

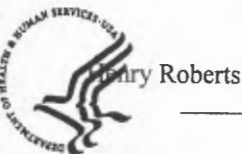
**History**  
**of the**  
**U.S. Food and Drug Administration**

**Interviewee:** Catherine W. Carnevale, VMD

**Interviewer:** Suzanne W. Junod, Ph.D.  
Robert A. Tucker

**Date:** February 10, 2009

**Place:** Rockville, MD



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Interview with Catherine W. Carnevale, VMD

February 10, 2009

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, February 10, 2009, we're interviewing Dr. Catherine W. Carnevale in Rockville, Maryland.

Participating in the interview with Dr. Carnevale is Dr. Suzanne Junod and Robert Tucker of the FDA History Office.

Doctor, we usually like to touch on the brief personal history and educational history, and then move on to your career, particularly with FDA.

Dr. Carnevale, would you like to begin in that way, please?

CWC: Sure. Do you want to start before I came to FDA?

RT: Yes.

CWC: Okay.

I was born in the Washington, D.C. area in 1946, August 19, actually, at George Washington Hospital, and lived on Western Avenue, 5239 Western Avenue -- I even remember the address because it was the first address I ever learned -- and went to Janney Elementary School on, I guess, Albemarle Street,. I continued there through third grade, and then my family moved out off of River Road, at 5701 Springfield Drive. At that time

it was considered Washington 16, D.C. That was the address because they did not have post offices in the suburbs of Maryland because, really, they were just starting to have suburbs in Maryland, and this was a mile and a half out of, past the D.C. line. It eventually became Bethesda 20016. I went to school at Wood Acres Elementary School from fourth grade through sixth, then Western Junior High School. Western no longer exists as Western, but that was on Massachusetts Avenue right above the Little Flower Library, which is there now. I then went to Bethesda-Chevy Chase High School. I was supposed to go to Walt Whitman and be in the first class at Walt Whitman High School, but I very much wanted to be on the BCC pompon team, and so I managed to convince the superintendent of schools in a letter that he should let me stay. And BCC at that time was one of the top 10 high schools in the country, so that was another reason why I wanted to stay there.

RT: Is this an endowed school?

CWC: It is a public school, but BCC has a very good foundation now, so to some extent they are endowed.

So, anyway, that was my history as far as public school.

After BCC, I wanted to go to a women's college just because, growing up in Washington, I felt I wanted to be a little bit cloistered. I was not a focused student at BCC. I didn't really care very much about my studies, and I wanted to see what would happen if I was cloistered in an all-women's school.

So I went to Mary Baldwin, and it worked. It was absolutely perfect, small classes. They were very interested in pushing the sciences. I had no interest in science.

But the fellow who was the head of the biology department was just a marvelous teacher. He was very eccentric, and he loved to teach, and suddenly you had all these women who wanted to go into the biological sciences. I have to say, from my class, we had incredible successes, many professors, M.D.'s, and veterinarians, which is what I became.

It turned out that I had a knack for chemistry and other sciences. And here I had planned on getting a degree in art history or Spanish or something. But I became totally dedicated to science and graduated with excellent grades, but couldn't decide where I wanted to go on to school. I knew I wanted to continue my studies but I just didn't see a career with a bachelor's degree in biology.

And so my major professor asked me what I was interested in doing, and I said, "I really want to work with animals, but I don't want to just spend my time killing them, like I did in the laboratory." I'd had summer jobs from the time I was 15, and I had worked in laboratories.

And he said, "Why don't you become a veterinarian?"

And so, I researched that. Unlike most veterinarians who grow up with the idea of becoming a veterinarian, I hadn't done that, and had really not had too many pets nor had I spent time on farms. But I researched it and said, "This looks absolutely perfect."

There were 17 veterinary schools at that time. I think I looked into virtually every single one of them, and most of them did not allow students from out of state. The University of Pennsylvania, having a Quaker background, saw women and men as being

rather equal, and so they did bring in women. They had maybe a dozen women in their current class out of 70-some students, and they welcomed me with open arms. I also applied to Georgia because Maryland -- and I was a resident of Maryland -- had 10 slots in the University of Georgia Veterinary School. I made it in there too, and it was considerably less expensive. But eight men who had interviewed me were not really very gung-ho about having a woman in the school. The gentleman who told me I'd been accepted also told me that I would not be happy there. It was during the time of the Vietnam War, and men could get a deferral from the draft, so that was an issue in accepting women who were not subject to the draft. I convinced my parents to float me a loan for school, and I went to the University of Pennsylvania. That was where I wanted to go. And it was absolutely an exciting and deliriously happy experience. I totally enjoyed my time there.

RT: When did you enter?

CWC: I entered in 1968 and graduated in 1972. So, I graduated from Mary Baldwin in 1964, excuse me, 1968, and the next fall I was at Penn and graduated in '72.

I did not decide to go for a residency or an internship because I really wanted to get out and practice, and that's what I did.

RT: You had a job in a laboratory thereafter, didn't you?

CWC: No. I worked in laboratories for most of my college years and veterinary school years at summer jobs.

RT: Perhaps it was practice, then, that you went to a vet hospital in Paoli, Pennsylvania?

CWC: Yes. After I graduated, I got married to Richard Carnevale, who was still in veterinary school, and moved to Newtown Square, Pennsylvania, but I practiced in Paoli, Pennsylvania, which was on the Philadelphia Main Line. The associate dean actually found the job for me. It was an excellent practice, a member of the American Animal Hospital Association, and it had -- veterinary specialties were just getting started, but this practice had a couple of orthopedic surgeons associated with it who were professors at Penn, so we had the value of having them on staff too. And it was a multiple veterinarian practice. It was called Tredyffrin Veterinary Hospital.

RT: Was there any special species that you worked on?

CWC: It was a small animal practice. At that time, most veterinarians still got out of school and practiced in mixed practices.

**Recorder turned off, then on, and interview resumed**



RT: All right. We had an interruption. Would you continue, Dr. Carnevale?

CWC: Okay.

Well, we were discussing my experience in veterinary practice, and I think the last time we actually talked, Bob, I had mentioned that, because this practice was on the Main Line and in horse country, it was probably a little bit different than a lot of veterinary practices around the country. They had a number of pretty wealthy people among their clientele.

We did take care of the Eisenhower dogs. Descendents of President Eisenhower lived in this area. I took care of Chubby Checker's dogs. He and he and his wife, who was a Native American, raised Old English Sheepdogs and Great Danes, and they also showed their dogs. I vetted shows where their animals were shown. For those people who are younger than me, Chubby Checker is the person who sang "The Twist" and invented the dance The Twist back in the, I guess, early '60s, late '50s. So that was very exciting for me. There were ambassadors who brought their animals or had me take care of their animals in their homes.

So, for a young, green veterinarian, these were exciting times. I was able to do a lot of different kinds of surgery, perhaps some surgery that I should not have been doing, but at that time they, veterinary practices, did not send animals to specialists. So you did cancer surgeries, you did a lot of orthopedics, we certainly did spays and castrations. In those days, they did a lot more ear cropping and tail docking and declawing and all. I truly enjoyed surgery and medicine and all of veterinary practice.

Nevertheless, this was in '73 and on, and the economy was failing, we were lining up to get gasoline, we were going into a recession, and people were hurting for money.

The practice where I was located was doing fine. My husband by then was in practice as well.

Right before my husband graduated in May 1973, I found out that I was pregnant. I had my daughter at the very end of 1973. Veterinary practices pretty much were a 24-hour-a-day operation. I wasn't quite sure what to do with my daughter. My neighbor took care of her for about 10-plus hours a day. But when I had to run in on emergencies, I had to take her with me because my husband was also in a similar situation. So I would put her in a nice, clean, sterilized cage while I would do a C-section. My daughter, at my retirement, thanked FDA for bringing me on board so that she didn't have to grow up behind bars.

I totally enjoyed veterinary practice, but realized that I, for a few years, was going to have to find a job where I could work for eight hours a day. I looked at some state jobs and I looked at some federal jobs, and put my husband's application and my application in. We were called in by FDA to interview with a fellow named Dr. Mark in the Center for Veterinary Medicine in 1975. My husband and I both interviewed at the same time, and I was called Mrs. Carnevale and my husband was called Dr. Carnevale because that was the way life was then. On leaving, I told Dr. Mark, who was truly a delightful person, that although my husband and I were doing fine up in Pennsylvania, I wanted to be able to work full time, and that both of us would need to have a job in Washington, or there was no point in our coming down.

And so two weeks later, I got a phone call saying they had found a job for me, and the job actually sounded perfect. It was one working in the Division of Animal Feeds, and I was going to be -- well, they were inventing this job for me.

Do you want me to go straight into that, Bob?

RT: Sure.

CWC: It was in the Bureau of Veterinary Medicine, later the Center for Veterinary Medicine, and at that time Dr. Van Houweling was the Director of the Bureau. The Office Director was Dr. Phil Cazier. And I was to work directly for a fellow named Dr. Bob McDowell, the Branch Chief, and I think Bill Bixler was the Division Director. But I came in as a GS-11.

My job was being invented as I began it. I believe Dr. Cazier took to me and started giving me things that he did not want to do anymore because he was nearing retirement. So he gave me the job of being the Program Manager for the Tissue Residue Program. As you know, FDA is responsible for approving drugs for food-producing animals and setting tolerances for the residues of those drugs in food-producing animals. At that time the Bureau of Foods also figured into the equation because they were responsible for reviewing the safety of the residues for human health.

The Bureau for Veterinary Medicine was primarily responsible for the animal health side; that is, the efficacy of the drug -- does it work. And the Food Safety and Inspection Service at USDA, and called something else then, was responsible for protecting consumers under the Meat Inspection Act and the Poultry and Poultry Products

Inspection Act. So they would test for animal drugs and other contaminants like pesticides and heavy metals in animals and birds as they went to slaughter. I was responsible for the intersect between the agencies and crunching the numbers to discern whether the problems that we were seeing with residues in animal tissues were because of how FDA had approved a label, that is, how we had approved the use of a drug, or whether it was because farmers, producers, or veterinarians were misusing the drug.

At that time, this program was a big issue on Capitol Hill. They were having hearings all the time. And so I spent a lot of time helping USDA folks and FDA folks in coordinating testimony for hearings.

RT: What committees on the Hill were working in this area?

CWC: As I recall, it was both FDA oversight committees in the House and Senate and the agriculture committees, the House and Senate Ag Committees, coming at it from different angles.

Most of the time, USDA was testifying, but FDA had to testify too, as FDA approved the drugs for use.

I also was a Program Manager for the Pet Food Program in the Bureau. That job entailed primarily working with the state feed-control officials, because every state had a program where they had to approve, for a fee, the labels of all pet food sold in their states. It brought in revenues to the state and also brought them ability to control that type of animal feed, because pet food is an animal feed.

So I worked with the state feed-control officials and the overarching AAFCO (the Association of American Feed Control Officials), who had a committee called the Pet Food Committee. It would meet three or four times a year just to sit down and approve pet food labels, to see whether the information on them was appropriate, truthful, and only had claims that were scientifically validated.

Most pet foods are complete and balanced foods. They're intended as sole-source foods for animals. So, just like infant formula is a sole source for infants, you have to worry, with pet foods, whether they're getting all of the vitamins, trace minerals, you know, amino acids, and nutrients that are appropriate for them at all or particular stages of life -- like gestation, lactation, puppyhood. And when there is a problem with a pet food, you usually find out about it pretty quickly if it's a serious problem, as we recently found out with the China melamine situation a couple of years ago.

RT: Do you find that you learn that from adverse reactions in the animals, or do you learn it through research?

CWC: We learn it through the animals. For example, cats have a need for taurine in their food, and that, when cats started having problems, the pet food companies jumped on it and determined the source of the problem. But that occurred because a lot of people were feeding tuna fish to their animals rather than giving them a completely balanced diet, and so sometimes these things are found out not just through the pet food that is manufactured as pet food, but through alternative feeding practices of the owners.

The pet foods could claim that they were complete and balanced in a couple of ways. The first way was by doing their own feeding studies for the various life stages. The second way was to comply with the National Academy of Sciences, National Research Council guidelines on canine and feline nutrient requirements. NAS//NRC guidelines are built on all available science at the time they were compiled.

So, anyhow, that committee work was eye-opening, and it was also a total joy to work with the states. You know, I was still very green at FDA. I was only in the Bureau for Veterinary Medicine for three years, and I was learning how things worked on the Hill. This was better than a civics or a political science course in school. I was learning in practice how the Legislative Branch interfaced with the Executive Branch. I was learning how to write congressional testimony, and what was politically correct when you testified on the Hill. And because there were a lot of pieces of legislation that came out dealing with the Tissue Residue Program, I was also learning how to write legislation. As I was also working on regulations within FDA, I began to understand how the legislation took effect. In the Pet Food Program, I was learning how, what the states' roles were vis-à-vis the federal role. So I was very lucky, very fortunate, to take a position with Dr. Cazier, a fellow veterinarian, who was about to retire, and put his faith in me.

He took me to weekly staff meetings with the Commissioner, so I even met the Commissioner at that time. Dr. Schmidt?

RT: Alexander Schmidt.

CWC: Yes. I do remember his face.

Then Don Kennedy came in. I knew him pretty well.

So here I was a GS-11 and then a -12 and then a -13 when I was in the Bureau for Veterinary Medicine, and was fortunate, indeed, to have good mentors, but, even more so, an opportunity to, through trial and error learning things on my own.

Dr. Van Houweling left. I can't remember exactly what year, but probably 1978. Dr. Les Crawford came in to take over the helm in BVM. I had met Lester Crawford when he had come in on a sabbatical from the University of Georgia, so I already knew him pretty well. He put me in charge of a committee to figure out why, with USDA, why we were having this problem with sulfamethazine residues in swine.

The incidence of over-tolerance residues was 7 percent or higher in slaughtered swine. Something was going on that these residues were turning up at this high rate. I was working with people in the Division of New Animal Drugs, and statisticians and scientists from the Office of Science and in the Bureau of Foods. All of these people were trying to figure out why this was occurring. And at some point, the communication with the Director's office became strained. I think that the sulfamethazine problem had become political.

RT: Was that a secondary carcinogen?

CWC: It was. But that wasn't found out until much later.

TAPE 1, SIDE B

CWC: The sulfa drugs. I was -- I'm not sure whether the word is fortunate, but I certainly worked with the Delaney clause a lot in my work when I was in the Bureau for Veterinary Medicine, simply because the Delaney clause seemed to come into play on just about everything I did. I'm going to get back to the sulfa drugs in a minute.

We did deal with the diethylstilbesterol [DES] case that you asked about. The hormone was used in feedlot cattle as a growth promotant and there was much concern about its carcinogenicity.

The Delaney clause is found in three parts of that FFDCA, as I recall. With regard to veterinary drugs, a veterinary drug can be carcinogenic and still approved for use as long as no residue remains in the animal tissue, remaining in the animal tissue. This is called the Delaney . . .

SJ: Proviso.

CWC: Proviso. For the other two areas where the Delaney clause is in the Act, it is simply that you cannot approve something if it is carcinogenic.

SJ: Shouldn't be carcinogenic by appropriate tests in man or animals.

CWC: Thank you.



SJ: Which is where all the . . .

CWC: Which is where all the . . .

SJ: The fun starts.

CWC: The fun starts with the lawyers and the scientists trying to interpret Delaney and find practical, science-based ways of implementing it in the spirit of the law.

Now, back to sulfa drugs. Sulfamethazine (SMZ) was found to be a secondary carcinogen because it stimulates the thyroid gland. Because these drugs are fed to animals continuously as prophylaxis against pathogenic bacteria, if there are mutant cells in the thyroid, they will be encouraged, like other thyroid cells, to multiply by continual exposure to the drug.

Thus, SMZ was not considered to be a mutagen and, hence, a primary carcinogen. Instead, the mechanism for tumorigenesis was secondary; that is, stimulating growth and division of cells, some of which may be capable of causing tumors in animals.

And so residues of SMZ continued to be a significant concern. However, at the time I was in the Bureau for Veterinary Medicine, I want to be clear that the primary issue was simply the high incidence of residues. At a later date, SMZ carcinogenicity became an issue. I believe NCTR (National Center for Toxicological Research) did a review of the data in 2001 or 2002, so that's almost 25 years after my task force in SMZ

was disbanded. It's possible that concerns over SMZ carcinogenicity were the reason for disbanding the task force, but, if so, I was not informed of it.

RT: Was red #2 a problem?

CWC: One of my jobs was looking at letters that came into the agency saying, "My dog ate his supper and then died," or "I had 30 cows that had this problem, and I'm concerned about the feed." And so we would decide whether the Office of Regulatory Affairs (ORA) should go out and do a field exam at a farm or collect samples at somebody's home. There were many consumer complaints regarding animal feed. Virtually all were isolated incidents.

There were also issues involving human foods that simultaneously had to be addressed in pet foods. One of those was red #2. That was also an issue of the Delaney clause, as red #2 was an approved food additive. So I had to review the data and information on red #2 with regard to animals and work with the Bureau of Food scientists.

The semi-moist pet foods that were popular at the time looked like little cuts of meat as they colored with food coloring. The cans of pet food that contained bright-red meat were only this color because the nitrites and nitrates fixed the color. It was not just DES and red #2. A number of substances fed to animals or added to processed foods were being seen as potential carcinogens. There were many carcinogenicity issues that were hitting the fan right at that period of time, all of which presented unique challenges given available scientific knowledge and legal precedents.

There was so much interest in cancer at that period of time, in the '70s, that a lot of the studies that were being done, the long-term studies on animals, and we were starting to get all these *in vitro* tests for carcinogenesis and mutagenesis, and so you were starting to get results.

SJ: And the ability to test low levels of . . .

CWC: The ability to test for residues at low levels, yes. And so, it was a question of, did you have sufficient weight of science to take these products off the market under the Delaney clause?

It was interesting to see the intersect between the lawyers, the law, and the science, as a new employee.

The DES case was the single most intense job I think I did when I was in the Center for Veterinary Medicine, and what I did was a tiny fraction of what was being done in compiling all the data, the science, and legal argument to support that case.

I can remember Jeff Stribling working on that case. It was just a huge, huge effort by the agency to deal with diethylstilbesterol. It had been used in most feedlot cattle.

SJ: And they ultimately did pull it off the market.

CWC: Ultimately, yes.

RT: Did the State of California, in their sort of unilateral . . .

CWC: Way of doing business?

RT: Right. Where they cut out all these products that they believed might cause cancer.

CWC: Prop 65. Is that what you're talking about?

RT: Yes.

CWC: Yes. Proposition 65 was passed in California at a later date. Clearly California did not feel that the U.S. government was doing enough to protect consumers from cancer-causing substances. DEES was being addressed in the late '70s. Prop 65 was in 1986, I believe. Prop 65 required that all substances causing cancer or other serious effects like birth defects be listed and published and dealt with so they could not cause adverse effects.

Prop 65 was a bit of a thorn in our side because two standards or mechanisms were operating -- one federal and one state -- which caused confusion in the minds of consumers and had practical implications in the marketing of foods and other products. In the early '90s I worked with the author of Prop 65 in a public-private sector think tank to find common ground on knotty pesticide controversies that, ultimately, enabled new pesticide legislation. It was marvelous.

RT: Well, I know that's an issue among the states and industry in a number of areas. In the area of hazardous substances, there were a number of states that passed their own laws, and then the Hazardous Substances Act by Congress really was an effort to preempt the state laws.

Anyway, that was the way they finally dealt with preemption, because it really makes a difficult scenario when you have multiple requirements for the same substances or products.

CWC: I came across preemption a number of times in my career, for example, in the marketing of raw milk and imported Grade A products. Most recently when I dealt with the GATT (General Agreement on Tariffs & Trade) negotiations in the late 1980s and early '90s, the resulting agreements under the WTO (World Trade Organization) tell member countries to deal with sub-national government measures to assure that they comply with the WTO obligations. In other words, if another country thinks a state government's law runs counter to a trade agreement obligation, the U.S. government will be responsible for defending the state measure or convincing the state to change it.

RT: For those who might not be familiar with it, what does the GATT stand for?

CWC: Well, why don't we deal with that later on, because GATT came along maybe 20-some years after what I'm talking about right here, so, chronologically, I don't want anyone to get confused.

RT: Then let's defer it until later.

CWC: Okay.

It's 12:40. Maybe we should consider going upstairs. Is it possible to do this upstairs, I mean, or is it too noisy?

RT: We can do it in our own little conference room.

CWC: Okay.

RT: We won't be crowded then.

CWC: Okay.

And last time we did this -- you want to turn this off?

**Tape recorder turned off and on**

RT: Dr. Carnevale, I believe that you then worked in ORA, Office of Regulatory Affairs. Would you like to move to that part of your career?

CWC: Sure, sure.

Before I do, however, Suzanne had wanted me to mention that I did work on aflatoxin policy in the Bureau for Veterinary Medicine, dealing with aflatoxins in peanuts. Throughout my entire career, I worked on aflatoxins, but in different respects.

RT: Doesn't it occur in corn and corn products?

CWC: It occurs in corn, peanuts, cottonseed, and other oil seeds. But when I was in CVM, Joe Rodericks in the Office of Science, I believe, was doing, I think, a risk assessment on aflatoxins in peanuts. Because peanut meal is used in animals as a feed ingredient, I worked on aflatoxin when I was in Veterinary Medicine.

But far more work was done on it when I was in ORA, so we'll try to go through my ORA career in some sort of order at this point, if that's all right.

RT: That's fine.

Now, when was your transfer from Vet Medicine to Regulatory Affairs?

CWC: Well, I started in CVM, that is, the Bureau for Veterinary Medicine, in '75. I left in '79.

What happened was that Kennedy, the Commissioner at the time, decided to charter a committee to work on pesticides. We were starting to get a tremendous amount of interest from the Hill on pesticide residues in foods. Consumers were hearing more and more about the toxicity of pesticides, although much of the concerns were related to the environment or the toxicity of the pesticides to farm workers who applied them. Still,

people were hearing that pesticide residues occurred in their foods. Press reports did not usually distinguish between risks posed by these high levels of exposure in farm workers versus the miniscule levels of exposure that the average consumer ingested in his or her diet. So we were starting to have congressional hearing upon hearing.

I need to back up just a little bit to explain that the Environmental Protection Agency [EPA] is responsible for approving pesticides for use in specific food commodities. So EPA would approve a pesticide for use in an apple orchard, for example. In doing that, they would write up label instructions for this specific use and they would set a tolerance for the residues of the pesticide remaining on or in the apples. The pesticide tolerances even were set under Section 408 of the Food, Drug and Cosmetic Act. FDA's job was to test for the pesticide residues in foods (other than meat and poultry, which is USDA's job) and take regulatory action against foods containing illegal residues.

Now, I'm going to make this even more complicated.

So, EPA sets the tolerances under Section 408.

Another section of the Food, Drug and Cosmetic Act was Section 406 that deals with unavoidable substances in food.

Section 406 is used to set tolerances or action levels, which do not have the same standing as tolerances, as action levels are guidance, for substances like the chlorinated hydrocarbon pesticides that had been used in the late '40s, '50s, and '60s and withdrawn from the market, such as DDT, dieldrin, heptachlor, and aldrin. These are the pesticides that were exposed in *Silent Spring* by Rachel Carson. These pesticides persist in the environment for dozens of years, if not longer, and caused death in songbirds,



accumulated in human and animal body fat, and caused thin eggshells/breakage in Bald Eagles. After they were banned in the U.S. and most other developed countries, we had to have some way of dealing with their persistent residues in foods and have consistency in deciding what was a legal residue and what was not.

FDA decided to utilize action levels to do that under 406. These guidance levels were determined by FDA in consultation with EPA.

Consumers were becoming increasingly alarmed at pesticides in the food supply. Despite the fact that FDA, especially EPA, were saying that the levels being found in parts per million or in parts per billion were not as consequential to human health as, say, pathogens in the food supply, nobody seemed to hear us. There was definitely a public panic over pesticides in food.

So FDA felt something needed to be done to examine our policies and our regulatory strategies to assure they were science-based and responsive to the concerns we were hearing. The Commissioner's Task Force had representatives from the Bureau of Foods, the Commissioner's office, the Office of Regulatory Affairs, and the Bureau of Veterinary Medicine. I represented BVM. It was headed up by John Wessel. And it produced a report for the Commissioner and set forth recommendations that needed to be implemented so FDA could focus more on pesticide residues, be more transparent with the consumer, increase the numbers of samples we were taking, and basically respond to the public panic, which required more information and data.

Once we completed the report, John Wessel and Paul Hile, the Associate Commissioner for Regulatory Affairs (ACRA), asked if I would go up to the Office of Regulatory Affairs and work on implementing that report on detail. That's how I landed

in ORA. John Wessel was Scientific Policy Coordinator in ORA. We had a staff of three, counting our secretary.

That office was an interesting office. It didn't just work on pesticides; it worked on all sorts of contaminants in the food supply. But its focus was policy -- figuring out, for example, how to deal with an emergency that involved a contaminant in foods or feed. We would assure that all stakeholders needing to be involved in the emergency were engaged -- states, USDA agencies, appropriate FDA offices, congressional offices, the White House, public interest groups, and the public. We worked on the science, the law, and coming up with a reasonable and a cogent regulatory position to handle the incident. We were not necessarily the lead but our office served the purpose of looking at all the pieces and advising the ACRA.

So, when there was something like a dioxin spill, we were in the middle of it and trying to make sure that what was happening in the field was coordinated with other things that needed to be done so that the agency could have a science-based, well-thought-out, and understandable message to tell that would be coordinated with the positions of the other agencies that might also be involved in a particular incident. So, our office dealt with industrial chemical and other contaminant emergencies; with the whole pesticide issue, which got even more interesting as we went along; we dealt with action levels for chemicals in the food supply like the pesticides but also other types of chemicals, like the PCBs (polychlorinated biphenyls).

SJ: Can I ask you one question before we move on?

CWC: Yes.

SJ: Sorry, I didn't mean to interrupt your train of thought.

There's a provision in -- I can't remember if it's in, well, it's a Delaney provision that required special attention and special tolerances for carcinogens that concentrate during processing.

CWC: That may be Section 406, which deals with substances that cannot be avoided by good manufacturing practices, but perhaps you are thinking of something else.

SJ: Okay.

CWC: The violation of the law would be in Section 402. But perhaps we should leave your question for a retiree who is a legal scholar.

SJ: Right.

CWC: The heightened concerns about pesticides in food continued for probably close to the next decade. Pesticides was definitely the number one food concern from the very late '70s pretty much throughout the '80s. And industrial contaminants, because of things like PCB spills, dioxins in milk cartons and so forth, came a close second.

The microbiological contaminants that were actually causing human illness and deaths were way down on the totem pole, I believe, because people expected an occasional case of food poisoning from food that had been left out on the counter for too long or a similar reason. That view changed in the '90s after the Jack In the Box hemorrhagic *E. coli* incident and once the U.S. began experiencing more foodborne illness outbreaks associated with produce.

TAPE 2, SIDE A

RT: We're all set now.

CWC: Bob, I know you wanted to hear a story or two from my time in ORA. One involves chlorinated hydrocarbon pesticides. As I said, most of them had been outlawed due to the public outcry after *Silent Spring* and the concerns over what this class of pesticides were doing to the environment and humans.

SJ: Although I need to point out at this point that FDA pharmacologists had been very concerned about these exact same pesticides, what they call the persistent pesticides, during World War II, right after they had been invented, and refused to certify that they were safe when asked to do so, I think, by the Army or somebody. I don't remember.

CWC: Yes. Well, and they certainly weren't safe. But part of their value was their persistence in the environment. Chlordane was injected into the soil around houses and

kept the houses free of termites for 20-plus years. And so the Environmental Protection Agency certainly took the balance into account, in doing their risk-benefit assessment, and decided one by one to pull them from the market as safer alternatives were found.

Those of us who are older than 60 can remember when DDT was sprayed for mosquitoes, certainly up and down the East Coast, that there were concerns about malaria. These pesticides were what we had at the time. Safer pesticides were coming along, but one needed to have incentive to use newer, safer, less persistent and often more expensive pesticides.

So, going back to the story. It occurred in Hawaii in 1981. A pesticide called heptachlor, which is a chlorinated hydrocarbon pesticide, was still allowed for limited use on pineapple plantations. The pesticide accumulated in the bottom of the plant, so there was not a concern about the pineapple itself.

After the pineapple was harvested, the remainder of the plant was used for animal feed. The pesticide really was down so low in the plant that, again, the residues had not been a problem.

RT: Was that pineapple on Oahu more than the other islands?

CWC: It was only on Oahu, as I recall.

But what happened was, there was a new harvesting machine that they were using for harvesting the green chop -- that's what they called the animal feed that was made out of this leftover green part of the pineapple plant. As you know, pineapple plants, they just have one little pineapple growing up from it, and the rest is this very tuberous,

fibrous leaves that were left over in the fields. They wanted to make use of it, so they decided to use it for animal feed. And this new harvesting equipment went down further on the plant, and so it scooped up the bottom of the plants, where the heptachlor had accumulated.

And so, the green chop went into animal feed, was fed to dairy cows, and it was used for every single dairy on the island of Oahu. Therefore, every single, solitary dairy cow was exposed by ingesting the green chop, including those that were freshening or pregnant and those that were being milked.

The state of Hawaii occasionally would run their milk samples for a number of different contaminants, certainly including the chlorinated hydrocarbons. So they did one of their periodic testings and they saw some peaks that concerned them. They actually thought they were heptachlor.

They sent the milk samples off to FDA's San Francisco laboratory. San Francisco ran the samples, and they said, "Oh, absolutely, these are heptachlor residues." And then the question was, well, where the heck are they coming from? They quickly found that heptachlor was used on pineapple plants, but why were the residues suddenly showing up now?

They went back and looked at all their previous samplings of milk where they were not finding these residues in the past results. So the only new variable was this new equipment to harvest the green chop. And so you had every single dairy animal in Oahu with heptachlor in its fat tissue and in its mammary glands. Milk, of course, has pretty high fat levels and, therefore, had pretty high heptachlor levels, and it had been there for

a while. And what do nursing mothers drink a lot of? Well, they drink a lot of milk.

What do young children drink? Well, they drink a lot of milk.

So you had a very bad situation over there, and the health commissioner was very concerned about it and under the gun. They were starting to have press conferences with mothers holding their babies, fathers holding their babies. It was quite emotional and people were angry. Plus you had laws in effect in the state of Hawaii where they did not allow milk to be shipped in from other states. Oahu ended up having to airlift new dairy cattle into the state because they couldn't bring milk in. They had to bring the cows in, instead.

And so, anyway, I was flown over there along with the San Francisco Regional Director and the head of the pesticide program in the Environmental Protection Agency. The cameras were running as we were stepping off the plane.

RT: Was that Earl Johnson?

CWC: It was Ed Johnson.

RT: Ed Johnson.

CWC: Edwin Johnson, in fact.

We met with the Health Director, who was quite a politician and had been in his position for many, many years. The situation was very ripe at that time for producing major political scandals in the state of Hawaii. We federal government officials really

wanted to understand as much as we could about the situation and work with our scientists to help the state put things back together. We had an action level for the heptachlor residues in milk based on the toxicological data available to date.

We did not know how long these animals were going to be contaminated, but we assumed it would be for a very, very long time.

We also did not know what was going to be the long-term effects of the pesticide in women who had breast-fed their children, children who had been consuming milk. Kids were being tested, breast milk was being tested. It was something.

Hawaii was considering having milk banks, you know, breast milk flown in from out of state, all of this sort of thing.

They had a lot of questions, and we did not have a lot of answers. We simply tried to reassure them that we were trying to get those answers as quickly as humanly possible.

RT: Was there consideration of what disposition would be made of the infected herd? In other words, were those contaminated animals not acceptable as human food because of residues?

CWC: That's absolutely true, and thank you for raising that.

The animals could not be slaughtered legally because they had heptachlor levels in their fat. Samples of tail fat were collected from the live animals for analysis by the state and USDA.



The sad thing with any milk contamination incident is that the dairy cows have to continue to be milked every day and the milk thrown away. The animals were being put out to pasture as soon as possible to save on feed and labor costs. I do not remember anything being said about, you know, can't you get rid of all the fat in the milk and just use the skim milk. I believe that that was considered to be not a viable alternative from a legal standpoint, but I do not recall.

RT: Were those animals, for example, good for tankage and diverted, perhaps eventually, to fertilizer?

CWC: I can't imagine that would even be seen to be a viable alternative. I don't remember that ever being raised.

FDA was busy gathering the information that we needed to do a health-hazard evaluation. I mean, that's really why I was there, to make sure that we had all the data that we needed at FDA to do a proper health-hazard evaluation for the milk itself. We had an action level of 0.3 parts per million but were thinking about lowering it. Milk levels were several times this amount. We had a situation where we actually had these residues and we needed to decide what we were going to advise for this specific situation.

These animals were just put on pasture and left. They became the subject of a study to determine how long these residues were going to persist in their tissue. They continued taking tail-fat samples to measure the amount of heptachlor for months and years.

Heptachlor has since been pulled off the market, of course.

RT: Was there any, do you know of any final results regarding the longevity of the residues?

CWC: I do recall that a couple of years later that the residue levels had gone down considerably. We were surprised at how quickly they did deplete.

SJ: I'm sure those are published.

CWC: Yes, a lot of publications, and lawsuits, came out of this.

But I guess the point I wish to make pertains to the value of Scientific Coordinator's Office within the Office of Regulatory Affairs to provide the intersect among the states, the different federal agencies. It had the standing and ability to focus on an incident of this magnitude and assure that all bases were covered, i.e., decide what things needed to be done on this particular incident. ORA had its role, CFSAN had its role, CVM had its role, EPA had its role, the state health department had its role, the state agriculture department. So you had all these different units and roles and it was useful to have a coordinating office in FDA to process all that was happening and proceed with getting the work done so that this situation could be resolved. It eventually was resolved.

They got new sources of milk into the state, that is, new dairy cattle. I believe that the state health director retired after this. And Hawaii followed those children for many years to discern if there were impacts on learning, impacts on incidence of cancer or other health effects in children.

And all of this was incredibly frustrating just because we didn't have the science, the scientific answers. Nevertheless, while the circumstances really pulled on your heartstrings, it also made me see how much FDA was needed, that science had to stand behind every decision we made in protecting the food supply, and that the state depended on FDA's and EPA's scientific knowledge, experience, and authority to help them in this situation.

So, that's one example of the kinds of jobs that this office of scientific coordination took on. It had three different names, I think, while I was there. But it really was a policy office, and one that would allow you to coordinate with the various stakeholders.

RT: Was there a community institution program that followed this? Or is that kind of jumping the gun?

CWC: You mean the Community Nutrition Institute lawsuit on aflatoxin?

RT: We talked about aflatoxins before, regarding my job in BVM. When I was in the Office of Regulatory Affairs, we dealt with aflatoxins too. Aflatoxins fall into that unavoidable-contaminant category. And in ORA, because I was not kind of strictured by just dealing with animal-feed type issues like I dealt within the Bureau of Veterinary Medicine, suddenly I was dealing directly with human foods as well as animal feeds.

Aflatoxins are a toxin that are produced by *Aspergillus flavus*. *Aspergillus flavus* is a mold, so it grows where most molds would grow, in hot and moist conditions.

Aflatoxin is considered a mycotoxin, which means a mold toxin, and there are many thousands of mold toxins that are toxic to humans and other animals. *Aspergillus flavus* is found in America's favorite crop, which is corn. Corn is grown all over the U.S., but we think of it mainly in the South, I think, and certainly that's where aflatoxins are primarily found in corn. They're primarily found where there's an early summer, moist conditions.

Just like what occurred with the heptachlor situation, there was a reason for aflatoxin levels increasing in the mid-'80s. There was a change in the way corn was grown. Corn used to be grown with rows about three feet apart. Farmers decided that they could have increased agricultural efficiency and the equipment could still get down the fields if they'd grow it two and a half feet apart. And what that did was to give more of a foliage umbrella to trap the humidity. These higher moisture levels could cause more mold on the ears of corn, and the production of aflatoxin. Aflatoxins didn't really occur in the sweet corn that we eat, like corn on the cob. The mold was mainly in the hard corn that is used for animal feed.

So, you'd get the *aspergillus* growing in the corn kernels and then southern state weather conditions perfect for the toxin production. You didn't need very much of the toxin. The nature of aflatoxin is that a very small amount of it is enough to cause some pretty evil effects. It's toxic to the liver, so it's a hepatotoxin. It can cause cancer over time. And it is toxic to animals, as well.

We were having a number of bad crop years in the early to mid-'80s. The FDA's action level for aflatoxins was 20 parts per billion in corn. The level in milk was 0.5, I think, parts per billion in milk. There were a fair number of studies that were coming out

that showed that ruminant animals could handle, because they could detoxify the aflatoxin in one of their four stomachs. So the question was, can we safely feed aflatoxin-contaminated corn to ruminant animals? Can we take this bad corn that has been tested and found to have higher levels of, perhaps, 100 parts per billion or 400 parts per billion, and feed it to dairy cows or feedlot animals or sheep or goats? Thus, in bad aflatoxin years we could make use of this corn and not just have to throw it away, which was increasingly causing enormous economic impact on the corn farmers in the South.

So we ran the science and found that, yes, in fact, these animals could consume higher levels of aflatoxins without adverse health consequences, residues in edible tissues, or levels above the level of concern in milk.

So we decided to grant exemptions to states, when there was a bad year and the states were willing to take the responsibility to channel corn with higher levels to the appropriate animals. The agency scientists and certainly I felt that it could be done safely. It required that states and FDA manage the corn supply, the entire corn supply in the Southern states.

In any case, we had meetings with states, we had meetings with the industry, we had meetings with everybody. We tried to see if this fix was workable because we were finding out about contamination levels late in the season. How long can the corn stay in the elevators? Normally, there's a quick turnover. And we had to produce *Federal Register* documents that were announcing the exemption early enough to allow time for states to apply and be granted the exemption and get their program started. So, although this was a logistical nightmare, we had gone through a similar situation almost in a Chinese fire-drill way a couple of years previously where millions of bushels of corn

had had to be dumped. We did not want that to happen again if there was a way to avoid it. And so we went out with a *Federal Register* document and changed the action levels for aflatoxins in feed that would be fed to specific types of animals based on the science we had. And the document was as tight as we could make it science-wise. The science behind these levels is still solid.

We explained the legal basis for the policy in terms of aflatoxin being an unavoidable contaminant, that is, it could not be avoided by good manufacturing practice. We were changing our action levels to provide for the safe use of this feed. And I think it was a good thing. The work that we did back then is valid today.

RT: With the advent of ethanol, was that a possible consideration in disposition of this kind of . . .

CWC: Ethanol production existed back then, too, and that was part of the consideration. It was a very small-scale type thing, so the vast volumes of corn that we're talking about could not have gone into ethanol production without swamping the facilities extant at that time. But certainly that option was there. And I don't know whether, how much of that is being done now as an outlet for the aflatoxin-contaminated corn.

The thing that crossed my mind back then was not, are we doing the right thing as far as channeling the contaminated feed. It was more, can we channel it? Can we have control over it?

By itself, FDA was not going to be able to follow corn shipments from the elevator to the feedlot. We didn't have inspectors out there who could follow a train. So

the question was whether it was really going to help, as the states absolutely had to make sure they had control over the corn.

RT: Was there congressional committee interest in this?

CWC: The Hill was quite interested, and consumer groups were interested in it.

What happened was that we published the proposed action levels; we got comments back on it, we answered the comments. We went out with the final guidance and we were sued by the Community Nutrition Institute, I believe. The suit went through the courts and ended up in the Supreme Court. The remaining issue for the Supreme Court was whether FDA was utilizing action levels, which are supposed to be non-binding guidance, as though they were rules having the force of law.

#### TAPE 2, SIDE B

RT: As you were saying, Doctor, the question was, are we using action levels as . . .

CWC: Rules, as regulation.

Was the agency utilizing guidance, which is what action levels were, as though they were the subject of rulemaking in establishing regulations with due process so that there was an adequate chance to comment on them? And were we using action levels as though they had the force of law, which rules do?

Despite its importance and the amount of work involved, the Supreme Court case was a new experience for me. I had never been involved in something like this. Mike Landa had been the primary FDA attorney on the aflatoxin guidance. But once a case goes to the Supreme Court, the Justice Department is doing all the prep. And so Mike and I were down there a lot working with them on what the rationale was, explaining, I think, a lot of the science so that it could play to a lay courtroom. So it was interesting for me to twist my brain around to the way the legal argument would be viewed by the nine justices on the Supreme Court. I was quite surprised when they actually heard the case, how it was all done in a very brief period of time. I think it maybe took an hour or an hour and a half total. When the lawyers actually stood up, and they would barely get five words out of their mouths before the justices would come in with a question. And I thought, my God, how can they possibly understand the merits of the case!

But the nice thing was, I was able to sit there in front seat and hear the whole thing. As I had been involved in preparing the case, I now understood much better why the Justice Department lawyer who was in charge had asked me the questions that I thought were kind of ludicrous and why he had prepared the way he did.

The Supreme Court handed down their ruling that FDA was in fact misusing action levels. From that point on, it was totally out of my hands, and the agency started writing up its policy on action levels, how action levels were to be pursued and utilized, and that they were guidance, not binding on the agency or on industry or on anybody. I was certainly involved in that, but it became more generic after the Supreme Court ruled on the case.



I did, however, have to give quite a number of talks for various organizations to explain how we got to this point.

RT: Community Nutrition Institute, you said?

CWC: Yes. I'm not sure whether they even exist as that body anymore.

RT: Was that an industry group, then?

CWC: It's a public interest group.

RT: Does that pretty much cover your ORA tenure?

CWC: Well, those are two highlights of my time in the Office of Regulatory Affairs.

I'd like to mention one other thing, since I started out with pesticides.

One of the things that we did in helping the agency come to grips with the pesticide issue, was to address a couple of, I think, big-ticket items. First, we started Pesticide Coordination Teams in each FDA field office and held annual conferences, annual conferences of these Pesticide Coordination Teams. The PCTs were composed of someone from the laboratory component, inspection component, and compliance component who together would coordinate the district's pesticide work.

CWC: At that time pesticides were in the spotlight and a fast-moving and a technical

area. Districts needed to understand the policies and the science. And laboratories, some of the issues with the laboratories was that they were not analyzing the samples that were brought in fast enough to allow the products to move into commerce. You know, what do you do with perishable commodities that must be held from commerce until test results are available?

For the inspection folks, how do you get people out to all these different ports of entry? We did not and never have had enough people to do this, so what is the alternative and how do we assure the broadest coverage possible?

And then the compliance people, where the issues were, oh, you have a tolerance at one part per million. Well, if the pesticide is found in a product where it's not approved, how far down do you go? Do you go down to .01 parts per million, or do you go down to one part per billion? Should we really be stretching the methodology that far? Is the residue a real hazard such that the food must be removed from the market and destroyed? Does it matter if it's a real hazard or should FDA's enforcement goals focus on compliance with U.S. pesticide laws? How much time do we want to expend on enforcing pesticide tolerances if the residues have negligible health consequences?

So all of these issues came into play, and the PCTs needed to understand what the thinking was at headquarters, what EPA was doing, what we were doing, etc.

And the annual conference was intended to bring everybody up to speed, bring them together, make them feel like they had people they could call if they needed assistance. PCTs were a boon to coordination of FDA's pesticide program.

The second thing we did was to publicize our program and its results. At the time, we were testing 20,000 samples a year for pesticides. And we didn't have any way

to get the results out to the public, while the public continued to say pesticides were the most significant health hazard from foods. We needed outreach. We needed transparency. And so we finally managed to get some seed money and kept finding more and more bits of money and people who could put together a report that would go out as an annual report. And it wasn't enough just to have a report that would go out that would go out on white paper. It needed to be something colorful, with graphs and photographs depicting program operations and have a discussion as not only what we were finding, but what was the significance of what we were finding in terms of consumer health.

So we put together a full-color annual report, which continued for close to a decade and was very well received. It sometimes went through several printings. It was so much in demand.

In the '90s, however, the paradigm shifted. People started getting salmonella from cantaloupe and hemorrhagic *E. coli* from eating hamburgers. The public started recognizing that they were far more likely to see someone in their family become ill or even die from pathogens or toxins in their food supply than from pesticides. Besides, by then a number of the most critical pesticide issues had been addressed.

New pathogens seemed to be emerging, pathogens appeared to be increasing in incidence, and food-borne illness was increasing in incidence. Pesticide laboratory analysis diminished and microbiological work -- bacterial, viral, protozoan, toxins and parasites -- increased alongside new mechanisms by CDC to detect foodborne illness.

But this all occurred after my career in the Office of Regulatory Affairs. So let's go back.

By the late 1980s, I was working more or less continuously for the head of ORA, the Associate Commissioner for Regulatory Affairs, and I was dealing with all centers. At that time they didn't have a deputy ACRA, so I was reviewing all documents that would go into the ACRA for decision or signature.

RT: Was that John Taylor?

CWC: Well, I actually did that for John Taylor and I did it for Ron Chesemore.

I did this work for several years in partnership with Bill Schwemer, who was the Assistant ACRA, and was traveling much of the time. I was there for the cyanide-in-grapes situation, the AIDS drugs demonstrations, the generic drug problems, and saw many non-food, high-visibility conundrums evolve to resolution from the inside.

I decided to go over to the Center for Food Safety and Applied Nutrition when there was a decision that CFSAN -- it was no longer the Bureau of Foods -- wanted to take pesticide and contaminants policy back from the Office of Regulatory Affairs. There was no reason why it needed to be in the Office of Regulatory Affairs. And I think that it was just time to do that. So I agreed to go over. This was by an agreement between Ron Chesemore and Fred Shank, Ron Chesemore being the ACRA and Fred Shank being the Director for CFSAN, that they would bring the policy and the policy coordination and interaction with other agencies, and so forth, back to CFSAN. This was about in '89 -- it had been in ORA for probably close to 15 years. There were reasons why it was placed in ORA, but I won't go into those. And so I went over to the Center for Food Safety.

The reason for my coming over to CFSAN was pesticides policy. I served as a Special Assistant to Fred Shank. I had been a GS-15 for, I don't know, four years. I became a 15 under John Taylor, while I was still working for John Wessel.

So I worked under Fred Shank and did pesticides. Very soon after I came in that office, a number of disparate pesticide activities converged in an effort to find common ground in regulating pesticides and incentivizing the use of more modern and safer pesticides. There was a lot of concern among public-interest groups and the Hill that the exposure to pesticides in children was, that children were far more susceptible to pesticides than adults, and they were not being adequately protected.

There was concern that newer pesticides were coming along, and still the old pesticides had a marketing advantage. There was no good way to get the more toxic pesticides off the market.

There was a lot of concern about cumulative exposure to pesticides, that many had the same mechanism of action, depending on type. Like carbamate pesticides all had the same mechanism of action even though they were different chemicals, and the organophosphates had the same mechanism of action, so they could have a cumulative impact.

Despite all the hearings on the Hill, despite meetings at the White House -- there were even meetings in the West Wing with staffers on what can we do about this, what can we do about that, is there some way we can write new legislation. Well, politics being politics, who happens to be in the Presidency, the timing was always off a bit.

In the meantime, a group called the Keystone Center decided to pull all the food-related pesticide stakeholders together to have a dialogue. The group was named for

Keystone, a town in Colorado where it is located. The group facilitates dialogues and finding common ground on difficult issues. And I actually pulled up something on their website today, so you can have that.

RT: Okay.

CWC: But this Keystone public policy dialogue pulled together representatives from the pesticide producers, you know, the farm chemical industry, the public interest groups worried about consumers, the public interest groups worried about farmers, the EPA, the FDA, the USDA, Hill staffers that focused on pesticide regulation. They chose people from a pretty senior level who were willing to talk and who could make decisions in representing their organizations. And I'm not sure how many people were there. Maybe about 50, maybe about 40, maybe about 40.

And I mentioned to you earlier, Bob, that the lead attorney who wrote Prop 65, he was there. There were a number of luminaries there. There was this one lawyer who had been the chief spokesperson in bringing forth the Alar incident on *60 Minutes*. We all knew her because she was now a "star," I believe she worked for NRDC (Natural Resources Defense Council), she was there. Linda Fisher, EPA's Associate Administrator of Pesticides and Toxic Substances, was there. And it was quite a group.

In any case, everybody met in Keystone, Colorado, for, I guess, two meetings a year. All meetings were not for attribution. We were there for a few days at a time and in a large room with a round table, with facilitators. The whole idea was to figure out where is the common ground, what can we agree on.

It was interesting. I was chosen to be the FDA representative to this group. It was useful for me to explain to them how far FDA could go, to understand how far other folks could go, to understand what the public policy issues were as far as how consumers would perceive the results, because there were real risks and then there were perceived risks, and we had to deal with both.

These dialogues normally are supposed to go on, I think, for like a year and a half. This one went on for two and a half years, and we really had to. We had these marathon sessions that would go past midnight so we could get this thing completed.

But the amazing thing was, we did finish it. It was a good product. I wrote one of the chapters for the report, with a lot of people inputting on it.

We presented it on the Hill in the Capitol, with a big press conference. We laid it out as to what we had talked about and what we had agreed on. And we needed to do that. I mean, by that time we were all pretty much together. I mean, we were presenting this as a body. And we needed to do that so that people could understand what territory we had covered and that it was a thoughtful and very disciplined process and that something was going to be done with the results of the report.

RT: I'm not sure whether I garnered the impetus for this project. Who led that initiative?

CWC: I don't know.

I do know, however, that the Keystone Center takes on public/private policy issues that appear to be complex and stuck and need a think-tank approach.

The pesticide controversies had been going on for years, with calls for legislation. We had the situation with the pesticide Alar, considered to be a hazard on apples, and Meryl Streep is running down the street trying to grab her child's lunchbox to pull the hazardous apple out of her child's lunch. I mean, that is what came to people's TV sets. You had a public that trusted Meryl Streep and did not trust the government as to how they were being protected from pesticides in food. So you had a real crisis. The Keystone group was always looking for areas where there were conundrums and a possibility for public policy convergence. Clearly, they had that kind of situation with pesticides.

So they decided this would be a good topic because, with all the squabbling and good intentions, discussions, and so forth, nothing was happening.

Anyhow, let's go from there.

RT: That's good.

CWC: What came out of the Keystone report went to the White House. The Domestic Policy Council started having two meetings a week for a while with the senior-level people in the government on this to see if we could put together legislation.

And by that time, as I recall, Mike Taylor, who had not been in the government when he was on the Keystone dialogue, had come to work at FDA. He and I together attended these meetings in the Old Executive Office Building. He was the Deputy Commissioner at that point. But I was the staffer who kind of kept the ball rolling, I guess.



So we came together to see if we could wrap some legislation around what the Keystone group had come up with. Eventually this initiative, with everybody coming together, put together what was known as the FQPA, the Food Quality Protection Act, in 1996.

RT: It was FQ . . .

CWC: PA.

RT: So that was the . . .

CWC: Did I pull that out too?

RT: Probably.

CWC: I did. Here you go.

RT: Good.

CWC: I pulled three things off the web this morning, and that's what the extra hour gave me.

RT: Oh, that's great.

CWC: So that legislation was finally a reality in 1996.

The Food Quality Protection Act did a number of very important things, but since I mentioned a few at the beginning, I'll focus on those. It gave children a tenfold protection factor above adults in terms of looking at pesticide exposure.

#### TAPE 3, SIDE A

CWC: Okay. Now, I was saying that, in the end, what did this piece of legislation do, and I was saying it did give children a tenfold increase in protection. What that meant was that, in figuring out children's exposures, you add up all the different exposures. Like children might, on a per capita basis, eat a heck of a lot more applesauce than adults do. The scientists at EPA would add up the pesticide exposure from applesauce, from stewed carrots and all the various things that young children and infants eat. Once EPA had the total exposure, they could say, "Okay, that's it. We need to reduce the use of this pesticide or we cannot approve any more food uses for this pesticide," because children cannot tolerate additional exposure even though adults might at a tenfold higher level. Thus, children's acceptable daily intake would be 10 times below the adult level. That's what EPA would use under the FQPA as their benchmark for children versus the benchmark for adults. That was an extremely important change in this piece of legislation.

The other thing was the incentive to bring newer, safer pesticides on the market. There was not a good way to kind of evaluate the newer pesticides against older

pesticides that might be more toxic, and provide a mechanism to get those older ones off and the newer ones on. The marketplace does not give preference to the less toxic but likely more costly new ones.

A number of things took care of this problem. All the pesticide uses and tolerances were going to be reviewed to assess safety and there would be a re-registration process.

Although I had moved on to a new job by the time the Food Quality Protection Act came out in 1996, I was lucky enough to be the person who announced this new piece of legislation to the World Trade Organization (WTO). At that point I was spending most of my time on international activities, and this was, I think, the first piece of U.S. legislation that pertained to food safety that was announced at the WTO. It, kind of, made me feel like it had gone a full circle because I had been there from the germ of an idea of having the legislation to actually announcing it to the world. EPA had asked me to do this. It was, after all, their piece of legislation.

But, anyhow, from 1996 to 2006, 99 percent of all the tolerances, the pesticide tolerances that were in effect in 1996, had been reviewed. So it took a decade to do this. When you realize that each pesticide has to be approved based on a mountain of data, to go back and review of all these tolerances is just a huge task that takes years.

RT: That's good, isn't it?

CWC: Definitely.

I guess what I'd like to turn to now. . . . At one point I changed from being a special assistant to the Center Director, to being the acting head of Executive Operations in the Center. So I became a supervisor for several years. I still stayed at the same grade level. I had mentioned to the Center Director that I'd be willing to be a supervisor and, as CFSAN had just been through a reorganization, that slot was open. But I did not discontinue my pesticide responsibilities, and I did not discontinue the new international work that I had begun, because the Center Director had . . .

Well, I'll tell you what. Let me go back and make this into more of a story, I guess, because I want to tell how FDA became involved in international trade negotiations.

I came into the Center in '89. Prior to my coming to the Center, I had had a document that kept appearing on my desk, and, to be truthful, I think I ignored it because I just didn't think it was going to go anywhere, as it was in serious conflict with the Food, Drug and Cosmetic Act. The document was really the beginnings of what became the World Trade Organization Sanitary and Phytosanitary Agreement. Its real name now is the Agreement on the Application of Sanitary and Phytosanitary Measures. We call it, for short, the SPS Agreement.

RT: Okay. S-P . . .

CWC: S-P-S.

RT: Okay, SPS.

CWC: And I'll give you -- do I have a piece of paper on that? Yes. Does this have SPS in that? I don't know. I'll write it down for you. Okay?

Back in the late 1980s, the GATT, which stands for the General Agreement on Tariffs and Trade, GATT -- gosh, you almost have to start further back. Let me just do this quickly.

After World War II, the countries who had won the war wanted to prevent the protectionism seen as one cause of the war. Therefore, they decided to establish a world trade body. And so they went to Bretton Woods, near Mount Washington in New Hampshire, to work on this, the International Monetary Fund, and U.N. organizations. The negotiators could not agree on a trade organization, but they did agree on some common ground to reduce tariffs and quotas for international trade. They put all of those agreements together into a General Agreement on Tariffs and Trade. So, that was GATT.

RT: The General Agreement on . . .

CWC: Tariffs and Trade.

That was back in 1947, I believe. So I'm going to go through this as quickly as I can.

So, GATT was an agreement, and that was as far as they could go.

But the countries involved in GATT had decided that they would have another round of trade negotiations every so often to take GATT a step further, because they

eventually wanted to have this organization that would reduce protectionist trade practices. And so, every so often they'd have a round of trade negotiations.

In 1986 or '87, the GATT Uruguay Round of Multilateral Trade Negotiations began. It was called the Uruguay Round because it began in Uruguay -- and most of the rounds were named for something, whoever had started it, for the town where it began; such as the Tokyo Round and the Kennedy Round, and most recently the Doha round. The Uruguay Round -- lasting from 1987 to 1994 -- was the longest round they ever had, I believe. And once the round was begun, the negotiations were conducted in Geneva at the GATT Secretariat headquarters, that used to be the old League of Nations building, you know, President Wilson's League of Nations.

Well, all GATT negotiations pretty much had been about tariffs and quotas and subsidies. But more and more, countries were finding that if they reduced tariffs, there would still be non-tariff trade barriers. These could be things like health regulations or regulations to protect the environment. But they were still trade barriers, because if EPA establishes a tolerance for a pesticide, FDA may use that limit to stop a food product that contains residues over that tolerance. So it is a trade barrier to food entering the United States, even though the tolerance is also a measure to protect health.

If one looks at things from a trade standpoint, the things that FDA considers to be health regulations -- I mean, FDA establishes health regulations for the good of the American consumer -- in international trade they are seen as trade barriers. To negotiate an agreement to deal with them, they have to be seen in both lights.

So, back in the Tokyo Round, negotiators had put together a code called Technical Barriers to Trade. A number of countries signed onto that TBT code. But

more and more, in the food and agriculture area, countries were encountering trade roadblocks related to human health, animal health, or plant health measures taken by countries dealing with things like what FDA did, what EPA did, what USDA did in terms of regulating food and agriculture. For example, the Animal and Plant Health Inspection Service that won't allow products in that may come from a country that has a particular animal disease not present in the U.S.

I can remember one incident with grapefruit where the country would not allow entry of U.S. grapefruit, claiming they contained the pesticide Alar. There was no reason why Alar would be used in grapefruit. There was no way a producer would ever go through the expense of applying a pesticide that had no purpose or use in a particular crop. Korea said they had tested the U.S. grapefruit and it had Alar in it. We requested their methodology and did some testing ourselves. Korea's claim did not hold up. Korea, I believe, just had a bumper crop of grapefruit that year and they didn't want or need U.S. grapefruit. So, we knew that this kind of situation was happening repeatedly in trader countries.

Several countries -- Australia, Finland, Canada, the U.S. -- got together and wrote a draft of the Sanitary and Phytosanitary Agreement. That's the SPS Agreement we just talked about.

The idea was to put some disciplines around parts of the GATT that gave countries the right to establish measures protecting health, protecting your environment, as long as the measures were not arbitrary and justifiable. SPS put some disciplines around these provisions. If a measure is to protect health, there needs to be sound science behind it. A country should not just come up with a measure the day before it is

implemented. You needed to make it transparent so that other countries have a chance to comment before it goes into effect. There were a number of things that they saw as important disciplines to limit the GATT exemption found in what was then Section Twenty B (XX.B.)

While in ORA, I saw the germ of this SPS Agreement come to my desk, and I commented on it, comments reflecting how it was in conflict with the Food, Drug and Cosmetic Act. The drafts were directed at protecting the free flow of trade, not protecting the health of humans or U.S. agriculture. In my view, it was going nowhere, so I spent my time on other things.

Eventually drafts came to my desk so often that I called up the Foreign Agricultural Service [FAS] who was sending it over to me, and I said, “What is this? FDA doesn’t get involved in trade negotiations. This thing is totally in conflict with the Food, Drug and Cosmetic Act.

And they patiently explained to me how international trade negotiations work. If there was something in a trade agreement that was in conflict with U.S. law, the U.S. law would be the thing changed, not the trade agreement. The idea was to prevent the conflict in the first place.

The reason was pretty simple. In trade negotiations the White House had to have one person at the table, and that person was normally from the U.S. Trade Representative’s office, part of the Executive Office of the President. In the case of SPS, USTR had delegated negotiations to the Foreign Agricultural Service, USDA. Congress allowed USTR to negotiate for the U.S. government under their Fast Track Trade Authority, giving up their ability to modify what would eventually become U.S. law, if



Congress decided to pass it. For their part, it was understood that USTR would keep Congress advised at every step of the negotiations, so Congress could indirectly weigh into U.S. negotiating positions and understand the state of play. And then, in the end, when the final agreement was agreed to by negotiators, there would be a good chance that Congress would give a thumbs-up. If a member of the Executive Branch, such as FDA, was not at the table when the SPS agreement was being negotiated, then FDA would be blamed for not protecting its own law.

I said, “Oh, thank you very much,” and I went to see our Office of International Affairs, which at that time was run by Stuart Nightingale, and Stuart Nightingale said, “Well, why don’t we take this to Jim Benson,” who was the Acting Commissioner at the time. And so we all met downtown, and I sat on the edge of the room, with all the high-level folks in FDA at the table. And Jim explored what he had in his briefing papers. He did ask me a few questions.

My thrust was, “You need to get someone to the table over there because if we’re not there, the Food, Drug and Cosmetic Act may be compromised, our ability to protect the public may be compromised, and laws that have gone through due process to be established in the United States could be toppled.” And I added, “It needs to be a lawyer. This is a legally binding agreement.”

So they agreed. They decided to send Catherine Copp there to participate in the negotiations. And she said, “No, I can handle legal issues, but I need to have a program person. I’m not going without a program person who knows the programs.”

Jim Benson looked at me and then around the table and said, “So, are you in agreement that the two Catherines will go?” And that was how FDA began its entry into trade negotiations.

Catherine and I only went to a few meetings in Geneva. We went to a lot of meetings here in Washington. It took time for the USTR lawyers and the FAS lead negotiator, Jim Grueff, to understand FDA programs. At that time there were all these tiny single-subject meetings going on in Geneva in which they couldn't fit a whole U.S. delegation, so the U.S. negotiators needed to know our programs. The negotiators did not realize at that point how important FDA and EPA were to become in getting the final agreement. But, believe me, in the end we became quite a team.

Still, in the beginning when we went over to Geneva, Catherine and I started getting angry that we were excluded from the small, but often pivotal meetings. We felt like here you have the trade people, Foreign Agricultural Service (FAS) is an advocate for U.S. agriculture, so they're trade, just like USTR, and those were the people who went into the little meeting rooms to have side discussions with a small group of countries. Decisions would emerge from these meetings that regulatory agencies -- like FDA, EPA, APHIS -- did not appreciate.

After vociferous complaints, the U.S. leads found ways to bring us in in shifts. We didn't like that either.

But I think the trade leads ( basically the FAS lead negotiator, his lawyer, and the USTR attorney) found themselves having to redo things so many times because the regulatory agencies needed to have a balance between the trade aspects and health protection -- that is, human, animal, and plant health -- and for EPA, the environment as

well -- in the agreement. So they needed us. The regulatory agencies just had not done a good enough job of explaining to them how much they needed us. So, weeks went by.

Fortunately, when we went to Geneva, we'd all go out to dinner together as a delegation. Slowly we were getting to know and trust and bond. I remember one time, I had my husband's wedding ring in my wallet for safekeeping, as he had taken it off the previous week to play golf. Anyhow, I had forgotten it was there. So a street minstrel comes over to our table and starts strumming his guitar, and everybody digs into their pockets and pocketbooks to give him change, and I dug into my pocketbook to give him change. And about 45 minutes later, he came back with my husband's wedding ring.

RT: Wonderful.

CWC: He said, "Did anyone at the table lose this wedding ring?" and of course he was saying it with a French accent.

And I hardly even looked up, suddenly realizing that it was mine. Laughter erupted when I grabbed it and then again when they realized it was my husband's.

So, you know, those kinds of little events, and all of us working into the night and so forth helped to forge bonds with one another. I'm sure some people on that delegation are still telling the story about the night that Cathy gave her husband's wedding ring away.

Nevertheless, there were some down-and-out fights where we'd get up and walk away out of sheer frustration. There was a tremendous amount of work.

I remember one time when I was putting information together that I didn't even know it was possible to put together, I mean, just pulling from all different sources and putting together charts and graphs.

And Catherine Copp was wonderful from the legal side, and ably defends the Food, Drug and Cosmetic Act, so she kept everyone straight while I was doing my more scientific work.

And so our delegation went as far with the SPS language as we could take it. There was one evening session over there, I can remember, where they put groups of two at tables -- this is in the GATT headquarters, which is now WTO -- and gave us a bottle of wine, two bottles of wine, actually, white and red, and told us to sit there until we could come up with text that would meet our needs. It was an interesting exercise. The Secretariat tried everything to find language that all countries could agree on.

All of that was happening in '89 and '90. The actual agreement was not signed until '94 and did not go into effect until '95. I'm sure that is on this piece of paper, but . .

RT: It is.

CWC: What happened was the French and other farmers started holding all these demonstrations, burning tires in the street, all that sort of thing, in defiance of the GATT Agriculture negotiations due to concerns about loss of subsidies. The European farmers and other events stopped all movement on the agriculture negotiations. So, there was a hiatus on SPS as well as it fell under Agriculture.

During that hiatus, the U.S. decided to negotiate the North America Free Trade Agreement [NAFTA], so I was asked to represent FDA on the SPS portion of it. And that was negotiated, oh boy, in less than two years, I think. But because we had the global SPS language essentially completed, the experience of working on that portion of the agreement in the GATT negotiations, it was much easier to write this section under North America Free Trade Agreement. There were only three countries. You only had Canada, the U.S., and Mexico. I also worked on the Technical Barriers to Trade section of the NAFTA. The sections had different names under NAFTA but were essentially the same thing. So we got that done pretty fast.

NAFTA went into effect in 1994, and that was when I started doing training for all of CFSSAN and some of CVM and ORA on these agreements. The Commissioner's Office of Policy and its International Affairs staff partnered with me on this. Because suddenly FDA was dealing on a world stage and had new and binding agreements whose provisions were U.S. law. FDA had to abide by NAFTA. Congress passed NAFTA in 1993, I believe, and the GATT agreements, which became the WTO Agreements, the following year. NAFTA went into effect in '94 and all WTO Agreements in 1995.

And how do these agreements become binding on us? Well, Congress actually passes a law, so that everything in the trade agreement becomes U.S. law. That was what happened with NAFTA and, finally, when the Uruguay Round was concluded, that's what happened with all the agreements under WTO. The law can have more than is in the trade agreements; for example, it might state how the U.S. interprets and plans to implement the agreements, but it certainly has to incorporate the trade agreement provisions.

So when NAFTA was finished, we all went over to the Watergate, and all the lawyers got together for a legal wash of the agreement to assure that it would be legally binding. These sessions went into and sometimes through the night. I had to be over there off and on to make sure what the U.S. had written into the NAFTA, at least the parts I worked on, would have the effect we intended. Otherwise, our hard-fought language could have come undone. I mean, once the lawyers get their hands on the language, you never know! It was necessary to have the negotiators and the USTR lawyers sitting side-by-side in these marathon sessions, but it worked and got done. I recall Bobbi Dresser and perhaps others from International Affairs, likely Walter Batts and Linda Horton, working on this phase, too.

The next year, the Uruguay Round was concluded and we never got another shot at any of the wording. So what we had negotiated back in the early '90s with the SPS Agreement was basically what was cemented in '94.

And in '94, what happened was that all the countries that were involved in the negotiation signed the agreement in Marrakesh, Morocco.

And that was where the 1947 wish for a global trade body became reality, as all the signatories agreed to establish the World Trade Organization. The GATT agreement became one of the agreements to be administered by WTO and the GATT Secretariat became the WTO Secretariat. There was now this new world trade body, and every country who signed in Marrakesh had to abide by all the agreements negotiated once their countries ratified the agreements, which needed to be done by the following year.

So the TBT Agreement was no longer a code signed by a few countries. It became a full-fledged agreement. With regard to the agreements affecting FDA, SPS

applies to the food safety areas. TBT applies to all other areas that FDA regulates because it applies to all technical barriers to trade. The SPS is essentially a carve-out of the TBT Agreement. So TBT can apply to the way we regulate drugs and medical devices and so forth.

RT: What was that last acronym?

CWC: TBT?

RT: TBT stands for?

CWC: Yes. The Technical Barriers to Trade Agreement. Both the SPS and the TBT Agreements pertain to non-tariff trade barriers, such as the regulations established by FDA offices that may adversely affect international trade.

RT: Okay. That applies to drugs?

CWC: It applies to all technical measures other than those covered by the SPS Agreement. It is nowhere near as strong or as tight as the SPS agreement, just because it's so broad, so it's too difficult to be quite as specific.

WTO Agreements became binding in 1995. We were involved with the congressional staff putting those laws together, and it was done very quickly with some language on equivalence decisions of which I'm not too enamored.

Nothing was in conflict in neither NAFTA nor the WTO SPS or TBT agreements that required change in any part of the Food, Drug and Cosmetic Act.

RT: That's good.

CWC: Other agencies did have to change portions of their laws; we did not.

Catherine Copp had stepped out of this. I should mention Linda Horton was very much involved in the final stages of the Uruguay Round. She was more involved, I think, in many respects than I was at that point in time, as she pushed for some end-run changes in the TBT provisions. SPS was pretty well completed.

I don't have very much more to go. Okay?

RT: All right.

CWC: So, after that, because CFSAN had become so invested in food safety and trade issues by that time, I took a lateral reassignment in 1996, and was named the Director of the Office of Constituent Operations.

RT: Yes, could you describe the mission of that office?

CWC: Now, that involved more than just international. We also did all the outreach work in the Center. But for international, we covered international standard setting, all the Codex Alimentarius activities, technical assistance, training to foreign governments,



compliance with international trade agreements now, and we also had an international visitors program that really brought in hundreds of visitors annually into the Center. We didn't bring them in; they asked to come in.

And eventually I was supervising about 35 people and three separate staffs covering consumer outreach and education, industry outreach, and all international functions. The international areas grew and grew. Finally, in 2003, when CFSAN was reorganizing, I gave up the outreach functions, which I enjoyed but did not have my full attention, and they were taken over by Dr. David Acheson. I focused on CFSAN's international program only, so I became the Director of CFSAN's International Affairs, reporting to the CFSAN director's office.

What can I tell you? Everything changed after WTO for the agency as a whole, but I think FDAers are still coming to grips with the fact that they're impacted by an international trade agreement.

It took CVM no time at all to understand because the beef hormone case was the first case under the SPS Agreement. The U.S. brought the challenge as Europe was not allowing importation of U.S. beef that had been treated with growth hormones. That was the first case and it came up immediately. I was involved with that simply because FDA folks were not used to WTO. I was just, sort of, ushering them into this new realm. Once we got CVM fully acclimated and understanding the need to commit the appropriate expertise and resources -- and I think that was Bob Livingston primarily, but Steve Sundloff was certainly engaged -- that once they were fully locked into that process, I just stayed home from Geneva (where the cases were heard). I'd review SPS cases -- the legal briefs -- just to make sure that the agreement was playing out in line

with how it was negotiated. But I have to say it was so much fun watching that beef hormone case. Everyone was feeling his way along, but there was also high drama, especially when the EU lawyers threw the “precautionary principle” at us, as though everyone knew what it was. Of course, we managed to find out pretty quickly and spent the next six or seven years grappling with the use of this principle in other international for a. By the way, the U.S. won the beef hormone case.

My office focused on Codex Alimentarius, certainly after Joe Leavitt became the Center Director after Fred Shank. Joe really wanted to wrap his hands around Codex Alimentarius and how we were dealing with international standard-setting. He wanted to give Codex work the attention it needed, and we did. Joe and my office made sure that we gave sufficient resources to the Codex. To this day, FDA has an earmark for Codex in its appropriations that Congress gave us. The food industry really went to bat for FDA to get an earmark, even though that isn’t exactly the way we would have wanted it.

For six years up until retirement in 2008, I served as the U.S. delegate to a Codex committee that came directly out of the Uruguay Round negotiations, and that was -- it has a long name.

RT: Okay.

CWC: That was, the Codex Alimentarius Committee on Food Import/Export, Food Inspection and Certification Systems, which is also known as CCFICS. I was engaged in that committee from its outset. It started as soon as the SPS agreement had been pretty much cemented. The first meeting was in 1992 to get kind of a head start on having

WTO in place, even though Codex, sponsored by the U.N.'s Food and Agriculture Organization and WHO, is entirely separate from WTO. Nevertheless, in setting international food standards, its purposes are to protect consumer health and promote fair trade. CCFICS has now been operating for 17 years and has been extremely active. Fred Shank was the initial U.S. delegate, and then Bob Lake.

There are about 22 Codex committees. CFSAN has served on virtually every single one of them. FDA expends many FTEs on Codex and we make sure that the international standards are prepared with the best science, and certainly taking U.S. conditions into account.

The reason why Codex is even more important now is because the WTO SPS Agreement now gives standing to Codex as an international standard-setting organization. More importantly, Codex standards are used as international benchmarks, or safe harbors, in a WTO dispute, like the beef hormone case. So any standard that FDA sets can be challenged if it is not based on an international standards under the terms of the SPS Agreement. So we'd better make sure the international standard looks the way we want it to look, or we can find ourselves in trouble later.

So, I guess this is where I'd like to wind down the interview.

You know, my career, obviously, has been rewarding. I've probably not gotten as many awards from FDA as many others have.

But I'm very proud of several awards I've given such as the award we gave to the University of Maryland for stepping in where FDA did not have the person-power or resources to train other countries in setting up and running food safety programs. U.MD.

has shown great leadership in becoming a global food safety trainer. FDA has done quite a lot to assist in this regard, but FDA does not receive funds to do any of this work.

I'm also proud of a bronze medal I got from EPA for doing a training course in Central America to get their labs up to speed in dealing with pesticide residues. It was an EPA project which had a lot of FDA help. We put together, with help from FDA laboratory staff and FDA retirees, a laboratory manual in Spanish for the Central American countries so that they could test their products that come to the United States as well as to other places in the world.

I also received an award of merit from my alma mater, the University of Pennsylvania, 25 years after graduation. That was a nice surprise. It was actually for my work at FDA, in the international arena. I think they thought that was sufficiently unusual for one of their graduates to warrant the 25-year award.

RT: That was from . . .

CWC: University of Pennsylvania School for Veterinary Medicine. And that was in 1997. Not long after WTO.

RT: Well, that's very interesting.

Well, Dr. Carnevale, we certainly want to express appreciation for your input. You've made a very valuable contribution to the FDA's oral history, and we thank you for it.

CWC: It was my pleasure.

END OF INTERVIEW