

Interview with Jerome (Jerry) H. Heckman

August 10, 2006

TAPE 1, SIDE A

RT: This is another in the series of taped FDA oral history interviews. Today the interview is with Mr. Jerry Heckman, partner in the law firm of Keller and Heckman located in the Washington Center, 1001 G St., N.W., Washington, D.C. The interview is taking place in Mr. Heckman's office. The date is August 10, 2006. Participating in the interview is Dr. Suzanne Junod and Robert Tucker of the FDA History Office.

Jerry, as we begin these interview, we like to touch briefly on a little personal history, where you were born, educated, received your law degree, and then move into the areas of interest that brought you to involvement with the Food and Drug Administration.

JHH: I was born in Washington, D.C. on June 7, 1927, I think at G.W. Hospital; I'm not positive of that. I've lived here my whole life, never lived anywhere else.

I went to John Eaton School, Alice Deale Junior High School, Woodrow Wilson High School, then Georgetown University undergraduate school.

Then I had to go in the Navy. I was a naval air cadet. While I was a naval air cadet, they sent me for a semester apiece to Hampton Sydney College and Duke University. And then I went to flight school.

And after I finished, after I got discharged by the Navy, I came back to Georgetown, graduated from the college in 1948, and at first didn't go to law school. After a bit, I did. And then I went to Georgetown Law School and graduated in 1953.

In 1953, I first clerked briefly for Judge Bassilon. Then I went to work for a law firm called Dow, Lohnes and Albertson. I think they now just call themselves Dow Lohnes, but at the time Dow, Lohnes and Albertson were all alive and well. And I was there and became a partner there and actually stayed there until 1962, so that when I first got involved with food-and-drug law, I was a partner at Dow, Lohnes and Albertson.

I really set out in the law business to be a communications lawyer. I did radio and television work really from the beginning, 1953, and I really did it all the way up till about 1964. But in between, I represented a client who had communications equipment interests basically in, well, what really then was sort of microwave heating, but I don't want to make that too much of a detail

thing here. We had an issue with the Federal Communications Commission over the use of so-called industrial heating equipment, and I became connected to the Society of the Plastics Industry as a result of doing that work.

And then, in 1957, the then-president of that organization, Mr. William T. Crews, asked me to find him a food-and-drug lawyer because he had some concern about food-and-drug matters, the exact nature of which I didn't know at the time. So I checked around. I talked to H. Thomas Austern and a fellow named Markel, Mike Markel. Maybe you heard of him; I don't know. Those were the only guys I knew. Neither one of them wanted to be bothered with this, for whatever reason.

So I told Mr. Crews that I couldn't find an expert food-and-drug lawyer to deal with it, but tell me what it is and maybe we can do something. We had a pretty good-sized law firm for those days. It was like the third-biggest law firm in Washington, which means we had about 35 or 40 people at that time.

In any case, he told me, and then I told him that since this was, in effect, a new matter, legislative matter, that I'd be glad to take a crack at it with the

help of some of my partners if the members of the Society felt that was okay.

And he called a meeting. We had this meeting, the first meeting of the SPI, what is now the SPI Food, Drug and Cosmetic Packaging Materials Committee, on March 1st, 1957, and we all got together there and discussed the matter. There were people there from Continental Can, Visking Corporation, which was a part of -- do you want all this?

SJ: Yes.

JHH: . . . part of Union Carbide. A Dow person was there. Bakelite [sp.] Company, Phillips Chemical, Foster Grant, Sterling Molders, Hercules Powder Company, Colgate Palmolive Peat, Koppers, and then there were some people that didn't come who were invited from Borden and Enjay, which was kind of a part of Esso, Exxon at that time.

We had this meeting. We discussed this piece of legislation, actually at that time three pieces of legislation that were in the Congress and that were causing some concern. That legislation ultimately, in due course, became the Food Additives Amendment of 1958.

We were discussing it because these people were all interested in food packaging, not necessarily food itself, but food packaging, and this legislation, it looked like

Congress was focusing, as a result of the Delaney hearings, focusing on food additives, meaning exactly that, things added to foods. But they were throwing into the package regulation of packaging materials. There was concern about that.

Prior to that time, the way packaging materials had -- are we okay? Am I going too far with this?

SJ: No.

JHH: Prior to that time, packaging materials were regulated by people going into FDA and seeing a guy named Arnold Lehman that you may have heard of, a famous toxicologist.

In fact, I remember, I'll never forget, I used to go in his office, and there was a great sign on his desk that said, "You, too, can become a toxicologist in two easy lessons of 10 years each." That was Dr. Lehman. He was a wonderful man, though.

And they would go in to see him and give him data, and he'd give them a letter saying it's okay. That's how they got FDA clearance. And they'd go to USDA [U.S. Department of Agriculture] and see the guy there, whose name is temporarily escaping me; I've got that somewhere, but I'll find it later if need be. And he'd give them a letter from the USDA point of view, like for meat packaging. That's

what they were used to. And here all of a sudden FDA is coming in and there's going to be legislation proposing lord knows what kind of regulation, but probably regulation that requires the filing of petitions with a lot of formal data, and that could take a long time to deal with. So we got into that situation.

There were a lot of other packaging type organizations also involved. Some of those were the Adhesives Manufacturers Association; Pulp and Paperboard Association. Joe Noon was there from National Agricultural Chemicals because this bill included some coverage of packaging materials that included pesticides. The Adhesives Manufacturers' guy was Ken Loomis. Let me see who some of the others were. I'm not sure that it matters if I give you . . . American Pulp and Paper was a guy named Robert O'Connor. And there were people there from most of the packaging industry's trade associations.

And for us, I was there with John Conahom [sp.] of Hercules Powder. And we prepared testimony and we testified before the committee. And what we told the committee at that time was that we thought that what they were proposing was a very inapt way of regulating packaging, because they were going to require the same thing for a packaging material as they did for a direct

food additive. We thought that was going to be really crazy. But what happened is that the flow was such at that time that they were going to pass that law no matter what we said. They didn't hardly even think about us. In fact, we were, if anything, an afterthought. About all I could really say . . .

Well, what we proposed at that time -- that is a little interesting. At that time, we had a bill introduced by Congressman Miller, H.R. 8112, which proposed a food-contact notification system whereby, instead of filing petitions and that sort of stuff, we'd file a notification, and FDA would have, I think at that time we said 90 days to look it over, and it would become effective if they didn't say there's something wrong with it. That was what we proposed. They obviously just totally ignored that because they were all wound up with the chemical industry and the food people, and they weren't paying much attention to us.

SJ: But Hercules was involved in another issue that was a direct food additive. They were the ones with the [unclear] and the poly whatever.

JHH: Yeah, but that's -- yeah.

SJ: They were treating that [unclear].

JHH: But a lot of the companies I'm talking about were involved on the other side, too.

SJ: As well. Okay.

JHH: The people I dealt with were packaging people from those companies.

SJ: Okay.

JHH: Almost all of the companies I mentioned before were chemical companies with broad interests across the board, in drugs, foods, everything.

So, anyway, we went through that legislative process, and, frankly, we felt like we got reamed. Nonetheless, you've got it, you've got it.

We started having our meetings and doing things that, actually, I think Food and Drug found pretty useful. We early prepared a manual on the Food Additives Amendment of 1958, where we told people about what sort of information they'd need to put into a petition, how to do migration work, and things like that. In fact, we did it so well that the then-deputy or assistant commissioner -- I don't know which, I forget which [Winton B.] Rankin was, Winton Rankin.

RT: He was deputy, I believe.

JHH: He was deputy? Probably was deputy.

. . . in a speech he gave at a Food and Drug Law Institute, complimented me and the committee on not just screaming about the law, but doing something about it, is

the way he put it. I could read you what he said, but that's a big deal.

Actually, some of that is in this paper of mine, and I'll give you this paper.

RT: Thank you.

JHH: But I'll tell you how it came about, too.

So, in any case, we started dealing with the law.

One of the early things that happened, which is, I think, sort of interesting, is, we had a thing that Dr. Lehman, a paper that Dr. Lehman had prepared. He actually prepared a few of them, but -- some of these things I keep handy. This one was in the Food and Drug Officials of the *U.S. Quarterly Bulletin* in October of 1956, and in that article, Lehman gave a description of packaging materials that he thought were acceptable. So we had a kind of prior-sanction list. Prior sanction was one of the things that was exempt under the Food Additives Amendment. So we basically took the position, and FDA more or less agreed with us, that anything on that list was prior-sanctioned. You don't have to petition for that.

But, strangely enough, suddenly FDA raised, I think Ken Kirk, another Associate Commissioner at the time -- I don't know if they were deputies or associates; you can, I can find that out and you can probably figure it out, too.

In any case, Larrick was the Commissioner; Billy Goodrich was the General Counsel; Rankin and Kirk and Arthur Cecchi were on the same level, as far as I could tell, at FDA under the Commissioner. I could go over there and see them all right away. I didn't have to go to Parklawn and this and that. They were all down there on Third Street.

So, in any event, we started dealing with the law, and one of the earliest things that came up was somebody all of a sudden starts questioning polyethylene. So the polyethylene guys , the guys who produced it, got together, formed a thing called the Committee on Food Additive Status of Polyethylene, and they put together a real, a massive document on safety data and the like with regard to polyethylene.

A fellow, another name you may have heard, I don't know, Ben Osher [sp.] of Food and Drug Research Laboratories . . .

SJ: Exactly.

JHH: . . . was working with them. His partner was Ken Morkridge [sp.]. They ran Food and Drug Research Laboratories. And they were trying to convince FDA to give them a letter or something saying we agree that this substance is GRAS [generally recognized as safe] and prior-sanctioned. And FDA may have been willing to do it, but

they wouldn't. FDA would not give them any such letter. And the reason they wouldn't, primarily, was because some Italian guy had implanted some polyethylene under the skin and came up with cancer.

So we had to get by that, and they hired me to represent them, and I did. And I talked to Kirk, and Kirk said, "Look, if you'll, there's all of this data you've already collected because I asked this. We'll consider that a petition if you want, and we'll agree that, and we'll then issue a regulation on polyethylene," which they did and which was the very first regulation -- well, no, actually polypropylene was first. But it was the second regulation issued for a packaging material under the law. So that's how we did that.

But in exchange for agreeing to do that, I got them to give me a letter agreeing to all the things that had been on the Lehman list were prior-sanctioned, and that's something that we relied on for years thereafter.

SJ: In other words, you kept a list of all the things that Lehman had given letters for.

JHH: Yeah, and we then asked them, and then I got this letter in 1960, I think. Wait a minute. July 22, 1960, from J.K. Kirk, agreeing that all the other things in that list could be considered prior-sanctioned, which was

generally helpful but not necessarily totally dis[unclear] of what was going to happen in the years to come. But that's how we got by with polyethylene, so that then, finally, the polyethylene regulation, I think, issued in about, despite the fact there wasn't any real question or anything, no issues, got issued only about two years later. And our people were getting extremely exercised about the amount of time it took to get anything cleared, very angry.

Later, it came up -- and this is a place where my dates are not, I didn't have time to go look back -- later, we had an issue with polystyrene. It's really strange. What happened there is -- I think that was in about '63 or '64, in that range -- somebody started raising questions about polystyrene. We put together a group and we're going to go in and we're going to tell FDA, "Hey, it's prior-sanctioned and GRAS."

Well, one of the companies decided that there was a little advantage to be gained by filing a petition before the rest of the companies could catch up. So the Dow Chemical Company filed a Food Additive Petition on polystyrene, and they proposed that the criterion for clearing it be no more than .4 percent residual styrene. At that particular time, the rest of the companies couldn't

make it with that low a level of polystyrene. They weren't quite ready yet. So they were around .75 to 1.

SJ: And this is for use as a packaging material.

JHH: In packaging?

SJ: As a packaging material.

JHH: Oh, in packaging material, for polystyrene cups and wraps and stuff.

So they go and file this petition. They tell us all of a sudden that a meeting, after it's been accepted for -- I don't know what they hell they thought I was going to do, but I can tell you what I did. Within a week, I filed another petition asking for the higher levels, and then FDA said, "You guys played it out." So it just hung over there for about five years, until the rest of the industry caught up, and then we all agreed on .5 percent, and that's how polystyrene got regulated. But it was a really weird story, you know.

SJ: That is.

Can I ask you one question before we go on?

JHH: Sure.

SJ: Ben Osher [sp.] also died before I could get an interview with him. And one of the things I'm very interested in is how that . . .

JHH: He was about 100 when he died.

SJ: I know. Well, we had several informal conversations, and I have a few notes from those, but, I mean, he was talking mostly about cyclamate.

But what I'm really interested in is how his lab came to be. Do you know anything about when it may have come about or [unclear]?

JHH: It was already there when I got involved in the business. I was there many times in Maspeth, New York. I don't know how it came . . .

SJ: A lot of animals?

JHH: Yeah, he had plenty of animals.

SJ: Primarily.

JHH: It used to make me . . . Yeah, I didn't like that. He'd take me through where the animals were. I wasn't too happy about that, but . . . Mostly dogs, a lot of dogs.

SJ: Dogs.

JHH: Cute dogs, really cute dogs.

Anyway, yeah. But Ben was a good guy.

SJ: You ought to see our files on the [unclear] with the bunnies.

JHH: I knew him a long time. He was a good friend. As a matter of fact, he later sent the Chewing Gum Association to me to represent. I did that too.

But that's how polystyrene got regulated.

Meanwhile, our people, we're having these regular meetings, and we're doing manuals, we're coming up with test methods, we're working on all these issues, but they're getting more angry by the minute about how things were going.

One of the things that really made them furious was, right after -- I'm jumping back a little bit, but I have to because I just can't do it the other way. Right after the law was passed, and for a couple of years, more or less, a year or two, Arthur Cecchi was going around -- he was in charge of packaging -- going around and giving speeches and telling people, "Look, if you have a material and you do migration studies, and when you do the migration studies, if you can more or less demonstrate that no more than a part per million of whatever substance you're looking for comes out, tell us that, send us a letter, and we'll send you a letter and say it's okay." A lot better than a petition.

The only problem is that in 1961, I think -- that's in here somewhere -- in 1960 or '61, Ken Kirk stands up at a Food and Drug Law Institute meeting and tells everything, "You guys have been getting these letters from us, and we're not going to give them to you anymore. From now on,

if you want us to give you an opinion, you've got to file a petition." No more letters agreeing to, in effect, no migration. Man, we were furious! And then he repeated it again the next year.

And old Deputy Commissioner [John] Harvey was giving speeches, really ridiculous speeches. This is his rationale, his rationale for what they were doing: If you had enough concern to test to see if there was migration, then it was reasonably expected to become a component of food, and it's a food additive. That was his rationale.

All of that's in this paper, so you can look up [unclear] want to. This is an extra copy.

So that was driving us crazy. I mean, people were . . .

We in my office developed a system whereby we started evaluating data, and if the data was appropriate, letting people know that, in our opinion, it was not a food additive. It's not the same as getting a letter from the government. But actually, as the years went by, those letters became kind of as good as. And we still do that, by the way. That's why we have 18 scientists here.

SJ: But if you don't test, then . . .

JHH: That's crazy. That's the dumbest thing I ever heard.

SJ: It doesn't even make sense.

JHH: So, but in 1966, I wrote this paper, which was a little, well, it was a big paper. And I in effect screamed about all of this and said they ought to change the law, which of course they didn't exactly do.

But what did happen is that we started raising a lot of Cain about it, and Les Ramsey [Lessel Ramsey], another FDA guy, good guy, started considering the matter and stuff like that, and we really raised a lot of hell, to where we got the then-Commissioner to answer to a congressional committee and say that FDA was looking into this thing; do something.

The something they did was to call a national conference on indirect food additives, held in 1968, at which time Les Ramsey announced that FDA was considering a proposal that would in effect say that if you tested and had 50 ppb or less of a substance coming out, and it was not a carcinogen, pesticide, or known toxic or something material, that then FDA would say it was okay. Now, he was telling everything that's what they were going to do. The only this is, they never did it. They proposed, and in 19, give or take, in 1970, I think, he told me that it had become politically impossible. As far as I'm concerned,

all that meant is that there was a new Commissioner,
because Goddard was . . .

SJ: [James] Goddard left.

JHH: Yeah. Goddard was the guy who had in effect
effected this. I had known him from way back when. So it
was politically impossible, so we were left again out in
the cold, so to speak. But we continued to write those
letters.

In 1970 is when I picked up my first scientist. This
law firm has 18 scientists on staff because we analyze the
data that clients send, and we do our own evaluations and
give opinions. Not very modest, but if I must say so, I
think they've become of considerable meaning to foreigners
and to our own people, and most people will accept one of
our letters as saying the status is okay, even now, because
the Food Contact Notification, which I'm going to come to
in a minute, is a lot easier than a petition, or a lot less
time-consuming. But they're still a big deal to file one.
So that took place.

Then these other events I'll throw in, for whatever
it's worth.

In 1972, the so-called PVC [polyvinylchloride] crisis
arose. What happened is that Goodrich had been doing some
. . . Most of the times when you've got a toxicity

problem, the first place they see it is in the workplace. Kind of makes sense. So it so happens that Goodrich had been doing some internal study itself and had come up with a bunch of cases of angiosarcoma of the liver amongst workers in PVC plants, and they started reporting that. At about the time they started reporting that, I am in the business of trying to get Alcohol and Tobacco Division clearance for a PVC liquor bottle. Well, when that news came out, and then one of the distillers . . .

SJ: So that makes sense, but I just never thought of it. So that kind of packaging issue . . . Okay. Are packaging issues specific to products? In other words, I would have thought that a food-and-drug [unclear] . . .

JHH: Some are and some not.

SJ: What would have made you go to them?

JHH: Now, when Alcohol and Tobacco regulates liquor, so they therefore assume the responsibility for checking on the packaging as an extra little attraction. If you want to sell a package for liquor, you have to have ATFD approval.

SJ: And do they have regulators there that do that kind of thing?

JHH: Have what?

SJ: Do they have regulators there that look into that kind of thing?

JHH: Yeah, they've got enough people to look at that.

SJ: Okay.

JHH: It doesn't happen that often, but they have enough to do it.

See, at that time, I didn't . . .

Get this picture. PVC is prior-sanctioned. That's one of the Lehman list, prior sanctions. Goodrich comes up with this new data. Obviously, FDA is not going to let a carcinogen be out floating around out there. We take the position early -- this is one of my great mistakes in life -- that there was no problem because what was causing the angiosarcoma of the liver was vinyl-chloride monomer, and our belief was that vinyl-chloride monomer was evaporated in the course of making PVC and couldn't possibly get into foods because it volatilizes at 15 degrees below C, below zero Centigrade. So you'd say, well, it can't be there, it's got to volatilize off. The only problem is that one of the distillers -- I think it was Brown-Forman, I'm pretty sure -- checked some bottles because we had had experimental authority to use these liquor bottles. We were going to apply for permanent authority. They checked.

They were getting 25 to 50 ppm of vinyl chloride in some of their checking. So, surprise, surprise!

SJ: Is that fairly high?

JHH: It's too high for any carcinogen, for sure.

SJ: Right.

JHH: But my scientists then had advised me there's no way it could be there because it volatilizes.

Now, I have to check with a scientist every now and then.

So I got shocked into finding out that we had a problem, and FDA proposed rule-making to in effect delimit the prior sanction. That rule-making was never finished.

SJ: To delimit?

JHH: Never finished to this day.

SJ: Delimit?

JHH: Well, I mean they were going to put criteria up for when you could use PVC.

SJ: Okay.

JHH: They started off, when it started, they were going to ban the use in rigid containers altogether, going to allow the use in coatings and film on the theory that there it's an open structure, and the volatilization is going to take place.

Now, we filed comments, and then we followed up, and we began -- and we had a lot of data that whereby we were able to show that the alerted industry could now make bottles where there was no vinyl chloride or no vinyl chloride was coming out.

That rule-making, which started in 1973, if I remember correct, has never been finished. What happened is, up till about 1980 or so, they were getting ready to it again, and all of a sudden the environmental people started filing huge, and they got the people stirred up and trying to make FDA do an Environmental Impact Statement before they issued a regulation. They had, I don't know how many people they assigned to do the Environmental Impact Statement. Nobody ever got it done. So they eventually just withdrew the rule-making.

RT: May I interject a question, Jerry?

JHH: Sure.

RT: You mentioned that you had scientists as consultants.

JHH: Still do.

RT: Do they have laboratories do that sort of thing?

JHH: No. We don't do any lab work.

RT: Okay.

JHH: It's all work that's desk work, analyzing data that clients provide.

RT: I see.

JHH: We get data from almost every lab in the country, and some in Europe and Japan.

RT: Okay, thank you.

JHH: But their job is to look at that data and advise the clients -- well, they do these things. They advise clients on protocols. Most of them come from FDA, by the way. A number-one guy is Les Bordinski [sp.]. He was at FDA a long time. And Mike Flood, also an FDA guy. And our main toxicologist here is Bob Shepline [sp.], who was at FDA.

SJ: Oh, I've known him for years.

JHH: So, you know, we hire guys who have integrity. We don't want to just hire anybody . . .

TAPE 1, SIDE B

JHH: They will write protocol for the clients to do migration testing or other testing, not -- they don't write toxi . . . Shepline [sp.] does toxicological protocols, but none of the others do. And then they analyze the data when it comes in, and they tell the client about how it has

to be validated and all the other things that FDA looks for.

RT: As an employer, General Counsel, I'm sure they're careful about the conflict of interest of prior involvement with things they're reviewing. Right?

JHH: Yeah, but that's hardly ever happened.

SJ: [unclear] here long enough [unclear].

JHH: They don't really do anything that has, that gets in a conflict with any company, not really.

Anyway, where was I? Oh, I was telling you about vinyl chloride.

So as far as I'm concerned, the vinyl chloride document is still open.

But vinyl chloride is being used and sold, and there's been a problem with the phthalates, as you know.

SJ: Was that when EPA [Environmental Protection Agency] was being formed or had already been formed?

JHH: No. EPA was formed in 1976, so the rule-making started in '73 and continued while we collected data and gave it to FDA. And the attack on environmental grounds came in 1982.

SJ: Because I was thinking maybe EPA was trying to take the issue [unclear].

JHH: It was, the environmental groups came from all over the place. I can't even remember the names of all of them. But there were like a thousand things filed, crazy stuff. They get them stirred up pretty good.

Anyway, that was vinyl chloride.

Now, in 1969, I got hired by the Monsanto Company and got involved with the manufacture of bottles for soda. That was, I think, about the time the world, the soda bottles began. And we started developing, they started developing an acrylonitrile bottle. It really was beautiful; it was gorgeous. I had some; I don't know if I've still got them. They could mold those into the shape of a Coke bottle. They were great-looking. Only problem is . . . Well, let me take it . . .

At the same time as we're doing that for Monsanto, DuPont and some other companies are coming up with PET for soda bottles. They couldn't mold them into the fancy-looking shapes, but they were making them in a way that was a lot more economical.

SJ: I was going to say, they're probably cheaper.

JHH: And that almost always will carry the day. In that particular case, it sort of did carry the day. But that's not, well, it all overlaps, but it's a part of my story, but not the whole story.

So we go to work for Monsanto, and on June 5th, 1972 -- a few dates you remember -- I got a letter from Dick Ronk, who is heading up the food-additive packaging materials work at that time, agreeing that we could consider the acrylonitrile bottle safe and covered by the old prior-sanction and GRAS status. That was a big mistake he made; I guess people would say that.

We had these enviros, crazy guys going around doing all kinds of funny stuff, and all of a sudden FDA comes out with a letter saying, "We're no longer satisfied that these bottles are safe, so we're saying that we withdraw the letter and you've got to file a petition and go back at this thing." Well, we didn't like that too much, so we demanded a hearing.

We got a hearing. We got a big, long hearing in front of that character Davidson, the FDA . . .

SJ: Oh, the law judge.

JHH: Yeah, the FDA in-the-pocket administrative-law judge, who never finds against FDA no matter what, not ever.

Little did I know at the time or remember that I had dated his sister before I got married in 1948. He was the youngest child. There were nine kids in that family. He was the youngest.

So we had this extended hearing, and then he comes out with this red-hot opinion that FDA had the right and the power to say that the acrylonitrile was not safe.

See, we took the position that there was no detectable acrylonitrile in those bottles with a method sensitive to 10 ppb. And FDA starts taking the same position that, in effect, Harvey had taken. You tested it? It must be a food additive, so we can rule that it's not safe even without any data to indicate that, and we thought that was really crappy.

We took that opinion to the Court of Appeals, and in the Court of Appeals, Judge Leventhal [sp.], -- who was nearly at the end of his life -- he died a few weeks after he wrote the opinion for the Court of Appeals, in which he said to FDA, "No, no, no, no, you can't do this Second Law of Thermodynamics stuff and say that if things are in contact, they're going to transfer. You've got to have some data to show that there is transfer." And that's how Monsanto v. Kennedy was decided.

It's been a major landmark case ever since. FDA has referred to, we refer to it, and everybody refers to it for the principle that if you want to see whether a packaging material really is a food additive, you can do migration studies. And assuming that the level of migration is low

enough, you can take the position it's not a food additive. Not the level of migration, but the level of detection is low enough and you get none detected, take the position it's not a food additive. We obviously take the position that it's not a food additive for the most part. We use 50 ppb as the criterion, but not if there's cancer data or any kind of tox data.

Then we do a risk assessment. Shepline [sp.] or Matthews does a risk assessment, unless FDA has already done one. Then we use theirs. And we say that you can't have more than one-tenth of what that risk assessment says is a factor, you know, the one-in-a-million chance. You can't have more than one-tenth of that coming out, and that's how we do that.

But the Monsanto case was a landmark decision for that reason.

So now I've told you about PVC, I've told you about acrylonitrile.

There were other cases in between, but . . .

SJ: [unclear] says that the hundredfold margin of safety came from toxicology studies they did with elixir sulfanilamide in the '30s?

JHH: Yeah. Well, that was, well, the elixir sulfanilamide, that killed about 100 people. I don't know what the hundred . . . What is he saying, a hundred . . .

SJ: [unclear] risk assessment, they use one in a hundred.

JHH: One in a million.

SJ: Right, sorry. Hundredfold I guess is what I'm saying. And I got this all mixed up; I may well.

JHH: I'm not sure what . . .

SJ: In other words, in the early years of FDA, we just said no, and Lexington Mill said no, you have to relate it to . . .

JHH: Oh, yeah, yeah. The hundredfold factor, yeah, was a factor. In those early days, they used to take whatever, like if you did feeding studies and you got a level at which there was an effect, you multiplied that by 100 to see what a no-effect, what FDA would agree was no effect. But that was really in ancient days.

SJ: Exactly.

JHH: Of course, Peter and I are both in ancient days.

Yeah, actually, I first met Peter in about 1962 or '63. He was right out of law school, working for Tommy Austern. And he called me up to ask me if the Chewing Gum Association could make reference to our polyethylene data

because they were developing the chewing-gum regulations, and polyethylene was going to be a part of it. That's when I first met Peter Hutt.

And Tommy Austern was as much a mentor for me as he was for Peter or anybody else because we lived in the same apartment building where he died, and he used to call me up and say, "Come on down here," and do stuff. He was my guy. He was a great guy. But he was bossy as hell. But he was a really good guy. Yeah, brilliant, unbelievably brilliant.

So those were some of the things that happened.

Yeah, I knew Vinny [Vincent] Kleinfeld and Kaplan and Hutt, Austern, all the guys at Covington. We got a former Covington guy here now name of Striker, because I gather they've tapered off some of their regulatory practice except for Peter, who's still going around giving speeches and teaching school and stuff like that.

So that was acrylonitrile.

I'm going to make a big jump and get you up to date.

SJ: Good, keep -- you're doing great.

JHH: I'm about of juice here.

Time went on. We continued to do what we were doing in the way of giving letters, filing petitions when we had

to, waiting two to five years for FDA to act on a petition, getting more furious every minute.

In 1994, a bunch of lawyers and fellows whom we all sort of represented, easily identifiable clients. You know, Peter and the other guys at Covington -- I'm not doing a good job of remembering who all of them were; most of them are retired now -- Lambert, Gene Lambert and some other guys, they represented a grocery manufacturer, but then so did some guys at Hogan and Hartson, so Rick Silverman was there, Stuart Pate [sp.] was there for the Soft Drink Association. They had a big meeting. Oh, who was the congressman -- [unclear], come on, Jerry.

The Republicans were coming along, and he was having the revo . . .

SJ: Gingrich?

JHH: Gingrich, yeah.

SJ: Oh, my favorite guy, eliminated the House History Office in favor of somebody who taught at Stone Mountain [unclear], some tiny little college [unclear].

JHH: Well, he was talking about reforming things, if you remember.

SJ: Yes, painfully.

JHH: So these guys get together and say, "We've got to take advantage of some of this reform atmosphere." We weren't working with Gingrich or anything like that.

SJ: No, right.

JHH: But they were getting together, and they wanted, they'd say, "We've got to do something; now's our chance to do something about the Food Additives Amendment." So they all get together and they figure, they decide that what we ought to do is go to FDA, go to FDA and Congress and say, "You can bill us like \$300,000 for a food additive petition, and then you use the money to farm it out to independent experts, so take a look at it more quickly and give us a quick answer. We're willing to pay that kind of money for that kind of service." Well, hell, after the Food Additives Amendment was adopted, they didn't have more than about 20 or 30 petitions ever filed for direct food additives. I had 275 pages of *Federal Register* with indirect food-additive garbage on it.

So I'm at this meeting and I'm saying, "Whoa, wait a minute. Three hundred thousand dollars? None of my people are going to pay anything like that for an indirect food additive. That's crazy."

"Well, what can we do to take care of your people?"

So I tell them we can come up with food-contact notification.

Well, they agree that in order to keep me from screaming bloody murder against the change they were going to advocate -- which they never got, by the way -- that they would all help me with food-contact notification.

So I wrote this language for food-contact notification bill, addition, to what was FDAMA, Food and Drug Modernization and Accounting Act [sic] of 19, what was it, '97, 1997. And Bob Lake at FDA worked with me, and the two of us sort of shepherded this through the committee and through the, over the Hill, and we got the law changed; so that now, for an indirect additive, you don't have to file a petition. You can file a notification, like we first asked for in 1957. File a notification, and FDA will -- and they're doing a great job on it, by the way -- it'll become effective in 120 days after you file it. They don't have to write any regulation or anything like that. They just let it become effective.

But then they have a web page and they publish all the ones that have become effective on the web page, which is really kind of nice. And that's been going on this year. They never let us alone.

This year, FDA decided to take the money for that program out of the budget, not provide for it. So we had to go and just raise hell with Congress and get them to tell FDA, no, you continue doing it. Because even FDA says it's a model program. And that's where it is right now.

Now, we've got a continuing problem here because FDA, whereas I proposed modest fees originally, the food industry shot those fees down, so there are no fees attached. But FDA wants us to pay some fees, so I think eventually we'll end up there.

But right now, it's in the budget for '67, I'm sorry, '07. We've got to worry about the budget for '08 and subsequently, so we're going to be fighting that battle every year unless we come up with some way to do it, and we're all working on that.

SJ: Yeah. CFSAN has got some real financial issues.

JHH: Well, yeah, they do, because the reason they have big financial issues is because the FDA now has fees for drugs, new drug applications, fees for devices, and fees for agricultural chemicals, so all of those entities have kind of a hook. You pay \$22 million for drug fees, and then we want, you need to appropriate a certain amount. That's an add-on. We don't have any fees, and none of the food industry does. So when they look at the budget and

they're going to cut the budget, where are they going to cut? Food, right away. That's what they did. And that's kind of the problem of the day.

That's a fairly respectable synopsis of my [unclear], I think.

SJ: I think [unclear]. I'm trying to catch up here in terms of . . .

Were you ever involved with any Delaney issues? Probably not with the packaging, but . . .

JHH: Sure. No, no. We had -- PVC was a Delaney issue.

SJ: But, you know, FDA worked very hard to try to never invoke the Delaney clause.

JHH: Right.

SJ: Because they were opposed to it scientifically and they thought it could and should have been held otherwise.

JHH: We never, we really never go to the mat on a Delaney issue, but vinyl chloride was a Delaney issue, acrylonitrile was a Delaney issue, and we beat both of them by trying to demonstrate there's no reasonable expectation of migration. We had to deal with the Delaney clause both times. I had to deal with a lot with regard to colors. And you deal with it.

They came up with, as you probably know, they came up with so-called constituents policy.

SJ: Yeah, I did an interview with George Pauli, who worked on that.

JHH: Who?

SJ: George Pauli.

JHH: Yeah, George did some of that.

SJ: I got a good interview with him.

JHH: But, yeah, we used the constituents policy all the time.

SJ: Even though it's technically illegal?

JHH: No.

SJ: I mean, [unclear]. But, see, maybe you could explain that to me because I think I've gotten a little confused.

JHH: Well, okay. Vinyl chloride is a carcinogen.

SJ: Right.

JHH: Therefore, it's banned; it would be illegal. But polyvinylchloride is a polymer made from vinyl chloride. If you can show that the vinyl chloride is not there, that it's the constituent that's the carcinogen, not the additive, and you're okay.

SJ: But did the courts uphold that?

JHH: Yeah.

SJ: They did uphold the constituent part of it.

JHH: They did uphold it; they absolutely did.

SJ: What they didn't uphold is the *de minimis* part of it.

JHH: [unclear] the name of the case. But they absolutely did.

SJ: Okay. It was the issue of the colors that they wouldn't, the *de minimis* use of colors.

JHH: It was a color. It was yellows, I've forgotten, something 6.

SJ: Something like that. That's where the courts wouldn't uphold any leeway. Is that correct?

JHH: The what?

SJ: It was over *de minimis* use of colors that the court upheld the Delaney clause, in essence.

JHH: In this case that I'm talking about, which I should remember the name of but don't, it was a color. But the thing that was causing, that was a carcinogen, was a constituent of the color.

SJ: Okay. So the courts did uphold that.

JHH: Yeah.

SJ: Okay. It was a different case that I'm thinking about, then, that they upheld the overall Delaney clause.

JHH: Could be.

SJ: Because I think they were hoping to expand it a little more broadly.

JHH: I think they don't have much choice other than to uphold it. It's stupid, but that's what they do.

SJ: My dissertation was accepted on the Delaney clause.

JHH: Why cancer? Why not heart disease, why not a lot of other things?

SJ: Well, in my dissertation I argue that it was sort of a sign of the times, but people didn't understand the science behind it, and they certainly couldn't explain it to anybody. And that was just the public's way of saying, here's a line in the sand, you won't cross it.

JHH: You're absolutely right.

SJ: And they did exactly, in one sense it functioned exactly like the public wanted it to. It either forced the scientists to talk . . .

JHH: Do you tell [unclear]?

SJ: No. It either forced the scientists to explain it, or it forced them, certainly, to use a different rationale to avoid crossing the line.

JHH: Man, I had the most bitter arguments with Vinny Kleinfeld about that. You wouldn't believe the stuff he used to pass out.

SJ: You remember having Gloria Swanson . . .

JHH: Steinem?

SJ: Swanson, the '20s still-picture actress was really interested in the Delaney issues. And he dated, well, he took her out a few times for dinner. She was [unclear]. That's what he remembered. I didn't get anything much more substantive out of that, but . . .

JHH: He was okay. Kaplan was the real partner in that firm. There was a real prince. But Kleinfeld was a doctrinaire Democrat. He was committed to Democratic . . . We had terrible arguments about Delaney.

SJ: Well, Alan Kaplan was just -- I wrote a paper for him that was called "The Peanut-Butter-and-Jelly Sandwich."

JHH: Oh, that Tommy Austern story, peanut butter.

SJ: Exactly. Well, the rumor was that Billy Goodrich is really the one that was responsible for the length of the hearings because he just didn't devote the time to it needed, but I didn't put that in the paper, obviously. But I used the peanut-butter-and-jelly sandwich to talk about . . .

JHH: Billy was [unclear] before he died, Billy bestowed upon me all of his papers. They're somewhere in our storage facility because he never, I think, I don't

know, maybe we got rid of them, but they're somewhere around.

SJ: Hopefully . . . Don't tell me that. If you've got them somewhere, we've got a home for them.

JHH: I don't know if we still have them or not.

SJ: Well, write yourself a note because those . . . And I'll tell you why. Because Billy Goodrich was one of the ones I was telling you about who wanted it to read like a Harvard Law School article. We offered him for years, we offered for years to give him an office in our office and pay for his parking and whatever it took, because he wanted to actually write it himself.

JHH: He's a very private guy. He didn't like a lot of fanfare.

SJ: Yeah. So, anyway, we never could get him to do it. And he would never sign off on his oral history interview, so we waited till he died and his widow signed off on it.

JHH: She did?

SJ: Yeah. But anything we've got to document some of his work at FDA would be a gift to the rest of us.

JHH: I don't know if these people, these people change so much. I'll ask our records people if they know, and that'll get them to at least start looking for it.

SJ: Well, that would be a huge gift.

JHH: [unclear]. That's the guy that does the
computer thing.

END OF INTERVIEW