University and joined the staff of Senator Fulbright. The assumption was that he would serve Fulbright for many years. But in the 1970 election, Sen. Bumpers upset Fulbright. The nation was
shocked. Nobody expected that. Whaley was out of a job. Senator Fulbright used his good offices to have Storm appointed as the Associate Director for Public Affairs at the NIH. So when Marston wanted a talk written on the ethics of research, Whaley drafted that talk. Marston’s talk outlined most of the studies that were ultimately carried out by the National Commission. He wanted studies done on vulnerable subjects including prisoners, children, pregnant women and human fetuses. He also identified as vulnerable the socially disadvantaged, a study that never made it into the Rogers-Kennedy Bill. He identified what were then called the “institutionalized mentally infirm subjects” -- today people would call that a pejorative term but that was the language of the time -- and prisoners and children. I think that was most of the list.

Marston gave that talk at the University of Virginia. It was picked up by the *Washington Post*. In due course Marston created a series of task forces, first at NIH and then Public Health Service-wide, that were organized at Marston’s direction by Ronald Lamont Havers, who chaired all of those different committees. There was a committee on research involving prisoners, a committee on research involving children, a committee on research involving the institutionalized mentally infirm etc.. It is interesting to note that at that time nobody seemed to think that people with cognitive impairment who were not in institutions needed special protections. There also were committees on research
involving pregnant women and the human fetus. I think these were the most controversial of all because this effort took place a couple of years after \textit{Roe v. Wade}. In the public mind, fetal research and public policy concerning abortions overlapped. Congress passed a law saying NIH could do no research relating to abortions. Research on various kinds of contraceptives -- at least some of them alleged to prevent conception by producing spontaneous abortions -- continued. There was lots of controversy as to how NIH would implement the law. Much of that research was presided over by Charles U. Lowe, the Director of Intramural Research for the National Institute of Child Health and Human Development. When Lamont-Havers, following Marston's lead, created these committees, Dr. Lowe chaired the one dealing with pregnant women and human fetuses. Some of the task force produced sophisticated policy drafts. I don't remember all the details of that period, but when the 1974 bill creating the National Commission was enacted, all of that material was turned over to the National Commission. It turned out to be the basis for the reports that were edited, refined, and published by the National Commission. It is not well known that the outline for virtually all of the major reports issued by the National Commission had already been done by Public Health Service Task Forces that had been working on these issues for a couple of years under Dr. Marston's direction.
I know from Barbara Mishkin that she was involved in researching and writing a lot of those.

Barbara worked closely with Charlie Lowe in those days. As far as I know, Donald Chalkley made all drafts available to the National Advisory Commission and then spent many hours both with commissioners and staff explaining the nuances of the issues and the trouble spots that he found with those draft reports. I don’t mean that as any kind of a criticism of the National Commission, but it does suggest to me that there was a connection between: (1) the Kennedy Foundation needing research guidance to know what research could be conducted involving handicapped persons, (2) the Kennedy hearings, and (3) the Kennedy-Rogers Bill. It was during this period that Marston picked up the ethics theme, and with the help of Storm Whaley and Lamont-Havers organized an approach for dealing with these issues. For the first time, so far as I know, the ethicists, some of whom were from the Kennedy Institute at Georgetown, were included as advisors to the PHS. Clergy persons, lawyers, and scientists worked together to produce reports prior to the work of the Commission. Public Health Service employees and outside advisors helped with that work.

I think the decision to include advisors other than scientists came out of those seminars that were started by Andre Hellegers, LeRoy Walters, Charles
MacKay, and me. The seminars, the Marston speech, the PHS task forces and the National Commission are all part of one movement. The Public Health Service had progressed to the point where it published proposed rules on fetal research in 1973, the year before the Commission came into existence. Those rules were not finalized until after the Commission held hearings, and issued its own report. I served on the committee to do the final drafting of regulations concerning fetal research that was also headed by Dr. Charles U. Lowe.

What the Commission changed, I think, was the relationship of those policies to the regulated community. Prior to the National Commission, when NIH talked about issuing policies that might restrict certain kinds of research or adding certain kinds of requirements about informed consent, the research community objected strenuously. The National Commission, headed by Dr. Ken Ryan, an obstetrician, changed the climate. Rules were now seen as reflecting the views of the research community that had testified copiously during that period before the Commission. For the first time, researchers “owned” the roles in a way they never would have without the National Commission. Although the content of federal regulations wasn’t much different after the National Commission, the climate was entirely different. There was an enormous change in the way ethics regulations were accepted and welcomed.

In 1973 Congressman Roncalo, a democrat from upper New York state
obtained some pictures from a laboratory in Finland that was doing research with
aborted fetuses. A Finnish researcher was trying to keep fetal brain cells alive by
perfusing decapitated fetal heads. Rep. Roncalo arranged to have pictures of
perfused fetal heads circulated to every member of Congress with a note saying, in
effect: “This is what federal research dollars are paying for at NIH.” An
enormous political eruption occurred. Congress, in passing the law that
established the National Commission, put a temporary moratorium on fetal
research as a result of Roncalo’s action. The research community, at least those
who were doing research with pregnant women and fetuses, was on the defensive.
Eunice Shriver organized Stone Ridge Catholic High School girls located across
the street from NIH. The girls marched to NIH -- all wearing white blouses and
jumpers, all carrying candles -- protesting the cruelty to “unborn babies.” Shriver
had called and used the good offices of her brother, Ted Kennedy, to make sure
they would be met by an NIH official who would explain the NIH position on
funding such research. She agreed to stage a peaceful demonstration. Only high
school girls, nuns and Ms. Shriver were to be admitted to Wilson Hall, the
Building One auditorium at NIH. I was an observer that day, and I was aware of
the agreement. However, some female reporters from The Washington Post and
some from several of the network newscasts also showed up wearing white
blouses and jumpers trying to pose as high school girls to get into the meeting! It
struck me as very funny!

Did the media get hold of Roncalo’s pictures of the Finnish doctor’s heads?

Yes, the media had Roncalo’s pictures. I saw those pictures several times. I am not certain, but I think some of the girls carried the Roncalo pictures in the procession. The papers carried pictures of the demonstrators outside the building, but I don’t think any reporters finally made it inside. I remember Charles Lowe standing in the Wilson Hall auditorium on the top floor of Building One trying to reassure the demonstrators. In a Catholic high school in those days we rarely acknowledged that pregnancy occurred, or that sexual relationships were a reality, much less did we protest about abuses of fetuses that had allegedly been aborted alive. I don’t know what that meant to those young women. But I’m pretty sure that they were very innocent and naive. Charlie Lowe was at his most unctuous! NIH officials were quite happy to let him handle the situation. I hung around the back of the auditorium just to hear Charlie Lowe deny that the pictures pertained to NIH-supported research. I can tell you there were many, many hours of meetings within NIH to try to track down the source of the pictures. It finally turned out that one NIH Fellow, I think he was from Case Western University, had actually traveled over to Finland to observe the work the Finnish doctor was
doing. That was the only NIH connection with the Finnish research. Most of this
event is recorded in Mark Frankel’s book, but I can’t remember the level of detail
that he recorded.

Swazey: When you were drafting the human subjects regulations, you said when we were
talking during our break that you drew on Chalkley’s policy.

McCarthy: We drew on Chalkley’s 1971 HEW Policy for the Protection of Human Subjects.
That policy is still known as the “Yellow Book” because of the bright yellow
cover on the publication. I had just arrived at NIH at the time and I wasn’t a part
of any of that policy drafting, but I was told that the Yellow Book was almost
exclusively the work of Don Chalkley. He headed a drafting committee, but, at
least as it was told to me, he did most of the work and produced the document. In
the light of today’s somewhat more sophisticated approach to human subjects
research, you can criticize the 1971 policy, but I think it was the best thing in print
at the time. I don’t think Don Chalkley gets enough credit for shaping the system
that was essentially endorsed by the National Commission and that continues
today. The policy is frequently upgraded and modified, but the basic outlines of it
are still found in Chalkley’s 1971 Yellow Book. The rationale that Chalkley gave
then would be slightly altered today, but fundamentally he cited the same
arguments that are used today to justify the regulations for the Protection of Human Subjects. I think Chalkley was a great visionary. On the other hand, I don’t think he had the slightest idea how to implement his vision. Consequently - I think Don would agree with this -- the office was relatively ineffective despite the fact that he knew exactly how the system ought to work and how it ought to be put in place. He simply didn’t know how to implement the policy. He didn’t rely on the authority of the Secretary, the Assistant Secretary, the head of NIH. He didn’t attach conditions to grants and contracts involving human subject research. NIH, and HHS, later used such conditions on awards to make sure that institutions paid attention to the policy. Don’s approach was to write institutional officials a letter and say, “Do it!”

Another unsung hero, by the way, who really should be featured and maybe interviewed, is Ronald Lamont-Havers, who was himself a scientist-expert in rheumatology. So far as I know, he never had any training in ethics, but he had an innate interest and he attracted people who were concerned about research ethics, listened to them, and did his utmost to incorporate their ideas into policy. I think he made an enormous contribution but he never claimed any credit for developing ethics policy.

Swazey: Why, after the National Commission, has human subjects research continued to be
such a major theme for the other commissions, and also for other advisory bodies?

McCarthy: I can give you a partial answer. I don’t know the full answer to your question. The first reason I would give is that unlike virtually any other federal agency, the NIH budget, with the exception of one or two years, from 1944 to the present has been increased every year. Even in the Reagan years when most federal budgets were slashed, the NIH continued to have more dollars each year in real terms than they had the year before. In some years like this current year, the budget jumped enormously. Whenever a federal agency gets a bolus of money, especially at a time when few of the other domestic agencies do, it draws lots of attention.

Rep. Daniel Flood from Pennsylvania chaired the House of Representatives Program Oversight Committee during the 1960s and 1970s. Flood drew attention of the Congress and the media to poor management, waste, and inefficiency in Congressionally mandated programs. The steadily increasing budget at NIH caught Flood’s attention. Year after year, Flood conducted hearings on the administration of NIH. Each year’s hearing was more rigorous than its predecessor. Each year, NIH officials pledged to Flood that the increasing flow of federal dollars would be efficiently distributed according to merit. As a result, NIH was motivated to improve its peer review system through constant evaluations and adjustments. Over time, the peer review system grew increasingly
sensitive to ethical -- as well as scientific -- issues in research. NIH dreaded
having Flood’s Committee find any reasons to curtail its budget!

In 1969 and the succeeding years, when the NIH budget expanded beyond
a billion dollars per annum, Flood’s Committee and many other parts of the
Congress focused careful attention on all aspects of NIH awards. Since one ethics
scandal, like that of Tuskegee, generates so much publicity, ethics violations are
seen as potentially threatening to the entire agency. Nevertheless, implementation
of the human subjects protections causes delays in starting and completing
research. Ethics oversight is costly. IRBs place a heavy burden on institutional
budgets. Thus there is always a tension between the desire to get research done
efficiently and quickly and with minimal expense, and the desire to conduct
research according to high ethical standards.

Furthermore, although ethical principles remain fairly constant, the
application of ethical principles to new research activities such as fetal research,
research in children, pregnant women with AIDS, stem cell research, cloning, use
of fetal tissue, pain research, genetics research, DNA tissue banks, and emergent
research all require imaginative new applications of the ethical principles.

Policies in these areas are, to say the least, controversial. Officials are reluctant to
issue policies unless they have been developed or reviewed and approved by
expert advisory bodies.
Although much of the work that NIH funds is related to the functioning of living cells or the parts thereof, the NIH is organized around major disease and major organ categories. Cancer, heart disease, blindness, diabetes, lung diseases, kidney diseases, eye diseases, neurological diseases, are only too well known to the general public and to Congress. That is why NIH is organized into Categorical Institutes -- because common diseases provide the kind of issue that the public is willing to address through allocation of tax dollars. The public has always been willing to support research into such diseases which touch almost every family in America and the world, but the public may cease funding such research if even a whiff of scandal touches it.

The categorical structure of the NIH was largely formulated, I think, by the so-called health lobby that was headed by Mary Lasker and her associates. I'm sure you know more about that history than I do. Mary Lasker directed a lobby group that counseled Dr. Shannon, Mr. Fogarty in the House and Senator Hill in the Senate. Although research, particularly basic research, often cannot be associated with a disease or an organ, the Lasker group felt that in fact the NIH institutes should be “categorical” institutes dealing with cancer, a major killer disease, heart, which is both an organ and a killer disease, diabetes, arthritis, and so on. As a matter of fact, in lobbying for more money for NIH they focused attention on the diseases that afflicted the families of the members of budget
committees in both Houses of Congress.

Swazey: The disease-of-the-month club.

McCarthy: Yes. For example in the civil rights days, what came to the floor of the Senate? Sickle cell anemia, because it affects mostly African Americans. There always has been a political element in the way NIH is organized in order to generate broad support for its growth from taxpayers. About 90% of the NIH budget is paid out to research institutions and the vast majority of those are major universities around the country. As a consequence, if anyone suggests that the NIH budget should be cut, suddenly the White House, Congressmen and Senators receive telephone calls, or letters, or visits from university presidents in leading universities all over the country. Since NIH funds research in nearly every state, whether they're big or small states, no Congressman or Senator can afford to initiate a major cut in research expenditures without taking political risks. It's a sort of medical-industrial complex analogous to what Eisenhower used to talk about with the military-industrial complex. That makes it almost recession-proof. But if several universities violate human subject rights, then the universities lose their influence and the entire system becomes vulnerable.
Wiltrick: Why does that mean that there’s a continuing attention to protecting human subjects?

McCarthy: In my opinion, and it’s probably not the whole reason, it’s because any research scandal, any publicity about subjects being harmed, especially loss of life or permanent damage, any such publicity usually affects in a detrimental way both the university that carried out the work, and NIH which has the obligation to oversee the research. It threatens that kind of budgetary phalanx described above. Any time you want to get NIH’s attention all you have to say is, “You’re not carrying out the will of the public to carry out research in a proper ethical manner.” If you shake the money tree, everybody is concerned!

Swazey: Is that why, would you say, the President’s Commission had the mandate to look at the adequacy of the federal regulations?

McCarthy: Yes. It is my belief that most of the legislatively created advisory commissions and boards that deal with health issues are better able to focus on research than on health care delivery. Research ethics are better understood, and much easier applied than the ethics of health care delivery. To date few people have advocated direct interference in the doctor/patient relationship. It is assumed that physicians
and other health care workers are bound by oath to work for the best interests of their patients. If the doctor/patient relationship is abused, large malpractice judgments can be sought from the courts. There are few major malresearch cases because research, by definition, departs from standard practice. Malresearch is much more difficult to prove. Furthermore, a research investigator is, by definition, working for the good of society, and is not expected to be working exclusively for the best interests of subjects. Consequently, the rights of subjects must be vigilantly protected by oversight. Finally, Senator Kennedy has exercised control or influence over the creation of virtually every health advisory committee. He has had an interest in research ethics ever since he came to the Senate. His interest is reflected in the Congressional mandates assigned to each of the advisory bodies.

I saw early drafts of the President’s Commission bill and I recall no mention of research in those early drafts. I was present at most of the hearings that led to enactment of that bill, and I heard no mention of research. I think when they were drafting the structure of the Commission they looked back at the previous National Commission, and I suspect they just incorporated some of the language pertaining to the adequacy of protections for human subjects. There also was another problem with the President’s Commission. The way Congress created the President’s Commission it was unlike the National Commission
because it wasn’t assigned to any department or agency. The support for that Commission, the travel, the stipends paid to the participants, the staff, were not assigned to any agency. There had been a moratorium on federal hiring so consequently the law created a Commission with no budget and no staff. It had no building space, and no start-up money. HEW Secretary Califano had found money in the Secretary’s discretionary funds to run the old Ethics Advisory Board that dealt with human in vitro fertilization and embryo transfer. When Califano got fired and Patricia Harris came succeeded him, she had no interest in the Ethics Advisory Board. She had been a civil rights activist and was interested in civil rights and putting as much personnel and emphasis as possible in that area. She had virtually no interest in research or research ethics. She took the money -- it was actually Charlie Miller, the acting Assistant Secretary for Health, who took the money -- that Califano had set aside for the Ethics Advisory Board and used it as seed money for the President’s Commission. The Ethics Advisory Board had several studies in process, one of which, at least in my judgement, was very important: that study dealt with whether the government should compensate injured research subjects. Mr. Gaither, the chairman, and Dr. Hamburg, the vice chair, went to the President’s Commission and said, “We had this study well underway, we are almost ready to publish on this. Can you take it over and include it in your mandate?” So the Ethics Advisory Board asked the President’s
Commission to take on at least one major research ethics project in addition to the
other studies, which were related to health care delivery. In return, HEW
provided start-up money for the President’s Commission.

I know Barbara Mishkin said it was a considerable shock when she suddenly
discovered the EAB didn’t exist anymore.

In 1978, I had resigned from the Ethics Advisory Board staff to take on the
directorship of OPRR, and Barbara succeeded me as Staff Director of the EAB.
Barbara and I were very close. I thought she would be a wonderful Staff Director,
but the Board was shot out from under her. That action would not have occurred
had Califano continued in office, but he gave a talk against the use of tobacco in
South Carolina. In both North and South Carolina the talk created some cracks in
Jimmy Carter’s major political base. For his pains Califano was fired summarily.
His firing had nothing to do with research or the Ethics Advisory Board. But I’ve
never seen such revisionist history in my life: twenty-four hours after Califano
was gone, a memo went out saying, “No one is to use his name anymore. If you
must refer to Sec. Califano refer to him as ‘a former Secretary of HEW’.” His
office was repainted, the furniture was changed, all of the pictures were replaced,
and a completely new staff for the Secretary was all in place within 48 hours after
his departure.

That sounds like China and Russia too! This was under Carter? It sounds more like Nixon.

This was under Carter. It was apparently directed by Hamm Jordan, Carter’s administrative assistant, because Califano had gone out of his way to offend Jordan. Califano’s staff told me that when Jordan called with orders from the President, Califano, with a big grin on his face, very impishly said, “If you want that done, tell Jimmy to call me himself, otherwise I’m not doing it!” I presume that sent Jordan up in smoke.

I had been Joe Califano’s confessor when he was a McNamara “whiz kid” with the Department of Defense. So we got to be pretty close friends. He then went into private law practice for a while, and served in the Johnson White House. We got separated; I lost track of him. I hadn’t talked to him in a number of years. I left the active priesthood, got married, got my job at NIH. I never knew why or how I was selected to be the staff director of the Secretary’s Ethics Advisory Board. I don’t think it was a choice by Califano. As it happened, Jim Gaither Chairman of the EAB and his assistant, Phil Halpern, who was a law professor from the State University of New York at Buffalo (SUNY), had
interviewed a number of people about ethics at NIH. I was on their list. I must’ve
said something they liked because they selected me to be their Staff Director. I
never knew how that decision came about. I simply got a directive from Califano
saying, “You will be the staff director.” I don’t think the Secretary had any idea
that I was the same person he had known in a previous time.

Swazey: Was there a lot of mutual shock when you connected?

McCarthy: Califano was notorious for starting every meeting by putting those at the meeting
on the edge of their chairs. He would often begin the meeting by saying, “Alright,
what kind of bullshit is this about?” or, “Why are you people here wasting my
time? What is on your docket that is so important that I have to give you my
time?” He would say this in a loud, hostile voice...partly because he was a
marshmallow inside. When we met with Califano about the upcoming report of
the Ethics Advisory Board, Dr. Frederickson, Director NIH, and I sat on one side
of the table, and Califano came in with his whole staff entourage, about 15 of
them. He sat on the other side of the table. He surrounded himself mostly with
civil rights lawyers who had been active in the 60s. They were very concerned
about the rights of subjects. They transferred much of their civil rights zeal to the
research subjects community. They found offenses against civil rights
everywhere. Califano began the meeting in his usual belligerent fashion.

Suddenly he stopped and looked at me very carefully. He asked Frederickson what my name was. Frederickson told him. Slowly, he began to smile. From that point forward, the meeting proceeded quietly. Califano agreed to approve each of our requests, though he was fired before he could make good on that commitment.

I never knew with certainty what was going on in the Secretary’s mind. Part of what we had come to seek approval for was the regulation concerning subjects who were cognitively impaired. The civil rights lawyers were very suspicious that we were creating a system that would compromise the rights of these subjects.

They wanted to have each potential subject represented by a “subject advocate,” a term which the research community understood to mean “legal counsel.” The research community was adamantly opposed to any such arrangement. A strange thing happened when this issue was being debated. A White House intern was sent to HEW. His name was Richard A. Tropp. He regularly sent memoranda to all the parties claiming to state Califano’s position on various parts of the draft regulations. The secretary was often said to take contradictory positions. These memoranda heightened controversy, and confused the drafting committee. The memos were always signed with Tropp’s initials: R.A.T. They came to be known as the “Rat Memos.” Eventually Califano stated in a public meeting that he had no idea who Mr. Tropp was, and he disavowed the content of the RAT memos.
Nevertheless, the memoranda contributed to the failure of the Department to issue special regulations for protection of cognitively impaired research subjects.

Swazey: That answers a question that nobody I know has been able to answer, which is why nothing happened to those National Commission recommendations.

McCarthy: Well, there is more to that story but that’s at least a piece of it. The other part of that story was the big controversy within NIMH, the National Institute of Mental Health, which was, at that time a part of ADAMHA, between those who were contending that psychiatry must progress by improving psychoanalysis versus those who argued that mental illness has a biological base and must be treated by drugs, or by genetic therapy, or some other kind of physical approach to mental illness. That division was very deep, and coupled with the attitude in the department, those who were arguing for a biological base for treating mental illness were having trouble getting money for research using drugs to deal with schizophrenia, depression, bipolar disease, etc. They were afraid that regulatory restrictions would drive their colleagues away from doing controversial research in a very vulnerable population. They were afraid it was going to shut down their whole approach to mental illness. They believed that if they were restricted, the psychoanalysts would gain control of NIMH. Dr. Gerry Klerman was the head of
NIMH at the time. He believed that mental illness needed to be treated primarily by administration of drugs. He would never sign off on those regulations. He kept trying to make the regulations less restrictive. He argued that it's a hard area in which to conduct research, and few people are doing it. If you set the bar very high you will drive all the remaining researchers out of the field. On the other side of that issue were the civil rights lawyers downtown who said, "You are trying to exploit people with mental illness. We must require a consent auditor and somebody to exercise research oversight." The two sides neutralized one another, and nothing happened. You couldn't get sign off from anybody on that topic. I couldn't...I went to the Secretary's office, I went to NIMH, I went to the lawyers, Rick Cotton, HEW General Counsel. I never could get to first base with those regulations. I thought even weak regulations would be better than none, but we couldn't get anything moving. Secretary Harris wouldn't sign off unless the PHS agency heads concurred, and so the issue stalemated and died.

Before I let you go can we talk about what I have a sense has been a ground shift in the past few years from emphasis on rights of access to research back to a concern with protecting human subjects. We've had media discussions of various research scandals again, reports on the inadequacies of IRB supervision of research, and just a whole lot of things going on. What accounts for it?
I doubt there’s a single cause. I think I know some of the ingredients of that issue, but in some ways I’m as puzzled as anyone else as to why this has occurred. One element of this question, I think, is caused by the fact the old National Commission classified pregnant women and, almost without thinking, “women of child-bearing potential”, as vulnerable. Initially, I think “vulnerable” was a fairly innocent term that meant “worthy of special protection,” but it quickly was transformed in the 1980’s, particularly with the advent of AIDS, into a pejorative term meaning “vulnerable populations who can’t make decisions for themselves.” Once that occurred I think there was a backlash against the fairness of researchers in recruiting subjects. I think that was tied to the fact that in the early 1980s there was lots of controversy over admission to AIDS trials because outside of a clinical trial there was virtually no medical assistance for anybody who was diagnosed with HIV. Initially, it was thought that AIDS affected only gay males. They regarded research as their best chance for survival. They sought to increase research funding and they wanted to be subjects. They mobilized gay males all over the country to campaign for more research, less restriction on new drugs, and for community based research. When it was discovered that women also develop AIDS, and that they had been excluded from research, they became angry. Women with AIDS who were pregnant were, for a time, excluded from research. They deeply resented the exclusion. So women who were infected, joined the gay
community and demonstrated publicly. They argued that participation in research is their right. In the process they described research as if it is nothing different than cutting edge therapy, and often spoke of the risks associated with participation in research as negligible. They believed that the best available therapy for whatever kind of disease or condition you have is to be found in research. That clearly was contrary to the thinking of the National Commission, which insisted on warning the public that you need to think twice about getting into research because, although it may offer benefits, it almost certainly offers risks. Some of those risks may even be deadly, or permanent, or disabling. That kind of message was often lost in the early days of AIDS research. Then when the FDA relaxed some of its restrictions on the early dissemination of drugs that had not yet been licensed for AIDS, a number of deaths occurred, partly as a result of not following the regimen, but partly as a result simply of taking as yet untested and unsafe drugs. People who had believed that research was safe therapy sometimes overreacted by saying that researchers will exploit you if you let them. I think the pendulum first went one direction, that research is essentially risk-free, and is swinging back in the other direction, that research is very risky business, to be avoided if possible. Neither extreme is accurate.

There have been other factors that are involved in this process, one of which is the change in the way we fund research. Back in the 1970's when I came
to NIH research was mostly funded in RO-1 grants, that is to say, grants made to a single institution for research to be carried out by a single principal investigator on a cohort of subjects recruited from a local community. There was a trusting relationship between the institution, the investigator, and the subjects. There was mutual trust analogous to the kind of trust that patients often have in their personal physician. Everybody knows that people criticize the medical profession in general, but they trust their own doctor. The analogy is that research subjects knew and trusted their own research investigator not to harm them and to track the data in such a way the trial would be stopped should they be at significant risk.

But in the 1970's NIH began to fund more and more multi-center projects, and as a consequence a typical research grant today is a program project grant that may involve 10, 20, 30, or up to 125 different institutions all recruiting a huge cohort of subjects for a research protocol that was designed centrally. As data develop they are sent to data and safety monitoring boards. Local IRBs have very little ability to know whether the ongoing research is dangerous or not. Most data and safety monitoring boards do not feed back to the IRBs, so when the IRBs do their continuing reviews, they have little evidence to guide their decisions. IRBs ask, “Have you seen any risks associated with this research?” If the local researcher says, “No,” then the research is continued locally, whereas, if you have 20,000 or more research subjects and a trend toward serious side effects or even deaths
begins to manifest itself, the only ones who are going to know of the trend are the
ones who are collecting and analyzing the data centrally. Now and again, as with
the breast cancer study that led to a discovery that a helpful breast cancer drug,
tamoxifin, is associated with an increased risk of endometrial cancer, the only
persons who could possibly know that are those who are members of the central
committee reviewing the data. In that case a number of women had advanced
endometrial cancer. Some died. Local IRBs had no way of knowing that the
endometrial cancer was linked to tamoxifin. Subjects felt betrayed. That situation
has led to a backlash. Once again the public recognized that research is risky. So
I think a major issue confronting research as it's currently funded is to monitor
data in such a way that it gets fed back to the local IRB and the local investigator,
who can warn subjects about risks that were not recognized in the beginning.
There have been several examples of adverse events that were not made known to
local IRBs. It’s not widespread, but when it happens, everybody, including the
local investigator, the local institution, and the local coterie of subjects, is
shocked.

I also think there’s been a shift in policy in OPRR. OPRR was
emphasizing only one aspect of its twofold mission. When Congress enacted the
law, which was part of the same law that created the National Commission, it
insisted that OPRR provide an education program. During the Reagan and Bush
years travel money was so restricted that OPRR had to cut back on education programs. Although I doubt you could prove a correlation, I believe that as education programs declined the number of reported failures to comply with the regulations increased. I believe that there is a direct correlation between failure to educate investigators and IRBs about the rules and the necessity to sanction failures to follow the rules. I think the cut-backs were penny-wise and pound-foolish. You can run about 20 education programs for the cost of one major investigation. Investigations are usually sensational. The media almost never cover an education event, no matter how good the quality is. But let there be a subject injured in the course of research or a failure by a leading institution to follow the rules, and you have front page news. As a consequence I think the downgrading in education led to the increase in both infractions and punishments. OPRR shifted the educational emphasis from an appeal to the Belmont Principles to letter of the law compliance. “If it was not recorded, it did not happen” was an OPRR dictum. It shifted emphasis from human rights to Paper Protections. Instead of doing the right things as a matter of principle, it emphasized: “Don’t get caught.” That minimalist approach usually leads to trouble.

Swazey: What do you do, Charlie, and I am certainly the last one to denigrate educational programs, when you have institutional officials at places like Duke, to cite a
recent example, saying to themselves and to the media that “the violations were just technicalities”? I sat there and said, “My Lord, after 20 years, they don’t get it!”

McCarthy: Let me answer the question this way. I went to virtually every national meeting of research administrators that was held during the time I was director of OPRR. I made it very clear to administrators that if they would call me and let me know their problems we would work with them in two ways. One, we would help them correct the problem and bring whatever federal pressure that was necessary to bring investigators into line and to get the money necessary to do the staff work, so that these so called “technicalities” could be corrected without embarrassment to the institution. We reached a point where we had many institutions calling for help. We settled most of those cases that never hit the press quietly and efficiently. Sometimes we got people fired, sometimes we forced the hiring of additional staff for the IRBs, sometimes we required the IRB to do a self-assessment, sometimes we insisted the institution get a new chairperson for the IRB. All of that occurred because the administrators understood that they could escape publicity if they would work with us.

I think after I left that policy discontinued. Now each deficiency is the subject of a press conference. It’s a different way of trying to force institutions to
pull their socks up. But what has happened now is that when institutions have a
problem they hide infractions. Without federal pressure the problems get so big
that they can’t be hidden anymore. When that happens, if there have been no
documented harms, the University defends itself by calling the infractions
“technical violations.” So it seems to me that the former system was less
expensive, less costly to research, less risky to subjects. But that’s a statement
coming from one who pursued the old policy. I have a definite bias, but it seems
to me that it worked better than the new policy of “Gotcha! We’re out to catch
you doing something wrong.” Now, in retirement, I receive a call at least two or
three times a month telling me, “We have a problem, we don’t dare tell the
government. Can you help us to find a way or make recommendations to resolve
our problem? We want to do research in the right way but we don’t dare work
with the government for fear of reprisals.” The best example I can think of is a
university that called me. I took two colleagues along, we evaluated them for
three days. Then we outlined a remedial course whereby they would update their
software to track their research; they would increase the staff for their IRBs; they
would create a new training program for their investigators; and they would hire
somebody new in the provosts’s office whose primary job was to ride herd on the
human subjects dimension of the whole research program. All those
recommendations were made to the institution. A few weeks later OPRR got hold
of that report and suspended all the research in the institution, which had already
begun to initiate its remedial action. The OPRR action set the whole process of
correction back by about a year. The university’s only defense was to say: “OPRR
was unable to prove that anybody had been injured.” OPRR’s action probably
cost the institution around $5 million in federal and industrial grants. We don’t
know how many research subjects were upset because they were left in the middle
of a suspended, unfinished project. I believe that part of the problem is the
attitude of those who are trying to enforce the rules and failing to understand that
these “technical shortcomings” can be repaired without necessarily putting them
on the front page of the Washington Post. Problems need to be discovered, and
the best way to discover them is by whistle blowers in the institutions. If the
institution understands that it can take remedial steps with government assistance
and support, but if caught without having identified its own problem that it will be
seriously sanctioned, I think you get better compliance.

Swazey: I know that Barbara Mishkin is spending a considerable amount of her time now
going from IRB to IRB. Institutions are calling her to do compliance audits and
saying, “Are we doing things okay?” I’m sure you could do that 20 days a week,
and that’s good.
McCarthy: I have a little team of people now that I work with; we do as many site visits as we can. But the danger now is if we or Barbara writes a report, saying “You’re out of compliance on four different counts,” and somebody leaks it and that report goes to OPRR, that institution may be sanctioned. It seems to me the next step is to say, “We can’t tell anybody that we’ve got problems. We’ll try to deal with it ourselves but we can’t even tell the president of the university or the chancellor we’ve got a problem because if it gets to our trustees then it’s out in the open.” So some institutions are hunkering down, and not correcting their problems.

Swazey: What does that whole climate bode for the thrust to develop a certification program for IRBs.

McCarthy: There are two programs, there is accreditation and certification.

Swazey: I guess I’m thinking of the accreditation.

McCarthy: The accreditation effort is directed to creation of a corporation to conduct a confidential evaluation of programs for the protection of human subjects. PRIM&R has taken the first steps to do that. The new corporation will be analogous to AAALAC; a corporation that evaluates programs for humane care
and use of animals. An institution will be able to get a confidential evaluation by
competent people that its human subjects program is operating properly, within
the rules, and that its training programs are adequate, and that its recruiting
processes are legitimate. OPPRR/OHRP will have to respect the accreditation
process for humans as it has done in the past with AAALAC accreditation of
animal care and use programs. That is to say, that an institution that fails to win
accreditation is given a grace period before sanctions are imposed.

I also think part of the problem is just that the NIH budget continues to
grow, it's getting bigger, and bigger, and bigger. OPRR has about the same
number of personnel now as when I came, and while we now have computers that
make the effort more efficient, I think they need more and better staff. Therein
lies a problem for which I have no good answer: some OPRR staff have been
failed scientists. They are the people who tried careers at the bench or in the
clinic, but were not successful. They look for administrative jobs. The really
sharp research people don’t want to do research oversight. So the research
community tends to be more clever than the investigative community or the
oversight community. I don’t know any complete answer for that. Part of the
answer lies in persuading investigators to do the right thing rather than threatening
them if they do the wrong thing.

The problem has been particularly critical with FDA, because when the
FDA’s Bioresearch Oversight Program was created, Congress gave them a budget. FDA decided, “We need a lot of inspectors but we have a small budget. So we will recruit at relatively low salary levels.” Inspectors are given a checklist and they are asked to go out and evaluate very sophisticated, complex research. Inspectors are seldom sophisticated scientists so they look at forms and files rather than risks and benefits. They often miss serious shortcomings. If an institution’s paperwork is up to date the institution is seldom criticized. That can result in institutional complacency.

Swazey: What about Tuskegee? Has that reverberated down to have an effect on protection issues?

McCarthy: I think the Department of Health and Human Services has made serious efforts to make sure that the justice principle, enunciated by the Belmont Report, is honored in fact as well as in theory. That means that an honest effort must be made to recruit both genders and minorities in numbers consistent with their representation in the catchment area. In other words, if you’re in Chicago you need to make sure that both genders of Polish people as well as other European Americans are included, and African Americans and Hispanics. You don’t have to include Native Americans because there are very few of them in that particular area.
Whereas if you are at the University of Colorado or New Mexico then you ought to be including Native Americans and Hispanics, but not very many African Americans. So unless there is some scientific reason -- if you’re studying ovarian cancer you may not want to recruit men -- you should get a cross-section of the catchment area. In order to do that, you have to have some kind of outreach to the community. Right now the Black community is very disaffected as a result of the residue of the Tuskegee study, and it’s very hard to recruit African American people for research even when the risks are not very high. Community out reach is now a research buzzword, as yet it is far from a reality.

Swazey: You had indicated during our break that the black community is nervous now about being in research.

McCarthy: I think so. I think it’s partly due to a recent popularization of Tuskegee. A black cab driver asked me the other day, had I read Bad Blood? As best as I can recall that was published about 1974. This man had just discovered it as if it was brand new. I hear much more about Tuskegee today than I did in 1971. Why that has occurred I cannot say, but that it has occurred, I have no doubt. I think “Miss Evers Boys”, the inaccurate dramatization of the Tuskegee study, has had a big impact. I’ve heard more reference to Tuskegee on television in the last few years
than I did at the time it was first exposed. Part of the reason, I think, may go back
to President Clinton is making a public apology for Tuskegee. I am a member of
a local Kiwanis Club in Richmond. The group asked me to give a talk about
research. Since the membership is about 60% black I thought I ought to mention
Tuskegee. The blacks said, “We know all about that. That’s when white doctors
gave syphilis to black subjects to see how long it took them to die.” That’s an
incorrect but popular version of Tuskegee. The study was bad enough, but this
version suggests that investigators set out to kill blacks with a disease that would
cause slow, lingering death.

Swazey: That would not incline one to become involved in research.

McCarthy: That kind of rumor gets widely spread in a place like Richmond. These are
middle class blacks, most of them are principals of high schools, teachers,
professionals. They are prominent in the political scene. So I’m hearing incorrect
versions of Tuskegee from relatively well educated blacks. That really scares me.
The facts themselves are indefensible. The rumors are worse. I don’t know if
that’s universal. I hope it’s not but it’s certainly true in my area.

END OF INTERVIEW