History

of the

U. S. Food and Drug Administration

Interviewee: Alan L. Hoeting

Interviewer: Robert A. Tucker

Date: April 21, 1999

Place: Minneapolis, Minnesota

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Alan L. Hoeting

As a conditional gift under section 2301 of the Public Health Service Act (42 U.S.C. § 300 cc), and subject to the terms, conditions, and restrictions set forth in this agreement, I, Alan L. Hoeting of [redacted] do hereby give, donate and convey to the National Library of Medicine, acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at The Holiday Inn, Minneapolis, MN on April 29, 1999 and prepared for deposit with the National Library of Medicine in the form of recording tape and transcript. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

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INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: April 21, 1999 Place: Holiday Inn, Minneapolis, MN

Interviewee(s): Alan Hoeting

Address: [redacted]

Last FDA Position: Director, Office of Enforcement, ORA

FDA Service Dates: 1957 - 1992

Interviewer(s): Robert A. Tucker

Address: Food and Drug Administration

Number of Tapes: 3 Length: 140 minutes

RT: This is another in the series of oral interviews for the FDA History Program. Today, April 21, 1999, the interview is being conducted with Alan Hoeting, who is the former director, Office of Enforcement, Office of Regulatory Affairs, in the Food and Drug Administration at Rockville headquarters. In addition to Mr. Hoeting, Robert Tucker is conducting the interview which is taking place at the Holiday Inn at Minneapolis, Minnesota.

Al, we like to begin these interviews with a brief resume of your early history, and let us proceed with that, please.

AH: Surely. I grew up on a farm in South Central Nebraska and graduated from the University of Nebraska, College of Agriculture in 1957. Ten days after graduating from college, I began my career as a food and drug inspector at St. Louis.

RT: Before we move into that, you majored in agricultural vocation? Or what was your degree in, Al?

AH: My degree was in Agriculture Education.

RT: All right. Did you say the year of your graduation?

AH: I graduated in June of 1957.

RT: You were raised then in Nebraska? Where were you born, Al?

AH: I was born at Fairbury, Nebraska, and grew up on a farm near Fairbury.

RT: All right.

AH: I began my career with the Food and Drug Administration on June 17, 1957, at St. Louis. In February of 1958, I was transferred to Chicago as an inspector.

RT: What was your entry grade at St. Louis?

AH: GS-5.

RT: Did you have any particular experiences at St. Louis other than the usual early training experiences?

AH: I had the usual training experiences, inspections of grain elevators, probing or sampling of wheat from grain cars, a trip down into the Ozarks to inspect blackberry picking and canning operations.

RT: Who was in charge of the St. Louis office at that time?

AH: Roy Pruitt was the district director, and the chief inspector was John Guill.

RT: So you had an opportunity to transfer. You were about to speak of that.

AH: Well, the agency transferred me to Chicago as a GS-7 inspector in February of 1958, and I conducted the usual range of inspectional activities at Chicago. One thing unique about my experience at Chicago was that I happened to be in the Ocean Spray cranberry plant at North Chicago, Illinois, at the time that the agency became concerned about the finding of aminotriazole in cranberries. I was at the plant conducting a routine sanitation inspection, and began to receive these calls from the district office wanting information about the coding systems, distribution systems of Ocean Spray

cranberry company because all of the Ocean Spray cranberry people were at a meeting on the East Coast and were not available. So I happened to be an inspector with one and a half years of experience obtaining all kinds of information for the entire agency about the coding and distribution of cranberries.

RT: Did you get into any drug work in your career at that point?

AH: Oh, I was involved in drug work at both St. Louis and Chicago.

RT: Were those field investigations of amphetamine misuse and so on?

AH: I had done some amphetamine misuse kind of investigations, but most of the drug work I'm speaking of are inspections of drug manufacturing plants at St. Louis and in Chicago as well.

RT: Were there any major firms involved? There were some problems in Chicago at one point with large drug manufacturers. Were you involved in any of them?

AH: I was not at that time.

RT: At Chicago you worked for whom? Who was the director?

AH: George Daughters was the district director, and Doug Hansen was the chief inspector.

RT: How long did you serve there?

AH: I spent three years at Chicago and was selected as one of six field people who were sent to Washington, D.C., with the Bureau of Enforcement on a detail of four to eight weeks to assist the Bureau of Enforcement with their backlog of work. The agency had undergone significant growth in the period from 1957 through 1960, and the workload was overwhelming the headquarters' offices. Ordinarily the field people would have had twelve to fifteen years' experience before they would have been assigned to a headquarters Food and Drug officer job. They selected two groups of six field inspectors and chemists to see whether they could train us in the handling of headquarters Food and Drug officer jobs.

RT: Is there any particular problem area that required field reinforcement of headquarters or was it just a general overload?

AH: Headquarters offices, Bureau of Enforcement, were overloaded with requests for information from the regulated industry. They were overloaded with requests for information from the general public. The regulatory recommendations from the field were stacked up in offices pending review at headquarters. The agency had too many people in the field and too few people at headquarters to process the field recommendations for action.

RT: Your transfer over to headquarters occurred in what year again?

AH: I was transferred to the Bureau of Enforcement, Division of Advisory Opinions (DAO), in June of 1961. This office provided advice to the regulated industry on proposed labeling for products and on the regulations and requirements of the agency. This office also answered inquiries from the general public and assisted other agency offices in developing agency policy.

RT: While at the Division of Advisory Opinions, did you specialize in any particular phase of that work?

AH: I was assigned to the drug advisory opinion part of the operation and from there handled both comments on proposed drug labels, as well as on veterinary drug and medicated feed issues.

RT: Was Morris Yakowitz your supervisor?

AH: Morris Yakowitz was the director of the division and Abe Lederer was a senior Food and Drug officer who took me under his wing and trained me in the operations at headquarters.

RT: You didn't engage too much in the food aspects of enforcement then. Is that correct?

AH: That's correct.

RT: OK.

AH: In 1963, the Division of Advisory Opinions (DAO)was transferred from the Bureau of Enforcement to the Bureau of Education and Voluntary Compliance (BEVC). This bureau was headed by General Fred Delmore who was a retired army general. The unit at that point was stationed in one of the temporary buildings over in the mall of Washington, D.C. That area now, that building has now been taken down and I think occupied by the Smithsonian Air and Space Museum.

RT: Probably Tempo D or R, one of those. Anyway, those are gone now.

Now the work that you were conducting, did that continue to be about the same under General Delmore's unit as it had been earlier?

AH: Yes, it was. I continued to work on general drug matters and handled virtually all of the medicated feed and veterinary drug issues that came before the agency at that time.

RT: Were there any particular outstanding problems that the agency dealt with in those areas then?

AH: I don't recall any special issues in that time frame.

In August of 1965, I was named as the special assistant to the commissioner for veterinary affairs, reporting directly to J. Kenneth Kirk, who was the equivalent of the current associate commissioner for compliance. My assignment was to take charge of the Division of Veterinary Medicine which was operating as a component of the old Bureau of Drugs, which included both human and veterinary drugs. The Division of Veterinary Medicine had an enormous backlog of applications for approval of medicated feeds and new drug applications (NDA's) for veterinary drugs.

The problem for the Division of Veterinary Medicine was a complex one. On one hand they didn't have enough manpower, and the second part of the problem was that they were subservient to the human drug portion of the old Bureau of Drugs, and as such all of the rules and regulations and procedures were written for processing of new drug applications for human drugs.

The medicated feed applications which were approved for individual feed mills around the country were actually approved as supplemental applications to the new drug applications which were held by the primary manufacturer of the veterinary drug that

was being added to animal feeds. This process worked fine for processing of new drug applications and supplemental application for changes in the dosage or labeling of a drug. But it becomes a very cumbersome paperwork process when you have literally thousands of supplemental new drug applications to the new drug application held by Eli Lilly, Merck or Hoffmann-La Roche or whoever the primary drug manufacturer happened to be.

RT: Now individual feed mills across the country that formulated or reformulated feed mixes for animal for growth promotion or whatever, were those then considered drug processors or manufacturers and did they require this process of clearance?

AH: Every one of these medicated feed applications from a feed mill required processing as a drug manufacturer, and after the Kefauver-Harris Drug Amendments were passed, each of the feed mills had to register as a manufacturer of drugs and as such were subject to inspection every two years by the agency.

RT: Was the agency able to do that kind of inspection frequency with the resources available at that time?

AH: No, we were not. Of course not. The bigger problem from a center standpoint was that there was a change in the law and the agency was able to first approve the drug from the data submitted by the primary manufacturer of the drug and the agency in turn would approve medicated feed applications for each of the feed mills.

This is part of the work log and task problem that we had there. It was an extremely cumbersome paperwork process that I got into when we first went over there.

RT: All those clearances then were processed at headquarters rather than in the field?

AH: They were all processed at headquarters, yes. But in the process I also was charged with the responsibility for handling the paperwork for moving the Division of Veterinary Medicine out of the old Bureau of Drugs and upgrading its status to that of a bureau within the agency. We went through a process of publishing the documents for reorganization of the unit as a bureau. We processed position descriptions and personnel actions for the transfer of all of the people from the Bureau of Drugs to the Bureau of Veterinary Medicine. We selected a portion of the chemists, and statisticians, and clerical personnel, and support and financial personnel out of the old Bureau of Drugs and reassigned those people to the Bureau of Veterinary Medicine.

RT: Was there an official manager of this veterinary aspect of the work prior to the separation from the old Bureau of Medicine?

AH: Dr. Charles Durbin had been the director of the Division of Veterinary Medicine. Unfortunately, Dr. Durbin was out ill and hospitalized for quite a period of time. When Dr. Durbin recovered from his illness, he was reassigned from the old Division of Veterinary Medicine to be the director of the Division of Veterinary Research in Beltsville, Maryland.

RT: So if I understood what you mentioned a few moments ago, you were then placed in charge of this new veterinary adjunct of the organization.

AH: For about six months, I was in charge of all aspects of the Division of Veterinary Medicine except for the veterinary medical decisions which were made by Dr. Fred Kingman.

RT: About how many people were involved in this new aspect of the work at that time?

AH: Oh, I think there were approximately fifty people that were first involved in the old Division of Veterinary Medicine, and this number was upgraded to some eighty or ninety people with the upgrading to the Bureau of Veterinary Medicine.

Dr. M. R. Clarkson was appointed as the first director of the Bureau of Veterinary Medicine in 1966. He had previously been the director of the animal health or meat inspection in USDA for some thirty-odd years before retiring. He went out of USDA to become the president of the American Veterinary Medical Association, and then came back to work with FDA as a re-employed annuitant as the first director of the Bureau of Veterinary Medicine. So I had the pleasure of working with Dr. Clarkson for one year, and then with Dr. C. D. Van Houweling who was appointed as the director.

RT: OK.

AH: So I had the pleasure of working with both of those individuals.

RT: Was Dr. Van Houweling already with the agency, or did he come from somewhere else?

AH: He came to the agency from the U.S. Department of Agriculture. Both of these individuals were highly qualified and capable executives. I remember watching Dr. Clarkson call in his secretary one day and dictating a scientific advisory report for the National Academy of Sciences (NAS) in one four-hour setting.

One of the other things that I did with the old Bureau of Veterinary Medicine was to personally hand carry the contract from the commissioner's office of FDA to the National Academy of Sciences to conduct the effectiveness review of the veterinary new drugs which had been approved by the agency between 1938 and 1962.

RT: At the time you're speaking of, do you recall the commissioner at that time. Would that have been Mr. (George) Larrick or later than that?

AH: Dr. (James) Goddard was the commissioner at that time.

RT: As you managed and developed the new veterinary drug unit, were there any particular problems encountered that were a challenge?

AH: The biggest problems that we encountered with the veterinary drug matter was the reducing the backlog of veterinary new drug and medicated feed applications and establishing some order to that process.

Another major problem that we had was setting up the new bureau and starting a process to revise the regulations for processing veterinary new drug applications and medicated feed applications.

RT: During this period, you mentioned the problems of just expediting and facilitating clearances. Were there any legal cases that were developed by the agency in this field at that period?

AH: I don't remember any specific legal cases that came to my attention.

I was called into the commissioner's office one day for an interview. Commissioner Dr. Goddard and Deputy Commissioner Winton Rankin conducted the

interview. They asked me whether I preferred the jobs at headquarters or the field, and whether I preferred line jobs or staff jobs. I said I was from the old school and I tried to do whatever the boss asked me to do. From this interview, I was selected for one year of graduate study with full salary at the University of Wisconsin, School of Business Management.

RT: What was the year that you spent out there?

AH: I went to school at the University of Wisconsin from September of 1967 through June of 1968.

RT: Following completion of that advanced work, where did you next go for the Food and Drug Administration?

AH: I was assigned from Madison, Wisconsin, to the position as the deputy district director at Cincinnati District in Cincinnati, Ohio. Ted Maraviglia was the district director at the time. I assisted Mr. Maraviglia with the entire scope of activities of the district director, of coordinating activities between inspection staff and the laboratory staff and compliance staffs, and first became associated with the state officials in Ohio and Indiana which states were partly under Cincinnati District at that time. I attended my first meeting of the Central States Association of Food and Drug Officials while I was at Cincinnati.

RT: Among the major areas of work there, did you get some drug activities as well as food in Cincinnati?

AH: We had drug activity; we had food activity; we had an entire scope of federal-state relations activities. The Intensified Drug Inspection Program (IDIP) was initiated during this time. Inspectors were assigned to conduct comprehensive and long-term inspections until the firms were brought into compliance or taken out of business.

RT: You had some rather significant drug manufacturers in that area, Eli Lilly and others. Were there any particular regulatory concerns with such firms of that industry at that period?

AH: Well, I guess there was one significant situation. There was a complaint of lack of effectiveness of Eli Lilly's syrup of ipecac which was used to induce vomiting. The complaint was that it was ineffective, and after some personal trials by Lilly personnel, the drug was found ineffective because of some subpotency in the active ingredient of syrup of ipecac.

RT: How was that issue resolved? Did it lead to any regulatory action? Or was it handled in another way?

AH: I think Eli Lilly corrected the problem by recall of the drug. There was no regulatory action taken.

RT: That was the point I was asking about.

AH: Then in June of 1970, I was named as the acting regional director at Boston for a period of sixty days, which in turn was extended for another thirty days. The agency had gone under some rather major changes in reorganizations during that time. I was assigned to Boston for ninety days to serve as the acting regional director.

RT: That wasn't the RAC, Regional Associate Commissioner, appointment? This was later when the regional director performed?

AH: This was at that time the regional directors' jobs were being formed. In the fall of 1970, all of the regional director and district director positions were advertised as being vacant. Agency personnel were able to apply for any and all of the district director and regional director positions that they would like to be considered for.

It was rather difficult to select from the ten regional director and sixteen different district director positions around the country that you would like to be considered for and which you would be willing to transfer to with your family.

(Interruption)

RT: All right, we're on again.

AH: I was appointed as the district director in the Detroit office in November of 1970. The Consumer Affairs officer at Detroit had set up a meeting for me with the press on my first day on the job in Detroit. I had left the office to obtain some information about which to talk at this press conference, because I was totally unprepared for a press conference. I returned to the office in a few minutes and found that we had the microphones from four television stations and three radio stations on the desk of the district director in Detroit. In addition, there were photographers and reporters there from two Detroit newspapers and one from Windsor, Canada.

The agency had just sent some investigators into stores to look for unsafe toys. The responsibilities of the Product Safety Commission (PSC) were assigned to the Food and Drug Administration at that time, and we had just received the approval of the Toy Safety Act.

RT: That act was enacted as I recall in 1966, giving us new responsibilities.

AH: And we were just first in 1970 doing our first survey for unsafe toys. Anyway, I discussed how we were out in toy stores looking for unsafe toys and demonstrated a few examples of the kinds of things that we were concerned about.

One of the first experiences I had there was establishing standards for testing of toys because the agency had no standards. I was asked what kind of tests were made on toys. I replied that the agency tested toys which can be used by children in cribs and that might break and release sharp objects which might cause choking by an infant. I demonstrated the holding of one of these toys at a height of about four feet and dropping the toy to the floor and stated that was one of our tests.

I understand that now one of the official tests for unsafe toys is to drop these small toys from a height of four feet ten times to determine whether any sharp objects are released.

RT: So that was an empirical decision at the time that turned out to be sort of practice.

AH: It became practice, and that's sometimes the way standards and policies are established.

Another interesting thing that happened early in my career in Detroit was that we received a call from a former FDA employee who was then with the Environmental Protection Agency (EPA), because they were not experienced with recall procedures. EPA asked FDA to send our recall and emergency coordinator, Ray Simplici, over to the Ford Motor Company to set up the first recall ever of an automobile.

RT: So the decision apparently or the interest of EPA wasn't predicated on the fact that we had any jurisdiction over automobiles, but rather our protocol for recalls. Is that what you're saying?

AH: That is correct. FDA has had experience with literally thousands and thousands of recalls. In fact, some two to three thousand recalls per year during my last years with the agency.

One of the first recalls, of course, was with the elixir sulfanilamide situation in 1937 which was responsible for the deaths of over one hundred people. The agency at that time was able to recover 234 gallons of the original 240 gallons of elixir sulfanilamide that were manufactured by the S. E. Massengill Company. The agency had a rather case-by-case procedure for handling recalls when I first started with the agency in 1957.

RT: Now the elixir sulfanilamide incident was contributory, was it not, to the revision of the Federal Food and Drug Act?

AH: The elixir sulfanilamide incident was responsible for the passage of the Federal Food, Drug & Cosmetic Act of 1938 and for the requirement of pre-marketing proof of safety of drugs before they were placed on the market.

The recall procedures were rather informal when I first joined the agency, but were structured first in the agency procedures manuals and eventually in the Code of Federal Regulations. These procedures are sound and simple. They require the agency to make a determination of the hazard involved with the particular product involved, and whether a recall is necessary at the wholesale level, the retail level, or the consumer level. We typically obtained complete distribution information on products which were subject to a recall. This is a procedure that has been much more simplified and made

easier with the advent of computers, where a company is able to quickly printout the names and addresses of all of the establishments that have received shipments of Code No. XYZ of such a product. It's much easier today than it was when shipments of a specific product or specific code number of an article had to be traced with a visual review of the paper records.

RT: Now the recall procedure concept, is that based on a statutory requirement of the act or an administrative process, regulatory process?

AH: The recall procedure is based entirely on administrative processes and for the most part is a voluntary action on the part of the regulated company.

RT: Would you suggest that it's more efficient than the seizure and injunction processes?

AH: The recall procedure is one of the most efficient and effective regulatory tools that the agency has at its disposal.

I at one time strongly supported the need for legislation to force firms' recall of a violative product, but came to realize in my later years that a written request over the signature of the commissioner and the issuance of a press release are able to effect recalls much more quickly and effectively than might be possible if the agency were tied down with a bunch of legal procedures that might be set up by statute.

RT: All right.

AH: We were involved in a major investigation during my tenure as Detroit district director. In 1973, a large number of Michigan farm animals were exposed to the toxic

chemical polybrominated biphenyl (PBB) when this fire retardant was mixed with dairy feed. The potential adverse health effects on exposed animals, contamination of food derived from exposed animals, and human consumption of PBB containing food has been categorized as the worst agriculture contamination disaster ever in the history of the United States. The incident resulted in the quarantine of over five hundred and seventy farms and in the destruction of over 34,000 cattle, 3,800 hogs, 2,200 sheep, 1,500,000 chickens, and about 5,000,000,000 eggs, and large quantities of milk, butter, and cheese. Lawsuits totaling millions of dollars were filed against Farm Bureau Services and Michigan Chemical Company concerning the financial losses and health problems alleged to have been caused by PBB.

The public became very concerned about the safety of the meat and milk supply in the state of Michigan. As a result, the Michigan legislature lowered the tolerances for PBB in milk and meat and initiated a statewide test of a biopsy from all culled dairy animals born before January 1, 1976.

The long-term evaluations of the potential health effects of individuals exposed to PBB in 1973 and 1974 were sponsored by FDA, the National Cancer Institute, and the Center for Disease Control in cooperation with the Michigan Department of Public Health. The National Cancer Institute and National Institute of Environmental Health Services were involved in bioassay and toxicological tests with PBB.

I think, fortunately, the conclusion drawn by the state health officials was that there had not been any significant demonstrated adverse health effects which had been observed from this unfortunate exposure to PBB. This was an extremely complicated situation because the people living on a small number of farms perhaps from the range of thirty-five to seventy farms received exposures to very high levels of PBB, while the rest of the farms and the general Michigan population were exposed to trace levels of PBB.

RT: The cross contamination occurred in what way?

AH: This would come from the cross contamination of the feed mill, from the equipment that had not been adequately cleaned after PBB had been mixed in the dairy animal feed.

It was a very traumatic and trying period which was aggravated in part by the fact that the price of milk had been high, but dropped approximately five dollars a hundred weight at the same time that the energy crisis occurred, thereby increasing the cost of fuel and fertilizer to the farmer and lowering their individual incomes.

In addition to that, the word went out early that the largest dairy farmer involved received a settlement of over $1 million with Michigan Chemical Company and Farm Bureau Services, and everyone else thought they'd submit some claims at that time.

It was an extremely complicated situation. We had Senator Griffin and his fellow U.S. Senator from Michigan hold thirty-six hours of hearings over a four-day period in four different cities in Michigan during that episode.

I testified on another occasion before a committee in Washington concerning the PBB experience. There were cartoons daily in the newspapers in Detroit accusing Michigan Governor Milliken, the director of the Michigan Department of Agriculture and FDA officials with not taking adequate and appropriate action to remove all PBB from the food supply and food channels in the state of Michigan. It was a very trying period for all of us regulatory officials in the state of Michigan.

RT: Was it about this time that . . . ?

AH: Let's stop for a minute.

(Interruption)

RT: Al, we've been discussing the PBB problem. Were there other regulatory matters that stand out in your recollection at Detroit?

AH: Yes. In 1975, the Detroit newspapers were carrying stories about an FBI investigation of the deaths of seven patients due to respiratory arrest at the local Veterans' Administration Hospital. The FDA involvement began when it was learned that all of the patients were receiving intravenous solutions at the time of the respiratory failure.

The investigation showed that the respiratory arrests probably were not manufacturer related. Gary (Garrett) Salmon, one of our supervisory chemists, obtained a search of the World Literature and located an analytical method for determining the presence of curare in animal tissues and specimens. Mildred Walters, one of our drug specialists, validated the methodology for muscle relaxants and found curare in the patients' specimens and intravenous tubing. Mrs. Walters was eventually a government witness for the FBI in that murder trial.

RT: This was a hospital staff person?

AH: A Veterans' Administration Hospital staff person.

Detroit District also had the experience in 1975 of executing the agency's first criminal search and seizure warrant in an investigation. We had learned that Laetrile (Amygdalin) was being offered for the treatment of cancer by a local health food distributor.

Compliance officer Bill Schwemer was responsible for doing the background search for the criminal search and seizure warrant and coordinating the execution of that particular warrant with a U.S. Marshal. In September of 1976, the firm and its

principal officers were convicted for criminal violations of the Federal Food, Drug & Cosmetic Act.

In 1977, Detroit District Supervisory Investigator David Kaszubski and other personnel were involved in the largest botulism outbreak in U.S. history. A total of fifty-nine cases of botulism were caused by the use of a home-canned jalapeno pepper sauce at a restaurant in Pontiac, Michigan. Due to excellent work by the Oakland County Health Department, the source of the outbreak was quickly determined after the first cases were diagnosed, and fortunately many of the victims were employees of a hospital located directly across the road from this particular restaurant. Because of the quick action by the health department and the fact that these patients were close to medical care, there were no deaths caused by this improper preparation of food in a retail restaurant. The restaurant was subsequently prosecuted by the state and fined for the illegal use of home-canned food.

We had another interesting situation occur in the Detroit District in 1979. The Three Mile Island nuclear electric facility had a major potential accident and possible leak of radioactive material from the nuclear power plant at Harrisburg, Pennsylvania. Headquarters asked that the Detroit District supervise the packaging of some 93,000 bottles of potassium iodide solution for emergency shipment and possible use at Harrisburg, Pennsylvania.

The FDA assigned an investigator to the Parke-Davis & Company to supervise the packaging and analysis of the potassium iodide solution so that the drug was literally packed with FDA's "man-in-the-plant" program. The Parke-Davis plant worked around the clock from 4:30 p.m. on April 1 through 1:00 p.m. on April 3. Because of a teamsters' trucking strike in Detroit, the potassium iodide was flown by chartered airplane from Detroit to Harrisburg. Fortunately, the potassium iodide was not needed in the treatment of any people in Pennsylvania.

We received a call on the second day of the packaging operation from a local radio station, which had received information about the fact that potassium iodide was being packaged in Detroit for use at the Three Mile Island nuclear power emergency. I asked the radio station not to publicize this information because we did not want to alarm the public of the fact that the government was preparing potassium iodide for possible treatment of people exposed to radiation. The radio station said they thought they had to go with the story, but they would hold the story if I could obtain a request from Washington to hold that story. I was able to contact the press office, who in turn contacted the people in the White House, who in turn got back to the Federal Communications Commission to ask the radio station in Canada not to publicize this information.

The end result was that the station publicized the story anyway, but the message came out that the government was preparing potassium iodide solution as a precaution in the event that it was needed at Harrisburg, Pennsylvania. It was a very trying afternoon.

We had another major criminal investigation in 1983 in Detroit. There had been a large quantity of counterfeit and misbranded over-the-counter (OTC) drugs which had been manufactured and were being distributed as controlled drugs for sale and use by teenage kids.

RT: Is that the steroid?

AH: No, these were not steroids. These tablets were made up of caffeine and various rather inert ingredients and were made to appear that they were in fact serious controlled drugs.

We initiated some surveillance investigations and determined that these drugs were being held and shipped out of establishments in Maybee, Michigan; Temperance,

Michigan; and Northwood, Ohio. We'd actually chartered an airplane at one point to maintain surveillance on the driver as he sped from one of the Michigan facilities to the Ohio facilities where the parcels were shipped out via the United Parcel Service.

We again obtained criminal search and seizure warrants for all three locations. We had rented five large trucks, to be accompanied by investigators and U.S. Marshals to conduct the search and seizure. The seizure warrants were executed. We seized over twenty million capsules and tablets of counterfeit and misbranded OTC drugs with an estimated value of $3 million and also seized approximately two cubic yards of cocaine substitutes with an estimated retail value of approximately $100,000. We were literally measuring the quantities of these drugs in cubic yards.

It was very dramatic when the trucks went out from the Detroit District office building. It was unfortunate we did not have a trumpet or bugle to sound the attack signal when those trucks issued. The investigators came back late that night with the trucks filled. We filled the entire garage at Detroit District with those drugs for several days until we were able to sort through the drugs, sample the drugs, and complete our investigation. The drugs were eventually all destroyed on their court order. Compliance Officer Dennis Degan managed the details of this complex and precedent-setting investigation.

RT: Was this operation conducted by the regular district enforcement, or was this a BDAC, Bureau of Drug Abuse Control, activity?

AH: This investigation was conducted entirely by U.S. Food and Drug inspectors and three U.S. Marshals.

RT: Of course, at that time, our FDA field personnel were not carrying firearms.

AH: That is correct.

RT: Protective weapons.

AH: That is correct, and I guess in retrospect, we probably should have had more manpower and reenforcement of the investigators as they executed those warrants.

(Interruption)

RT: I might ask you, Al, during this period you were the district director at Detroit and you were under the regional management arrangement. Who was the regional Food and Drug director during the period you were at Detroit?

AH: Oh, God.

RT: Was it Bill Clark or . . . ?

AH: We had Lloyd Claiborne . . .

(Interruption)

RT: I was just asking when the tape ran out about the RFDDs, and you mentioned that Lloyd Claiborne was one of those persons. The others were . . .

AH: Don Healton and Bill Clark.

RT: Thank you.

AH: What began as a single buy of anabolic steroids without a prescription in 1984 grew into a coordinated interagency investigation of international scope including Canada, Mexico, United Kingdom, West Germany, and East Germany.

The steroid investigation was launched when Detroit District investigators made three over-the-counter purchases of anabolic steroids from an employee of a gymnasium in Novi, Michigan. Sufficient evidence was developed from this limited investigation to support criminal search warrants at the distributor in Michigan and his supplier in Dayton, Ohio.

Detroit District compliance officer Dennis Degan summarized the evidence from these investigations as well as previous investigations which had been conducted on an ad hoc basis by Atlanta, Chicago, Denver, and San Francisco Districts. Mr. Degan prepared a chart which showed the nationwide distribution of anabolic steroids between these various distributors. Mr. Degan's summary was referred to the Department of Justice for investigation of January 1985. The Department of Justice requested that the FBI and U.S. Customs Service become involved in the investigation.

Mr. Degan was named as the FDA field coordinator, and Mr. Eugene Thirolf was named the lead attorney for the Department of Justice. The investigation showed there was widespread illicit distribution of anabolic steroids with an estimated value of $100 million per year. Some of the steroids were being smuggled into the United States from Mexico and other foreign countries. The illegal use of steroids appeared to be associated primarily with power lifting, weight lifting, body building, football, and a whole range of sports-related activities.

The nation's newspapers and magazines reported "Thirty-Four People Indicted," "Four Held in Illegal Steroid Sales Ring," "Feds vs. 'Roids, G-men Hit the Steroid Trail," and "FDA Targets Illegal Steroid Distribution," et cetera. Approximately 150 to 200 persons were eventually prosecuted for federal felony and misdemeanor violations associated with the illegal distribution of steroids. The various suspects were

charged with violations of various federal laws, including conspiracy to defraud the United States, extortion, conspiracy to collect by extortion, introducing and/or receiving misbranded steroids in interstate commerce, sale of counterfeit steroids, introducing steroids into interstate commerce without a prescription, illegal importation of anabolic steroids and other drugs, aiding and abetting, perjury, impeding federal investigations, income tax evasion, and mail fraud.

State and local officials in over one dozen states initiated investigations of their own or cooperated in some way with the national anabolic steroid investigation. U.S. Customs Service apprehended over one hundred persons who were attempting to smuggle steroid drugs through San Diego, California. Hundreds of thousands of dollars worth of steroids were seized by U.S. Customs agents.

The computer made it possible for Mr. Degan to index, sort, and retrieve volumes of evidence on a nationwide basis. Over one million financial, telephone and/or other records were summarized and entered into the FDA computer.

The use of several hundred Grand Jury subpoenas and criminal search and seizure warrants made it possible to obtain volumes of evidence which would not have ordinarily been available to FDA investigators. In addition, the FBI and U.S. Customs Service placed surveillance teams on some suspects in order to develop probable cause for obtaining evidence to obtain criminal search warrants.

As the federal effort to curb anabolic steroids became more successful, the demand for these drugs was filled by clandestine manufacturers and distributors of counterfeit and bogus drugs. The term "bogus" was used to describe drugs which simulated or appeared to be like an anabolic steroid. In approximately 1990 or 1991, U.S. Congress classified anabolic steroids as "scheduled drugs" and transferred the responsibility for prosecuting illegal distribution of anabolic steroids from the Food and Drug Administration to the Drug Enforcement Administration (DEA).

RT: Al, have you encountered experience with tampering with foods and drugs in the Detroit District?

AH: Yes, I have. The regulatory and industry officials have always had to deal with isolated reports of tampering with foods and drugs in market channels. These reports of adulterants and/or tampering usually involved a single container for a single person or a single family. The problem might have been an accident at the manufacturing plant, such as leaving a cleaning solution in a filling machine, or be caused by a mischievous employee who placed a worm or other foreign object in the container. In other cases, a food or drug container may be used as a vehicle for delivering a toxic substance to a potential homicide victim.

Seven persons died in Chicago on September 30 and October 1 of 1992 after taking some Extra-Strength Tylenol capsules which had been filled with cyanide. The FDA immediately issued a nationwide warning for consumers not to use Extra-Strength Tylenol. Within a few days, FDA had tested over one and one-half million capsules of Tylenol and found no cyanide in any capsules outside of the Chicago area. Our Detroit District laboratory opened and examined over 104,000 Tylenol capsules at that time. Johnson & Johnson temporarily withdrew Tylenol capsules from the market and reportedly suffered losses totaling about $100 million.

During October of 1982, FDA received hundreds of real and alleged complaints about tampered products. Some examples of these complaints included hydrochloric acid, sulfuric acid, sodium hydroxide, isopropyl alcohol, and pins and needles in various foods and drugs.

Some local police departments and USDA personnel were involved in investigations of nails and razor blades in Ball Park frankfurters in 1982. All seventeen instances of foreign objects in Ball Park frankfurters occurred within a ten-mile radius

of Livonia, Michigan. The frankfurter recall, resulting publicity, and loss of sales reportedly cost the manufacturing company about $1 million.

RT: Was that manufacturer in Wisconsin?

AH: No, it's Hi-Grade Products in Michigan.

RT: OK.

AH: The federal response to this epidemic of tampering with foods and drugs was to publish on November 5, 1982, final regulations for tamper-resistant packaging. The tamper-resistant packaging regulations required that OTC human drugs, cosmetic products, contact lens solutions, and tablets which are ingested or applied to the eye or within the body be packaged in tamper-resistant packaging in a manner to alert the consumer if the package has been previously opened.

On October 13, 1983, the Federal Anti-Tampering Act was signed into law. This statute provides severe penalties ranging from ten years to life in prison for tampering with consumer products with reckless disregard for the health or injury to another person. Persons who tamper with a product with intent to cause serious injury to a business or who knowingly communicate false information that a product has been tainted are subject to prison terms of three to five years in addition to significant fines.

On February 10, 1986, a young woman in Yonkers, New York, died from cyanide poisoning after ingestion of Tylenol capsules. Three days later, FDA's New York regional laboratory found cyanide in a second bottle with a different lot number of Tylenol Extra-Strength capsules collected from a retail store in Bronxville, New York. FDA then issued a nationwide warning advising consumers to cease use of

Tylenol capsules, and Johnson & Johnson announced its decision to cease manufacture and distribution of all drugs in capsule form.

On February 14, 1986, a Schenectady, New York, consumer reported finding three pieces of glass in peach baby food manufactured by Gerber Products Company. The New York State Department of Health examined twelve unopened jars of peaches from the same lot and found no glass. The press coverage of this complaint generated a number of similar copycat complaints. No one at the time realized that the glass found in the first container was a white milk glass of a type found in a cookware, as opposed to the clear flint glass used to package infant foods.

On February 18, 1986, a consumer in Georgia reported finding glass in four jars of baby food manufactured by Gerber and six jars of baby food manufactured by Beach Nut Foods. A local county sheriff held a press conference to warn other consumers about the glass in baby food.

FDA analysts confirmed the presence of glass in three of ten open jars of baby food collected from the Georgia consumer. Even so, the results were very suspicious because the probability of finding glass in one jar of baby food was less than the probability of winning the Michigan lottery.

On February 19 and 21 of 1986, FDA sent investigators back to all three Gerber plants to reaffirm that they were still operating in accordance with Good Manufacturing Practices and using state-of-the-art manufacturing systems which would have prevented adulteration of baby food with glass.

On February 19, 1986, the Detroit office received its first complaint of glass in baby food from a consumer in Bay City, Michigan. We eventually received a total of twenty-two complaints in Michigan.

On February 27, 1986, a Philadelphia television station reported a consumer finding glass in a box of Gerber dry cereal. On the following day, three more Philadelphia consumers reported finding glass in the same product.

In a period of five weeks ending March 21, 1986, FDA received a total of 461 complaints from consumers about glass in Gerber's baby food. We received many complaints about glass in baby food manufactured by Beach Nut and H. J. Heinz.

FDA eventually received over five hundred complaints of glass in Gerber's baby food. About 30 percent of the complaints did not have a sample or other documentation to support their complaint of glass. No glass was found in the samples obtained from about 20 percent of the complainants.

(Interruption)

RT: All right, Al.

AH: FDA confirmed the presence of glass in 240 opened jars of baby food collected from consumers. We found as many as 242 pieces of glass in one 4½ ounce jar and anywhere from ten to fifty pieces of glass in many jars. We found glass of all types, colors, shapes, and sizes. However, baby food was packaged in clear flint glass jars and very distinctive glass from what we found in many of the containers.

FDA performed an elemental analysis of the glass found in ninety-three jars and found that 70 percent of the jars contained foreign kinds of glass which were not used in the packaging of baby food. For example, window glass, tumbler glass, light bulb glass, et cetera, et cetera.

Gerber Products Company helped us first identify the Owens-Illinois laboratory at Toledo, which performed our initial analysis on the glass to demonstrate that this was foreign glass. Shortly thereafter, Fred Fricke at the Elemental Analysis Laboratory in Cincinnati developed methodology to perform a detailed elemental analysis on this glass which affirmed the findings that the agency had initially received from the research laboratory of Owens-Illinois.

FDA did find a few samples that contained "tramp glass." This is an industry term for large pieces of glass that got stuck in the jars during the manufacturing process and which were not washed out during the washing and blasting-with-air process prior to filling with baby food.

FDA examined 55,000 previously unopened jars of baby food and found small specks of glass in only fourteen jars. These specks of glass were so small that they escaped the screening process during the filling of the jar or were possibly sucked into the jar by the vacuum when the jar was opened. Jars of baby food are occasionally broken during shipment and specks of glass may lodge or stick to the shoulders of the glass jars in the shipping case.

The number of complaints about glass soon returned to a more normal level of incidents. Even in the best of operations, it probably is not possible to totally eliminate glass in food products packaged in glass. Contrary to popular belief, some of the FDA scientists had found that small particles of glass do not pose a significant health hazard.

During March of 1986, there was considerable publicity about the finding of staples in Girl Scout cookies in several cities in Illinois. On March 13, the commissioner of the Indiana Board of Health issued a public warning not to eat Girl Scout cookies after receipt of six complaints about needles and pins. The publicity from the first six complaints and public warnings generated thirty-five more such complaints about Girl Scout cookies in Indiana. Girl Scout cookies were manufactured in only three plants which were all equipped with metal detectors to prevent this kind of problem. FDA checked these metal detectors and found them to be working properly.

As an interesting side issue, the Center for Foods personnel and the headquarters recall personnel were prepared to ask Gerber Products Company to recall their baby food from the market after the first consumers' reports of finding glass in the products. I objected to this action because Detroit District had considerable knowledge of the

operations of Gerber Products Company and saw no reasonable way in which glass could be present in large numbers of jars as were being reported by the consumers.

We made a decision one afternoon, that very afternoon to collect samples of two thousand jars in each Minneapolis , Chicago, and Detroit Districts and to examine them for glass. As I recall, we found one tiny speck of glass on the shoulder of one jar from those examinations, and it was with that information that the decision was made not to request Gerber Products Company to recall their products. Some months later, Bill McKinley, the president of Gerber Products Company, personally and publicly thanked the agency for its responsible action during this glass scare with their baby food products.

On September 30, 1986, the Central States Association of Food and Drug Officials (AFDO) sponsored a one-day seminar entitled "Response to Tampering of Food and Drug Consumer Products." This conference was held at Toledo, Ohio, and was attended by over six hundred persons mostly from the regulated industries. The proceedings of the conference were distributed nationwide and had nationwide interest.

I hope the copycat tampering episode with food and drug products will not happen for some time again because most articles are now packaged or sealed in tamper-evident containers and because the public is well aware that making false claims of tampering may cause them to be sent to prison.

RT: Well, Al, you've covered several of these kinds of tamperings. Were there others that come to mind?

AH: Yes. In May of 1986, the Upjohn Company was the subject of protest from a number of people who were objecting to Upjohn's recent distribution of a morning-after birth control pill and were demonstrating against the company. Our Grand Rapids resident post received an anonymous telephone call from an individual who reported

that they had injected cyanide in some containers of Kaopectate in the Grand Rapids area. So the information was called into Detroit, and I made the decision that Detroit would send its investigators out to visit the drug stores in the Grand Rapids and Kalamazoo area to collect samples of Kaopectate. Our investigators visited over three hundred stores and collected over 2,600 containers of Kaopectate for analysis in the laboratory. These containers were analyzed and found not to contain any cyanide. So the matter was closed, and no further announcement was made of this incident.

The chairman of the board of the Upjohn Company sent Commissioner Frank Young a letter in June of 1986 thanking FDA for the prompt action that had been taken in the handling of this tampering incident and for the manner in which it had been handled with the Upjohn Company, the media, and the concerned public.

RT: Al, while you were in the Detroit District area, what kind of relations and cooperative activities was your office involved in with the member states of that jurisdiction?

AH: We had a number of excellent relationships with the officials in both Michigan and Indiana. We had always worked very closely with the state medicated feed officials in the regulation of medicated feed industry. We'd also worked closely with the dairy inspection personnel in both states and the food inspection personnel in both states.

I was asked at one time and I did testify before the Michigan state legislature on whether or not they should permit the substitution of generic drugs for brand name drugs in their state drug compendia operations.

On another occasion I briefed the Indiana governor about the agency's position on Laetrile as an anti-cancer drug. The governor after this briefing did in fact veto the legislation that had been passed by the state legislature in Indiana.

I also on several occasions arranged for testimony by Dr. Albert Kolbye and other FDA personnel before the Michigan state legislature concerning the action levels that had been established by the Food and Drug Administration for PBB in fat of meat, milk, and eggs. Those were all very hazardous kinds of assignments because Dr. Kolbye had been threatened several times because of his evaluation of the relative toxicity of PBB and other drugs. On each occasion we had to arrange for escort by personnel from the Michigan State Police to protect Dr. Kolbye when he came to testify at these hearings. We actually had as many as ten security officers present during one of the hearings before the Michigan Department of Agriculture concerning PBB.

RT: Dr. Kolbye was a headquarters person from Foods.

AH: Dr. Kolbye was the head toxicologist and scientist from the Center for Foods and was an expert on the toxicity of trace levels of chemical contaminants of various kinds.

I also had the good fortune as district director of Detroit to represent the agency on June 18, 1981, as a part of a small group of Food and Drug officials and relatives of Dr. Harvey Wiley to participate in the dedication of the Harvey W. Wiley Historical Roadside Marker. The Wiley roadside marker is located along Indiana State Highway 56 about three to five miles west of the village of Hanover, Indiana. Dr. Wiley was born at a nearby farm and began his academic training at Hanover College in Hanover, Indiana. The roadside marker was funded by funds from the Association of Food and Drug Officials (AFDO).

(Interruption)

RT: Dr. Harvey W. Wiley was of course considered the father of the Food and Drug Administration for his early work in the Bureau of Chemistry in the Department of Agriculture, the forerunner of the present Food and Drug Administration.

We've covered a lot of the experience you had in Detroit. What was your next assignment?

AH: I was appointed as the director of the Office of Enforcement at Headquarters, which is a part of the Office of Regulatory Affairs at the Parklawn Building. I was appointed to this position in November of 1988.

The Office of Enforcement included FDA's Division of Compliance, Management & Operations, which conducts the agency's final review of proposed enforcement actions; the Division of Compliance Policy, which coordinates the development and compilation of the agency compliance policies; and the Medical Products Quality Assurance staff, which coordinated the quality assurance reviews of drugs and medical devices purchased by the federal and state governmental agencies. The Medical Products Quality Assurance staff was assigned to my office in approximately 1990 and replaced the regulations of preparation office for the agency as a part of my responsibilities.

I had approximately fifty to fifty-five senior Food and Drug officers as a part of my staff at the Office of Enforcement. We conducted and I chaired many ad hoc enforcement meetings where the agency was evaluating investigational information or other information in making a determination of whether the agency should expend further resources on the investigation in terms of investigation, referral to the Department of Justice for Grand Jury investigation, or to close the investigation based on the information that was available at that time.

RT: In that role, were you working for the associate commissioner for Regulatory Affairs?

AH: Yes.

RT: Would that have been Paul Hile?

AH: No. I was actually selected and appointed by John Taylor as the associate commissioner for Regulatory Affairs. He was replaced very shortly after I arrived by Ronald G. Chesemore.

But the director of the Office of Enforcement was clearly the focus point of review and decision making when it came to many compliance matters facing the agency. I frequently started the day with four to six appointments scheduled per day and would usually have one change with, and about once a week a late afternoon meeting with the commissioner or some other high-level official of the agency.

The ad hoc committees reviewed all of the reports of finding of a submission of false information in new drug applications for the approval of generic drugs. We referred these investigations on to the Department of Justice and eventually to the U.S. Attorney's Office in Baltimore. We had at various times twelve to sixteen persons assigned to the U.S. Attorney's Office to work with the U.S. Attorney in conducting those Grand Jury investigations on the submission of false information in the generic drug applications.

The generic drug scandal was really a major concern for the agency and for Congress. Congressman (John) Dingell was responsible for the agency establishing the Office of Criminal Investigations with criminal investigators armed with firearms. The generic drug investigation I think eventually resulted in the prosecution of approxi-

mately twenty-five persons for having submitted false information to the agency in these generic drug applications.

RT: The Office of Criminal Investigations personnel were authorized to carry firearms. Did the cadre of people that went into this unit primarily come from the Food and Drug Administration or from other agencies?

AH: The cadre of people that went into the Office of Criminal Investigations were persons who were a part of a classification series as criminal investigators and as such they came from other agencies such as the FBI or the Secret Service or the Drug Enforcement Administration (DEA).

I was part of the group that reviewed the panel of candidates for the director of the Office of Criminal Investigations. But once that person was selected by Mr. Chesemore, I really had no role whatsoever in the operation of that Office of Criminal Investigations.

RT: Aside from this area, what were some of the other major problems you dealt with?

AH: The Office of Enforcement was responsible for setting up and scheduling a monthly enforcement meeting for Dr. Kessler when he came on board with the agency. We would pick an enforcement topic of some type and then have the field offices or a field office and the center office responsible for that particular activity fully brief the commissioner on the complexity of the enforcement matter that we were dealing with.

Dr. Kessler, of course, took the action very shortly after he arrived of seizing orange juice because it was labeled as fresh, when in fact it frequently was forty to fifty days old. Dr. Kessler also took strong enforcement action regarding proper labeling

of products with no cholesterol claims and low fat claims which obtained credibility for Dr. Kessler as an enforcement official.

One of the enforcement meetings that we set up was with the Center for Foods on the subject of adulterated orange juice. We had encountered a firm in Chicago several years before which had been found manufacturing orange juice, alleged orange juice, from water and citrus pulp wash and beet sugar and other ingredients to make the product look like it was reconstituted orange juice. We'd had an inspector at Detroit which had found a drum of citrus pulp at a dairy manufacturing plant during a routine inspection of the dairy plant and raised questions as to what the citrus pulp was used for. He was told it was used to manufacture orange juice which, of course, opened an investigation for us there.

But, anyway, at the briefing of Dr. Kessler, we had our field people in and we had the scientists in, and we discussed the problem with the fact that we did not have good analytical methodology to determine when a product was made from legitimate reconstituted orange juice or when it was made with citrus pulp wash and other ingredients.

I prepared a chart listing the names of a number of potential target firms that we might like to investigate, whereupon Dr. Kessler walked into the room with a reporter who allegedly was there to take silent television tape of our meeting. We had to quickly cover the names of the firms on that chart, and I proceeded to discuss in very generic, in general terms the nature of our investigation.

But, anyway, after the reporter left, we had identified a total of about two thousand firms in the United States that manufactured reconstituted orange juice. One of our investigators who had been involved in some of these investigations estimated that 10 percent of these firms were in fact preparing adulterated products on the market.

The problem that we faced then was, well, what are the names of those two hundred firms? This investigator called some food broker friends of his that he had met

through his years as an investigator and obtained the names of seventeen firms that day as potential targets for investigation. These food brokers were basing their information, of course, upon the prices that they had been offered reconstituted orange juice for sale in the stores that they were buying food products for. It was a very interesting situation, and the agency did in fact successfully investigate and prosecute a number of firms that manufactured phony orange juice.

RT: In the role of directing the enforcement activities and decisions, have you encountered any contacts or oversight hearings by the Congress relating to these matters?

AH: Yes, I have, and by way of background, I should explain that during my second year as an FDA inspector in Chicago, I was troubled by the fact that I was unable to determine the ingredients that were being used in the manufacture of Kool Aid. I could enter the plant, and I could conduct the inspection, and I could weigh the finished packages, but I was unable to determine exactly what ingredients were being used to manufacture that product, and that always troubled me. A complete inspection of records had been granted to the agency in prescription drug manufacturing plants and in controlled medical device manufacturing plants, but we had never had this broad inspection of records authority in any other one of the products regulated by the agency.

I was one of a group of FDA employees, including Commissioner Kessler and General Counsel Margaret Porter, who testified before the Subcommittee on Health and the Environment of the U.S. House of Representatives on energy and commerce on January 17, 1991.

The committee was reviewing legislation which would have given FDA additional enforcement authority including recalls, embargo of suspected violative

products, subpoena of records, civil money penalties, full records inspection, and copying of records.

The Democratic party was the majority party at the time in the House of Representatives, and the Republicans were in charge of the executive branch of the government and as such supervisor of Dr. Kessler.

I had drafted testimony in support of the additional enforcement authorities, but this was summarily rejected by reviewers at higher levels in the Department of Human Services. This left Commissioner Kessler in the position, I think, of wanting to basically support enhanced enforcement authorities sought by his subordinates but which was disapproved by his superiors. A decision was made at the eleventh hour not to submit any written statement to the committee, but to have three field managers and myself answer questions about the need for additional enforcement authorities. When asked, we each dutifully described situations in which we could have more effectively protected the public with these enhanced enforcement authorities.

Congress took no action on this bill at that time.

RT: Al, do you recall who was the sponsor of that particular proposal in Congress?

AH: No, I don't recall who was the sponsor. I know that Congressman Waxman was the chair of the committee at that time. I should also note that J. Dennis Hastert was a minority member of that particular House committee, and he now is the speaker of the House of Representatives.

At the request of a staff member of the Senate Committee on Health, I testified a second time in support of additional enforcement authorities (S. 2135) for the Food and Drug Administration in May, 1992. This was a most unusual situation, because I had already submitted my retirement papers and was on annual leave pending my final separation from the agency.

I had been collecting information at the Office of Enforcement for a number of months of specific investigational situations where additional enforcement authorities could have been useful to the agency. However, none of these reports, nor the advice of the Office of General Counsel, were available to me because I could not testify as a representative of the Food and Drug Administration and with the approval of the Food and Drug Administration. So I was testifying before the committee as an individual.

RT: This was before you were officially separated, or was it?

AH: This was before I was separated.

I drafted the testimony as my wife was driving the car on the road back from Wisconsin to Washington, D.C. As I recall, the enhanced enforcement authorities were again opposed by the food industry and supported by the American Association of Retired Persons and by the Public Citizens Research Group as they had been the previous year.

I failed again to convince Congress of FDA's need for authority to review and copy records and to temporarily embargo regulated products believed to be adulterated or otherwise in significant violation of the law. Knowing the history of major changes in the food and drug laws, I suspect there will have to be a major disaster with either microbiological or chemical contaminants with a food or a cosmetic product before industry and the Congress will ever agree to grant additional enforcement authorities to the agency.

RT: Well, Al, in your rather extensive and varied career, you've served under a number of commissioners of the agency. Do you have any impressions that you'd like to share with regard to some of their regulatory views or issue-solving patterns?

AH: During my career with the agency, from the period from 1957 to 1992, I worked for ten of the sixteen persons who held the position as commissioner of Foods and Drugs from the period from 1906 to 1992. I used to sit in the commissioner's conference room and marvel at the fact that I had worked for nine of the persons whose pictures were hung around the wall of the commissioner's conference room. Many of these commissioners, of course, served only two to three years. While others like Dr. Frank Young and Dr. David Kessler for five or six years.

Dr. Young was particularly impressed and persuaded by his experience with the persons with Acquired Immune Deficiency Syndrome (AIDS). These persons were well organized, they were intelligent, they were articulate, and because of their affliction with the AIDS virus were prepared to take unusual risk with investigational drugs. I know Dr. Young had some very personal and very terrifying experiences in appearing before some of the AIDS activists, and I believe that his experiences during that period had caused the agency to change its attitude somewhat toward the release of investigational new drugs and treatment of persons with AIDS or cancer or other serious conditions with these investigational drugs.

I was also impressed with Dr. Kessler's attention to detail and willingness to spend the time to develop a clear understanding of the agency's position and policy on the matters that we were considering. Dr. Kessler was very supportive of all of our activities in the enforcement area.

I was always amazed at how these many persons with backgrounds in medicine and science could so quickly adopt and conform to the traditional attitudes and philosophies of the Food and Drug Administration.

FDA policies and precedents and traditions are based on the work of Dr. Harvey Wiley and others at the time of the passage of the Food and Drug Act of 1906. These persons in turn influenced the people who were with the agency when the Federal Food, Drug and Cosmetic Act was enacted in 1938. My own training and experience was

influenced and in part conducted by persons who had been with the agency when the Federal Food, Drug and Cosmetic Act was passed in 1938. I think many people from outside the agency probably do not appreciate the long history and manner in which the precedents and policies of the agency have been passed from one generation to the next generation.

One of the things that I was proud to accomplish during my tenure as a director of the Office of Enforcement was to have the agency recognize that promoting honesty and fair dealing in the marketplace was a major responsibility of the Food and Drug Administration. The 1935 Senate Committee Report on the Federal Food, Drug & Cosmetic Act stated in part that the mission of the Food and Drug Administration is to protect the public health and to promote honesty and fair dealing in the marketplace. The economic violations such as net weight, fat content of butter and cheese, percentage of fruit in jams and jellies were an important part of the programs of the agency from 1906 through the 1950s.

The public concern about pesticide residues in food and food additives in the 1950s was a major concern to the public. Effectiveness of drugs was also a major concern of the agency in 1960 and '62. As a result, there was a major shift in the agency resources from the economic kinds of considerations to the public health aspects of our mission. And as a result, promoting honesty and fair dealing was largely lost from recognition of our mission of the agency. I was especially proud that we were able to get this responsibility recognized as one of the two key parts of our mission statement during my tenure there.

RT: In regard to promoting fair dealing and so on, there's another area I'm sure you've had some experience with. That's fraud in the quackery field.

AH: The regulation of health claims for vitamins, minerals, and special dietary foods and foods in general have been a problem for FDA regulatory officials for over one hundred years. Dr. Wiley was concerned about the safety of saccharin, preservatives in foods, food additives, and health claims for foods.

In 1962, the agency published proposed revisions of the twenty-one-year-old regulations governing foods for special dietary use. Commissioner Larrick said the average consumer of vitamin and mineral supplements is not well informed about the need for supplementing his diet with these articles. The feeling was that many consumers were being misled to believe that their diets were inadequate and that a great many conditions of ill health could be the result. Another problem was that many of the dietary food supplements contained ingredients which had no known nutritional value whatever and/or it contained high dosages of Vitamin A or Vitamin D which could produce adverse health effects. The agency received over 54,000 comments and objections to the 1962 proposed dietary food regulations. The health food industry had a very well organized communication network and lobby support group.

(Interruption)

RT: OK, Al.

AH: This is continuing on special dietary foods.

The agency published final special dietary food regulations in 1966. These regulations placed restrictions on low calorie and reduced calorie claims, established eight classes of foods that could be fortified with vitamins and minerals, and placed limits on the nutritional elements that could be added to fortified foods, and prohibited the promotion of "shot gun" vitamin and mineral preparations containing ingredients with no known dietary value.

These final regulations were stayed to permit resolution of twenty-three issues. Subsequently, testimony was taken from 138 witnesses. These proceedings occurred during a period when the consensus of informed opinion was that the average person could consume a balanced diet by eating a variety of wholesome foods available at the grocery store.

Subsequent studies showed that 46 percent of the low income and 18 percent of the upper income children in New York City suffered from low levels of Vitamin A. Eight percent of the low income and 3 percent of the upper income children were found with low hemoglobin levels, and about 25 percent of the lower and upper income children ages seven through twelve were found with diets deficient in Vitamin A and Riboflavin.

These reports awakened the public and the agency to the fact that significant segments of the population were in fact suffering from malnutrition. A White House Conference on Food and Nutrition was held in December of 1969 which resulted in the preparation of a 341-page report with recommendations, some of which were in conflict, unclear, and others unrealistic.

The new concept involved the development of nutritional guidelines and the second concept involved the nutritional labeling of foods. Interestingly enough, we've had nutritional labeling for animal feeds for over fifty years.

A Consumer Affairs Officer, Lilyan Goosens from Indianapolis, and I held the first public hearing at Purdue University with consumers on various proposals for nutrient labeling of foods.

(Interruption)

RT: OK. Now continuing.

AH: OK. FDA has now developed nutritional labeling systems for all food products, and the public recognizes that diet and physical exercise may have a significant effect on health. But we as a society and as a regulatory agency are still struggling with proper labeling of the various alleged health benefits of botanicals, herbs, and components of food.

I recently received a notice of a conference on nutraceuticals, which were described as being a $65 billion global market for foods as medicine. They planned to discuss at this conference the possible use of nutraceuticals for anti-aging, anti-cancer, anti-fatigue, arthritis, depression, mental acuity, learning and memory, diabetes, dyslexia, Alzheimer's disease, and obesity. To an old retired Food and Drug official, this sounds a lot like health fraud.

RT: Well, Al, do you have any other general comments you'd like to include in this tape.

AH: I think few people outside of FDA headquarters appreciate the impact of the outside influences on FDA decision making, planning, and operations. It was not unusual for FDA personnel to testify before fifteen to twenty congressional committees in one year when I was at the agency. Each of these hearings required resources from the Office of the Commissioner, Office of General Counsel, Office of Legislative Services, one of the product centers, and frequently the Office of Regulatory Affairs.

Likewise, investigations by the General Accounting Office (GAO) required manpower support to obtain the desired information and to respond to the findings and recommendations of the General Accounting Office.

Other areas that required resources include responding to freedom of information requests (about 1 percent of the agency's resources), adverse drug and device reporting systems, working with and responding to requests from state agencies for assistance,

et cetera, et cetera. All of these functions are important, but they, in one way or another, are taking resources away from the primary responsibilities of the agency of new product review and inspections and sample analyses of products in the marketplace.

Lastly, I think the agency is grossly understaffed to handle the many and various responsibilities assigned to the Food and Drug Administration. Many emergencies such as infant formula recalls, bacteria poisoning from canned foods, cyanide in analgesic capsules, large scale investigations of blood banks and generic drug companies all required major diversion of resources. Manpower can and always has been shifted from routine operations. But import shipments are still being offered at the port of entry on a daily basis, and the centers still must continue to receive, review, and act on new product applications as quickly as they are submitted to the agency.

RT: Al, you served a long career. Was there any particular issue or circumstance in the agency that led you to decide to retire when you did? Or were you just ready to do that?

AH: I went to Washington originally with the idea that I would probably stay approximately four years, which I did do. I worked very hard at my position in Washington and was usually in the office by 7:30 in morning until 5:00 or 5:30 at night, at which time I would take home one or two briefcases filled with files for review for meetings for the following day. It was with this experience and workload that I decided that it was time to give the opportunity for some younger persons to undertake the responsibility of the agency.

RT: Well, that sounds reasonable. We have the dates I guess, but do you recall the number of years you served?

AH: Thirty-five years.

(Interruption)

RT: In our earlier discussions, Al, I think you mentioned something about a possibility of an anniversary coming up for the Detroit District. Perhaps that would be worth including here.

AH: Yes. The Detroit District Office of the Food and Drug Administration will be celebrating its fortieth anniversary of existence on May 14, 1999. The Detroit building is unique in that it was the first building ever constructed specifically for the Food and Drug Administration. In all previous years, the agency had occupied offices in a federal building or a customs building or other building that might be rented to the government. I think one of the more interesting events in FDA history was the building of ten FDA district offices in the period from 1959 to 1964.

When we celebrated the twenty-fifth anniversary of the Detroit office, we invited Allan E. Rayfield, who had been the director of the Bureau of Field Administrations Operations during my early years with the agency. We asked Mr. Rayfield to speak to us at the celebration of the twenty-fifty anniversary of the Detroit building. Mr. Rayfield stated that he had personally searched sixteen cities for building sites during the 1950s and had in fact identified building sites in each of these cities for an FDA district office.

The first of these offices was of course built at Detroit. Mr. Rayfield had met in the offices of the General Service Administration in Detroit and had met with Arthur Pollack, who was a real estate investor in the City of Detroit. After some initial negotiations that nearly broke down, Mr. Rayfield and Mr. Pollack worked together to build the first FDA district office building. By training, Mr. Pollack was a civil

engineer, and Mr. Rayfield was a chemical engineer. Mr. Rayfield's son was a student architect and assisted his father and Mr. Pollack in the initial design of the Detroit district office building.

The Detroit district office building was named the George Potter Larrick Building in honor of the commissioner of Food and Drugs from the year of 1954 to 1965. The building was dedicated on May 14, 1959, and was initially staffed with approximately fifty-five personnel, which included the four inspectors that had been previously stationed at the resident post in Detroit.

The Dallas District office was opened later in 1959. A single resident inspector, Eugene Spivak, had previously been stationed at Dallas District and was included in the first staff of the district. New district offices were built following the Detroit model in Dallas, Cincinnati, Buffalo, Boston, Baltimore, Atlanta, Kansas City, Los Angeles, and last, Minneapolis. The Minneapolis building was completed in 1959.

If they are still alive, Mr. Allan E. Rayfield, Fred Garfield or Mr. Reo Duggan can provide more detailed and specific information on the historic nature of the building of FDA's field offices. These buildings were all privately owned and built for long-term lease by the government. We were fortunate to have a very long and very excellent relationship with the builder of the first building at Detroit, and I'm sorry to see this end of the use of this facility.

RT: Well, I want to thank you for this interview, Al, and we appreciate very much your participating in the Oral History Program for the agency.

AH: Thank you.

APPENDIX to Alan Hoeting Interview

DETROIT DISTRICT
A MODERN FDA FIELD OPERATION'S SILVER ANNIVERSARY
MAY 1959 to MAY 1984

There are two ways to commemorate an anniversary. One is to look back on the past -- the good old days or the bad old days, depending on the events and the individual point of view -- and express nostalgia for one or bitterness for the other.

The more fruitful approach is to look to the future, using the anniversary as a kind of magic mirror that reflects the past and reveals the future.

The 25th anniversary of Detroit District calls for the more fruitful approach because it represents one in a series of milestones on a road on which we have much farther to go than we have yet traveled.

A review of the past is in order but only in sofar as it helps us to draw a workable roadmap for future progress.

Edited by -

Dennis Fodale
Louis F. Schneider
Raymond Semplici
May 14, 1984

HISTORICAL DATA PRIOR TO THE OPENING OF THIS GEORGE POTTER LARRICK BUILDING IN MAY 1959

The first group of FDA inspectors were appointed in 1907. After a few weeks of training at the USDA Bureau of Chemistry in Washington, D.C., they were dispersed to their assigned duty stations. One man was assigned to each city, except for Boston and New York, which had two inspectors.

ODEN R. SUDLER, M.D., was the FDA Inspector assigned to Detroit. According in the 1910 inspectors manual, his address is listed as the Food and Drug Laboratory, Telegraph Building, Detroit, and his home address was 501 Woodward Avenue. In the 1911 Inspectors Manual, his office address was unchanged, but his home address was 142 St. John's Ave., Highland park, Michigan.

A laboratory was first established in Detroit in 1908. It operated until 1914 when it and six other small laboratories were closed in the interest of increased efficiency of the service. H. L. Schulz was listed as "Chief of Detroit Laboratory" and judging by the work reported accomplished in the annual report for FY 1912 (as compared with Boston which had four chemists) he was probably the only chemist in the laboratory.

During the first years of FDA operations, chemists reported to the Director of the Bureau of Chemistry and inspectors reported to Walter G. Campbell, Chief Inspector, in Washington, D.C.

After 1914, both inspectors and chemists were supervised by the chiefs of the Eastern, Central and Western Districts. By 1916, the Districts were further sub-divided into stations.

For example, the upper penninsula of Michigan was assigned to the Minneapolis Station while the rest of the State was assigned to Chicago Station for the period from 1920 to 1931.

Those serving this area from 1936 until the District Office Opened were:

1936: Victor G. Lapaiana, Resident Inspector
1944: Frank M. Hereford, Resident Inspector
1944: George W. Sooy, Resident Inspector
1945: Morris W. Thompson, Resident Inspector
1952: Melvin B. Kaump, Resident Inspector
1959: Theodore E. Herman Resident Inspector
1959: William Jackson, Resident Inspector
1959: Irving Pollack, Resident Inspector

DETROIT DISTRICT WHO'S WHO LIST

District Directors

George T. Daughters	1959 to 1967
Thomas W. Brown	1967 to 1970
Alan L. Hoeting	1970 to Present

Deputy District Directors

George R. Fowler	1960 to 1968
Aurthur J. Beebe	1968 to 1970

BRANCH DIRECTORS

Investigations

Theodore C. Maravigla	1959 to 1961
Thomas W. Brown	1961 to 1964
Hayward E. Mayfield	1964 to 1965
Aurthur J. Beebe	1966 to 1968
Clifford G. Shane	1968 to 1970
Eugene S. Spivak	1971 to Present

Laboratory

Howard M. Bollinger	1959 to 1960
Thomas J. Welch	1960 to 1968
Anthony C. Celeste	1968 to 1970
Louis F. Schneider	1971 to Present

Compliance

John P. Dempster	1972 to Present

Pesticide and Industrial Chemicals Research Center

Stephen M. Walters	1981 to Present

Administrative

Robert J. Rolfsen	1959 to 1965
Sadonna C. Davis	1965 to 1970
Gustav A. Butterbach	1971 to 1974
James R. Pendergraff	1974 to 1976
Mary L. Harkins	1976 to 1981
James D. Dunlak	1981 to Present

SUPERVISORS

Investigations

J. Joseph Hanagan	1959 to 1960
Irvin Pollack	1959 to 1964
Nathaniel L. Geary	1962 to 1967
Charles L. Dickinson	1959 to 1972
J. Donald Sherry	1964 to 1969
Nicholas L. Parsons	1966 to Present
John H. Kelso	1968 to 1974
John A. Hamilton Jr.	1967 to 1968
John W. Davis Jr.	1970 to 1984
Raymond H. Stutzman	1972 to Present
Romualdas Korsakas	1973 to Present
Kenneth C. Shelin	1972 to 1976
Joseph Buran	1972 to 1976
David M. Kaszubski	1976 to Present
Sandra L. Williams	1977 to Present
Raymond K. Hedblad	1977 to Present

Laboratory - Chemical

Garland L. Reed	1959 to 1962
Loren Y. Johnson	1962 to 1964
Joseph C.M. Griffin	1962 to 1968
James T. Haigh	1963 to 1969
Abraham I. Kleks	1966 to 1967
James H. Burkel	1969 to 1973
John H. Turner	1969 to 1971
Garrett D. Salmon	1969 to 1980
Norbert V. Fehringer	1972 to 1973
Elizabeth Williams	1973 to Present
James E. Westfall	1974 to Present

Laboratory - Microbiological

Eric E. Batchelor	1967 to 1968
Ralph J. Kalinowski	1969 to 1970
Doyle Smith	1970 to 1972

Science Advisors

Dr. Davis F. Boltz, Ph.D.
Dr. Kenneth E. Stevenson, Ph.D.
Dr. James A. Howell, Ph.D.

Veterinarians

Max L. Crandall, DVM

Compliance Officers

A. Former

J. Thomas Welch
John J. Hanagan
Mervin H. Shumate
Edward R. Floyd
James C. Simmons
Gerald E. Vince
Carroll L. Dennis
Goodman C. Everett
William Schwemer
Judith A. Putz

B. Current

Raymond Semplici
Kenneth C. Shelin
Dennis P. Degan
John E. Klemmer

Consumer Affairs Officers

A. Former

Diane M. Place
Sandra L. Barwick (Simmons)

B. Current

Lilyan M. Goossens

Consumer Consultant

Mary Jane Bostick

SIGNIFICANT HISTORICAL EVENTS AT DET-DO

1962: BOTULISM FROM CANNED TUNA FISH.

March and April will be remembered as "tuna fish months" by many health officials throughout the nation. Three Detroit women were clinically diagnosed as victims of botulism following a luncheon.

Subsequent epidemiologic and laboratory findings found Clostridium botulinum, Type E, in commerically canned tuna fish as the causative organism.

This was the first outbreak of botulism from commercially canned products in 40 years. Detroit District Microbiologists were instrumental in the detection of the causative organism.

1963: CONTAMINATED SMOKED WHITE FISH CAUSE MICHIGAN COUPLE'S DEATH

In early October 1963 Detroit District received a report of the deaths of a Kalamazoo, Michigan couple, and smoked white fish was the suspected cause of deaths.

Investigation revealed that the couple had purchased the fish from an unknown source near Grand Haven, Michigan while on a fall color tour.

They placed the smoked white fish, which had been wrapped in white butcher paper, in the trunk of their car. They consumed the unrefrigerated fish on arriving home several days later.

They became violently ill and subsequently died. Detroit District Laboratory confirmed the presence of Botulism Type E Toxin in the remaining uneaten smoked white fish.

1963: SMOKED FISH PROCESSING REGULATIONS ESTABLISHED AFTER DEATHS FROM CHUBS

Two weeks following the contaminated smoked white fish incident in Kalamazoo, Michigan, Detroit District was alerted of illnesses and deaths in West Virginia and Tennessee related to the consumption of smoked chubs.

These chubs were processed by Darnbos Fisheries located in Detroit District. The chubs were packed in vacuum tight packages and had not been adequately refrigerated.

The Detroit District laboratory found Type E. Botulism Toxin, and subsequent investigation revealed the processing of the product provided inadequate protection from the fermentation of Botulism Toxin.

These incidences resulted in publication of regulations requiring specific processing procedures for smoked fish.

1964: BUILDING'S PARTIAL SECOND FLOOR ADDITION

The construction of the second floor over the garage began in 1964 and was occupied in 1965. This established the third laboratory (Lab C) and the district conference room.

1964: SALMONELLA FOUND IN COMMERCIALLY DRIED MILK

In October 1964 Detroit District Laboratory found Salmonella present in non-fat dried milk. This was the first time salmonella had been found in commercially dried milk.

1967: BOOZ, ALLEN AND HAMILTON MANAGEMENT CONSULTANTS

During 1967 and 1968, Detroit and Kansas City Districts were assigned the responsibility of working with Booz, Allen and Hamilton (management consultants) in developing a new scheduling and planning system for inspectional and laboratory activities.

Detroit District representatives were Raymond Semplici (inspection) and Ronald Moquin (laboratory). The entire pilot study was coordinated at headquarters by J. Paul Hile.

1970: DISCONTINUATION OF SPLIT-STATE COVERAGE

On April 1, 1970 Detroit District's jurisdiction of the northern part of Ohio was transferred to Cincinnati District, and Det-Do assumed responsibility for the entire states of Indiana and Michigan.

1971: AUTOMOBILE INDUSTRIES FIRST AUTO RECALL

Since the Environmental Protection Agency (EPA) was not experienced in recall procedures, Raymond Semplici, then Detroit Recall & Emergency Coordinator, was specially assigned to that agency for the purpose of assisting them in the initiation and monitoring to conclusion their first recall of automobiles, which occurred at the Ford Motor Company.

1973: MICHIGAN PBB PROBLEM

In 1973, large numbers of Michigan farm animals were exposed to a toxic chemical when polybrominated biphenyl (PBB), a fire retardant, was mixed with dairy feed. The ensuing adverse health effects on exposed animals, contamination of food derived from exposed animals, and human consumption of PBB-containing food has been categorized as the worse agricultural contamination disaster ever in the United States. The incident resulted in the quarantine of over 570 farms and in the destruction of over 34,000 cattle, 3800 hogs, 2200 sheep, 1,500,000 chickens, about 5,000,000 eggs and large amounts of milk, butter and cheese. Lawsuits totalling millions of dollars were filed against Farm Bureau Services and Michigan Chemical Company concerning financial losses and health problems alleged to have been caused by PBB.

Michigan Chemical Co. closed its plant in St. Louis, Michigan and Farm Bureau Services eventually declared bankruptcy. Both firms were prosecuted by FDA for adding a poisonous substance to feed.

The public became very concerned about the safety of the meat and milk supply in the State of Michigan. As a result, the Michigan Legislature lowered the tolerances for PBB in milk and meat, and initiated a state wide test of a biopsy from all cull dairy animals born before January 1, 1976.

Long term evaluations of the potential health effects of individuals exposed to PBB in 1973 and 74 were sponsored by FDA, the National Cancer Institute and the Center for Disease Control in cooperation with the Michigan Department of Public Health. The National Cancer Institute and National Institute of Environmental Health Services have been involved in bioassay and toxicological tests with PBB.

1973: DETROIT DISTRICT MICROBIOLOGY LABORATORY CLOSED JULY 1, 1973

This laboratory was a Clostridium botulinum testing facility for Detroit, Buffalo, Cincinnati and Chicago Districts.

The district had an animal laboratory with a complete separate environmental control ystem, isolated from the rest of the district laboratories.

Expertise with C. botulinum analysis dated back to the 1963 food poisoning caused by A & P canned tuna fish. At that time, bacteriologist Ralph Johnston was involved in the analysis as well as method development leading to an FDA Award of Merit, and two papers published in scientific journals in collaboration with John Feldman and Rosemary Sullivan Bringman.

In 1968, a botulism food poisoning which resulted in one death, occurred in Western Michigan. The sample of fresh chickens was picked up and analyzed by Microbiologist Virginia Hatzenbeler over one weekend and C. botulinum, type B, toxin was determined.

The botulism expertise as a laboratory was further tested by the Bon Vivant botulism case and Stokely-Van Camp green bean suspect botulism food poisoning in 1971.

Detroit District was a lead laboratory in initiating analysis for C. botulinum using the canned food method rather than the direct toxin test in mice.

In 1971, Microbiologist Gary Dykstra initiated research in C. botulinum toxin differentiation using a gas liquid chromatographic technique. He established a good exchange relationship with the on-going research in C. botulinum toxin recovery at Michigan State University Department of Food Science, Food Microbiology Laboratory. This work was continued in consultation with the Detroit District Microbiology Science Advisor, Dr. Kenneth E. Stevenson, Ph.D.

In 1971, Detroit District Microbiology Laboratory did the initial analysis on the Abbott Labs large volume parenterals involved in adverse reactions and septicemia, reported by a Detroit area hospital. As a result of this experience, the Abbott LVP Six Month Production Monitoring Program was initiated using the new USP approved millipore filter method.

In the interest of improving the efficiency of the microbiological activities in Region V, the Detroit District microbiological section was transferred to Cincinnati District on August 5, 1973.

1973: TRANSFERS TO THE CONSUMER PRODUCT SAFETY COMMISSION

Fourteen Detroit District employees were transferred to the Consumer Product Safety Commission by transfer of function on July 1, 1973. The new agency was created by the Consumer Product Safety Act. CPSC was assigned responsibility for enforcing The Flammable Fabrics Act, the Poison Prevention Packaging Act, the Federal Hazardous Substances Act and the Act of August 2, 1956 which prohibits the transportation of refrigerators without door safety devices.

1975: VETERAN ADMINISTRATION NURSES ACCUSED OF MURDER

Beginning 8-16-75, local newspapers began carrying stories of an FBI investigation of 7 patients deaths due to respiratory arrest at a local V.A. Hospital.

FDA involvement began when it was learned that all patients involved were receiving intraveneous solutions at the time of their respiratory arrest.

The investigation showed that the respiratory arrests probably were not manufacturer related. Garrett D. Salmon, Supervisory Chemist obtained a search of the world literature and located an analytical method for determining the presence of curare in animal tissues and specimens. Milda Walters, Drug Specialist Chemist validated methodology for muscle relaxants, found curare in patient specimens and I.V. tubing, and she was a government witness for the FBI at the murder trial.

1975: FIRST CRIMINAL SEARCH & SEIZURE WARRANT

On 9-30-75, Laetrile (Amygdalin) for the treatment of cancer was seized on-site at a local health food distributor. In September of 1976 the firm and its principal officers were convicted of criminal violations of the Act.

1976: PROSECUTION & DISQUALIFICATION OF A CLINICAL INVESTIGATOR

A landmark prosecution case for Detroit District and a particularly difficult investigation began in 1976 and ended in 1979 with the conviction of Jerome J. Schneyer, MD, for his failure to establish and maintain investigational new drug records with intent to defraud and mislead, and his failure to permit FDA Investigators access to such records. Dr. Schneyer had been falsifying blood chemistry records in an investigational new drug study and because of his refusal to turn over patient records the evidence was turned over to a Grand Jury. He recognized the futility of his position during the Grand Jury testimony and negotiated a plea bargain agreement which resulted in a $12,000 fine and a probationary sentence requiring some community service for two years. Dr. Schneyer was also disqualified by FDA as a drug investigator.

1977: LARGEST BOTULISM OUTBREAK IN U.S. HISTORY

In March, 1977, Detroit District Supervisory Investigator David Kaszubski and other employees were involved in the investigation of the largest botulism outbreak in United States history. A total of 59 cases of botulism were caused by the use of home canned jalapeno peppers at Trini and Carmen's Restaurant in Pontiac, MI. Due to some excellent work by the Oakland County Health Department, the source of the outbreak was quickly determined after the first cases were diagnosed. The restaurant was closed and all of the suspected jars of jalapeno peppers were removed from the restaurant. Fortunately the quick action by the Health Dept., the Center for Disease Control, and the FDA resulted in no fatalities from the outbreak and a prompt cessation of the source of the outbreak. The restaurant was subsequently prosecuted and fined for the illegal use of home canned food.

1979: THREE MILE ISLAND NUCLEAR EMERGENCY

Detroit District Investigation Branch supervised the packaging of 93,314 bottles of Potassium Iodide Solution for shipment to Harrisburg, PA. for possible emergency use in connection with the Three Mile Island Nuclear Emergency.

Parke-Davis and Company maintained a staff of 40-60 persons working at their plant around the clock on the packaging operation from 4:30 pm., 4-1-79 until the packaging was completed at approximately 1:00 am., 4-3-79. The Potassium Iodide was flown by a chartered airplane from Detroit to Harrisburg.

Parke-Davis made no charge to the government for the labor, facilities, equipment and packaging materials utilized in connection with the project.

DET-DO Laboratory analyzed samples of the solution and found an average of 99.8% USP potency. FDA and Parke-Davis received excellent media coverage from TV and radio stations. An article in the DETROIT FREE PRESS on 4-4-79 bore the headline: "U.S. and Private Effort Produce Nuclear Antidote".

Mr. Hoeting visited the Parke-Davis plant on 4-3-79 to express the District's appreciation of the effort made by Parke-Davis to package the drug. The Parke-Davis exercise was unique in that the product was packaged in the Parke-Davis plant for FDA with the FDA "man-in-the-plant." FDA Investigators signed the final quality control release and production records.

1980: PESTICIDE AND INDUSTRIAL CHEMICALS RESEARCH CENTER (PIRC)

This Center was established at Detroit District to develop and improve analytical methodology and instrumental techniques, and to use these methods and techniques in conducting investigations to determine the existence of new and/or unusual potentially hazardous residues of pesticides and industrial chemicals in foods, feeds, and related materials. The Center is staffed with a Director, and four full-time research chemists.

This Research Center is one of seven Field Office Research Centers developed to upgrade the quality of field science activities.

1983: CRIMINAL SEARCH & SEIZURE WARRANTS AT THREE LOCATIONS

Detroit and Cincinnati Investigators, accompanied by U.S. Marshals, executed simultaneous Search and Seizure Warrants at facilities operated by Brant Pharmacal Corporation in Maybee, Michigan, Temperance, Michigan, and Northwood, Ohio., on March 2, 1983.

Twenty million capsules and tablets of counterfeit and misbranded OTC drugs with an estimated value of $3 million were seized at Maybee and Northwood along with records, packaging and labeling equipment, and packaging materials.

About two cubic yards of cocaine substitutes with an estimated retail value of $100,000 were seized at Main Labs in Temperance, MI. along with records and literature.

The firm and its principal officer pleaded guilty on 3-21-84 on charges of delivery of fradulently misbranded drugs. The guilty pleas were part of a plea agreement which limited the term of imprisonment to one year and provided that the defendant cooperate with FDA and refrain from future sales of illegal counterfeit drugs and cocaine substitutes.

1984: FIRST CFSAN APPROVED CRIMINAL SEARCH & SEIZURE WARRANT

On 2-2-84 a team of 13 FDA personnel and one U.S. Marshal simultaneously searched three buildings of Michigan Pharmacal Corporation in Ferndale, Michigan for B-15 Tablets which the firm reportedly concealed from FDA during a voluntary destruction of B-15 on 12-2-83.

Seized were 11,821/50 tablet bottles of B-15 (calcium pangamate) with an estimated value of $40,000.

1984: OTC LOOK-ALIKE DRUGS SEIZED IN INDIANA

On 2-17-84 Detroit Investigators and a U.S. Deputy Marshal seized OTC Look-Alike drugs with an estimated retail value of $84,000 at Body Dynamics, Inc. of Indianapolis, IN.

Also seized were unapproved new drug formulations containing caffeine, phenylpropanolamine, benzocaine, glucomannan, kelp, bee pollen and other ingredients.

FDA AWARDS OF MERIT - INDIVIDUAL

Year	Recipient	
1964	Ralph W. Johnston	For microbiological identification of Clostridium botulinum, Type E, in canned tuna fish.
1975	Norbert V. Fehringer	For exceptional analytical performance demonstrated during the investigation of the Michigan PBB Problem.
1980	Eugene S. Spivak	For sustained superior performance in maintaining high morale and productivity in Investigations Branch.
1982	John W. Davis, Jr.	For outstanding contribution to FDA Programs covering Medicated Feeds, Illegal Residues in Meat and Poultry, and Federal and State Cooperation.
1982	Francis L. Barnes	For significant contributions to implementation of low acid canned food regulations, FAO Food Inspection Manual, and proposed Infant Formula Regulations.
1984	Louis F. Schneider	For strengthening analytical chemistry and research management in FDA.
1984	Dennis P. Degan	For brilliant performance in the preparation and management of complex regulatory cases.

FDA AWARD OF MERIT - GROUP

1983	Detroit District Employees	For exceptional performance in the management and rapid implementation of the recall of SMA Nursoy Infant Formula.
1984	District Employees	For exceptional performance during the investigation and seizure of a large quantity of look-alike drugs and cocaine substitutes.

FDA COMMENDABLE SERVICE AWARD - INDIVIDUAL

1976	John L. Kunkel	For identification of potential health hazards at community canning centers which focused nation wide attention on this problem.
1980	Dennis E. Swartz	For superior performance in FDA's Field Radiological Health Program which enabled Detroit District, Region V, and Regional Operations to reach priority goals.
1981	Romualdas A. Korsakas	For sustained superior performance in managing special projects and activities.

FDA COMMENDABLE SERVICE AWARDS GROUP

1974	Data Processing Unit	To Data Processing Unit for efficient operation enabling district managers to receive current reports for better management of available manpower, money, and other resources.
1975	Detroit District	For outstanding performance demonstrated during the investigation of the Michigan PBB problem.
1980	Investigation Branch	For sustained superior performance and productivity over a five year period.

FDA COMMISSIONER'S SPECIAL CITATIONS

Year	Recipient	
1974	Joseph P. Hile & Detroit District	For outstanding performance, initiative and resourcefulness in safeguarding the welfare of the american public which has brought tribute to the FDA and Federal Service.

1980	R.A. Korsakas	For contributions to and support of the Agency's efforts in dealing with the illegal use of diethylstilbestrol that occurred in 1980.
1980	John W. Davis, Jr.	For overall management of the 1980 DES Investigation.
1980	Raymond Semplici	For processing the regulatory aspects of the 1980 DES Investigation.
1980	Timothy G. Johnson	For coordination and reporting of the progress on the 1980 DES Investigation.
1982/3	Detroit District	For uncommon dedication and effectiveness in protecting Public Safety during the 1982/83 product tampering emergency.
1983	N. L. Parsons	For training over 200 persons in cardiopulmonary resuscitation and successful application of this procedure to a drowning victim.

DHEW/DHHS REGION V AWARDS - SUPERIOR SERVICE

Year	Recipient	
1979	Nine Detroit Employees	For the capable management of the emergency packaging and shipment of Potassium Iodide Solution for possible use to protect the persons living near the three mile island nuclear reactor.
1980	Eight Employees Investigations Branch	For sustained performance in maintaining high morale and high productivity.

DHEW/DHHS REGION V AWARDS - REGIONAL DIRECTOR'S CITATION

1969	Diane McLane Place	For sustained high level performance in the administration of the Food and Drug Consumer Education Program.

1973	Raymond H. Stutzman	For efficient coordination of the combined staff of FDA, State and Local Health Officials during the emergency recall of mushrooms contaminated with Botulism organisms.
1973	John W. Davis, Jr.	For efficient coordination of the combined staff of FDA, State and Local Health Officials during the emergency recall of mushrooms contaminated with Botulism organisms.
1975	Sophie Romaskas	For contributions to the efficiency of the Agency, and commitment to the development of fellow employees and the Stay-In-School Program.
1975	Laboratory Branch	For exemplary performance in the development of analytical methodology to protect the public halth from PBB contaminated foods and providing outstanding support to state agencies in carrying out their duties.
1981	R.A. Korsakas	For sustained superior performance in the management of special projects and activities.
1981	Wallace M. Ribbron	For commitment to the development of youth and his continuing involvement in the community organizations which share this goal.
1981	Dennis L. Fodale	For sincere and dedicated service as EEO Counselor.
1982	Lilyan M. Goossens	For innovative and sustained leadership in consumer education and FDA liaison with educators, legislators, and business representatives in Indiana.

DETROIT FEDERAL EXECUTIVE BOARD AWARDS

Year	Recipient	
1965	Ralph W. Johnston	Scientific Award for finding Salmonella in Non Fat Dried Milk (NFDM).
1972	Milda S. Bauza	Outstanding Federal Women's Award as official recognition and appreciation for her superior achievement in Professional/ Scientific Category as a Chemist (Drug Specialist) at FDA.
1973	Diane McLane Place	For outstanding and dedicated service as Chairperson Consumerism Committee of the Federal Executive Board.
1977	" " "	For outstanding and dedicated service as Chairperson for the Federal Women's Program Luncheon 5-4-77.
1980	" " "	For outstanding endeavors in compiling the Consumer Directory.
1981/3	" " "	For outstanding service to the Federal Executive Board as Chair of the Consumer Committee.
1982	Francis L. Barnes	The most outstanding Federal employee in the Professional/Scientific Category.

DETROIT DISTRICT CERTIFICATES OF APPRECIATION

Dr. George Whitehead, upon his retirement as Director of the Michigan Department of Agriculture.

Dean Lovitt, upon retirement as Director, Plant Industry Division, Michigan Department of Agriculture on 1-5-83.

Robert Brady, Special Assistant to the Commissioner, on 4-21-83 upon his departure from FDA.

Dr. E. C. Schall, Retirement as Indiana State Chemist and Seed Commissioner 7-15-83.

WSJV Elkhart, Indiana, for public service in support of Consumer Education on 1-3-84.

Allan E. Rayfield for his building of 1Ø FDA District offices including Detroit on 5/14/84.

Arthur Pollack for his support of the Detroit District during the past 25 years, on 5/14/84.