History

of the

U.S. Food and Drug Administration

Interviewee: George Pauli, Ph.D.

Interviewer: Suzanne W. Junod, Ph.D.

Date: July 2, 2004

Place: College Park, MD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CASSETTE NUMBERS

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: July 2, 2004 PLACE: College Park, MD LENGTH:

INTERVIEWEE: INTERVIEWER(S):

NAME: George Pauli NAME: Suzanne W. Junod, Ph.D.

ADDRESS: ADDRESS: Food and Drug Administration

FDA SERVICE DATES: FROM: July 1977 TO: March 2006

TITLE: Associate Director for Science & Policy, Office of Food Additive Safety, CFSAN

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Interview with George Pauli

July 2, 2004

SJ: We're here at the Parklawn Building today, on Friday, July 2, 2004, conducting an oral history interview with George Pauli from the Center for Food Safety and Applied Nutrition (CFSAN). The interview is being conducted by Dr. Suzanne W. Junod of the FDA History Office.

George, tell us a little about how you came to work for the Food and Drug Administration and what led you to the area that you specialized in?

GP: Okay. I'm a chemist. I can't say I was always interested in science. I probably wasn't interested at all in science, but coming from a family where no one had ever gone to college, and being the youngest of seven, I was looking for a way of getting an education that might pay off in the long run. So I studied chemistry.

I got a bachelor's degree at the University of Michigan. I thought that was going to be it because going to college was it. But many people told me, if you're going to be a scientist, you have to get a Ph.D. So I went on to Indiana University and got a Ph.D. But I wasn't so much interested in research as I was in education, communicating what science had done for my education, and I wanted to communicate to others.

SJ: And what was your major?

GP: I studied chemistry as an undergraduate; physical chemistry as a graduate student, in "closely related to food" work, like structure determination of gaseous molecules, as remote as you could find.

I was looking for a career in education. I spent a year in an internship program at Earlham College, a wonderful Quaker college in Indiana, and then accepted a position at Lafayette College, a very high-quality liberal arts college in Pennsylvania. And I feel that I started getting my liberal arts education by being on the faculty rather than being on the student side.

I was there for quite a few years, but they had a program to continually bring in new people. So, unknown to me, we had a quota for tenure, and we were already over it when I got there. So I started looking for a new job in the mid-'70s, a bad time to get a job.

I actually was hired by the college to do long-range planning, which I thought was rather interesting for someone who didn't get tenure, but I stayed, got a couple extra years, and still looked around for opportunities. I took a postdoc position at Lehigh University and put my name on the American Chemical Society registry probably about 1975. I got a letter in 1976 that said, "Do you still want to be on the registry?" and I thought, why should I? I hadn't gotten one inquiry from it. And a few months later, I got a letter from Richard Ronk saying that there is a big hiring program at FDA in the Division of Food and Color Additives, and if I was interested in applying, please fill out certain forms and apply. That was a real nice bolt from out of the blue. I had never thought of a career in the federal government because I didn't know there were such things, for practical purposes.

So I applied, and one of the young, new supervisors, Thomas C. Brown, came out to interview me in the Allentown-Bethlehem-Easton Airport. It was a nice, wonderful, plush interview in the café in a small airport. And at that time, he was looking for, among other things, people to manage a petition they expected on irradiated food coming in from the Army, and I happened to know the terminology about radiation because I'd taught about it a little bit, and a little bit of knowledge can put you ahead of a lot of people in this world. So I moved up on Tom's screen quite a bit, and got a call from the personnel office in early winter 1977, offering me the position. I joined in July of 1977, near the end of a very large hire that took place over the year, and as often is the case, ended with the end of the fiscal year.

We were all new. The program that we were hired on had new money for lots of reasons. They were reviewing "generally recognized as safe ingredients" (GRAS) that had been ongoing in the '70s and

growing. There was concern about companies doing laboratory research and faking the results, so there started a bioresearch monitoring program. It came out of the Searle Company, looking through some of their files had raised questions. Actually, Searle came out pretty good. But the program started, and many of us were hired in on that program. And there was also funding to review ingredients that had been considered "generally recognized as safe," mainly ingredients that had been used in food for many years prior to 1958. The thought was, why not look at the things that FDA approved since 1958, to see if they still meet the standards that we would have in the 1970s? And so a large number of us came in, and a program started to obtain data on essentially every ingredient that was used in food, other than a common agricultural commodity.

One of the things that happens when you do that is, when you hire in maybe 30-40 consumer safety officers, which are the regulatory scientists, and maybe 10-20 toxicologists and additional chemists, you have a lot of untrained people on board who (1) don't have the institutional way of thinking, and (2) often have some time on their hands because they don't have a lot of assignments. So there was a lot of crosstalk, and there were too many new people for the supervisors to keep up with. So the new people taught each other as they came on board, and the supervisors' sort of tried to keep reins on the whole thing.

There were several things happening at that time due to concern about carcinogens in food. The 1970s were really a focus time on that. To the best of my knowledge, it probably kicked off in 1968-69, when, based on some data from laboratory animals being fed and implanted also, I think, calcium cyclamate and sodium saccharine. They saw bladder tumors, and the first judgment was it must be the cyclamate. And because there wasn't a lot of testing the cyclamate salts were taken off the market as sweeteners, and more concern followed that there might be other things out there like that. And one of the things about the cyclamate salts, they were on the market because they were generally recognized as safe for use in food based on limited use in drugs. But in the 1960s, the diet soda-pop industry took off, and so what was a minor ingredient suddenly became a major one, and that raised some concern.

Also, there was enough concern about cancer in general that somewhere near that time President Nixon announced the war on cancer. He started a program where, at the National Institutes of Health (NIH), and in particular the National Cancer Institute (NCI), many chemicals would be tested for their carcinogenic capability by feeding or inhalation studies or whatever was appropriate, in large amounts to rats and mice. More and more new data became available, raising questions about carcinogenicity in some chemicals that had been in industry for many years.

Part of the things that were being learned at that time was that vinyl chloride was a carcinogen based on actual studies with workers. It is a chemical used to make polyvinyl chloride, known as PVC, commonly found in pipes, hoses, and many consumer articles. Polyvinyl chloride was used in some films for contact with food. There was at that time an interest in moving from glass bottles to plastic bottles, and the industry started moving to polyvinyl chloride, so FDA started becoming concerned about that. It was a container that hadn't been on the market for years and years.

So the concern about cancer grew – we saw a possible link. It wasn't definitive. In fact it was incorrect. But the link between the cyclamate salts and vinyl chloride coming from the polyvinyl chloride. . .

SJ: Let me ask you a question right here, before we talk about PVC. Did you know Ben Oser at Food Research Labs?

GP: His lab did the cyclamate test. No, I did not know him. He was by then a senior person in toxicology, and my background was physical chemistry. So I had to come to FDA to hear of people like Ben Oser, which I did.

But it wasn't just the cyclamate or the polyvinyl chloride. Nitrosamines raised concerns. Products that could be formed by nitrite salts that are used to cure meat can react with other components and produce nitrosamines, and nitrosamines are carcinogenic. So FDA and the Department of Agriculture

were concerned about nitrosamines in meat, vinyl chloride from polyvinyl chloride, cyclamate salts, and a whole raft of color additives. Eventually color additives seemed to rise to the fore.

In the 1960 color-additive amendments, unlike the food-additives amendment of 1958, products that were already on the market could stay on the market for one of two reasons. If there was a consensus on the safety because of their long use, they would be generally recognized as safe and did not require approval. Or if there wasn't enough information for there to be a general recognition of safety, they would have to get approval from FDA with an extension time given for the companies to obtain data, get petitions in, and those products were going to market.

There was no extension for color additives. There was no exemption for those that had been on the market for 50, 60 years with no indication of safety. They all had to be approved from scratch, and there was a provision put in that, unlike the other extension that the product could continue to be marketed provided that a sponsor step forward to sponsor a petition and commit to obtaining data to petition for approval of color additives. And so FDA created what was a "provisional list" for those things that were still allowed while testing was ongoing.

SJ: But who had a sponsor?

GP: If the testing wasn't ongoing then they did not meet the provisions. Many color additives were approved during the 1960s, particularly for food and drug use. FDA had a rather novel interpretation that they couldn't evaluate the safety in cosmetics without knowing the complete formulation of the cosmetic. However, FDA didn't have pre-market approval authority over the complete formulation of a cosmetic and the industry disagreed.

During that time, FDA approved no color additives for cosmetics, and the industry sued and won, and the court said, "No that is not a criterion." Other things just delayed closure on evaluation.

The 1960s were also the time that FDA learned about thalidomide in drugs and causing birth defects. At the time of thalidomide, food ingredients were not normally tested for birth defects.

So all these color additives on the "provisional list" that hadn't been approved for cosmetics, FDA said, "You have to get birth-defect testing." So that stretched things out a while longer.

Then, as things, went on, the parent compound for FD&C Red #2 on the "provisional list" did not get certified. FD&C Red #2 was the name for those batches that were certified to meet a purity standard by FDA. There was a question coming from a study (I believe in Russia) that it might be carcinogenic. Two problems: (1) we didn't have the data: we weren't quite sure what was done in a study in a country that didn't communicate with anyone on details of science; and (2) we had no knowledge of the purity of what they were using because it would not have come through our program.

But FDA decided to test FD&C Red #2, I can't say it was our best science, there were a lot of problems with the test. But the conclusions were that it might be carcinogenic. And it was uncertain, and so, because of the concerns raised, one of the provisions of the "provisional list" was that there could be no safety concerns.

So FDA revoked the provisional listing for Red #2 and put out a proposal that required new testing of every color additive that had not been previously approved. So there was a lot of work coming in, and this was coming together in the late 1970s.

Now, one of the things about the color additives is many of the chemicals used to make color additives are not the type of thing you'd want to be exposed to yourself.

When the color additive is of suitable purity, that's fine, and for that reason, even the 1938 Act put together provisions for FDA to certify the purity of certain color additives to make sure that the impurities were not going to be causing problems.

Well the other development in the 1970s is analytical chemistry became a lot better, and as we were looking . . .

SJ: Can you say a little more about that?

GP: Well, analytical chemistry – where people used to say if you get something down to a tenth of a percent, a hundredth of a percent, that was pretty good, and that would be like 100 parts per million. Well, they started getting down to, they could detect things at a part per million, then maybe a 100 parts per billion, 50 parts per billion, 10 parts per billion, a part per billion. And the analytical capability kept getting lower, and with these color additives, I think FDA gave directives to their labs to improve their methodology and look for some of these starting materials in the color additives because they may be present at levels that are problematic, but we just didn't know about it before.

So that was a twofold front really going on in that the analytical chemistry was improving in sensitivity, so our scientists could find lower and lower concentrations in a color additive, in a food additive, or on rare occasions in food itself. It's much harder to analyze food, but you can analyze what you can leach out of plastic with water; you can analyze a color additive itself in much better terms.

And so the concern for carcinogens in foods became quite strong, and with many chemicals being put on tests by the National Cancer Institute, we got findings from time to time. We have evidence that it's carcinogenic.

That raised a lot of questions because, among other things, the least used and probably least understood but most knowing portion of additive law was the Delaney clause, which applies to food additives in food and color additives in foods, drugs, cosmetics, and, as of 1976, medical devices as well. And people didn't really distinguish from the Delaney clause, what it really said. They worked on the spirit of the thing. If there's a carcinogen, you can't set a safe level, and so whenever they found a carcinogen, we thought, we can't have this in food. The Delaney clause, of course, is a legal document, not a scientific document, and there were a lot of platitudes about what it meant. Nobody ever looked into it.

When I came on board in 1977, this was the atmosphere. I remember a training course I was at where my branch chief, who was probably about 60 years old, was sitting on the floor of the hotel room putting together documents for the *Federal Register* for revocation of some color additives because we found a carcinogenic impurity in this color additive and that color additive. We didn't find a carcinogenic

impurity in another color additive, but it very well could be there, and we didn't have the methodology to determine if that was the case. And so, one by one, we started revoking the provisional listing of many color additives because they contained a carcinogen or some batches might contain a carcinogen but we couldn't tell which is which because we didn't have the methodology. And these color additives were going off the market.

I still wasn't involved in the actual project at that time; I was on the periphery. But eventually, I understand that one of the acting commissioners, a deputy commissioner then – I don't know if it was Sherwin Gardner or Mark Novitch, but one of them said, "I'm not going to sign another one of these documents based on this speculation. Get me a policy where we can deal with low levels of carcinogen that would raise no particular public health concern, because we can't just keep banning these things automatically because we think Delaney does it. There must be a way to make sense." And I know there are books written about FDA's creative interpretation of the law that we haven't had to change the Food, Drug, and Cosmetic Act very often because we figured out ways to interpret it reasonably so that it could always work.

SJ: Well, was industry complaining?

GP: I didn't know enough about industry at that time. I was the new kid and I didn't hear about it. I'm sure they didn't like it. But it's very hard for industry to promote their substance with a carcinogenic impurity.

SJ: They probably didn't have much choice.

GP: And additives have a bad reputation anyway, so . . . But they might have been complaining, but they were probably complaining, not to the working people, but to the political appointees and the like.

But I do know that one of these was finally sent back saying, “This seems to be an automatic knee-jerk response. Can’t you think of a way of handling this better?”

Another thing, as often happens when times change or when evens change in a specific way, there are currents coming from many, many directions. One current was coming from outside of FDA and another one was inside of FDA. Outside of FDA, there was much work over the years trying to assess the safety of low levels of ionizing radiation. Ionizing radiation could cause cancer. Everyone’s exposed to it form the sun, and also, from minerals in the soil. So there were several rather simplistic but novel approaches to assessing the risk. And the general approach taken was as simple as could be and fit my physical chemistry background. It was just, if a certain amount provides a 10 percent risk of cancer, if you cut the amount by tenfold, it’ll be maybe one percent risk of cancer. You cut by another tenfold; it’s reduced another 10 percent. Put a ruler down, draw a line, and no way of proving it’s true, but it’s a way of rationally looking at what are possibilities that are too small to detect.

Even when I was teaching, I saw a wonderful article in a 1972 *Science* magazine saying, how do you assess the risk of cancer at small doses of a carcinogen? And the person, who was a scientist named Alvin Weinberg, who coined the term called “trans-science,” questioned that it sounded scientific, but it transcended the ability of science ever to answer it, and we come up with models to say, this is how we will agree to deal with it. We can never prove that it’s true. But this is a rational way.

So an approach of assessing the risk from cancer, from exposure to a carcinogenic compound or radiation or whatever, at levels too small to detect in a practicable population, how do you extrapolate that to 250 million people, which is about the population of the country back then, when you can’t see anything in a hundred? Well, does that mean you wouldn’t see it if you had 250 million? There was just no way of doing it.

But the radiation people were beginning the risk assessment, and with my background on radiation from teaching, I understood the principles going out in that part of the world.

And our then Bureau of Veterinary Medicine was also coming up with what they called a sensitivity-of-method theory, a legal theory, for dealing with carcinogenic residues in meat-producing animals.

The Delaney clause applies in, as I mentioned before, food additives, color additives and animal drugs. And one of the issues that came up with diethylstilbestrol was that it was a growth promoter to be used in animals and it was carcinogenic. Could you use it in a way so that any residues in the animal were harmless to humans?

The Delaney clause for animal drugs said that you couldn't produce them, or use them, in an animal unless it left no residues in the animal. And our veterinary medicine people started working on the question, what does it mean by "no residues"? And they came up with what was called a sensitivity of method: no residues by the method that was sensitive to detect anything of harm; and it was lower than there, there were no residues. And so they were looking at – how sensitive did their method have to be? They had a new risk assessment to say, how sensitive does my method have to be to say it is essentially of no risk? And people used numbers to establish what it means to be no risk.

Well, things eventually settled out just because it's a nice round number that if using very conservative approaches that are likely to overestimate risk says that the risk from lifetime exposure is less than one in a million, for practical purposes that's zero. In fact, it probably is zero, but we can never measure for sure. And that became sort of a practical zero.

So in the human foods area we were thinking that was a logical approach for doing things. It had been developing in the scientific community both from the radiation standpoint and the animal-drug standpoint.

We were looking at how can you do things for a color additive? Well, with the acting commissioner sending a document back and said, "Come up with a more reasonable way of dealing with this than just prohibiting everything." A committee was appointed. I was not on it.

One of my current colleagues, Dr. Arthur Lipman, was on it, and from what he had told me and what I remember, we also had a Ms. Joan Shwing, Dr. Norman Chang, and then, later on, a person who

came in 1978, Dr. Joe Lomenzo, who worked on trying to come up with a theory where we could allow trivial amounts of carcinogens in foods as long as it was not of a public health risk. And being all fresh in FDA less than two years, they started looking at documents like the *Code of Federal Regulations*, the Food, Drug, and Cosmetic Act, but they were looking at it with a fresh eye.

An there is a regulation in the *Code of Federal Regulations*, in Part 70 – I don't remember the number describing the practical application of the Delaney clause for color additives – they may not be approved for use if the "color additive", including impurities, induces cancer in man or animal.

We started thinking that a color additive is not a thing, it is a mixture, including impurities, and so we looked at the whole picture and we started thinking that every impurity in the color additive is not a color additive, its part of a color additive. And they looked at the Delaney clause for color additives, and there's a provision there referring to – if a "color additive or part of a color additive is ingested" or something like this again, this reinforcement that there's such a thing as "part of a color additive", and that started to think in a new way. You looked at the Delaney clause and it said, "FDA cannot approve the use of a food additive or color additive if the additive causes cancer." But we see these other things as "parts of a color additive" or impurities of a color additive, and the Delaney clause didn't say anything about parts of a color additive or impurities of a color additive.

So people started going back and saying, "Let's take the law literally. Let's read it as it says, not as people have assumed what it meant." And so they started bouncing that idea around a bit, and gradually some of these people started leaving the agency. And we had a very diligent, thorough scientist colleague of mine two doors down the hall, Dr. Terry Troxell, who is still with us today. He found this kind of thing fascinating. He like the idea of risk assessment, and he leaped in. Before anyone said that the work group was this group or something else. Terry Troxell was now leading the charge of trying to develop this policy, building on some of the observations that were seen in looking at how we could do this in practical terms? What would it mean? And how can we sell it to FDA management? This was happening pretty closely.

And then Terry had a wonderful trait in that he was impeccably honest, and he did not want to win an argument because the other person didn't know something. He wanted to make sure he heard all parts of the argument.

TAPE 1, SIDE B

Terry Troxell was a scientist who liked to think in theoretical terms, liked to think very thoroughly, and liked to challenge his ideas. And he learned that I was a person that, whatever someone said, I could come up with an opposite point of view. Instead of that intimidating Terry or saying, "I don't want to talk to this guy, all he does is argue." Terry would come to my office and say, "What do you think about this?" He would look for someone to argue against what he was trying to develop. And as a result, he gradually refined the idea of a policy that was based on distinguishing between what was found in tests on an additive and what was found on tests of "part of an additive". And the approach was, if a test on the whole additive induced cancer, the Delaney clause prohibited any use. But if tests on the whole additive did not show cancer, of if the whole additive wasn't tested but a part of the additive was shown to cause cancer, we could evaluate the risk from that impurity, or whatever it was, and assess safety under general safety provisions. Keep in mind the idea that if a very conservative science tends to overestimate the risk. It leads to an assessment of a risk of less than one in a million for exposure over a lifetime – if people consume a lot of this that is zero, for practical purposes.

SJ: Is that part of an evolution from the hundredfold margin of safety?

GP: No.

SJ: Okay. That was a different. . . I thought so. . .

GP: Yeah. A hundredfold margin of safety is that there are things that, if you get too much of them, they're toxic, but if you get below a threshold, they're not toxic. And if they're not toxic at all to an animal at one level, if you go down a hundredfold lower, it's very unlikely to be harmful to humans. But with carcinogens, you're causing changes at the cellular level, and so you may not . . .

SJ: So that wouldn't be applicable.

GP: Wouldn't be applicable because it – well, it probably is in some cases, and it probably is for low exposures in many cases. But I say probably, because you can't prove it, and when you can't prove it, you start working on reasonable models. But in this case, we were looking at it from the standpoint of assessing exposure to the impurities and treating those differently than the additive as a whole. The impurity may be present in such a low level that it means nothing for the additive as a whole. We recognized that we were finding impurities at levels that before we thought didn't exist. So that was one of the approaches.

We were even looking at, "how are we going to sell this?" We were looking at dealing with impurities. But looking at semantics, we'd say, "how do you distinguish between an impurity and something else that's part of a mixture?" So we thought, we can come up a nice neutral term, and we thought "component" sounds neutral. But "components" is a term used in the statue in another provision. We didn't want to confuse that. So we considered the term "constituents". An additive is made of many "constituents". There's the major constituent that you probably want, or a minor constituent that you may not care about and there may be other minor constituents that you don't want. Let's look at it from the standpoint that, in practicality, if a major constituent causes cancer, the additive as a whole would most certainly cause cancer, and it would never pass a risk assessment. So we don't have to worry about that. That'll be handled by itself. But if a "minor constituent" caused cancer, where it was an impurity or not – for example, if it's a color additive, if the "minor constituent" had some coloring properties, is that an

impurity or is it not? But we decided just to avoid the semantics on whether it was an impurity or not and go with what we called the "constituents policy".

SJ: And for the purposes of the record now, I assume that during this time period, 80 percent, then and now, of color additives are coal-tar based. Or were we moving away from that?

GP: They're both.

SJ: Coal tar by itself is carcinogenic, so the more highly purified, then the better and safer it is?

GP: Actually, yes. The name "coal-tar color additive" is actually a misnomer today, but it still, it really describes the difference between color additives that are produced synthetically by the petroleum industry, chemical industry, and those that might occur naturally, like extracts of flowers and minerals and things like this. The so called coal-tar colors have historically been certified for purity, and they were required to be certified for purity in 1938.

Now, I say the name is a bit of a misnomer because, in the 1910s, '20s, maybe even into the '30s, the way the chemical industry got its raw materials was from products from coal, where you got all these tarry mixtures and you separated them. That was your raw materials for chemical synthesis. With development of the petroleum industry, everything is produced from the petroleum. It's no longer from coal tar. But we still use the names because they're the same chemicals that are produced in very similar ways, and that's the ones where you often have nasty impurities.

Well, even at that time – this would be in the late 1970s, probably '78 and '79 while the issue was raised by color additives, there was still a bias that color additives weren't necessary, which some people still think, but I know that when Giant Food tried to sell maraschino cherries that were white, they didn't sell at all.

But it would be nice if you got a nice, safe food additive that had something that was a little bit more innocuous, and we focused on a group of emulsifiers called "polysorbates" – polysorbate 60, polysorbate 65 and polysorbate 80. One of our chemists in the lab found that two molecules of ethylene oxide which are used to make the polysorbate would bind to each other and form a cyclic compound called dioxane, not dioxin by dioxane, and that was a weak carcinogen.

And we saw the industry was doing everything to get the levels very low. There was one company that was very nervous that they had found it and they were trying to improve their manufacturing.

We thought – we'll go out with a proposal to set specifications for the polysorbates for dioxane, and by setting this proposal to tighten up the standards, we will announce a "constituent's policy" as a way for people to comment on it – and in the process we would actually be taking a product that was on the market in millions of pounds a year, in a lot of foods, and improve the purity of it.

SJ: Let me ask one question, too, now. I've written a little bit about the bread hearing with Myri. Somebody told me that was the polysorbate.

GP: Yes.

SJ: Okay. They were originally called Myri by the Atlas Powder Company.

GP: Atlas Powder Company, which became Imperial Chemical Industries (ICI). Myri was a little bit different but they were related compounds, and we would find this impurity and all in most of them. But they put together a whole range – yes, the Atlas Company, the Myri, the Spans and the Tweens.

I was sort of interested in this because in my postdoctoral position before I came to FDA, I was learning about the Spans and the Tweens because they would be used in a technology called "emulsion polymerization". So I was learning about these, and I came to FDA . . .

SJ: Not just in food products?

GP: No. They were used to make synthetic rubber, to make all sorts of . . . In emulsion polymerization, you're essentially polymerizing an oily type of thing in water, and you need an emulsifier detergent. So polysorbates would be good detergents as well.

So I knew about these things, and as I mentioned – I'm circling back again, but in the program that I was hired to be brought in on, the cyclic review of food additives, we were looking at all the food additives that had been approved. And so as they were being assigned to people somewhat randomly, I said, "Well, let's put some of these together. I know something about the polysorbates and the Tweens and the Spans, so I'll take those." So I became interested in this impurity of the polysorbates because that was my class of compounds.

So Terry Troxell would come into my office, and we would look for all sorts of ways of how this would play out in terms of how you make things – does it apply to solvents, does it apply to this thing, does it apply to that thing, when is something an additive, when is it a constituent of an additive? We kept working these out.

And I do recall one time getting a call from Dick Ronk that Terry Troxell was giving him a briefing in his office and wanted me to come down to add to the argument. So I got to join in, and probably for the first time that I was not only Terry's sounding board, but I was part of the team that was putting together this policy. So I tend to be a theoretical thinker, my background being physical chemistry is more theoretically oriented, I found that it works very well with legal thinking. Its logic, logic, logic, and not a bunch of memorization. So I was able to contribute something along this line.

Well, the one thing I missed was a briefing that Terry and Dick Ronk and company gave for the Commissioner – I think it was in 1979 – Commissioner Kennedy and Chief Counsel Rick Cooper. And one of our consumer safety officers, who had better handwriting and better drawing skills, drew a chart, which I have a copy somewhere in my office, at least on overhead transparency, which we call the "yellow brick road". And the "yellow brick road" was a winding road that was colored in with yellow,

and we'd list one additive and another additive and another additive to the end of the thing. Just one after another would be banned because you found another carcinogenic impurity, and another one. At the end of the road, there's no such thing as an additive that's legal in the market. That was part of the "selling thing", the "yellow brick road" and the "constituent's policy" argument.

I wish I was there because I heard phrases later describing it as a shabby, transparent attempt to get around the Delaney clause. Others said it was a very creative attempt to get around the Delaney clause, but everybody was looking at it from that standpoint.

But the essence of it was, yes, this would probably work, and we have to continue to develop it. And so we continued to work on the idea that someday we would put together a proposal to set specifications and lay out our whole argument. And, meanwhile, the Office of General counsel was doing a little legal analysis to see what all the ramifications were. So, while I can't say they were on board, they were listening, and that was great progress.

An interesting thing interrupted our plans. While we were making plans for an important additive that sold over a million pounds a year, other things were going on, and we go back to color additives again. It was the "color additive provisional list". We were sued by Public Citizen who said that the "provisional list" was authorized for two years or two and a half years in 1960, but we could extend it for an additional term. Well, we extended it and extended and extended and extended.

In 1970, it was still there. And there was a lawsuit about 1976, just before I got here, where FDA, I believe, did consent. We would end the "provisional list" once we got all these new data in. Because of the problems we had with Red#2 where it was muddy and there were no data on the carcinogenicity concerns we raised, we required all the "ingested use" color additives to require two new studies, one in rats and one in mice.

So for all of those – some of these color additives might have been approved for use in foods in 1963 – we wanted two new, state-of-the-art studies for approval just to finish off the cosmetics and whatnot. The industry couldn't do them at all at once, so they were going to be bringing in data. We'd

put the data on public display as it came in and the "provisional list" would expire on, I believe it was January 19, 1981.

Well, some of the data weren't going to be in then, so we would still extend those where we had data coming in.

But we had four color additives where the industry said, "It's not worth doing this study. We won't ask for any ingested use. All we want is external cosmetic use, and possibly external drug use." So they didn't do the studies. They were still on the "provisional list".

We were going in so many different directions with so many new initiatives and new people that they just sort of sat there for a while, and this was where I got involved again because I believe it was probably around October 1980 when Dick Ronk was made deputy director of, I think it was probably still the Bureau of Foods, or maybe the Center for Food Safety and Nutrition by then. And there was a little bit of musical chairs as people took new roles, and I was appointed acting supervisor in my group because my supervisor was made acting branch chief.

And about that time, someone who was coordinating all the color-additive petitions came to me and said, "Do you realize that there are four "color additives provisional listings" that are going to expire in January?" Now, this was like October or so. "They're going to expire in January, and they are all in your group."

I said, "No, I didn't know that."

And it was rather interesting. And so I figured I'd better start learning about this. And one of them, we had a review memo from our color technology group that they had found a carcinogen, para-toluidine (p-toluidine) in this color additive at very low levels. And this color additive was used in minor uses, D&C Green #6, and I think its major used seemed to be a small minority company in Chicago that made hair coloring for the black community. And I said, "Are we going to ban this because of this trivial, small amount of p-toluidine? We've got the "constituents policy".

So this is when your career starts changing, and as I say, I was an acting supervisor, not a supervisor. And I was called up to the director of the Office of Compliance for a conference call with the

agency folks, saying, "We have this small company that maybe put out of business if we revoke the provisional listing on this color additive. But we've been working on the "constituent's policy" that you folks know about. We propose implementing it in two months just for the final rule." And he looked at me and said, "Would that work?" and I said, "Sure."

SJ: With all confidence?

GP: With all confidence. Actually, I did have all confidence, because by now I was involved in it heavily enough but a little naïve from other standpoints. I say this because the story gets more amusing than the history. We went to our Cancer Assessment Committee and said – which we had at that time – and said, "Can you do a risk assessment on this color additive?" And because it's the first time, let's do it with different assumptions so we can get different estimates of risk so that nobody can say that we're not being conservative enough. Exposures can be so small. They shepherded this whole thing through. They gave us a memo.

SJ: Because it was topical only.

GP: It was topical only, and it was relatively quick.

Actually, I think I wrote up a risk assessment memo myself. We didn't have a risk assessment committee at that time. I think I wrote something up myself because it was getting to be Christmas time. Our risk assessment major scientist was probably on leave, and so I had to get documents done, put together a *Federal Register* document and I filled it in, a two- or three-page memo for precedent setting policy, and sent it out to Parklawn and waited to see what would happen.

It wasn't that it was exciting; it wasn't, because I thought it had to be done. And I had never been involved in any big thing, so this was the way it would have been done. The interesting thing – this in January 1981 – the "provisional list" expired. President Reagan took office, and the first thing he did was

he declared a regulation-freeze on issuing of all regulations. So here's my draft regulation out there that General Counsel probably didn't have time to look at. The deadline came and nothing happened, absolutely zero. Therefore, the "provisional list" for not only the four topical colors that I mentioned, but for all the others that had data coming in that we were going to extend one more time, it expired for everything. So every color additive in the "provisional list" – I think it was something like 27 to 31 – expired, and technically they were all illegal.

I remember seeing a reporter quoting Bob Lake – you could hear his Georgian accent coming through in the newspaper – which sooner or later somebody's going to figure out that that's what this does, but meanwhile, we're not going to take regulatory action against anybody. And I think we wrote to a lot of companies saying this had expired but we won't take regulatory action.

But, in any case, the net result was that little accidental buying of time. By then, the Office of General Counsel was looking at things a little bit more and thought we'd better extend the "provisional list" for these some more, because we don't want to go out with a document that isn't thought through carefully. So instead of letting them expire or issuing new regulations, we extended the "provisional list" again, even for these topical ones where there were no new data.

I met by telephone a young lawyer named Phil Derfler. I never heard of Phil Derfler.

He said, "You can't do this."

I said, "What do you mean, we can't do this?"

He said, "Our regulations don't allow it."

I said, "Sure, they do."

He said, "I'm not concerned about "constituents policy". I understand that. But our color additive regulations say that for the application of the Delaney clause, we can't approve a color additive if a color additive, including its impurities, induces cancer.""

I said, "Yeah. That's the provision that we were using to understand the Delaney clause in developing the "constituents policy.""

He said, "No. As a matter of law, it means either the color additive or its impurities."

I said, "No. It means the color additive including its impurities."

And we were debating language in this provision and he sad, "Well, this is how people would interpret it legally."

I said, "No." And he figured he'd get back to that.

But I remember we had many, many conversations. I don't know which one is which, but I remember one, a 45-minute telephone conversation – I think I still hadn't met him – where we just argued why we could do something, why we couldn't and whatnot. And I'm suddenly very impressed by this guy, when after about 45 minutes, he said, "Say that again." And I said what I had just said before.

He said, "Elaborate about that." So I elaborated. "I think we can go on that." We had been arguing for 45 minutes, and he had been listening the whole time.

SJ: He had just found something he could use.

GP: He needed something that he could use, so he was trying to be supportive. He wasn't going to allow us to do a sloppy analysis. And I gained a good friend. And Phil Derfler was just wonderful through this process.

So instead of the short regulation that I had done – it was expanded and it was written, and he put a lot of effort into it. And we decided to out with an advance notice of proposed rulemaking at that time also for comment, and said that, "While we are asking for comment on the whole policy, there is nothing that precludes us from adopting the policy in this case at this time." And we went two ways.

Now, one of the interesting things – I'll start another story in a minute. There were a lot of trains of thought. It reminds me of that wonderful story, I think was on public television, that showed links through history, where everything was connected to everything else. But it literally was.

Another thing that was big at that time, and plays into this very strongly, was, we were also concerned with another beverage bottle made with acrylonitrile, a copolymer. It was called the cycle-safe bottle. It was actually going to be such a good quality plastic that you could recycle the plastic. It was

produced by the Monsanto Company. FDA was concerned about acrylonitrile leaching into foods. Our regulations for acrylonitrile were not very tight for residues leaching out, and we had never given a thought to beverage bottles. If something is extracted from a beverage bottle or, for that matter, a non-nutritive sweetener in a beverage bottle – you can drink a lot of beverage. So people sometimes think of concentrations, but one percent in an ounce is less than a tenth of a percent in 20 ounces. So we were concerned.

And at that time, we didn't know that acrylonitrile was carcinogenic, but there was evidence it was teratogenic, causing birth defects, and there was a lot of theoretical reasons that one might expect to be carcinogenic.

SJ: Now, during this period, were you testing substances directly, or were you still relying on NCI to do a lot of the tests?

GP: Well, the NCI would do the animal data, animal tests in many cases. The industry would do the animal tests in many cases. We might do analytical chemistry tests to say, "We've got a problem here, folks, and it's your problem." And so we would try to get analytical data to leverage the industry to get more data.

With the acrylonitrile, what FDA did – this was, again, before I came here – we proposed to issue new restrictions on the use of acrylonitrile in packaging and issued what was called an interim rule, I believe it was, to try to tighten up, and part of that, to preclude any use with beverages. The industry already had this bottle that they were relying on the old regulation for a beverage bottle. So they objected to that regulation and requested a hearing. And if my recollection is correct, Terry Troxell was working on that hearing, so he got into the area when he first got here, and we were concerned with the acrylonitrile in beverages.

Well, actually, the reason we had a hearing was, I think we denied a hearing, they sued and the court said, "Give them a hearing." So we went back to a hearing. After the hearing, we denied their

position in a *Federal Register* document, and they sued again. Now they had a final decision to sue, and the court could rule on the merits. And one of the major court decisions in the whole carcinogenic area was very confusing, but in Monsanto v. Kennedy, we sought some new things. We talked about levels of acrylonitrile being extracted from the bottle. But Monsanto had come up with a new bottle. We had analyzed the new bottle and we could detect it coming from there. And then they had a new bottle, and the facts kept changing, and the court was looking at this whole thing. And FDA was arguing that there will always be something coming from the bottle into the beverage. Laws of physical chemistry say that will happen.

And the court said, "While the laws of physics may say this will always happen, there comes a point where it is of no consequence. The law is very well based on the principle of "de minimis non curat lex" – the law does not deal with trivial: trivialities or trifles – and saying that whether or not this is an additive or not, whether it's reasonably expected to become a component of food that can be a scientific question. And lacking a sign of good faith, I will throw this back to FDA, but note, Commissioner, you have the authority to say this is not an additive, because even if it could get into food, that it's trivial because of the "de minimis principle".

And that had everybody scratching their head and saying, "Who won?" It says that FDA has the authority to decide. The court will not overrule it but "Use your brain, FDA." It makes sense. So our lawyers were scratching their heads. I think some of the industry lawyers including Jerry Heckman were probably scratching their heads.

SJ: It's also a kind of reversal. I mean, the term "de minimis". Harvey Wiley himself used the term "de minimis" but in a totally opposite way.

GP: I didn't know that. But it is a legal principle that says you don't have to take a law to its extremes. Suddenly it became a mantra.

TAPE 2, SIDE A

GP: So the Monsanto v. Kennedy decision reminding the Commissioner that he has the authority to ignore our trivial issues and he didn't have to say that acrylonitrile was a color additive or a food additive subject to the Delaney clause. We didn't have the "constituents policy" yet, and so today we wouldn't call it a food additive anyway. But coming in on that principle, it really puzzled people.

I know there was a legal analysis by our Office of General Counsel. It became a mantra; "de minimis" was the answer for everything. Whatever you want to do, "de minimis" was going to do it.

SJ: Regulatory discretion?

GP: Well, it is a form, but it's more than regulatory discretion. This would actually be giving a rule as opposed to ignoring something. But, in any case, that threw up another big roadblock. In fact, that had happened before. I think we briefed the Commissioner's office on our thinking on the "constituents policy", but it sort of overlapped.

People weren't quite sure what it meant, and I think within about a month the judge who wrote the opinion died, so nobody was going to ask him anymore what it really meant.

But we were working on our first approval for D&C Green #6 for topical use; we were developing a policy document as an advance notice of proposed rulemaking that this would establish a future policy. And our Office of General Counsel liked the "de minimis" approach to looking at things because a court of appeals said this is an authority FDA had. We liked the "constituents policy" approach of defining something, distinguishing between a mixture and a constituent of it, possibly because we developed it but clearly because it was superior to any of the others, in our view. But the Office of General counsel gave a little bit more respect to the appeals court judge than it did to some consumer safety officers in the Bureau of Foods.

And then, just for symmetry, to get the three parts, we threw in a legal theory based on sensitivity of method, as three different approaches that might be used, and everybody was happy. We didn't have to decide on the policy. Meanwhile, whatever authority you looked at, it was a new approval.

Well, I think it caught people by surprise very much because to intervene on that, there was a 30-day objection period to request a hearing, and after one objects, if FDA turns down the objection, they can sue in the U.S. Court of Appeals. Well, I don't think anybody recognized it until it was published, published nicely, April 2, 1982. We missed April 1st by one day, fortunately. And it was a policy that was important enough – that I saw memos from the Assistant Secretary of Health and from some people at the National Institutes of Health, so clearly the administration vetted it widely outside of FDA to see if it was really appropriate. And I think I might have even got the call from the Office of Management and Budget (OMB) on it once just to see how it was going.

But in any case, it published, and we were thrilled. It was for those of us that came in 1976-77, it was our first big hit, and it said we had accomplished something that continues to protect public health but doesn't put us in the position of taking steps to cause problems without any public gain on it.

But there were more to come, because we saw this whole pipeline. And while we hoped to work in the food-additive area first, we had all these color additives that were being retested coming down the line.

The next one was D&C Green #5 which had the same impurity. We had been through the whole analysis before, but this was an ingested color additive, not for foods, but ingested drugs and ingested cosmetics as well as topical. We had some other. . .

SJ: What kind of ingested cosmetics are there?

GP: Well, I'm not sure – lipstick would be an ingested cosmetic.

SJ: Okay.

GP: But probably mouthwash, mouthwash that you – because you wouldn't want to put a green lipstick. But it could very well be in mouthwash.

SJ: Oh, Scope, of course.

GP: Well blue and yellow too. But in any case, that was listing.

And we had some other problems on whether the additive itself was carcinogenic on that one, and went to the National Toxicology Program Board of Scientific Counselors to essentially peer-review our review and eventually make a conclusion that the evidence didn't say it was carcinogenic.

So we went on again with the "constituents policy" argument. This time we got objections. People I think were more looking at it and their thinking was along that line. We responded to the objections and said they provided no evidence that would justify a hearing, because they didn't raise anything that was other than a policy or legal issue, which did not require a hearing.

And so one person who tended to be against color additives, and who I think was a lawyer, decided to sue on that one. His name was Glen Scott, he sued FDA on that decision. And the court, in a very brief decision, if I can paraphrase it, said, "It makes sense to me." And so now we had not only the decision and there the first time, but we now had a decision out there upheld by a court of appeals. So we figure, okay, we're in solid.

A couple other things that sort of . . . I say we still didn't have quite the idea which legal theory, but in one of the color additive decisions we made in the early '80s – I'm not sure if it was the D&C Green #5, which we were sued on, or if it was another one – someone objected and raised certain legal grounds that something wasn't "de minimis". Our lawyer, Phil Derfler, said, "Why did you allow us to put that argument into our policy statement?" By then, he liked our CFSAN "constituents policy" legal theory better than the general counsel one. But, anyway, we went forward on that and sort of forgot the "de minimis" theory because the "constituents policy" legal theory worked and was upheld in the court.

Then, in the mid-1990s, something else happened, and I would focus on it coming to a decision point around 1985. We had two things happen about the same time.

We had a couple of color additives that induced cancer when ingested at very high doses, and they were used for ingested colors as well. And so we recognized that we couldn't do that on the Delaney clause. But someone took an approach of – what if we approve these only for external use and say that the amounts absorbed through the skin are so low as to be "de minimis" and we'll do a risk assessment. We will say that this proves that the risk is "de minimis". It was sort of that "de minimis" applied for the word "risk".

And I think that there was probably some confusion, at least I disagreed with some thinking about whether "de minimis" is an adjective, meaning trivial, or whether it's a particular legal term for particular purposes.

In any case – the Commissioner put some of these things to a committee chaired by the head of the National Center for Toxicology Research (NCTR), and they made some recommendations, and we went forward with final rules approving the use for color additives for external use only on the basis that it was "de minimis".

And about the same time, shortly thereafter, or at least before it went to court, the Secretary of Health and Human Services, Margaret Heckler, was about to leave office to become ambassador to Ireland, and wanted some landmark decisions to put to her name, and the idea of establishing "de minimis" as a principle that essentially would eliminate the Delaney clause, said, "Come up with another decision where we can use "de minimis" where Delaney would apply that has nothing to do with "constituents policy". And I was involved in that as well as Terry Troxell, again, when the decision came down in October of 1985 to put together a document.

We were concerned with methylene chloride, a solvent that's – it is carcinogenic at high doses when inhaled by laboratory animals. The science is fascinating. But we had concluded that the risk was unacceptable for cosmetic use. We didn't have cosmetic approval authority, so the Delaney clause didn't apply to cosmetic use. But in aerosol sprays, one could inhale enough that it would be a high risk that we

proposed to ban use in cosmetics, and at the same time noted that it was also used as a solvent for removing caffeine from coffee. And the residues in coffee are so low that even though present, the risk was so low that the risk was "de minimis".

Phil Derfler worked on that one, too, and I know he was nervous. He asked me to come out to Parklawn one Sunday afternoon. He was trying to work through some things, and he needed a scientist to bounce ideas off of. And he obviously was very careful, very thorough. And one of the things that he was recognizing that the "de minimis" legal theory applies unless Congress is "extraordinarily rigid". And then the question is, is Delaney one of those times when Congress was "extraordinarily rigid" or do we have discretion? And that really started coming into clarity as Derfler, an extremely good lawyer, was trying to make the argument.

SJ: And I think that is part of the problem with Delaney. It was a populist law in some respects. It represented almost a frustration with the scientists, who seemed to be able to obfuscate anything.

GP: Yeah, and it was. It was a prohibition on the agency, and the question is, were they being "extraordinarily rigid"? Well, the thing with methylene chloride in coffee, we never went to a final rule on the coffee part. We just let it hang there. We're still using coffee. It's nothing. But the decision on two of the color additives, D&C Orange #17 and D&C Red #19, did go to court; and the court said, "I sympathize very much. This looks like an absolutely trivial thing. But, yes, Congress was "extraordinarily rigid." The fact that the risk is so low to be trivial is fine, but that's a Congressional decision. If they want to change the law for things like that, they can. Whereas, in essence, the court in the acrylonitrile copolymer case ruled that, whether or not something is called an additive, something is "reasonably expected" to become a component of food. You have discretion, and even if you can detect it, it's so low you could say that's zero. But in the later decision the Court found that the Delaney clause was "extraordinarily rigid," so we have pretty much that situation under which we need to operate today.

Since then, also, the Environmental Protection Agency (EPA) issued a ruling where they tried to say that – well, at the time they issued the ruling, pesticides were regulated under a provision that a pesticide is exempt from the food additive definition – there is no Delaney clause. But if a pesticide concentrates in a food above the tolerance for the pesticide, it then becomes a food additive, and you want to write a food additive regulation. And they had a few cases where it could concentrate on the food, it would bring in the food additive provisions, and the Delaney clause would apply, and so they tried to say, because the risk is so low, we can ignore the Delaney clause. They were turned down also on that. So that's pretty much settled.

SJ: But then Congress went and changed that part of the law.

GP: Then Congress changed the law, not the Delaney part, but whether or not a substance would go from being a pesticide to a food additive. It remained a pesticide, and Delaney never applied to pesticides.

SJ: EPA argued that it was preventing newer, safer pesticides from coming on the market.

GP: It was probably a good point.

SJ: Now, whether or not that was true . . .

GP: It's reasonable, because sometimes, once it's on the market, you don't find evidence. Nobody tests it. But, in any case, that's essentially where we came around.

And so the "constituents policy" was very much based, not on Delaney, but on the definition of a food additive and color additive. When is something a food additive? When is something a color additive? Once it becomes a food additive or a color additive, Delaney applies, but working on the idea

that everything that you find in a food additive or a color additive is not itself a food additive or a color additive. And that's the analysis that my colleagues built up, and I was very fortunate not to be the supervisor on a document that had to address that under time frames.

And, again, I have to, I always defer to Terry Troxell. We always considered him the real shepherd of the "constituents policy", the creator. He was listed as one of the contact people. He and Al Rulis were essentially the co-authors of our Advance Notice of Proposed Rulemaking for the policy as a whole.

They at one time developed a proposal to codify the "constituents policy", and that proposal was in pretty polished form and was sitting on someone's desk in Parklawn, and the decision made, "Oh, we don't need that. We're working on the "de minimis" policy." Well by the time the "de minimis" idea got shot down in this line, we had about six years of experience, six years of precedent, working with it the way we were, and I think I probably angered Dick Ronk a bit one when I said, "No, I want to drop this. Let's get rid of the proposal. We've got the policy. The courts have upheld it. Why should we codify it? In fact, it's here." So we never did codify it. And somewhere, probably in my office or, I don't know where, we may have a draft copy of that proposal that never went public. But we have invoked it many, many times over the years.

I was happy to give a buzzword for a commissioner's speech once when this became a routine part of our evaluation because the analytical capability as such that you could find a lot of low-level, trivial amounts of things that didn't matter at all. And it's sort of funny that, just as I mentioned "de minimis" sounded so nice that it became a mantra.

The other one that became a mantra was the "constituents policy". People were writing in to say, we needed to change the Delaney clause because, by today's analytical technology, you can find parts per billion and parts per trillion of things in foods. And that was nice before we had a "constituents policy", but after a while – why do people keep saying that? We dealt with that part.

And even, in fact, my understanding – I wasn't there, but I believe the case, when we tried to approve some color additives where the color additives themselves were carcinogenic when ingested, and

we just said the ingestion tests were relevant for topical application because it could go through the skin, and we used the ingestion test for doing the risk assessment. Therefore, it must be appropriate for the evaluation, or why would we use it?

My understanding was some of the lawyers arguing against us were defending the "constituents policy" and saying, "This is different," and they were right. Everyone essentially accepted the "constituents policy". So that was a wonderful thing. And for a few times, at least on the 10th anniversary of his baby.

SJ: Now, when was the 10th anniversary, the publication of the ruling?

GP: Yeah, that's April 2nd in '92, then April 2, 2002. The funny thing was, April 2, 2002, I sent him a note, and he didn't know what I was talking about. He's gone on to other things.

He's working on mercury and chlorite and things like that. But the thing is I think what was really, what was very important is he dug into the literature to get scientific documentation of why this makes sense, why the way we were assessing risk was good science, that it's accepted science. As I mentioned before, he would go out of his way to find somebody that disagreed with him just to hear the argument, to know whether it would work. That's similar in many ways to my many arguments with Phil Derfler. They were arguments designed to try to find weak spots in approach. Make sure you don't get surprised in court with an argument you haven't heard before.

Eventually, we got a petition from Keller and Heckman, the law firm for Monsanto, for their new, new, new improved acrylonitrile copolymer bottle, and by then we said, "Yes, you meet the test." Unfortunately for them, it was a pretty symbolic victory because it was a more expensive product, and another one had already captured the market so . . .

SJ: Which one?

GP: Polyethylene terephthalate, PET.

SJ: PET, right. And it is recyclable.

GP: It's recyclable in a different way. The other one was reusable. This is recyclable. Essentially, when they recycle these, most of the time – I'm not sure always – they break it down to starting materials and just use the raw materials to make it fresh again. So it's a recycling rather than reusable type of thing. So, yeah, we have an approval on the books, but that product never made it to market because timing is important on capturing the market.

SJ: What have you been working on since?

GP: Well the combination of radiation and the "constituents policy" got me some nice experience so that I became a little bit of a troubleshooter. As a matter of fact, I've been put into a position where things that might be tough for me, a precedent-setting nature, I got a lot of plum assignments and I got a lot of very good people to work with me to make it get done.

Back in the early days, the person who had the assignment for nitrites came into my group, so I did a lot of those. We didn't make a lot of progress with it.

I was involved in the methylene chloride in coffee. That was Terry Troxell and I. At that time, I was given a special assignment with a small team of very good people, that if you needed something done in a hurry, give it here, and that was one where we got an assignment on October 30th. And it was assigned on December 18th with the Secretary's signature, which was pretty much record time for start to finish.

And then, I've always had the radiation assignment, and Al Rulis came back to the Division of Food and Color Additives, and eventually he developed a program and we reorganized, where

biotechnology came under my purview for a while, and olestra came into mine. Suralose sweetener was a toughie.

And essentially I was given the sort of assignments where I got less and less of the routine and had very good people working for me to make it happen. And the best person working for me – I'm now working for her, and that's Laura Tarantino.

In 1987 our deputy division director, Hamilton Parran said, "Take a look at this resume. What do you think?

I looked at him and self-consciously and facetiously said, "This is the best resume I've seen in 10 years." Of course, 10 years before that Al Rulis, Terry Troxell, and I joined so picked 10 years just to be like that.

So when Laura came, she came to work for me, and I got to teach her everything I knew, which probably took her about three days or something like that, and she's been running with it. And so when I say I got biotechnology, she got biotechnology and trained the people in that group, and she took on a lot of the really, really tough assignments. So we've become partners that way and I'm very happy that now she's our Office Director and I can officially report to her and give her the support that she gave to me. I hope.

But then those big ones, I think, are the sucralose and olestra and the radiation, biotech.

SJ: Well, we'll be doing more in-depth on those later, because olestra is another . . .

GP: That was fun.

SJ: . . . precedent-setting approval.

GP: Yes. And essentially that's what I got – my reward out of this is things for which there wasn't a precedent.

I'm always one of those people; I hate rote and repetitious work. People write speeches by cutting and pasting. I can't do it. I've got to start from scratch. I mean, I at least have got to change something because it might have to fit the last one but not exactly this one. But, yes, I've had a lot of fun. It's been good.

SJ: Well, thank you very much, especially for coming in on the last day before a holiday weekend.

GP: Well, it's my pleasure, I can guarantee you.

END OF INTERVIEW