



**Oral History Interview with  
Peter Greenwald  
Director of the Division of Cancer Prevention,  
National Cancer Institute (NCI)  
1981 - 2011**

**FDA Oral History Program  
Final Edited Transcript  
August 26, 2009**

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## **Oral History Abstract**

Peter Greenwald, M.D. helped to found the Division of Cancer Prevention at the National Cancer Institute (NCI) in 1981, and shaped its research until his retirement in 2011. He is a renowned expert on nutritional science, however, this interview focuses on his involvement in the controversy regarding nutritional health claims on food labels that erupted in the early 1990s. Dr. Greenwald's team researched the relationship between dietary fiber, which provided him insight to advise the FDA in its development of guidelines for health claims as well as efforts to update standard food identities.

## **Keywords**

nutritional science; dietary fiber; health claims; Kellogg's All Bran; cancer; National Cancer Institute

## **Citation Instructions**

This interview should be cited as follows:

"Peter Greenberg Oral History Interview," History Office, U.S. Food and Drug Administration, Department of Health and Human Services, August, 26, 2009.

## **Interviewer Biography**

Suzanne Junod, Ph.D. is an historian in the FDA History Office at the U.S. Food and Drug Administration. Soon after beginning her career at FDA in 1984, Suzanne helped to organize the FDA History Office. She is a subject matter expert in FDA history and her scholarly writings have been published in *the Food, Drug, and Cosmetic Law Journal*, the *Journal of Federal History*, and the *Journal of the History of Medicine and Allied Sciences*, as well as edited compilations. She is an active officer in the Society for History in the Federal Government. She earned her Ph.D. at Emory University in Atlanta, where she studied under James Harvey Young.

Xaq Froehlich is an historian at Auburn University, thought at the time of this interview he was conducting doctoral research at the Massachusetts Institute of Technology. His research focuses on the intersection of science, law and commodities, with an emphasis on the FDA's the history of efforts by the U.S. Food and Drug Administration (FDA) to manage food markets through the regulation of food labels in the second half of the twentieth century.

## **FDA Oral History Program Mission Statement**

The principal goal of FDA's OHP is to supplement the textual record of the Agency's history to create a multi-dimensional record of the Agency's actions, policies, challenges, successes, and workplace culture. The OHP exists to preserve institutional memory, to facilitate scholarly and journalistic research, and to promote public awareness of the history of the FDA. Interview transcripts are made available for public research via the FDA website, and transcripts as well as audio recordings of the interviews are deposited in the archives of the National Library of Medicine. The collection includes interviews with former FDA employees, as well as members of industry, the academy and the legal and health professions with expertise in the history of food, drug and cosmetic law, policy, commerce and culture. These oral histories offer valuable first-person perspectives on the Agency's work and culture, and contribute otherwise undocumented information to the historical record.

## **Statement on Editing Practices**

It is the policy of the FDA Oral History Program to edit transcripts as little as possible, to ensure that they reflect the interviewee's comments as accurately as possible. Minimal editing is employed to clarify mis-starts, mistakenly conveyed inaccurate information, archaic language, and insufficiently explained subject matter. FDA historians edit interview transcripts for copy and content errors. The interviewee is given the opportunity to review the transcript and suggest revisions to clarify or expand on interview comment, as well as to protect their privacy, sensitive investigative techniques, confidential agency information, or trade secrets.

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## Interview Transcript

SJ: Today I'm here with Xaq Froehlich and Suzanne Junod, and we're interviewing Dr. Peter Greenwald at the Executive Plaza at NIH. It's August 26<sup>th</sup>, 2009. And we're here to talk about cancer prevention as prelude to the . . .

PG: The main request had to do with the Kellogg episode in 1984 putting NCI's dietary guidance on their cereal boxes in a way that promoted "All Bran".

XF: So, as I was talking with him earlier, as you said, we're here with Dr. Peter Greenwald, and we're hoping he can give his recollection of this incident in the mid 1980s related to the All Bran cereal from Kellogg's and the National Cancer Institute's Cancer Prevention Awareness Program.

PG: Well, let me build up to that.

SJ: Let's get a little biographical information from you so we can get it set in time and place.

PG: Right. I'm a medical doctor certified in internal medicine. I also have a doctorate in public health, focusing on epidemiology, from Harvard. I went from Harvard to the New York State Department of Health. Before that, I was an epidemiology officer with CDC for two years. Then I worked for the New York State Department of Health in Albany for 12 years. That was mostly epidemiology of cancer, heart disease, and infectious diseases. There also was a nutrition program, but I was not deeply into nutrition.

XF: And this was during...

PG: This was from 1968 to 1981. Toward the end of that period, about 1978 and '79, I was invited to be on a committee of nitrites of the Institute of Medicine, which was arranged by Sushma Palmer. She was Executive Secretary of the Food and Nutrition Board. I think because of that and because they liked my work on that, I was invited to be on the Food and Nutrition Board in 1980 before I came to NCI. I joined NCI in October 1981.

At that point, I hadn't even heard of the Nutrition Board, so it wasn't a big deal to me. But after I became a member, I was very surprised at the conflict between some of the older nutrition scientists on the board who hated it when you said anything bad about fats – I don't know if I should say, but some from the University of Wisconsin, the dairy state, who are very solid nutritional scientists, but felt uneasy saying anything bad about fats. And the younger of us who were saying cut down the amount of fat in your diet. There was circumstantial evidence, mainly epidemiological evidence and some animal evidence, about risks of too much dietary fat. And besides fats, excess calories contribute to obesity. So there were real fights.

One of the fellows on the Board, Victor Herbert, sued the National Academy of Science over ownership of data. I ended up being a bit skeptical about how solid the evidence was behind the science. I was really looking at the evidence to back up their opinions.

In 1983 and early in 1984, I built up NCI's Diet, Nutrition and Cancer Branch. Ritva Butrum chaired it and stimulated an increase in the number of NCI-funded research grants on nutrition. Carolyn Clifford was in that group. And the main one who I worked with was Elaine Lanza. Elaine was a graduate of MIT's nutrition research program, and knew everything about

fiber. She knew the laboratory tests, the definition of fiber, and what digests what. She knew about cellulose and the 250 hemi-celluloses. At that point I was actually saying eat more vegetable, fruit, and whole grains; I wasn't saying dietary fiber.

Then, in February 1984, I went to the FDA. First I contacted Sanford Miller, who was head of the food side of the FDA. Frank Young stepped in for a short time. He was about to become the FDA Commissioner. The reason I went was I felt the "standards of identity", which were defining what was allowed on food labeling, sometimes went against some of the best public health evidence. In particular some of the foods, for example margarine, that might have been healthier than butter, but the FDA was forcing the labels to say "artificial" or some word that had a negative connotation. It seemed that the butter and other industries wanted that, and I didn't think it was evidence based. So I was saying to them, "Why don't you change your standards of identity to give them a public health message?". The FDA staff were very gracious and very nice. But Miller said, "You know, we've been working this way since 1936.

SJ: 1938.

PG: 1938, for a long time, "and we're not going to change, but we wish you the best doing your work." You know NCI. "We're happy that you're going to work on nutrition education, but we can't really partner in a formal way." That was what I believed at that point because that's what the FDA told me. A little later that year, NCI started a "Cancer Prevention Awareness Program".

SJ: Wait. I'll ask one question before we move on because I feel we won't get back to it. Did they give you any explanation of the history of this, or why they were just sort of cordial and...

PG: No. I don't remember that. I had the impression that FDA was based on laws. They had certain constraints and they had to be more cautious in a way and not just say "here's what we think." They had to check. But we didn't discuss the history behind the FDA position. We started the "Cancer Prevention Awareness Program" in the middle of 1984. Our Office of Cancer Communications, which was headed by Paul van Nevel took the lead. We put together a balanced message, and in general, we followed the USDA-HHS guidelines. Our message was: eat a balanced diet with more vegetables, fruits, and whole grains, cut down on fat.

At that time, I was still saying fruits, vegetables, and whole grains (rather than dietary fiber). Very shortly after, Dennis Burkitt visited NCI. Burkitt was a very famous surgeon who had gone through Africa, spent his life in Africa. There's a lymphoma, "Burkitt's lymphoma", named after him. He also had been reporting in *The Lancet* and some other journals, that African populations had much less in the way of gastrointestinal disease than Western populations. Burkitt was a very dynamic speaker. He had photographs of the mountainous stools of the people in Africa who ate huge amounts of roughage. He stated that Africans get less colon cancer, less rectal cancer, less appendicitis, because of the roughage. His view was highlighted in the popular press.

Well, he talked to Vince DeVita, the Director of the NCI, and convinced DeVita that there's something to this fiber story. DeVita then was invited to be on the MacNeil-Lehrer Show on PBS, and he mentioned this. He said, "I eat a bran muffin every day." Fiber was the word

used. Then he came back to me and said, “You can say what you want about fiber. It’s up to you.” I thought, well, let me just think about it a little. I got together with Elaine Lanza, and we reviewed the evidence. With the help of a support contract, we summarized the studies, just so we had all the studies together in case anyone asked, “What are you basing your statements on; what are you saying?” We thought about it and said, “Okay, we can say fiber.” We’ll say dietary fiber.

When the Cancer Prevention Awareness campaign was kicked off in mid-1984, Margaret Heckler, who was HHS Secretary under President Reagan, knew we were going to do it. She came to NIH to kick it off for us at Masur Auditorium. She came and gave a nice talk during which she invited industry to participate with us in the Cancer Prevention Awareness Program.

A few days after that, someone from the Kellogg Company called Paul van Nevel and said, “Can we visit? We would like to just hear what you’re saying and hear what the evidence is behind it.” We invited them to NCI. Paul, Elaine Lanza, and I met with a small group of very scholarly people from Kellogg, which included marketing, nutrition scientists, and lawyers. We spent an afternoon with them going over the evidence as we saw it, including that fiber has benefits, particularly against colorectal cancer.

At the end of the day, the Kellogg people asked, “Can we put your message on our cereal boxes?” Our response was a conditional yes. Yes, only if you put the entire message – eat more vegetables and fruits, cut down on fat, and eat more fiber – and they agreed to that. And literally, that’s what they did. If you go and find the pictures of the old cereal boxes, you’ll see that they have the entire message.

SJ: We have them.

PG: To us it was good news. The whole NCI message is there. A high fiber, low-fat diet may reduce your risk of some types of cancer. The whole NCI message is there. But the problem was, as you can probably figure out from that, my guess – and I cannot verify this – is that they held some focus groups, and they knew the message people would receive was fiber is All Bran; eat more All Bran and you'll get less cancer. And they blanketed TV networks with simultaneous ads on all major networks. Every TV station had the same message at the same time. They did a lot of marketing.

SJ: I know we're documented some of that. Let me just make sure. I actually know this, but I can't quite find it because the other cereal is no longer on the market. Kellogg's was All Bran. But didn't General Mills come out with Benefit around the same time?

PG: Right.

SJ: Or was it a little later? It had to be a little later, but not much later.

PG: Other cereal companies jumped in within months. We actually looked at sales figures over the next few years – there was a marked increase in sales of all of the high-fiber breakfast cereals for maybe two or three years. Then it started to taper off and come back toward the baseline. But for several years, there was a huge increase in high fiber cereal sales. We thought that was good. So that's what happened.

Now, there was a consequence that I didn't anticipate – I think I was a little naïve in this – that this was used as a wedge, I would say, by the Reagan administration, not by us, and by industry to put implied health claims on foods or this sort of thing on foods. That's still going on. For example, misleading statements implying orange juice prevents cancer. That went on. Many of the nutrition scientists at the FDA and elsewhere were quite upset with us, saying, "Look, you set this off. It's shaken up our whole policy of not allowing health claims on foods, which we think is a solid, reasonable policy that keeps us out of trouble," and changed the picture.

SJ: But that was nothing that you'd expressed in the earliest meeting. You didn't have a clue that that was, that they had, that they didn't explain that element of it.

PG: We did not, not at all. That's true.

SJ: Because FDA's immediate concern would be exactly that, that it would imply endorsement of a product.

PG: There was no discussion, and we did not discuss this part with the FDA. What I discussed was, more often discussed, standards of identity, and then four or five months later we got into this without really working with the FDA.

XF: Another way to, I guess, that I'd like to hear you comment on in your reflection is, there was a debate in the nutrition community, which I think surfaced in the [unclear] as well, about endorsement of a food as good or bad versus this holistic diet.

PG: Yes.

XF: And did you have a sense when you were meeting with Kellogg that putting this message on a food . . .

PG: No, we didn't talk about that. I thought they were going to put it on a number of their cereal boxes, although All Bran was the obvious high fiber food. And we did not talk about that with Kellogg's, as I recall. At the Food and Nutrition Board, that I remember more discussions of dairy products in general compared to other foods, say, meats in general, because there were people that were protective of the Ag industry on the Board that were less supportive of the dairy industry. There were these different forces. It also seemed to be some of the older guys who had the industry connections were sniping at some of the younger people who saw the evidence differently. They didn't discuss the process for evidence based decision making, or how do things fit together. I was surprised by that because the Food and Nutrition Board was a respected group.

SJ: Was this the same time – when I came, I got involved with the Surgeon General's report on health and nutrition, and it got postponed and postponed.

PG: The only one I remember was 1989.

SJ: It took a decade or more for that to come out.

PG: Yes. I know, in 1989, under Koop, there was a report. I wrote a nutrition chapter. Koop was my next door neighbor for the whole eight years he was Surgeon General. We were friends. We went on a cruise together teaching continuing medical education.

SJ: It wasn't something that was shaping what you were trying to do?

PG: That was part of it. NCI director Arthur Upton in '79 released a fairly weak letter or report to Congress about diet and cancer. Things sort of dragged along long for the next 10 years, but I don't know the detailed history.

SJ: But it wasn't something you were actively involved in?

PG: No, I was not.

XF: Well, actually, we could talk about that. I had a couple of questions related to the – I think it was the 1988 Surgeon General's and '89 was the National Academy of Science report.

SJ: And it didn't come out till a decade later.

XF: Yeah. But I was hoping to sort of take us back before we get to the sort of fallout of the All Bran campaign. And actually even before the 1984 thing, I was wondering if you could talk a little bit about the kinds of evidence – first of all, what was the link that was seen. You can talk a little bit about the fiber, the study you did.

PG: Yes.

XF: Also the kinds of evidence that was used, and then, more generally, about the scale-up of this prevention campaign and educational effort.

PG: On the kinds of effort, first of all, most of the discussion at NCI had to do with overweight and dietary fat, not fiber. Most of the evidence about fiber was epidemiological associations and some animal feeding studies that were also helpful.

Now, my impression of them – thought the epidemiology was quite consistent. Regarding fat, the measure in epidemiology was the percent of calories from fat in your diet, which is a way of adjusting for energy. So you examine how many calories from fat per thousand calories. The problem with that is it's not grams of fat, which is the total amount of fat you're taking in. It never occurred to us that cutting fat would lead to the food industry coming up with low-fat foods that contained a huge amount of useless calories, so blood sugar goes up. But following that period and that message, there were all these low-fat foods sold that were junk foods. We occasionally would joke and say, "You can meet the dietary guidelines by drinking more Coke," because you increase the denominator of calories and the percent calories from fat goes down.

I have another impression based on no evidence, and this had to do in general with the quality of the nutrition science community. There were some wonderful specific individuals, but research proposals are poorly written. If you want to apply for a NIH grant from a university, problems are the complexity of nutrition, the fact that you're looking at diet over a lifespan or over several decades, and you don't have a good way of knowing what happened over that period. Reductionist thinking, the idea that the smallest molecular connection provides the strongest kind of evidence, is a powerful way of applying science, but it doesn't work too well for the complexity of nutrition guiding eating behavior. That makes it difficult for people to get nutrition grants.

Another impression I have I would call gender bias. When I was in medical school, if I had wanted to study nutrition science, I could not do it. I could study biochemistry or the diet for diabetes. Nutrition was with home economics and for women and thought of as soft stuff. Young, upcoming scientists were not channeled there. So you didn't get a lot of outstanding young people going into nutrition science.

A third problem is that there always is a fringe group promoting food fads. They speak as if they are the authorities. Scientists don't want to be associated with that. These were problems, and still are. We don't support a huge amount of basic nutritional science at NIH. There's strong food science in this country supported by others. For example, how do you make a food product you can microwave, or one that has a long shelf-life. Although they use the same methods, these scientists don't know the NIH people. We don't have much of a leading edge of biomedical nutritional. Thus, we may be in for some surprises. Missing, even today, from the large proportion of the research is strong, basic nutritional science. There's some, but, to me, not a sufficient amount.

We were looking at epidemiology associations, some well done, some poorly done, and feeding rats or something like that. I remember a fellow named Roswell Boutwell, who's a good scientist looking at skin carcinogenesis in Wisconsin. He was denying the evidence that fat could have a downside. But when I looked at his method, he had an adjustment where he would adjust for the number of calories that it takes to burn the fat, which to me was a distortion, a fudge factor, but to him that was good science, and people respected him as a scientist. I have a problem with adjusting for calories because, whether you know the mechanism or not, if you lower your fat, you lower your calorie intake as well, and it's great that you can do both at the same time.

Thus, there was animal data, some basic data, and a lot of epidemiologic data driving the thinking. It's still true today. There's somewhat more basic science, but it's way short of what we need in the United States.

SJ: You were talking about that in molecular-level science.

PG: Yes.

SJ: I've done some work on food-additive history, and that concern – and you talked about with nitrates and nitrites. That was where the most scientific studies were being done. What little there was, was in those micro things as a trigger for cancer, and the Delaney Clause...

PG: They're single things like nitrites and nitrates in the stomach converting into nitrosamines, and vitamin C foods would counteract that. There's some specific single-nutrient

studies, very little on interaction, insufficient evidence. When we looked at the overall data, because there are always people that worried about, say, pesticide residues on foods. Fruits and vegetables hold the residues. The people eating the fruits and vegetables are healthier, so we dismissed that. You wouldn't have a good way to study residues anyway because there are millions of people exposed to trace amounts. To whom do you compare them? Also, there are many different chemicals and only a small proportion have been studied.

SJ: The FDA does a total-diet study, and they study the market basket, and consistently show very low levels of pesticide residues. There was nothing to trigger any public health concern.

PG: I think it's trivial. But we still get breast cancer advocates and others insisting that synthetic chemical contaminants cause a substantial number of cancers. There is a big Long Island study promoted by Congress worrying about air from La Guardia Airport and other exposures that are difficult to quantitate. If you say you don't have the evidence, they think you're in some sort of conspiracy. Pesticides possibly are causing some cancers, for example, perhaps one in a few hundred thousand exposed, but except for the occupational setting, we are unable to test this hypothesis adequately.

XF: One other concern raised at the time – and it was raised by Victor Herbert; I would be really interested in what he had to say about it, good or not. But it was reported, I think, in a *New York Times* interview, was that, with the concern that by eating fiber, it actually might sap the nutrient levels.

PG: Yes, something like that.

XF: And so, when he was making a case against recommending fiber. . .

PG: But nutrient insufficiency has not been seen due to eating fiber. These people usually are healthy. You know, Herbert started at the Thorndike Lab at Boston City Hospital, and Lou Sullivan, who later became HHS secretary, worked as a Fellow under him. Herbert wanted Sullivan to go on a severe folate-deficient diet to show whether or not folate could lead to anemia, and Sullivan refused, and so Herbert went on it himself. Herbert experimented on himself, and proved that folate deficiency can cause megaloblastic (large cell) anemia.

There were several times when I debated Herbert at the National Academy of Science. I had a picture that was from the New York Times Magazine showing Herbert's office wall. On his wall is a sign: Murphy's Law: Murphy was an optimist." You know Murphy's Law: what can go wrong will go wrong. So that was his outlook, that of a pessimist.

Herbert was also a paratrooper in Korea. He was a paratrooper. So I told a joke about him: Herbert once parachuted into a pasture. There were many big bulls in the pasture. Herbert, standing in the pasture, looked down, and saw a big brown pile. And all of a sudden he looked very worried, and said, "Oh, my God, I'm melting".

XF: You were mentioning that there were three things that were holding back studies in nutrition. The third was this concern about fringe so-called experts giving advice.

PG: Yes. The scientists don't want to be associated with promotion of quack nutrition. That's what I was saying.

XF: Sure. And from an FDA, a history of the FDA on this issue of health claims, if you go back, since 1938, one of the things you're struck by is this long history of concern with what, you know, the campaign was the biggest nutrition quackery.

PG: Yes, right. The FDA never got adequate authority to do its job. This is a problem even today. NCI supports studies of bioactive foods. There are many topics of interest, such as tea polyphenols, soy compounds, curcumin. While these are early in the research, they are being promoted by industry. At NCI, we would like the FDA to require INDs for research, as you do with new drugs. That's not required now. NCI still asks for INDs, because pharmacologic doses may be used. This is important for safety and for oversight. But the FDA does not have the authority to require this. As I understand the law, you can't.

XF: [unclear] nutritional.

PG: When we want cooperation of food industries in doing research, they don't want to get involved with something that makes their food look like a drug which would put them under drug regulations.

XF: So then, going back, it sounds like you answered a question I know that Suzanne and I were particularly interested in, which is sort of who initiated what, and it sounds like it was Kellogg's in response to...

PG: HHS Secretary Heckler's announcement of the Cancer Prevention Awareness Program opened the opportunity for them to come in. That's true. I think the Reagan administration and industry more or less exploited that opening beyond what I would have imagined.

XF: Although one of the things that happened as a result of asking [unclear], I know I was looking at some of the documents, and it's really key that they have the 1-800 number and it really was emphasizing NCI's paying.

PG: Right. And we had messages about dietary guidance. Our cancer information service was getting 600 or 700,000 calls a year on our 1-800-4CANCER number. Callers often were family members of cancer patients

XF: How novel was it for the National Cancer Institute to...

[END OF TAPE 1, SIDE A]

PG: How do we work with industry?

XF: How novel was it to try to use industry as a platform for spreading public health campaigns?

PG: It was rarely done. NCI's main involvement is with the drug industry, first of all, is largely the drug industry when we're doing clinical trials. We may do early studies. When you get into a larger trial, we have different kinds of agreements, cooperative agreements, material transfer agreements. The company may supply the drug, make up the pills, make up the placebos. We usually manage the trials. The industry agrees not to influence the trials. Study results will be published no matter what the outcome. Industry collaboration for cancer therapy is very important. For prevention, we have other problems because of many years needed to conduct the trials and issues that their business models don't fit since prevention has longer timelines.

Another thing that we've done, which was much later, about 1987: I asked our group to write a request for applications so state health agencies could apply for grants related to evidence based public health messages. A group from the state of California applied with a "Five a Day" program. We liked it because it was a positive message – eat more fruits and vegetables. So we talked with them and developed a national program that was somewhat different and more broad. We invited industry to take part. The main industries were the fruit and vegetable sector and the big supermarket chains. So we set up a national "Five A Day" program.

Our food industry colleagues said, "You're too slow, federal government." They then set up their own foundation, collecting \$400,000 in a week or two to get things rolling. We made an agreement that industry could use the NCI message, but NCI had to agree to the content of the message. They agreed to that. And so, for example, you could count a baked potato, but not

French fries. You couldn't count broccoli and cheese because it contained a lot of fat. Some companies wanted to push the limits to give their product a competitive advantage. Thus, we insisted on approving the content of the message. California had the "Five A Day" license, which we cross-filed on. That program took off.

XF: About what time frame?

PG: It's still going on. Well, it started in 1987 and is still going strong today. There were billions, literally tens of billions of gross impressions, which to an advertising person means one person sees one ad — for example, a person sees a "Five A Day" stamp on a plastic bag in the market one time; that's a gross impression. We have evidence that this program increased vegetable and fruit consumption a bit all across the country. It certainly increased awareness that vegetables and fruits are an important part of your diet. The federal part now has been taken over by CDC. We handed it off. The industry part is continuing. You can go into a market now and still find the stamp on the bags for produce.

XF: One reason I ask is because there is, you know, there's another, health plans is one dimension of this, but in some sense the NCI appearance on the back of the Kellogg's cereal fits with another history that has been of concern to the FDA of third-party seal of approvals.

PG: Yes, the credibility issue.

XF: Yeah. And so back in the '40s, there was an American Medical Association seal-of-approval program that eventually ended. And actually, in the '80s, shortly after the All Bran incident, the American Heart Association got in a lot of trouble trying to create its heart-healthy seal of approval.

PG: I liked the blood-pressure and cholesterol education programs that NHLBI, the Heart Institute of NIH, ran. They got together a common committee of NIH's Heart Institute and the American Heart Association, agreed on rules of evidence, what is evidence-based, and used the exact same message. Then NHLBI spent a million and a half dollars a year for a campaign that taught the public that if you have high blood pressure, you should follow you doctor's advice to bring it down and lower your heart attack and stroke risk. Blood cholesterol measures are important.

The cancer community had a weaker example, as there are differing opinions and mixed messages. An example is the mammography message for women in their forties. NCI basically says, "Talk with your doctor". The American Cancer Society has a message which was almost the same, but not exactly the same as the NCI. That was used as a wedge by the press saying, "Why can't you agree with each other?" The slight difference just adds confusion. It would be better if we were together on one message that agree on.

XF: Well, you know, it somewhat opens a risk. The National Cancer Institute is a public institution.

PG: Right.

XF: You know, this was a period where there was a lot of public-private interaction, but also a lot of concern about those linkages. And I was just trying to wonder, when you were meeting with Kellogg's, that there was a backdrop there as far as how . . .

PG: Well, we do have a sense that part of our mission is to educate the public about what's known about cancer risk, and how to lower your risk.

SJ: I guess the next step in all this was the Department had to step in. There were two agencies with very different perspectives. Maybe I overstate it, because FDA was extremely upset about this.

XF: They were upset.

SJ: Agreed. Maybe we aren't making that as clear as we could. This wasn't about gentlemen's agreements. But you have...

PG: I didn't get involved with any discussion of NCI-FDA differences – nobody said to me, “Don't do it” or “Slow down,” nothing. I never went downtown over Kellogg using NCI's message.

SJ: And that's good to know because in the subsequent legislation, it's clear that the Department understood that there were conflicting elements and issues here.

PG: Apparently, one group was upset at us, but I heard almost nothing about that, and was not involved in health claims issues.

SJ: Obviously, in the next legislation that was passed, there was a mandate to look at some specific health and nutrition claims.

PG: Yes.

SJ: Did you have any role in selecting those?

PG: No. I had no involvement with legislation.

SJ: And, obviously, CDC had a perspective on this as well.

PG: I don't know. There may have been someone from the NIH, perhaps Artemis Simopoulos. She chaired a NIH nutrition coordinating committee. I was not involved. I went to a few of the nutrition coordinating committee meetings and I thought they did was show-and-tell, not a lot of action. It seemed like a waste of time.

XF: Actually, about the same time . . .

PG: I'm not sure who attended from NIH.

XF: And about the same time that you were, that this campaign was first launching, Artemis stepped down, and there was actually, I was reading some articles. Some people were crediting a letter that you had sent as part of what the complaint that... I don't know how much of a role that played.

PG: Well, that's not exactly... I can tell you what happened. Artemis wanted to release a request for applications (RFA), with a budget set-aside from the Office of the Director of NIH. She wanted NCI to co-fund it, and I had said, "We can't do that unless we follow a process that involves NCI's Executive Committee and a presentation to our Board of Scientific Counselors. That would delay releasing the RFA beyond when she wanted to do it. She then went to Dr. Wyngaarden, who was the head of NIH, tried to muscle us into paying for a large part of her RFA. Vince DeVita and were called over to a meeting with Artemis and Jim Wyngaarden over this RFA issue. I just said, "Look, Jim, here's our process. I don't have any particular feeling about it, but we have to bring RFAs for review by our Board." Vince backed me up.

What surprised me was, Jim Wyngaarden then said to Artemis, "You know I don't want a lot of RFAs coming out of OD." He didn't think that was appropriate even though she was pushing for them. And she turned on him. She really turned on the director of NIH. I don't remember her words, but it wasn't a courteous, professional statement. She was dumped soon after. Now, I can't say absolutely that there was a connection with this episode and her leaving. It seemed that way to me.

When I see her now and then, she's not particularly pleasant. Yet generally she's a nice person. She knows a great deal about omega-3 fatty acids and olive oil. I thought her

relationship with the Director of NIH was the problem, not the more limited issue about whether NCI would co-fund that RFA.

SJ: Should we take a little break?

PG: Sure.

[break]

PG: One thing that we could use in nutrition that doesn't really exist is a system, maybe a cooperative group that sets up criteria of evidence, and looks at what we have in different areas. If you take bioactive foods, or so-called antioxidants – which I think are mainly redox systems, they're not just antioxidants...

SJ: Explain that.

PG: Okay. If you look at the beta carotene and alpha tocopherol study of 29,000 smokers, which we did collaboratively with Finish sciences, the smokers on beta carotene had a lung cancer rate of about six getting lung cancer per thousand men per year, and those on placebo for beta carotene had five lung cancers per thousand men per year. That's a 20 percent increase; actually, it was 16 percent. People call beta carotene and anti-oxidant, but in this case it was acting like a pro-oxidant.

In my view, the most astute doctor or the best epidemiologist could not discern that one-per-thousand difference. You need a really well-designed, large-scale, double-blind clinical trial. At that point in time, early 1980s, industry based on epidemiologic associations, primarily based on an index of beta carotene in foods, taught the public the word beta carotene, with an implication that it was on the side of good health, maybe even preventing cancer. We had nothing to do with industry marketing that idea. It was an initiative of the supplement industry.

When the study was done, it looked like, at least for smokers, there could be an adverse effect. Now, why? Some people were calling beta carotene an antioxidant. Most chemicals called antioxidants are redox systems. In one microenvironment, they're antioxidant; in another microenvironment, maybe in this case they're aerated along with the driver of the tobacco carcinogens, they might have been pro-oxidant or they might have been competing with other important carotenoids or other important compounds.

And "antioxidants" are in a huge array of very different foods. You can look at curcumin, for example, and there's something like over 80 different possible mechanisms of action, including antioxidant, or there's different vitamin E's that probably work in lipid systems and vitamin C in water systems. Yet now to the public, antioxidants always are good. When antioxidants are in foods, they are called good foods. We're not ahead of the curve with research; we're trying to study all these different things. So my feeling is, with all these bioactive foods and with more engineered foods coming online, that we need a better coordinated system of saying, let's be sure we analyze criteria of evidence, let's look at the data. Let's try to figure out where the evidence is strongest. Let's prioritize what research we need most. Let's do that research and define the metrics that will bring us to the point that we can say something to the public with confidence. We don't have that. We have just a scatter of different

studies going on and people making claims from the latest paper or some other unconvincing paper.

SJ: We have blueberries, pomegranate juice, and green tea.

PG: Yes.

SJ: The latest ones.

PG: Right. Gary Stoner of Ohio State did a very good study of berry extracts. But, I don't know if the berries from California or from a dry climate are different from Ohio berries. Maybe that's a lead. Maybe it's the low-hanging fruit literally for moving forward on research. We don't have a good system to put that into context, something the FDA might end up being happy with if we actually set it up. In the past few months, I've been advocating that at NCI at least we do set up a system like that, but we don't have it. NIH just stimulates a broad range of research.

SJ: The only cross-section I can think of at this point is resveratrol.

PG: Yes, okay.

SJ: Is it a food or is it a drug, or what is it?

PG: Well, that's an issue. So you take the grape skin and you extract resveratrol, and you say, "Oh, grapes must be good." They probably are. And then there are claims for broccoli sprouts. There's some evidence, but once you put in the concentrate in a pill and have a dose that's way beyond what you get from drinking wine, red wine or grapes, what is it? You might be getting a pharmacologic effect. And how are you going to classify it for study?

So our feeling – and we sponsor some of those studies – is when you get into a human trial, we want you to have an IND. I've been adamant that such investigators get an IND. I don't care whether FDA says you need it or not. We just want it because we have to monitor safety now as well as efficacy, and we know there's a possibility, if you have a great big dose, that something adverse can happen. If you take a huge dose, we're not that sure that it's always beneficial. There may be a balance. And even more difficult is to say there's a benefit against, say, heart disease or cancer, and find out 15 years later there's some effect on cognitive function. It's very tricky. You can't always do a trial because a trial just lasts four or five years, and if you're looking at, say, 20 years, how do you put that kind of evidence together? When I look at most of the data, I see quite a bit of epidemiology – not always consistent, very little basic science and not much in the way of clinical-metabolic studies. You can simply do things like absorption studies. You can at least find that out before you go into big trials whether something is absorbed.

The other thing that's hard to evaluate is, in prevention, logically there may be more than one primary endpoint to a trial. It might not just be cancer, but cancer, heart disease, diabetes, and something else, cognitive function. At NIH, we're set up categorically by disease category. That's great if you want to get money from Congress. But it's a problem in trying to get everyone together, to say we're going to co-fund together over a long period, because each

institute will ask, what's in it for them, and the time-to-event varies, for example, for heart disease versus cancer.

SJ: And unlike the drug industry, the profit incentive is rarely there.

PG: Yes, right. But even with drugs, we have trouble because we've done some of the studies that show problems with drugs, and the drug companies, are already selling the drug. We'll look for compounds that may already be available for some other indication. Raloxifene for arthritis reduces breast cancer risk. In that case, we were able to study it and show we could prevent about half of post-menopausal breast cancer. But we looked at those because it saves years and years and lots of money if you have an available drug already approved for some other purpose. Yet if a drug company has big sales and they see, like in some of the COX inhibitors for colon cancer that, well, you guys at NCI brought out a problem of increased heart attacks while doing the trial. This reduces sales. Thus, industry is not eager to support the next trial.

SJ: They feel as if they are running a risk?

PG: They already have an approved drug with a proved indication, so don't want it studied further.

XF: I have one other question about the period in the '80s, and I had a couple of questions.

PG: You might mean NCI dietary guidance in the late '70s.

XF: Yes.

PG: You know, Arthur Upton became NCI Director in 1978 or so. He released brief dietary guidelines to Congress. That is, a letter from the NCI director to Congress. The intent was there, but not much happened.

XF: Yes. I've interviewed Mark Hegsted, who had been a professor at the Harvard School of Public Health.

PG: Yeah, Mark terrific. And Senator McGovern also.

XF: One of the questions I was wondering, just also about the backdrop of this period is, you had the withholding of the RDAs, and there was a lot of controversy among nutritionists. It actually was happening in '84 and '85 as well, and they were supposed to come out and they didn't, and I was just wondering, was that a . . .

PG: I didn't have anything to do with that. I think a lot of that was based on the debates at the Food and Nutrition Board between the different camps. But I...

XF: Okay. So it was not related. And one thought that did actually – it was interesting when I was looking at some of the reports. Because of the, I mean, one negative thought for the National Cancer Institute of the All Bran incident came out when – it was very brief, but I'd just

be curious to get your own input about it. When the Surgeon General report was put together, one of the funders was the Kellogg's Foundation, and there were accusations that this might influence the direction of the report. Various people, probably [unclear] among them, were claiming that there was this progressive agenda that was trying to push forward claims about diet and health, and that this was shaping it. Do you...

PG: I didn't even know that.

XF: Oh, is that right?

PG: I didn't know anything about funding of Surgeon General Reports.

XF: Okay. I just wanted to ask. So really, just for me, then, the only other question I had was, in the long arch, how has this incident played out for the National Cancer Institute? Do you think that the National Cancer Institute position was ultimately justified or...

PG: Our position was justified. I probably would go back to saying eat a diet high in plant-based foods, vegetables, fruits, and whole grains; keep trim; get some exercise. The obesity problem is enormous and growing. We see type 2 diabetes in children, so that's a huge focus. I think there's new research in understanding bioactive food compounds and the impact on different systems and biology. We need a lot more basic nutrition research.

I see a huge amount of engineering of foods. Look at Monsanto, DuPont. Monsanto makes Round-Up-resistant soy, so if you're a California farmer, you can spray your crop with

herbicides, the soy will grow, you won't need as much water because the weeds are killed than use up most of the water, so you'll suppress the weeds. You'll need less power to bring the water to irrigate, so there's a big advantage to the farmer.

The aim of the aim of Bt corn improves the yield. Already, 60 percent of foods in the supermarkets are engineered. But the engineering is to either help agriculture or help food marketing. The debates may be the developing world wanting engineered foods and the small farmers in Europe against that. They claim adverse health effects when they really just don't want the competition. Or you get something like golden rice. A beta carotene molecule from daffodils is put into the rice gene. When eaten, it splits into vitamin A molecules. People are dying each year in Africa of multiple deficiencies, including vitamin A deficiency. If you use golden rice rather than regular rice, you'll prevent a great deal of blindness and some deaths. Plausibly, if we ever got enough knowledge, we could do things like that with cancer prevention and other diseases. It's years off, but I think we have to think about that because the engineering of foods is ongoing. It seems to me we need a leading edge in basic nutritional science and clinical nutrition science. Otherwise, there may be benefits, but we could be in for some unpleasant surprises because there just aren't enough people studying it.

Looking forward, there's a lot that we should do in nutrition science as well as studies of eating behavior. Our behavioral scientists tend to study individuals. We also need to study the behavior of institutions and of policymakers. That has a bigger impact. How do school systems work? How do you work with city planners to increase physical activity? In Bethesda, we live in an affluent area of beautiful houses with no sidewalks. In inner cities, kids can't go play in the park safely, they are afraid to walk to school. A lot of people drive to work, sit in front of the PC, drive home, then sit in front of the TV. Our environment needs to favor good health.

The health sector can't deal adequately with that. We can partner, but we've got to partner with different industries – the food industry, the schools, city planners, politicians, policy makers. Marketing and taxing, all that kind of thing can affect lifestyle. If you look at the history of tobacco, it's obvious that policies have a major impact. Tobacco costs drive use by teenagers.

XF: So from the vantage point of today, where we have, we do have lots of health plans and it provides a market incentive for the development of foods that would have these kinds of [unclear]...

PG: There are so many new food products, and they're changing all the time. You can't keep up with them. The best we can do is prioritize, to figure out what we really know with some confidence. There's such a myriad of emotion, particular by people taking vitamin pills. I don't know how they decide what to take. I look at the market; there's vitamin A, B, C, huge amounts sold. How does someone decide they want this one or want that one?

SJ: Now they are even questioning, you know, I mean, a company that developed One-A-Day was the biggest proponent of vitamin supplements, but there are even people talking about maybe that's not such a good idea. With certain cancers, it could stimulate cancers. None of this has any clarity.

PG: We don't have a lot of evidence on combinations of vitamin pills. But I think the One-A-Day is probably okay. I don't really believe its safety is proven, but I don't think it's likely to

hurt you. But when you take these large, unbalanced dosages, we just don't have data. And even for One-A-Day, we don't have much research. If you're going to sort of what's the upper level of vitamin intake and include consideration of multiple vitamins, you'll have difficulty.

XF: Given the advantage of hindsight, would you look back on the All Bran incident as a case of much ado about nothing, or as a case of maybe letting the genie out of the bottle? I mean, there are sort of two different ways . . .

PG: I think the genie out of the bottle is more accurate. In other words, it's not much ado about nothing because, whether intended or not, it did lead to a huge change. A lot of the change was not the intent, but it had a big impact.

XF: Or not the intent of the National Cancer Institute.

PG: I think there was a good impact on eating of fiber. It stimulated research on fiber. The NCI coding systems were insufficient at that time. The codes didn't say fiber; there was little study of fiber. And also the fat issues. There were scientific groups that said maybe we'd better study that, some for good academic reasons, some saying we think you're full of it. But there were studies, and from our point of view, they helped to focus peer-reviewed grants. A lot of research was stimulated. It focused more research on nutritional science – not as much as we needed, but it helped in that sense.

On the downside, probably it would have been better if we'd gotten together with the FDA on this specific issue beforehand. But Sanford Miller had said we should do it our way.

The FDA didn't want to work with us on this. The FDA was friendly, but I think they probably just would have tried to squelch any dietary guidance related to food products.

SJ: Can you summarize . . . Two questions. What role do you play in funding some of these nutritional studies today? And what are the current status of the fat-fiber connection?

PG: We fund a substantial amount of research. If you look at NIH funding, I'd have to guess, I'd say NIH funds most of the countries biomedical research on nutrition.

[END OF TAPE 1, SIDE B]

My impression is we'd have to check it out to be sure of accuracy because NCI funds about a quarter of nutrition research for NIH, NIDDK about a quarter, the Heart Institute about a quarter, and all the other institutes together about a quarter.

The limitation I see is that most what we're funding is epidemiological and animal model research. That's important but not sufficient. We really need way more in the way of basic nutritional science and more clinical research and more research on methods. Are there lab methods for validating intake? And there are many other specific questions.

We're funding, as a proportion of NIH, a lot, but as a total amount compared to, say, immunology or all sorts of other topics, a tiny amount. It's not a big expenditure of NCI or NIH as a whole.

SJ: And what is your understanding of the current state of the scientific studies on that link between fat and cancer and fiber and cancer and the two together?

PG: Again, not a great deal of study. Since that time, there have been conflicting data on fiber. There have been some very good epidemiologic studies suggesting benefits, especially against colorectal cancer disease. And usually, actually, even going back to Kellogg's, it's been insoluble fiber, not oat fiber, not oat bran. With heart disease, it's oats, the soluble fibers that show the potential benefits. With cancer, it's more the insoluble fibers. But you can break fibers into many, many more elements, cellulose, hemicelluloses, pectin and more.

SJ: We're still talking fiber, any kind, is helpful in something?

PG: Right. There very likely is a benefit in bowel function. There were a couple of trials that did not show a benefit. These were short term, one with an All Bran versus fake All Bran, and one with dietary fiber. There have been mixed results. My feeling in general is fiber is beneficial. Type of fat now is important. Transfat and saturated increase heart disease risk. I think the impact of overall diet, including being fat – obesity is the big problem. If we can cut obesity, which is a combination of eating behavior and exercise, the way society works, it would have major benefits.

You know, when I was little, a cup was eight ounces. Right? Then you couldn't get a Coke that was less than 12 ounces, and now it's become 20 ounces. A kid goes to the movie house and gets 32- or 40-ounce – think of the large one – of sugar water and caffeine, and the soft drinks are pushing a lot of the obesity. It's not just foods. It's the sugared drinks all the

time, and foods. You have to look at the aggregate caloric intake. Fat contributes, but you have to consider type of fat. Omega-3 fats have benefits for good health. We don't have definitive trials. We've got some suggestive evidence that I think is probably right. But as an NCI person, I'd say let's get the definitive evidence. We still don't have it, especially on fats.

XF: One criticism of studies – and you said earlier, you talked about how they are often reductionist and do not offer a clear clinical or a clear epidemiological result.

PG: Well, not epidemiological. Reductionist arguments are the best way to get funded through peer review. And that's why the basic scientists are the best at getting grants.

XF: But once, because of this reductionism, it focuses on one component, which is at the core of this whole incident, unintentionally, by the National Cancer Institute when Kellogg's put its endorsement of fiber on the product label.

PG: I saw fiber as a combination of fruits, vegetables, and whole grains. It came across as whole grains only.

XF: But I've heard from different, in different contexts what Michael Pollin popularly has talked about what he called [unclear] nutritionism and the tendency to focus in on one element. But even among nutritionists like Marion Nestle, you have this call for nutritionists to think holistically again. Do you see . . .

PG: I'm more with Marion Nestle. She started as a biochemist, you know.

XF: Yeah.

PG: She's smart.

XF: Do you see a challenge for cancer research in looking at diet and how you can actually measure this tendency toward sort of component research on the link between cancer and fiber and fat?

PG: Yes. I think we could do it, but not with the small amount of research that's been devoted to it, and not with the limited number of scientists in the field. I think we'd better raise support for them for a career to really work on those things. It's feasible to do it. I don't think there's any magic in figuring out how to do it. It's just that unless there's a substantial increase in resource allocation, including both money and training and getting university scientists thinking that's a field that we want to build up, it's not going to happen. And even when you have strong medical schools or strong nutrition departments, they don't work together. Look at Cornell – a strong nutrition department in Ithaca and a medical school in New York.

SJ: And they have a large and important nutrition heritage and history, program.

PG: Yes. You see it all over. They're just separate institutes even when they're part of the same university.

XF: I do have one final question if you can [unclear] answering all these. Your career in a sense captures a real shift in medical research in the sense that – and I know that in the ‘70s, when you were getting into this, there were even debates about this – which is focusing on cures for disease or cures for cancer, to a refocus on prevention, you know, what we were talking about here today, diet, but just generally about prevention. And I was wondering if you could, you know, if you wanted to say a little bit about that shift and some of the problems we’re encountering?

PG: Well, purposely, I did it in my own career. I could have been a good internist; I was trained to be. I just figured that one more clinical internist in the world compared to the paucity we have in prevention wouldn’t count for much. So I chose to work in an area that might have been harder in a way, but where we need attention. And when you look historically over the decades of what diseases are better controlled, it’s where the incidence rate was brought down either by engineering or by medical approaches like vaccines. I think there’s somewhat of a shift; there’s public interest in prevention, even Congressional interest. But when it comes to allocation of resources, prevention does poorly. Maybe some of the deans in the public health schools aren’t aggressive enough. In the ‘70s, it was hard for them to get resources, and so they moved away from medically trained prevention people to attract candidates who are easier to recruit and less expensive to train. I’m not knocking them as many are major contributors to the public health.

For example, in epidemiology, rather than biologists and physicians who then learned epidemiology, you got epidemiologists who were more like statisticians, great at doing

multivariate analyses and looking at big data sets, but not fully into the biology. Also the glory to the public health schools was getting NIH grants or doing something international, not training local health officers. Often today, retired family docs, semi-retired, run health departments. Rather than prevention, attention is given to hospital costs. We need to build up an infrastructure and an interest and a capacity, more public health scientists and physician scientists wanting to greatly expand the prevention field. Still, we're working on it. It's taking hold, better than it was, but there's a long way to go.

SJ: Sounds good. We've gotten some wonderful insights into NCI's perspective, specifically cancer prevention's approach to the science of diet and nutrition, and we thank you for spending an hour or so with us.

[END OF INTERVIEW]



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