

DIVISION OF CANCER PREVENTION
ORAL HISTORY PROJECT

INTERVIEW WITH

Dr. Arnold D. Kaluzny

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Biographical Statement

Dr. Arnold Kaluzny currently serves as a Professor Emeritus at the Department of Health Policy and Administration, School of Public Health, University of North Carolina at Chapel Hill. A native of Milwaukee, Wisconsin, Dr. Kaluzny received his Bachelors of Science Degree from the University of Wisconsin and his Masters of Health Administration from the University of Michigan. In 1967 he earned his PhD in Medical Care Organizations and Social Psychology from the same university. In addition to professorial duties at various institutions during the past three decades, Dr. Kaluzny serves as an advisor to numerous national and federal programs. Appointments include member or Chairman duties for the Advisory Committee to the Kansas Health Foundation, the Board of Directors of the AMC Cancer Research Center, the National Advisory Board for the University of Arkansas, and the Steering Committee for the Department of Veterans Affairs. His advisory position for the Division of Cancer Prevention and Control (DCPC) began in 1991 when he joined the DCPC Board of Scientific Counselors. Currently, he serves as the Senior Advisor to the Division.

This interview covers Dr. Kaluzny's contributions to the evolution of the Division of Cancer Prevention. He touches on his participation in study sections, as well as transition periods and policy decisions within the National Cancer Institute and the Division of Cancer Prevention. In particular, Dr. Kaluzny discusses the split between the Division of Cancer Prevention and the Division of Cancer Control and Population Sciences in 1997.

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**National Cancer Institute
Division of Cancer Prevention Oral History Project
Interview with Arnold Kaluzny
Conducted on December 18, 2008, by Philip L. Cantelon**

PC: Well, I don't know.

AK: Okay. I hope it goes better than the last conference call I had.

PC: Well, this is only conferencing with me for right now.

AK: Okay.

PC: I'm speaking with Dr. Arnold Kaluzny, K-A-L-U-Z-N-Y, on December 18, 2008, and I have your permission to record the call?

AK: Sure.

PC: Thank you very much. Let me start out, tell me a little bit about yourself, how you came to work with the Division of Cancer Prevention and Control.

AK: Like most things in life, my work with the Division involved a fair amount of serendipity. I came to Chapel Hill in 1967, as an Assistant Professor of Health Administration, working on a project that was looking at the implementation of various kinds of health care programs in hospitals and health departments. These programs were defined as

organizational innovations. As part of that project, we brought together a group of people doing research on organizational innovation to identify some of the major issues of the day. One of the people who attended was Dr. Saxon Graham. Saxon Graham was a sociologist from the University SUNY in Buffalo who had been doing a lot of cancer work, particularly in the area of cancer control and prevention. The conference was very successful, a small monograph was published and in retrospect launched a long term affiliation with the Division of Cancer Control and Prevention (DCPC) and the now Division of Cancer Prevention (DCP).

As it turns out, a few weeks after the conference, Dr Graham was scheduled to participate in an NCI site visit to the University of Chicago Comprehensive Cancer Center. He couldn't make it, and suggested to Wayne Hurst, the executive secretary, that he invite this young guy down in Chapel Hill to join the site visit team. He's a social scientist and interested in organizational innovation. We went up to Chicago, and I had a good day. I apparently asked the right questions with the right tone, and pretty soon, I was invited to participate in a number of NCI ad-hoc reviews and eventually was appointed to a chartered cancer control study section. So that's how I moved into the world of cancer control and prevention. The rest is history ... as they say.

PC: And how did you get to NIH and work with them?

AK: The Division of Cancer Control and Prevention was one of the divisions within the National Cancer Institute, which is one of the institutes within, the National Institutes of Health.

PC: And so you came just as doing this on an advising capacity.

AK: Right. The various institutes operate with all sorts of ad-hoc study sections selecting people from around the country based on relevant expertise. The various institutes invite people they think can add to the complement of folks that they need on various study sections, perhaps beginning with an invitation to be a member of a site visit. If you contribute and add value to the review you may get invited to be an ad hoc reviewer. Eventually, when there is a vacancy in your area of expertise on a chartered study section, e.g., the study section needs representation in a particular social science or clinical discipline with relevant expertise appointments are made with specified time limits up to four year terms. I consider participation, particularly on a chartered study section to be one of the highlights of my career. You get to know your colleagues very well and you have the opportunity to review the science/research as it is being proposed/practiced throughout the country. Participating in study section is something I recommend for every researcher who has an opportunity to participate in the NIH peer review process.

PC: And when did you do the first one of the DCPC?

AK: Well, oh, golly. It must be – I think this initial site visit was launched probably in 1970 or '71. And then there was a two or three-year period that I functioned as an ad hoc reviewer. I'd have to go back and check exactly when I was first appointed to a NCI chartered study section. As I recall, it was chaired by Dr. Talbot who at the time was the president of the Fox Chase Cancer Center. Bob Browning was the executive secretary and the group was composed of various disciplines including physicians, biostatisticians, epidemiologist, nurses with a cancer background and a community activist ... all outstanding people.

PC: Uh-huh.

AK: We would meet in Wing C of Building 31, up on one of those large conference rooms. Now, these rooms are reserved for the various policy boards and the study sections meet in area hotels.

PC: And what was the nature of the office then within NCI?

AK: Well, it was – you mean the Division of Cancer Control and Prevention?

PC: Yes.

AK: The DCPC was an extramural division in which they had a whole variety of programs dealing with cancer control and prevention. As you know when Dr. Klausner was the

NCI Director, the DCPC was partitioned into two components; one of which is now the Division of Cancer Prevention, and the other the Division of Cancer Control and Population Sciences. This occurred, I think, around '96 or '97, something like that. It was a pretty traumatic split. Two review groups were created, one for cancer prevention chaired by Dr. Edward Bresnick, and the other for cancer control. I was appointed to the cancer control group chaired by Dr. David Abrams, a sociologist from Brown University. The group was composed of an interesting cast of characters. Ernst Wynder was on that committee, as I recall, Helena Brown to name a few. Many of the people had been on various NCI study sections over the years in one capacity or another, and we met for a three or four-month period and then came up with a report. Probably the most significant contribution of that report was the fact that it declared for the first time to my knowledge, that the social and behavioral sciences were the basic science for cancer control.

Dr. Klausner appointed Barbara Rimer as the director of the Division of Cancer Control and Population Sciences. Peter Greenwald, who was the prior director of the DCPC, after a fair amount of trauma and some writing and support generated from the external community, was appointed the Director of the Division of Cancer Prevention, which is the current position Peter holds.

PC: You say trauma. What kind of trauma?

AK: Dr. Greenwald was required to apply for the position as opposed to simply making an appointment based on his acknowledged expertise and contribution to date. There was a

fair amount of effort by the external community who were very supportive of Peter – writing letters of support and, as you know, he's received during this period of time, various awards for his work in recognition of his contribution to the field of cancer prevention and control. Eventually, he was in fact, appointed.

PC: Let me – and this was something, the split was, you say, engineered by NCI?

AK: Rick Klausner was the NCI Director at the time, and I'm not sure of the logic for all of that, but it was a fairly arbitrary split. And that's how we ended up with now two extramural divisions.

PC: You, in the late 90s, you were on a panel that – '96, '97, Special Review Group on Cancer Control. And that was after the split?

AK: When was this?

PC: '96, '97.

AK: I think that's the panel I was talking about that defined what is cancer control, and provided the cancer control research agenda. Who chaired that? Do you know? Do you have that in front of you?

PC: No, I don't. I just have you as a member.

AK: Okay. I would venture to guess that's the one I was talking about, when they created these two separate panels to review and define what is cancer prevention and what is cancer control. That's the charge given to the committee, and in the process of doing that, suggesting a tentative research agenda. Bob Hyatt was also on that cancer control committee, and was appointed the Deputy Director of the newly formed DCCPS.

PC: Barbara Rimer.

AK: I have no idea what happened in the other committee. I think you ought to read those reports as background because they were really very definitive not only for the newly created Division of Cancer Control and Population Science but also for Peter's division as we know it now. As I recall the Cancer Prevention report was a rather negative review of the work that had been done within the DCPC.

PC: And this was problems in DCPC?

AK: Right, and associated with Peter's leadership.

PC: Uh-huh. And who chaired that one? Who –

AK: Dr. Bresnick from the University of Massachusetts.

PC: Okay. And so it was, basically, an attack on Greenwald.

AK: Yeah. It was not a friendly report.

PC: And was it set up that way to begin with?

AK: I don't know.

PC: If Klausner really wanted to get rid of it?

AK: Perhaps.

PC: I understand these things have happened at NIH.

AK: Yeah. It's a body contact sport up there [laughter].

PC: [Laughter]. And is that why you stay in Chapel Hill?

AK: That's right [laughter]. No, I have a day job, you know. This was not my main activity since I had teaching and administrative responsibility at UNC.

PC: Well, I thought you were emeritus now.

AK: I am. But I continue to be involved with the DCP. Always interesting and challenging and sometimes even entertaining.

PC: Well when they put the – how did Peter try to reassemble DCP? I mean, the bad review must've had some – to it anyway.

AK: Oh, yes. Well, Peter's a unique person. I don't know whether you know him very well, but he's one of the most unflappable people and an individual with a clear vision and commitment to developing preventive oncology as a clinical discipline and saw the DCP as an opportunity to develop the science base for preventive oncology.

PC: Well, you know, it strikes me that there's – I'm not hearing something. Maybe it's –

AK: Yeah, go ahead. I don't want to be subtle [laughter].

PC: No. Here is a division which is, not necessarily within the NCI mainstream, that is prevention rather than –

AK: Right, I think that's true. I think that's true.

PC: And so how much did NCI really know about what cancer prevention was when they issued a report?

AK: Well, I'm not sure they knew then or they know now. Prevention is not a well defined mainstream activity. As an extramural division, it's a fairly vulnerable unit within the larger organization, contingent on the priorities of the director of the NCI; I suspect however, that both prevention and control will receive greater prominence and focus, and will be a major priority as we go forward. Increasingly, attention is being given to disparities, outcomes research, various delivery issues and the economics involved. For example, the work of Martin Brown and Steve Clauser and their colleagues in DCCPS. Similarly the various programs within the DCP such as the Community Clinical Oncology Programs,(CCOP), the Early Detection Research Network (EDRN) the Consortium are significant efforts. So I think, I think it's coming along.

PC: Uh-huh. When the office got split in the, I think probably by the late 90s it was –

AK: Right.

PC: It was – and I shouldn't use the passive there. I think Peter reorganized it with, perhaps, some help from you?

AK: He re-organized it – that's right. What we had when it was split was simply a series of functional units. We had nutrition, we had CCOPs, we had biometry, preventive science, one or two other units. Peter was, rightly, concerned that these were fairly autonomous units. As we all know the opportunities in science are always at the intersection. The question becomes how do you begin putting this together to facilitate interactions in a

way that new ideas would emerge relevant to the development of prevention as a science.

The second was that the division needed a closer link to the clinical community.

PC: Excuse me. This was not in the report.

AK: No. This is after he was already appointed.

PC: Okay, thank you.

AK: Incidentally, this was somewhat of a problem in DCPC, but became really apparent as the focus was now clearly defined on prevention and the chemoprevention trials. You really need to have people interacting to capture the relative expertise of the various disciplines. The second problem was the division did not have a good link to the clinical community. It had the CCOPs, but it couldn't translate what it was doing in terms of how clinicians think about disease in terms of specific organ sites. I remember Peter drawing a diagram with the horizontal axis being the existing functional units and then the vertical axis being various organ sites relevant to clinicians, e.g. GI, Breast, etc. He was trying to think of how we could organize the division in a way that would facilitate interaction and link to the clinical community. I said, "Peter, that's a matrix organization, and the vertical axis represents product lines." That's how we ended up with this matrix structure which is, essentially how DCP was functioned from, say, 2000 till about a year ago. We had the original functional units, and then the designated research groups for GI, breast, urologic cancers and lung with directors for each. Project teams were created to facilitate the

interaction among the research groups. The problem was that instead of focusing on the development of specific products/service lines, a good share of other activity of the division was linked to the project teams. Everybody had to be in a project team. Well, this just didn't go very far. People were overwhelmed by participating in project teams and it became obvious that some adjustments had to be made. The present structure is leveraged without designating project teams, but requiring collaboration among the various research groups. For example, the chemoprevention research group, which is a functional unit, works across the organ site groups. We just had a retreat in which the nutritional science research group will be expected to work collaboratively with the various organ site groups. Another recommendation was that the biometry research group, which has tended to be somewhat isolated within the division, work collaboratively with not only the organ site groups, but with all the other functional groups within the DCP. Does that help?

PC: Yes. Yeah. The reason behind the changes was that there are too many meetings,

AK: Yes but it did serve a purpose because for the first time, people were talking to each other about the substantive issues of the division.

PC: And they had not been before.

AK: Well, not as much as you would think.

PC: Sort of like an academic department.

AK: Absolutely. You've been there, I've been there. You know, everybody's happy doing their own thing. And this forced a little bit of understanding of what other people are, in fact, doing. And we still are working and struggling with that in a much more explicit way than we had in the past.

PC: And was this matrix system something that North Carolina had been doing as well?

AK: Well, what they did – excuse me, what we did is when we launched this thing originally, Peter and Leslie Ford and Shannon Brandon and maybe one or two other people came to North Carolina, and we talked with Dennis Gillings, who is the president and CEO of Quintiles, which is this large contract research company, which does a lot of clinical trials, and spent the morning with him and his organization to see how they do things. Quintiles was based on project teams, as service lines responsible for specific projects that are being developed and/or managed. We also visited Burroughs-Wellcome, which has now been reorganized as Glaxo-Smith Kline, but they also had a matrix structure. Based on the visit, we simplified and tried to apply the concept to the DCP. Unfortunately in retrospect, project teams were created for all sorts of activities that really didn't need to have a project team and in the end, it died of its own weight. But from that came the fact that we're seeing leveraged relationships among the research groups and the organ site groups involving the substantive work of the division.

PC: From your perspective, when the two groups are split, did a lot of the people – what did the split do to the – to the morale, I guess, in the whole – in the division period?

AK: Well, I think, I think it was in the short-term – that's a good question. Short term, long term. Short term, people felt very good about that because the division was staffed by clinical and basic scientists with a very specific focus- cancer prevention and “real science”. The social science people were now in DCCPS focused on the broader issues of cancer control. If you look at our group within the Division of Cancer Prevention, these are all Ph.D.'s /MD's or both in the basic and/or clinical sciences sharing a common culture and training. And that was a short-term, I think, benefit.

Longer term and this may be just my perception, but I think there is some feeling, that the division could benefit from some of the economists and health services research people that were part of DCPC and remained in the newly constituted DCCPS. I don't know whether they had the choice, but particularly the group – some of the economists in the health services research unit, because increasingly, the issues of cancer prevention involves questions of economics, the cost benefit, cost effectiveness, the measurement of this activity, makes these disciplines very relevant.

PC: But don't you consider yourself among the social scientists?

AK: Well, yeah, but – [laughter] absolutely. I don't know why I have a special relationship with this group, but I suspect my interest in organizations – how and why they function,

is aligned with many of the challenges that DCP deals with as they manage the large clinical and bio-medical networks such as CCOP and EDRN etc.

PC: Uh-huh.

AK: If you look at the CCOP program, the early detection research network (EDRN), the consortium dealing with the early phase, chemoprevention trials involving the four organ sites, these all involve organizational issues, and that's probably my link with the DCP group.

PC: And yet, your perspective is, you know, step back and be a little distant. Well, you're part of it; you're not really quite part of it.

AK: That's right. You know, in the case study of the development and implementation of the DCP matrix structure we referenced Bosk, *Forgive and Remember*. Are you familiar with this book?

PC: No, I'm not.

AK: It's a classic. It's a marvelous book. It's the story of two surgical units within a hospital and how physicians handle failure. Bosk is an anthropologist, and essentially lived in these two units. As you know, the only way you learn surgery is you do it. And

sometimes you make mistakes, you make stupid mistakes, knowledgeable mistakes, and *Forgive and Remember* is an analysis of this learning process..

PC: Uh-huh.

AK: The book has a very nice methodological appendix, which talks about the challenge of maintaining objectivity when you are part of the organization under study. So I'm very sensitive to that. In one of the reports, I tried to address that because I think it is an issue if you're so close to these people. In fact, several years ago I mentioned to Jackie Havens, who for many years was the head of the ARC that after spending a week at DCP I feel like the organizational psychiatrist. Everybody tells me all their problems. She says, "No, Arnie, you got it wrong. You're not the psychiatrist. You're the priest."
[Laughter].

PC: Uh-oh.

AK: You just get to know these people, you hear all the problems. So I do think I have a very privileged relationship with the division.

PC: Well, when – let me go back, because you were associated with the division in the early 90s.

AK: Yeah.

PC: Before the breakup.

AK: Yeah.

PC: And how did it function? Peter was still there then. I mean, he'd been leading it for almost a decade.

AK: Peter, whether he's leading the DCPC or whether he's leading the DCP, is pretty much a “hands-off” manager. He believes that you get smart people and you let them do their own thing. And that's how they operated within the DCPC. This is great for people who are smart and dedicated, and he's got a lot of them doing this kind of thing. The problem is that, all this occurs within a large bureaucratic organization, and I think this is probably where there's some concerns expressed at different levels.

PC: The people at NCI don't always consider this the best management technique?

AK: Yes..., NCI is a big beaurocratic organization, yet the DCP runs pretty much like an academic department. That's the beauty about it. That's also what the problem is in terms of its ongoing day-to-day operations.

PC: Well, one of the things that I was reading on the matrix system –

AK: Yeah.

PC: — was that it was supposed to produce leadership.

AK: Yeah.

PC: Did it?

AK: Within?

PC: Yeah. If the system before was to produce leadership or, you know, let you manage, you're the leader, then the system that comes in was to improve motivation – I'm sort of quoting what was said at the time, motivation, leadership qualities –

AK: Right.

PC: Because these groups could emerge, they would be stronger –

AK: Right.

PC: What was it? Communicate and –

AK: One of the real virtues of, DCP is, while Peter tends to be fairly hands-off, he also believes in evaluation. This was the case with the matrix organization. Same kind of thing with the CCOP study. DCPC developed the Community Clinical Oncology Program, (CCOP) and he and Leslie Ford and now Lori Minasian have supported an extensive evaluation...assessing its structure and operations. What do we know about the management of these organizations that would help us improve the ability to accrue patients from a community hospital setting? But to your question, I think what was lacking was the fact that these were all clinicians, or scientists with limited or no management training. Although there have been several attempts as part of the OD effort involving Rhey Palmer.

We've been very fortunate within that division to have contracted with Rhey Palmer over the years. He's one of the best OD people and works very well with clinicians and basic scientists. He's very effective and has been able to engage the division in a constructive dialogue among the various research groups. But what's missing, and we recommended this on this evaluation of the matrix structure, was tailored management training for selected people with the division. The training would need to address the kinds of issues and problems that they face within an NCI/NIH context.

If you read one of the reports that we did, I was suggesting the Center for Creative Leadership in Greensboro, NC, and I have no financial interest in that place. The Center does this kind of training for groups of people specifically tailored to the needs of the

sponsoring organization. We were never able to get that approved or funded. The report was made, the recommendations were received, but no action was taken.

PC: When you say not funded, not funded from NCI?

AK: Right. Right. It was when – the time that we were having the various budget cuts, and as you know, they've taken a tremendous beating with the funding situation. So this never really happened. While we had some modest training efforts, for example, they did a 360-analysis, the follow-up has been minimal but we continue talking about a much more sustained effort to make something like that happen.

PC: What is the impact of the scientific advisory council or advisory board, board of science – you know, it changes its name from time to time.

AK: Right. The BSA.

PC: Yeah.

AK: The Board of Scientific Advisors.

PC: Yeah. On the agenda of the division?

AK: IT drives the agenda. I chaired the BSA at one point in time. The BSA is composed of outside people representing various disciplines relevant to the work of the division

PC: Uh-huh.

AK: So they have projects which are being conducted by the external – extramural community. But the concepts that result in these RFP's are developed by in-house people within each of these different research groups. The professional personnel from the various research groups present the concept to the BSA for approval and funding. This is a very rigorous process. A concept is developed, it's reviewed by – now it's called the DCP Coordinating Unit, composed of all the chiefs of the various research units within the division. If it is approved by the CU, Peter takes it to the NCI Executive Committee, composed of the directors of the NCI divisions, and chaired by the director of the NCI. If approved at this level, the concept is presented to the Board of Scientific Advisors. The approved and funded projects drive the research agenda of the Division, and DCCPS.

PC: Uh-huh.

AK: And so it's composed of outside people, basic scientists, clinical scientists, some patient advocates, sometimes management people. It was and remains a very rigorous group and the NCI people work very hard as they prepare their respective presentations... big money projects and reputations are on the line.

PC: And why have they – why does the BSA cover both divisions now?

AK: That's just how it was organized.... keeping in mind that the prior BSA covered the DCPC... which consisted of both prevention and control activities.

PC: So even – this is post-split or –

AK: Yes, post-split. Before, every division had its own BSA. But with the split, one BSA for two divisions.

PC: Was this a first at NCI?

AK: To my knowledge. I don't know how the other ones are operating.

PC: So what it did was force both divisions to compete against each other for the money.

AK: That's right, that's right. It's pretty brutal at this point. In fact – and sometimes this BSA gets involved with other kinds of projects too. I remember probably the most traumatic time I chaired was the first time – I was on the board for four years, two years as a member and two years Peter, through his ultimate wisdom, asked me to become the chair of the board. This was an unbelievable experience because I don't know if you've been up to that room. It's a big room, microphones a big table, you're highly visible. The first meeting I had as chaired did not involve the review of concepts but a resolution of the controversy about mammography screening for pre and post-menopausal women. The

issue was first presented to the National Cancer Advisory Board,(NCAB) which is the policy board of the NCI.

The NCAB ruled that this was a DCPC issue and referred it to the DCPC Board of Scientific Advisors. At the time, Ed Sondik, who's now the director of the National Center for Health Statistics, was Peter's deputy. I arrived expecting to chair the Board as we reviewed concepts for approval and funding when Ed mentioned that... "Arnie, we're going to have to make a change because the NCAB has requested that your committee review this mammography screening issue, and we won't have enough room for ABC, NBC, CBS cameras in Building 31. We're taking this whole thing to the Masur Auditorium, and we'll configure it that way." It was one of these holy-shit moments, you know? Like, "You've got to be kidding," [laughter]. The whole session was devoted to hearing testimony in support or in opposition to mammography screening for pre/post menopausal women. Various professional groups made presentations, some advocating, for example, the American College of Radiology, that every woman needs to be screened once a year, and others suggesting that yearly screening was not necessary for pre-menopausal women. It was quite an event ...At 3:00, the network cameras shut down as they prepared for the evening news and we went back to Building 31 with only one mobile camera, and it felt like a cozy little room. [Laughter]. We had an extensive discussion and made our recommendations. Two or three years later the issue was back on the agenda of the NCAB and as I recalled was resolved.

PC: When you chaired it, it was, what, '94, '95?

AK: Okay, that was it, '94, '95. Right. This was '94.

PC: Okay. And then right at the end of your term, then I would guess that that's when Clauser started to look at the –

AK: Right.

PC: — taking the split?

AK: Right. Right.

PC: And this was due, in large part, to your chairmanship?

AK: I doubt it. But one of the changes that did occur during my tenure was a greater appreciation that cancer prevention and control research occurs within a organizational context and the complexity of a changing health care delivery system. Peter recognized this and he doesn't get enough credit for things that he has, in fact, instituted. One of the things that was so visible when I chaired the BSA, from my view as an organizational person, was the fact that we were funding all these concepts with sort of a view of the health care delivery system like it was in 1950. Physicians in solo practice in the community doing the Lord's work, without any recognition of the realities of managed care, integrated delivery systems, the economics of health care.

I would talk with Peter about these kinds of things, and that we really need to begin thinking about research programs that are taking into account the organizational context of how care is being delivered. Peter was very supportive and in fact based on these conversations, invited Ed Wagner from Group Health in Seattle to present at the BSA. Ed is a physician epidemiologist and a pioneer in health services research within a managed care setting.

Ed came and did a terrific job. The result of that presentation was the eventual development and funding of what's now called the Cancer Research Network (CRN). The Cancer Research Network as an on going research program is administratively located in DCCPS but the concept of involving managed care organizations in cancer prevention and control research was first initiated in DCPC under Peter's leadership and his invitation to Ed to present at the BSA. The CRN is now in its third or fourth 5-year funding cycle and involves major delivery systems such as Kaiser in California, Group Health, Henry Ford Hospital. This is a major accomplishment and has taken years to develop the trust among these organizations to collaborate on various research projects, sharing proprietary data and providing a framework to resolve important cancer control and prevention research questions.

PC: Now when these ideas pop up, some of them also come in from those looking for extramural grants as well, correct?

AK: Right, that's right.

PC: So would they be added to the agenda or –

AK: Well, for example, it all depends on context. When, say, the consortium that runs the Phase 1, Phase 2 trials –

PC: Uh-huh.

AK: These are the project people, the NCI people who are involved with this, out in the community. And they are, in fact, helping doctors. They're very interested in promoting cancer prevention research, and will help community physicians prepare proposals, respond to individual RFPs. For example, within the CCOP, there's a very elaborate structure because within the CCOP program, local physicians operate through the NCI funded research groups, eg., SWOG, NSABP, ECOG, etc., and these groups have their own organ site committees, developing various clinical protocols, which then go into NCI for approval. Protocols are available for treatment, cancer prevention and control that accrue patients through the participating CCOPS.

PC: One of the things that's interested me that I've noticed, is that many of the division directors in DCP now are also on editorial boards of the journals. Is that something that happened when you first were associated with them? Because what I read now is, of course, much more recent, but it does allow them to keep a pretty good finger on the pulse.

AK: Give me an example.

PC: Well –

AK: The division – the chiefs within –

PC: The division chiefs also serve on editorial boards.

AK: Division chiefs within NCI.

PC: Of DCP.

AK: Oh, okay. I mean, you're talking about research.

PC: Branch chiefs, the branch chiefs.

AK: Okay, got it. Yeah.

PC: Yeah. Serve on editorial boards.

AK: Oh, yeah.

PC: And has that been a long tradition or something new?

AK: No. I think that's – they're pretty active in their own discipline. I don't think it's recent.

PC: Okay.

AK: And as you know, some – many of these people have a clinical practice at the NIH hospital.

PC: Uh-huh.

AK: For example, Lori Minasian, Eva Szabo, Howard Parnes, to name a few, are all practicing oncologists. These and others maintain a clinical practice and are very active in the academic/research/professional community.

PC: I noticed you've done a lot of consulting internationally.

AK: Yes.

PC: How does this office crack up to other countries' efforts on cancer prevention?

AK: Well, it's funny you ask because last week, I was in Paris. I told you that.

PC: Right.

AK: France just instituted the first federally-funded school of public health. As part of that initiative, the school is very interested in developing some collaborative relationship with the Institut National du Cancer ... and it was felt by my French colleagues that my visit might further that relationship . The invitation protocol was rather interesting because they just couldn't say, "Why don't you invite Arnie over and present a seminar describing some of the cancer prevention/control projects at NCI." Evidentially, protocol required that Dr. Niederhuber write a letter to the Director of the French Institut to inform him that Dr. Kaluzny was going to be in Paris, and perhaps he could meet and describe some of the ongoing NCI activities. It was rather circuitous but protocol works and we had a delightful discussion on a variety of topics of mutual interest. As it turns out these are really quite different organizations in both structure and function. The French Institut de Cancer is mainly a coordinating mechanism whereas the NCI is doing big-time research, both extramurally and internally. However both are dealing with the same issues of improving practice patterns within local communities. There was considerable interest in the development and implementation of clinical guidelines and various metrics to measure program performance. In fact I described the DCPC experience with clinical guidelines and the CHOP program as an effort to improve practice patterns prior to the CCOP.

PC: Yes.

AK: — Community Hospital Oncology Program (CHOP) that Jerry Yates and Leslie Ford directed, was an early effort by DCPC to improve cancer care in local communities. The

CHOP involved local hospitals and physicians and through specific disease site committees involving physicians in the various communities, developed treatment guidelines. The theory was that through involving the physicians in the local communities they would comply with the guidelines and thus improve care provided.

PC: Uh-huh.

AK: As I mentioned, NCI tends to evaluate programs and the follow-up data indicated that the only person who was, in fact, following the guidelines was the chairmen of these committees. As I recall, the evaluation is published in the *Journal of Clinical Oncology*, Well, Yates just about went ballistic when he saw that and terminated that program flat away. And it was a big program because these CHOPs had already created an association because they were getting money for running these community-based guideline committees within selected hospitals, so they had a real vested interest, but the data was quite clear that it wasn't doing anything in terms of changing practice patterns.

What followed was the Community Clinical Oncology Program,(CCOP) The feeling was the only way to change practice patterns, or the only way to improve care within local communities was to get state-of-the-art protocols to communities, and DCPC funded, in the early 80s, the first generation of CCOPs with the focus making available treatment protocols to 50 or so participating communities. The second generation of CCOPs had to do both protocols to treatment and control. The evaluation issue in both was whether these community-based programs would be able to accrue the required number of

patients. The program has clearly demonstrated its ability to accrue patients and has been in operation for more than 25 years.

PC: So this is, in effect, saying that the others are not into prevention as much as the United States?

AK: Well, they approach it a little bit differently than we do. But even within the NCI there is a growing interest in improving cancer care at the local community, along the entire continuum of care, including cancer prevention and control. For example the NCCCP which is not in DCP but a program that was mandated by Dr. Niederhuber and administratively located in the NCI Directors Office, is an attempt to improve cancer care within local communities where most patients are treated. The program is quite controversial within the DCP because the first thought was why not implement the program using the CCOP structure since they already have experience and infra structure to support these expanded activities. While the program remains separate, three ongoing CCOPs are part of the NCCCP providing a natural experiment to assess whether the CCOP infrastructure and experience facilitates or limits the ability to meet the objectives of the NCCCP. When I was in France it became obvious that there are many ways to achieve objectives. For example in the NCCCP program, one of the objectives is to implement interdisciplinary committees in the care process. This is a challenge for many US hospitals but as I was describing this the associate director of the Institut pointed out that in France all patients are reviewed by an interdisciplinary committee. "We just mandated it by law." [Laughter]. So, you know, people are doing, approaching these

things really quite differently. But I don't think there's any other country which is as elaborate or as sophisticated or as committed to cancer research on all dimensions than the NCI. The NCI does have, and the DCP in particular, and I'm sure the other divisions also, collaborative relationships with other countries. I know Leslie Ford and, Howard Parnes, have a very close working relationship with the oncology community in Italy. In fact, Leslie recently received an award in recognition for her collaborating with the Italian oncology community on the breast cancer trials..

PC: And Peter, himself, stays in the background on this?

AK: No, he does some international things, but he's really quite generous with his people. And, you know, he facilitates this but he doesn't have to showboat it.

PC: All part of management style.

AK: Yeah. I mean, he is, like I said, a very laid-back kind of person, which is both good and bad.

PC: And has the – I guess you hinted at this, but let me just go back, just clean up a little bit on it. The Division of Cancer Prevention has – how has its place changed in NCI over the years you've been associated with it?

AK: It's had a difficult time. I don't know the chemistry of it, but it's never been an easy working relationship with many of the directors.

PC: This is directors of NCI –

AK: Right, right.

PC: Not NIH.

AK: No. Drs. Niederhuber, Klausner, Von Eschenbach and Broder. The other divisions are big and powerful that they just take up all the air, so to speak. This I suspect, is further complicated by the reduction in funding and most recently the termination of the large SELECT chemoprevention trial.

PC: Uh-huh.

AK: Which is their big vitamin trial for prostate .

PC: Right, Selenium, yeah.

AK: This has to hurt because this was a major initiative within the DCP. And we have chemoprevention and nutrition science research groups in the Division. On the other hand, DCP has had some big wins, for example, the Tamoxifen trial is a good example. The issue is that Dr.

Niederhuber and the division have a different view of how science is moving forward. The director of the NCI is a presidential appointment so we will see what happens after the election. But Dr. Niederhuber has a slide that portrays the transition from a 20th Century paradigm, which is based on search and destroy, which implies the use of large scale trials to a new paradigm where the focus is on target and control. Between the two approaches is an exploding science of proteomics and genomics and synthetic biology making this transition possible. DCP is doing classic science with large randomized clinical trials that you need big bucks, big organizational structure to be able to discover preventive agents that would reduce certain kinds of cancers. The new model is focused on the new science that would be able to target treatment with low toxicity, a whole different way of looking at future activities and how we invest scarce resources. This would not be, in my judgment, such a big deal since science always has competing paradigms but in this case and time the NCI operates under severe cost constraints. The new paradigm is a bit of a gamble. We know the old paradigm works, because that's how science is practiced as demonstrated by SELECT and other large trials. The gold standard remains the randomized clinical trial. Unfortunately we are in danger of dismantling an infrastructure that is critical to supporting evidence based medicine. As a scholar of the history of science, I am sure you can appreciate the classic clash between these two paradigms.

PC: It's not the first time we've had paradigm shifts.

AK: That's exactly right. And the issue is whether we are prepared to take the gamble dismantling or at least downsizing an infrastructure that permits us to do these large trials, permits us to involve a network of researchers and scientists involved with the

identification of biomarkers of one sort of another, and the repositories necessary to collect material and then follow a population for 20 years to assess, whether certain screening/prevention interventions were effective or not in reducing mortality and morbidity... remains a major policy issue.

PC: It's also an interesting point of how good the extrapolations become out of the other paradigm, the paradigm –

AK: That's right, that's exactly right.

PC: And NIHS has been – had that when they first got funding cuts. They went to smaller programs and you know, more extrapolation, less testing on live animals and things like that.

AK: Right, right. I mean, this is classic, absolutely classic. What makes it so painful is the fact that in the best of all possible worlds, you'd want to ease into this thing and not destroy what you know works.

PC: That's right. I can think of a couple other examples, as a matter of fact. Things that I've looked at.

AK: Yeah.

PC: Tell me, what have we left out?

AK: Well, it's about time for me to close [laughter]. You know, I think – I don't know what – what are you going to do with this?

PC: This goes into the historian's office, and I don't know what will happen.

AK: Okay.

PC: They've just asked me to do these interviews.

AK: Okay. You're just a conduit.

PC: Yeah, the pipe. [Laughter].

AK: Well, what's been left out? I think the underlying dynamic within DCP is that preventive oncology is the future, and Peter and the division, are very dedicated to making this a reality... But it operates within a larger organization which has its own priorities, and it shifts from time to time, which is good and bad. But how this whole thing sorts out, is a question of time and resources. Unfortunately, one of the big challenges in the division is, and I've talked with Peter about this, is simply cessation planning. Who is going to have this vision? Peter is as old as I am, 70 I think...., who's going to have this vision and commitment And have we cultivated, your question earlier, the leadership within

the division that would be able to carry us forward? Without that, I think there are risks that prevention, at least as we think about it in present terms, could go latent for a while, but it's going to come back one way or the other. A good model is heart, lung, and blood. What they've done in the cardiovascular is almost a vision that we would like to see within cancer prevention. The whole business of biomarkers to get your lipid panel, get your blood pressure tested, and we got pills that one can, in fact, lower your low cholesterol and maximize, theoretically, your HDLs and so forth and so on. I think that's a model that is implicit, if not explicit, in the minds of some of the people who are visually trying to do science within the Division of Cancer Prevention.

PC: So it's not only leadership within. It's whether it will be recognized from within the NCI.

AK: Absolutely. I mean and, you know, all these directors have – they all bring their own agenda and they're, you know, very committed and very, very bright people. But it's a little bit like steering this huge boat. It doesn't turn around easily. On the other hand, it's – it's a very dynamic organization over a period of time, and potential of accomplishing great things, and also potential of doing some harm, I suspect.

PC: Well, has Peter done any cessation planning – succession?

AK: I raised that. Presently, he's thinking about it. We have talked about it, and I think other people have talked with Peter about it, and I think it's a major issue. We had a retreat just this past November as we were thinking forward. Because under the NIH rules, all the

directors of the various institutes have been requested to submit their resignation. That's just standard operating protocol. We had a retreat, talking about what are some of the scientific priorities that Peter will need to emphasize when he meets with the new director of the NCI, and may, in fact – Niederhuber might get reappointed, but in any case, the protocol demands or requires that at some point Peter gets to do his little elevator talk, along with all the other division directors, of what are the priorities for the division in the years ahead, and how that squares and aligns with the director of the institute will, in fact, determine where the future is. Part of that is going to be Peter's own personal plans for providing leadership and/or, you know, planning for – succession planning for his replacement.

PC: Good point. Uh-huh.

AK: I suspect he's thinking about it and, and will probably receive a fair amount of urgency shortly.

PC: Uh-huh. Good. Well, thank you very much. I've enjoyed our conversation, and I will get all things – we'll get it transcribed and –

AK: So what do I – what do I do with this? You know, we've had a frank and far-ranging kind of thing. I don't want to say something that's libelous.

PC: I don't think you have.

AK: Okay.

PC: As a matter of fact, you know, what is it the man said? Truth is the first defense against libel. [Laughter].

AK: Right, right, right, right.

PC: But I think this has been very, very helpful, and helped me understand it, and I appreciate your perspective –

AK: Okay.

PC: — as someone standing a bit outside the center.

AK: Who have you talked to, or who do you plan on talking with?

PC: I've talked with a number of people, with Leslie Ford, Lori.

AK: Okay.

PC: With Vern Steele.

AK: Okay, Vern, yeah. Well, Jim left, which is unfortunate, because Vern is, I think, acting for chemo prevention, CD – chemo prevention group.

PC: Uh-huh. And I'm leaving somebody out, and Ed Sondik later on.

AK: Oh, Ed –

PC: John Milner. And Barry Kramer.

AK: Okay. Yeah, Barry Kramer and Ed Sondik to be sure.

PC: Yeah.

AK: Because both those guys, just excellent.

PC: Good.

AK: Enjoyed it.

PC: Well, I appreciate it. So have I. Thanks very much, and the best for the holidays to you.

AK: Okay. Same to you.

PC: Thank you.

AK: You bet.

PC: Bye.

AK: Bye-bye.

[End of Interview]