

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

**Interviewee:** William W. Goodrich

**Interviewer:** Ronald T. Ottes  
Fred L. Lofsvold

**Date:** October 15, 1986

**Place:** Rockville, MD

INTERVIEW INDEX

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

Date: 10/15-16/86

Place: Rockville, MD

Interviewee(s): William W. Goodrich

Address: 4833 30th N. Arlington, VA 22207

Last FDA Position: General Counsel of FDA

FDA Service Dates: 1939 - 1971

Interviewer(s): Fred L. Lofsvold & Ronald T. Ottes

Number of Tapes: 7

length: 390 minutes

---

Tape	Page No.	Subject
1-A	1	Goodrich background
	2	Office of Solicitor-Food & Drug Division, Dept. of Agriculture
	3	1938 Food & Drug Law 28 Hour law
	4	Food Standards-Walter Campbell
	5	Charles Crawford, Paul Dunbar Food Standards, continued
	6	Flour standards
	7	Food Nutrition Board, Elmer Nelson Farina-Quaker Oats
	8	Canned fruit standards
	9	Certification of colors
1-B	10	Special Dietary Foods Sanitary conditions of food manufacturing & storage
	11	World War II
	12	Koch trial-Al Loverud
	13	Asst. General Counsel, Food & Drug Division
	14	Insulin Amendment 1941
	15	Antibiotic Certification, Miller Amendment, Phelps-Dodge case
	16	Durham-Humphrey Amendment National Ass'n. of Retail Druggist (NARD) - John Dargavel
	19	Oleomargarine-Factory Inspection Amendment
2-A	19	More on Insulin law
	20	Drug Advertising-Wheeler-Lea Amendment

Tape	Page No.	Subject
	21	Elixer of Sulfanilamide
		Sulfathiazole-phenobarbital tablet
		mixup, New Drug Applications (NDA)
	24	Physician Desk Reference (PDR)
		Kefauver Hearings, 1962 New Drug
		Amendments
	25	Henry Welch
	26	More on 1962 New Drug Amenments
2-B	28	1962 New Drug Amendments cont.
	30	Koch Cancer treatment
	35	Hoxsey Cancer treatment
3-A	37	Hoxsey cont. John Hluska
	41	Krebiozen
3-B	48	Laetrile
	49	Scientology
	50	Dianetics-E-Meter
	51	Cal-Tex, Bireley Orange beverage
	52	Device cases-Urbeteit
	54	Dinsah Ghadiali's Spectrochrome
		Difco antitiotic Disc - A.M.P.
		suturing device
	55	Bacto Unidisk
	56	Cooper Device committee
4-A	56	Cooper committee cont.
	57	Congressman Rogers
	58	Goodrich enforcement philosophy
	60	Peanut butter standard
	64	Commissioners Campbell, Dunbar,
		Crawford
	65	Chemicals in foods
		Spans, Tweens
	66	Bread standards
4-B	67	Poisonous or deleterious substances
	69	Pesticides-spray residues
	70	1954 Pesticide Chemicals Amendment
	71	Rule making
	72	GRAS(generally recognized as safe)
		Delaney Clause
	73	Food Additive Amendment
	74	Secretary Flemming - Aminotriazole
5-A	76	Color Additive Amendment
	78	More on Commissioner Crawford
	79	George Larrick
	80	Citizen's Advisory Committee
	82	Parnate
	83	Thalidomide
		Investigational New Drug Regulations
	84	Effectiveness of prior marketed drugs
5-B	85	Commissioner Goddard - Ted Cron
	86	Malcolm Stephens
	87	More on Commissioner Goddard
	88	Drug Efficacy review study

Tape	Page No.	Subject
5-B	89	Antibiotic Combinations
	90	Dr. Ley - Panalba
	92	Bill Devers, Prescription Drug Advertising regulations
	93	Harry Dowling
	94	Bob McCleary
6-A	96	More on Prescription Drug Advertising
	98	More on Dr. Ley - cyclamates
	99	Oral contraceptives
	102	Drug Abuse Amendments
		Harry Anslinger - Hale Boggs
	105	Counterfeit drugs
	Dimethyl sulfoxide (DMSO)	
	106	Dr. Jacobs - University of Oregon
		Vitamins
6-B	107	Mytinger & Casselberry
	111	Dietary food supplements
		Senator Proxmire
	112	Charles Ryne
	113	701(a) & 701(e) regulations
	114	Trade name- generic name
	116	Nader - Turners book
7-A	118	Phelps-Dodge case; Pinocchio Oil case
		Allbrook Frozen food case
		Interstate commerce
	119	GMP (Good Manufacturing Practices)
		Smith Canning Co
	121	CPEHS (Consumer Protection & Environmental Health Service
	123	C.C. Johnson
	125	More on Commissioner Goddard
	126	Review and Wrap-Up
	130	End of Interview

FL: This interview is one of a series of oral history interviews on the history of the Food and Drug Administration. We are interviewing today Mr. William W. Goodrich, retired General Counsel of the Food and Drug Administration. The interview is taking place at the Parklawn Building in Rockville, Maryland. The date is October 15, 1986. The interviewers are Ronald T. Ottes and Fred L. Lofsvold.

Mr. Goodrich, to start this off, would you briefly sketch your education, when and where you were born, the background of how you came to FDA, and the jobs that you held in the General Counsel's office?

WG: Certainly. I was born in Marlin, Texas, in 1915. I am now seventy-one years of age. I was educated in the public schools in Texas and I graduated from the University of Texas Law School in 1938 when I was twenty-two years of age. I worked for a year in San Antonio, Texas in private practice, and I came to Washington in June of 1939.

I came to work in the Solicitor's Office of the U. S. Department of Agriculture. At that time, it was run by Mastin White, who was the solicitor, and Ashley Sellers, who was the deputy solicitor. They both had taught at the University of Texas where I was educated, and through a friend of mine, James Russell, who was working at that time in the Solicitor's Office, Food and Drug Division, I became interested in coming to Washington.

When I first got here, I worked on problems of administrative procedures in the Department of Agriculture. There were great issues at that time about how the departments were actually performing their administrative procedures, and there were great criticisms of the department for not having written rules and not having a full understanding of what they were supposed to do under various statutes. Indeed, some of the regulations were not published anywhere but were handed out in pamphlets. The Federal Register was organized about that time, and my first job was working on that.

I worked on the procedures of two or three federal laws, including the Federal Food, Drug and Cosmetic Act, from June of 1939 until early in 1940, when I was transferred from being an assistant to Ashley Sellers to the Food and Drug Division. At

that time, I worked on 28 Hour Law cases and the Insecticide Act and a few things like that.

To give you an idea of what it was like in the General Counsel's office in early 1940, the Food Drug, and Cosmetic Act had been passed, as you know, in 1938, and became effective, except for some provisions, a year later in 1939. So the total agency--the General Counsel's office, the agency, everyone--was in a position of change and anticipation of what was going to happen under this new law.

For example, in the Food and Drug Division of the Office of Solicitor, there had been before the law was passed a very small group of lawyers--P. D. Cronin, J. B. O'Donnell, Johny Murphy, Dan Willis, Archibald McNaught, and George Shaw--and that was about it. They were doing notices of judgment and were preparing criminal cases and seizures for reference to the Attorney General. But they were not really very active in administration of the regulations or anything of that sort. The new law coming in had a lot of provisions dealing with administrative procedures, especially the adoption of regulations.

Two important things were happening there. First, the solicitor was employing a lot of new people and changing the nature of the General Counsel's office. And second, they were trying to develop procedures to deal with these various regulations. As we all know, the act calls for general regulations and it calls for some regulations to be promulgated through formal procedures. So at that time, the Solicitor's Office was staffing up for that, without a very clear idea of what it was all about.

J. B. O'Donnell and P. D. Cronin were products of the old times. They'd been around a long time. These were all new to them. So they had, under direction of Ashley Sellers and Mastin White, set about the establishing of hearing procedures and employing new hearing examiners and all that business. They employed three hearing examiners, and they set up procedures for formal rule making. In addition, they employed some older

lawyers than I was, like Jimmy Russell, Walter Green and Pat Perritt. They came in and I came in. So we were growing there.

At that time, the first order of business under the Act of 1938 was to deal with a number of drug cases that had been nagging the agency for a long time. That is, cases that involved drugs they thought were dangerous to health, primarily, Marmola, which was desiccated thyroid, and things of that kind which were sold over the counter for weight reduction without any real control. So one of the very first cases brought was the Marmola case, alleging that it was dangerous, and it ultimately was taken off the market.

In addition, there were some cases brought under the drug provisions dealing with false labeling. Prior to 1938, charges of misbranding on drugs had to be based on fraudulent claims. And so there was kind of a premium there for ignorance; that is, the less you knew about the drug, the more you could get by with in the claims. There were a lot of claims around that were first order of business for the agency at that time, and since we had a very good veterinary medicine division, some of the first cases brought were in that field. Dr. Salisbury's Rakos case was one of the first. We were moving into an area where at that time there was great question about whether under the Constitution you could regulate the truth of medical claims, that is, if there was a difference of opinion, you could not regulate. And so we moved into that area.

From my own standpoint, my first, job with Food and Drug, after I got through with the 28 Hour Law and a few things like that, was to work on Food Standards.

FL: Bill, what was the 28 Hour Law?

WG: That's a law that prohibits the carrying of cattle in rail cars for more than twenty-eight hours without letting them out to have feed and water. So that was one of the quarantine laws that we were administering. I also had a problem under the Insecticide Act which was a part of our administration at that time.

FL: FDA had the responsibility for that 28 Hour Law?

WG: No, FDA didn't, but it came under the jurisdiction of the Solicitor's Office of which I was a part. That was under the quarantine provisions of the Department of Agriculture.

Soon after I was transferred full time to the Food and Drug Division, I was assigned to Food Standards. Food Standards had been one of the major goals to be accomplished under the 1938 Act. There had been standards of quality under the McNary-Mapes Amendment, which was adopted in 1930, but that was a standard of quality only. When the '38 Act came in, one of the great centers of controversy was whether the agency should have authority to establish standards for foods. One of the great fears was that they would develop so-called "grade-label" standards, and that's what made it so terribly controversial.

The commissioner at the time was Walter Campbell. Walter Campbell was a very long-time director of the Food and Drug Administration. I think he came into control of the agency soon after Wiley left, sometime in the '20s. He was director of the Food and Drug Services for quite a long time. Campbell was an austere sort of a person, very, very intelligent. He was a lawyer by training. He had gone to work with Wiley early in the development of the Food and Drugs Act of 1906. And by the time I came here, of course, he was the director or the chief, I guess they called it, of the Food and Drug Administration. Paul B. Dunbar was his deputy. Charlie Crawford was the assistant commissioner.

In the development of the 1938 Act, Crawford and Campbell had taken the major lead for the Food and Drug Administration. And in the Secretary's Office, Henry Wallace was secretary, and Rexford Tugwell was undersecretary of Agriculture. Those two people were putting this legislation through as a part of the New Deal, under the direction of President Roosevelt and his people. Tugwell, as we all will recall, was a highly controversial person, and Wallace later became one, but at that time was not. Soon after



Roosevelt came in, Mr. Campbell saw an opportunity to bring the Food and Drugs Act up to date. In the annual reports of the agency for years before that, they had been pointing out difficulties that they were having in administering the act and what ought to be done to improve it. So they had a pretty good idea of what ought to be done, at least as they understood the situation then. So they worked on this.

Now, Mr. Campbell worked closely with Senator Copeland, who was from New York. He was a physician and had been a public health officer in New York. So he had a common ground with Mr. Campbell. Mr. Crawford worked closely with the House people, primarily Congressman Chapman from Kentucky. Congressman Chapman was a sub-committee chairman that was concerned with the bill, and the committee at that time was headed by Sam Rayburn, who later-became the Speaker of the House, and was a powerful man there for a long time. So in the development of the law, Crawford and Campbell had worked closely together, and Dunbar was the administrative type that ran the agency.

Crawford became ill about the time of the passage of the '38 Act, and took a leave of absence for about a year. When I got here, he was just back on the job. He had the responsibility for food standards and wanted to move that forward. So this is the area that I worked in. He had the department set up a Food Standards Committee, which involved some outside people, as well as some of its own people, and appointed Joseph Callaway, Jr., as secretary of the thing. Joe Callaway was very intelligent, a longtime employee of Food and Drug, and had a good idea of what he wanted to get done, as did Mr. Crawford.

So early in 1940, we set out on these standard-making operations. The first two important ones were canned fruit and flour and bread. Canned fruit was very important because of the controversy between cane sugar and corn sugar. Wallace, of course, being from Iowa, was a staunch supporter of corn sugar. So the issue in that hearing, which was very, very protracted and very controversial, was 1) should sucrose be the only sweetening agent, and 2) if it was not, how should the corn sugar be allowed, whether as

a sweetening agent, and if it were allowed as whole or part, how should it be labeled? Well, that hearing lasted for a long time and involved some very large interests. Very large law firms from New York represented both the cane sugar people and the corn sugar people. That hearing carried on through '40 and '41, up until the time we were transferred over to Federal Security Agency in 1940. FDA had started under the Department of Agriculture, and when I came into it in '40, we were going under the Federal Security Agency.

The flour hearing, which was held the beginning of that summer, was presided over by a fellow named Allen Wilcox, who later became general counsel of the department and worked there for a long, long time. The flour hearing started off as a relatively simple, straightforward, standard-making thing. They just didn't have a very good idea about what ought to be in the standards or what ought to be important. Of course, the moisture of flour was important, and one of the items that was believed to be controversial but turned out not to be very controversial was the bleaching of flour, because that had been a bone of contention with the old Bureau of Chemistry from almost the beginning.

That hearing got underway and went very smoothly for most of the time until the vitamin issue came up. About that time, the concern about pellagra and vitamin deficiencies in the Southeast was still with us. Some of the flour millers had begun to put vitamins, which were then becoming available, in their family flour mixes, particularly self-rising flour and salt flours which were used for biscuits primarily through the Southeast.

When the hearing got underway, we had not proposed any provision for optional ingredients of that sort. We had optional ingredients like brominated flour and self-rising flour and things of that sort. But the idea of putting a nutrient in food was new. So one of the firms was putting Vitamin B<sub>1</sub> in, another was putting Vitamin D in, another was putting calcium in, another was putting in this, that, and the other thing, There wasn't any

real rhyme or reason to that. Elmer Nelson was in charge of our Vitamin Division. He hit upon the idea of trying to make a reasonable standard for enriched flour. If we were going to have it, make it reasonable in terms of the ingredients that should be there and the amounts that should be allowed. So when he testified that we didn't really have any support for the single ingredients, he thought they ought to be multiple and rational.

The hearing then adjourned, and the Food Nutrition Board was organized by the National Research Council to consider the question. Dr. Russell Wilder was the chief actor in that. And from the millers, standpoint, a man named Hartenburg, who was with one of the Minneapolis millers, I believe Peavey, was the chairman of their group. The Food and Nutrition Board then got up a statement of policy and ultimately endorsed what Elmer Nelson had proposed; that is, to have a standard for enriched flour and bread that would be based on not one, but a combination of B vitamins and iron, which were the things most likely to be deficient in the diets of the people that they were aiming at, the people throughout the Southeast. The argument was that if a person was deficient in one vitamin, he was likely to be in the other two. That is, if he was deficient in B<sub>1</sub>, he was likely to be deficient in niacin and riboflavin, too. And iron would naturally go with that. So that's the way that standard was proposed.

This led me to my first real important meeting with Crawford and ultimately with Campbell. Crawford saw from the start that made a lot of sense. As a matter of fact, he worked with Elmer in bringing that up. But Campbell had a problem on whether or not we had that authority to specify those ingredients and so forth. When we met with him it was the first time I had really met with him on an important issue. And he came around with it, and we adopted those standards.

As you all know, that then moved onto the Supreme Court through the Quaker Oats case. Quaker, of course, didn't make flour, but they made farina. And in the flour hearing, farina was, of course, described as the middlings of wheat, just ground to a different consistency. Quaker had been adding Vitamin D to their farina. They took the

view that we were putting them out of business by making them add Vitamin B<sub>1</sub>, riboflavin, and niacin. If they wanted to have Vitamin D, it was an optional ingredient under the proposal. So that's the way that thing worked out.

FL: Bill, before we leave the flour, was there any consideration at that time of making enrichment mandatory as part of our standards?

WG: Yes, there was, but there wasn't any real feeling that everybody in the United States needed that, and for that reason, it was a beginning step. Also, there wasn't any clear basis that we could outlaw regular flour if it didn't have these vitamins in it. So we went along with the idea of it being an alternative standard.

FL: Actually two different products: flour and enriched flour.

WG: Right. Of course, the follow up on that, bread standard hearings came in just before the war. The War Food Administration made the enrichment of bread mandatory during the war years. So it did move in that direction.

FL: But not under our statute.

WG: Right. Well, they did it under the power to allocate materials, and that if you didn't enrich, they wouldn't give you any power or other things. (Laughter) So that's the way that worked.

Now, on the canned fruit, that hearing finished, and Food and Drug tended to be in favor of making sucrose the standard sweetening agent and allowing corn sugar, but with a declaration that it was neither corn syrup or dextrose. And the argument that was put up by the other people, of course, was that when they were used in baking they

inverted, and when they were used in canning, they were inverted to the same kind of sugar in the can, and therefore there wasn't any difference. If 25 or 33%, one or the other, was allowed, there wouldn't be any taste difference, either. That was proposed. Wallace put out a tentative order before we were transferred over to FSA. And then when we went to FSA, one of the first things Paul McNutt did--he was then the administrator of FSA--was to go ahead and finalize that order. That resulted in an appeal to the Court of Appeals in which the standard was upheld on the grounds that the cane sugar people didn't have standing to challenge because they weren't hurt.

In addition to those hearings, there were several other rule-making hearings going on. That is, the rules for habit-forming drugs were promulgated; the rules for the certification of colors were developed. Dr. Calvery was the head of Pharmacology at that time, and testified in that hearing. Those rules were put out fairly quickly; that is, soon after the law was passed, and this was the first time colors had been certificated as harmless and suitable for use. Calvery's group developed the format of FDC Red No. 1. The colors had the color index names, of course, beyond that. But he decided that it would be more logical to group them in that order: FDC, D. and C., and External D. and C. and so forth, and that's the way the thing came out.

FL: According to what they could be used in?

WG: Yes. There wasn't any very clear idea then, because it was all supposed to be harmless, and I think Calvery was just looking at them in terms of what was actually being used in various products and going along with the standards for that. There wasn't any great controversy there about it. The color industry wanted to maintain those old color index names, but they were not really meaningful to anybody other than the people in the business. So those rules were passed.

Another large hearing was over special dietary foods. And there I think we probably made a mistake in terms of classifying the vitamins as foods and as special dietary foods. The pharmaceutical industry, of course, opposed that; they wanted the products to be labeled as pharmaceutical items. We, in our innocence, wanted them to be food. The result was, that if they were classed as food, their labels would have to declare all ingredients, inert as well as others, whereas if they'd been drugs, only the active ingredients would have been declared. The idea of the minimum daily requirements were put in, and that, of course, fed the idea that if this was the minimum, three or four pills would be better for you. Those regulations lasted for a long time and probably did as much harm as it did good. But that was the direction they went into.

FL: Was there any pressure from the food industry to . . .

WG: No. It was all Food and Drug's idea that they could deal with them better under those regulations as special dietary foods than they could as drug items, because the agency really didn't have much experience with drugs at that time.

(Interruption)

WG: Moving from the food standards work, another operation that was going on in the agency was a greatly expanded campaign against the insanitary conditions in food manufacture and in food storage. This provision, that food held under insanitary conditions would be adulterated, was new in the 1938 Act. And so a major effort was made in the very earliest years to greatly improve conditions of sanitation in both storage and manufacturing. So that occupied a lot of the time of the field force. We had a lot of litigation over tolerances, particularly tolerances for tomato products. Mold and tomato products was one of those nagging things that kept us busy for several years.

In those early days, there weren't any good manufacturing practices on sanitation. Each case was just prosecuted on its own bad features--that is, if it was enough to testify to the court how bad the conditions were in this plant--and it was shown by picture or by explanation.

The field also was active in dealing with some more common poisons in food. The '38 Act had changed the idea that you'd have to prove the food itself dangerous to health if it had a poison in it. And there was a new rule, the so-called "per se" rule, on poisonous and deleterious substances in food. And so, a major campaign was underway in terms of getting at lead in apples and spray residues of that sort and then containers that were contributing poisonous substances to food. But there wasn't much going on in terms of pesticides and the use of chemicals in foods. That was all relatively new. In those days, about the only pesticides used were nicotine and lead arsenic, and some fluoride compounds, but relatively few. We had a lot of litigation over that stuff, with and without tolerances established. We'd try to establish tolerances for those early on, and did, and had a lot of litigation over residues in apple chops and things of that sort, but not any great big operation there.

The end of the war brought on a different problem, which I'll get to when we talk about spray residues in a little while. I left the department to go off to the war in June 1942, and was gone for four years approximately--I came back in January of 1946. Things had changed rather remarkably during that time. Mr. Campbell and Linton were tight-fisted with money, and so during the war, when other agencies were growing rapidly, Food and Drug didn't grow because they didn't want to request money that would involve them in hiring people that they didn't think were really up to their standards if that's what was all that was available. There was a lot of availability of people. You know, in 1939, when they were hiring, they had pretty much the run of the mill: a lot of people out of jobs, and a lot of people in the top of their classes came to Food and Drug about that time. So during World War II, the agency didn't grow much. It did some

inspection-type jobs for the defense and concentrated its efforts on trying to make food that was going to the military sanitary and those things.

When the war was over, of course, the idea was to try to grow again. And by this time, the money was tight; Food and Drug was a very small organization budget-wise in those years. It was a matter of three or four million dollars. And up to as late as 1955, we were at five million dollars. It was a real small operation; salaries were less and costs were less. So that's the way the agency moved along. The financial squeeze came really in the late '40s and early '50s. When the Eightieth Congress came in--I think that was '48--that's when we really got cut down a lot, primarily as a result of the chairman of the Appropriations Committee's getting sore with the agency about classifying some cut-up beets as not young beets and thought we were wasting our money on that. Therefore, they cut it down, and so the agency was strapped.

Campbell left, retired during the war, before I got back. So when I got back, P. B. Dunbar was the Commissioner. And in the General Counsel's office, Cronin died and J. B. O'Donnell died before the war. J. B. O'Donnell was succeeded by Edward Brown Williams when we moved to Federal Security Agency. He was the first real outsider from the old group brought in there. Ed went off to the war, too. So when I came back the office was headed by Dan Willis, and his deputy was Alvin Loverud. Before the war, Dan was concerned with court trials. He went out on the major trials. He was at the Marmola trial, and he was at the first Koch trial, which was tried during the war in '43. He met Al Loverud in Madison. Al Loverud was assistant U. S. attorney there, and actually tried the Marmola case. So he became interested in having Al come down. He got Al hired, and Al became the deputy. When I got back, Dan was Assistant General Counsel, and Al Loverud was his deputy.

Soon after that, Al went off to try the second Koch case. That came up early in '46. It was a full-time job out at Detroit. I became acting deputy at that time. The trial lasted almost a whole year. During the course of it, Al got sick, and I went out there and



spent several months beginning, say, about April up until the thing was over with with a hung jury roughly in September. So when I went out there, it was obvious something was seriously wrong with Al--he didn't have any energy and was quiet and so forth. But I came back on the plane with him. He said he had some problems and needed to go to the doctor right away. He told me he thought he had cancer.

So when he got back here, you know, he knew a lot about cancer, having just been through that damn case. As a matter of fact, he had an exam out there that didn't show anything. But when he got back here, he went over to Johns Hopkins and they discovered he had colon cancer. They operated on him. So he was out of commission. He came back to work I'd say in September, and he went over there probably in November and had the operation. No, it was before that, because I took his kids up to school because he was sick. Anyhow, he came back to work about the first of the year. And then he was up and down from there on. He died about a year later. So I became then deputy chief of the division. That was about 1947, and I had that position until I became assistant general counsel in 1952.

FL: When Willis left?

WG: That's right. Willis retired in 1952 and I became assistant general counsel.

FL: A position, then, that you occupied until your retirement?

WG: Right. I had that from January 1952 until August of 1971, when I left. I guess I really retired in March or April, but I stayed here through August, and left in August of 1971.

FL: In those days, the job was called assistant general counsel of the Federal Security Agency or the Food and Drug Division?

WG: Well, when we were in Agriculture, it was the Solicitor's Office. When we went to HEW--it was then Federal Security Agency--it was called assistant general counsel, Food and Drug Division, and kept that title as long as I was here. I believe they changed it to chief counsel after I left here.

FL: Actually, you were not a part of FDA, but were theoretically from the departmental office, assigned to Food and Drug matters.

WG: That's right. By that I mean all the budgeting for our office went through the department, in the Secretary's budget. Of course, that was probably good for us when the squeeze was on in the early '50s, but when Food and Drug began getting more appropriations, then that wasn't all that good. The hard times for Food and Drug, as I said, were those late '40s and early to mid '50s years.

My first experience with Food and Drug legislation was in 1941, when the Insulin Amendment was passed. Insulin had been under control through the patent provisions, and the supervision of the University of Toronto, until the patent began to run out. So when there was a danger of it running out, the manufacturers and the people who were really interested in diabetes were very concerned that they would have the same kind of protection they had had under the patent. So they proposed that the product be certified by Food and Drug. And so we proposed and Congress adopted the Insulin Amendment in 1941. That's the first time I got acquainted with the people up on the Hill, with the committees with whom we worked, and so forth.

Mr. Crawford was well known there and was well involved with the people. He had made friends with Allen Perley, who was by 1941 the legislative counsel of the

House of Representatives and was heavily relied upon by the House Committee on Interstate and Foreign Commerce. And Perley, being a friend of Crawford's, relied on Crawford for advice, and in turn gave him entree to the committee for explaining things that needed explanations that he, Perley, wasn't able to do. The way that committee worked at that time, they would call in the House legislative counsel to sit with them and advise them on legislation. The House legislative counsel would then advise them in closed session. If he had questions, he would then either ask Crawford or ask Crawford to come in.

So I began to do that beginning in 1941 with that legislation. When I came back, the first legislation we had after that was some of these antibiotic things. Certification of penicillin was the first. We had been doing that testing and certification during the war because the NIH group on biologics wasn't interested in it and Henry Welch was. So he set up to do the certification, and the Antibiotics Division became a big operation there. Immediately after the war, when penicillin became widely available, that operation grew rather remarkably.

I'm getting ahead of myself on drugs there. I brought that in at this stage primarily because of the effect it had on the budgetary situation of Food and Drug. When Food and Drug was being tightly squeezed by appropriations, they were able to cover some of their expenses through the fees that were earned in this certification. So that became a largely independent source of income and a largely independent source of trouble, as it later turned out to be. (Laughter)

The first really important legislative operation I had was with the so-called Miller Amendment. You'll recall that the court of appeals for the Ninth Circuit held in the Phelps-Dodge case that if food became adulterated while held in storage, the act didn't cover it; it would have to be adulterated when in interstate commerce or it would not be subject to seizure before introduction went in. We had contended in that case that because it was in original packages it was still in interstate commerce, even though it had been in

Phelps-Dodge's warehouse in Arizona for a year or two. We lost. So we went back to Congress immediately with the so-called Miller Amendment to have that decision reversed.

This was a proposal that wasn't really controversial at all. Everybody was kind of for it. It was a good experience for me to work on legislation because it was not one of those hot issues, but it later turned out to be. When we were working on that, a man from Denton, Texas--Morrison of Morrison Milling Company--proposed through an Oklahoma Senator, Senator Moore, I believe his name was, that that amendment be supplemented by an amendment which would make prosecution for insanitary conditions depend on intent. His firm had been prosecuted for insanitary conditions, and considered that a great disservice, so he made a crusade out of getting that provision in. And he did get it passed through the Senate, and we ultimately were able to knock that out.

But that amendment, in '47 and '48, introduced me to Perley as a working friend, that is, he was House legislative counsel, and to Kurt Borchardt, who was the counsel for the committee. That came in very handy in the next two years when the Durham-Humphrey Amendment came along. That amendment was the first real recognition and law of a difference between prescription and over-the-counter drugs. Now, we'd been dealing with that before under regulations. When the first regulations were put out back in '40, if a product was prescription, you could make your own choice. That is, if you thought it was prescription, then you labeled it for a prescription by putting on it: "to be dispensed by prescription." And if you made it over the counter, then you had to have adequate directions for use. And this resulted in a situation in that Vitamin C, for example, sold by Lilly, was labeled to be dispensed on a prescription, and the others were over the counter.

So in about 1942, Crawford devised the idea of amending the regulations to limit to prescription drugs all those drugs that could not be sold safely without prescription, and to require all those that could have adequate directions for use to have adequate

directions, trying to draw a sharp line between them. They got into the litigation over sulfathiazole with the Sullivan case during the war. That's when it was being sold over the counter to military people in the Alabama and Columbus, Georgia area, where self treatment was going on. That was considered to be a dangerous thing because the treatment was inadequate, and it was resulting in the spread of more serious venereal disease. So the prosecution of Sullivan started there. We won in the district court, we lost in the court of appeals, and it went to the Supreme Court where we ultimately won. And that was the first really big Supreme Court case. Dotterweich had been decided earlier, dispensing with intent in criminal cases, but Sullivan was decided about that time.

Well, we were still having a lot of litigation over these various drugs--which should be prescription and which not--but more importantly was the issue of the refills. And Crawford put Dunbar up to making a speech to the NARD (National Association of Retail Druggists) on prescriptions, likening the prescription to a check, and saying that once the thing had been cashed, then you couldn't cash it anymore. So you can imagine the consternation that caused among the pharmacists.

The National Association of Retail Druggists was headed by a guy named John Dargavel--a great, big, fat guy, and really a volatile person. He saw red, and swore he was going to get Dunbar fired, and also that they were going to get the law changed to where you didn't make those distinctions, or if you made the distinction, it would not be a crime for a pharmacist to use his professional judgment in filling or not refilling that prescription.

So the stage was set for the Durham-Humphrey Amendment. Mr. Carl Durham was a congressman from Durham, North Carolina. I'm not sure he was from Durham, but he was from North Carolina. He was a registered pharmacist. Then so was Hubert Humphrey. We were able to interest them in it, but only after we had interested Dargavel in coming along and getting some sort of legislation that would make this thing regular. He thought that the pharmacists should have a free run. We thought the pharmacists

shouldn't have a free run, and so the stage was set. And ultimately the NARD supported the legislation.

With their support, the Durham-Humphrey Amendment was passed in 1950, making this distinction between prescription and over-the-counter drugs. The big part of that was, in dealing first with classification, it kept the same classification that had been in effect under the regulations, but made that legal classification. Second, it required a label statement: "Caution: federal law prohibits refilling without prescription." We pirated that from liquor bottles, which says they can't be refilled. (Laughter) So we thought that was a good idea to put that right on the container. So that's where that idea came from. And then on the issue of refills, the telephone refill came to play, and so we had to deal both with the written authorizationable refill, and with the oral, the telephone type. That's what the Durham-Humphrey Amendment was all about, and it passed in 1950.

FL: Bill, in all those controversies surrounding that question, where did the medical profession stand?

WG: They stood aside. They ultimately would come along with Dargavel because the National Association of Retail Druggists was a powerful lobbying influence. They had druggists, and they were drugstore owners. And so they had stores in all districts of the United States. They had access to people who knew these congressmen. As a matter of fact, you could know pretty quick what was going on, because one of the members of the House committee would say, "Well, now, I just got word from my district that so-and-so . . ." We'd have to go and answer that. That's where I got well acquainted with the members of the committee, of answering those things. But in the final analysis, NARD and Food and Drug worked together on that legislation. Even though it wasn't what

Dargavel wanted, it wasn't completely what we wanted, but we got basically what we wanted

The next legislation I was concerned with was oleomargarine, that is, the proposal to repeal the tax on colored oleomargarine, and to adopt those labeling and sign provisions for oleomargarine. That amendment was passed in 1950. Following that, the Inspection Amendment came in '53. There, you'll recall the Cardiff case that pointed out a difficulty in the original inspection authority. That is, according to the court, you could inspect if you first requested and got permission, but if you didn't do that, you couldn't inspect. So that was unworkable.

FL: But the owner had to give permission or he could be prosecuted. (Laughter)

WG: Right. So we then proposed the Factory Inspection Amendment. That has always been controversial up there. It's amazing that many other laws, particularly in the public health area, provide inspections of various kinds and never are controversial up there. But with us, this was always controversial, and the reason was that the industries that we inspect and regulate are well represented in terms of lobbying effect and in contact with the Hill people. They kind of use the inspection as a specter of some inspector taking advantage of some poor local guy that had to submit to inspection whether he wanted to or not. So that amendment was pretty hard fought through the House Committee.

I will deal with the Delaney hearings, the Pesticide, Food Additive, and Color Amendments later. I think now we need to talk a little bit about drugs and new drugs.

FL: Bill, before you leave the legislation, could we go back to that insulin law? I've always been amazed when reading about the legislative action on that how rapidly it went through. Was it very speedy in the preliminaries also?

WG: Yes. The reason that took place that way was that there were only about four or five manufacturers of insulin. That was Lilly; Merck, Sharpe, Dohm; and one or two others--I forget the names. But they had been under certification control through the patent at the University of Toronto. So they were quite responsive to anything that the Insulin Committee of that group wanted, and Drs. Banting and Best who were the discoverers of insulin owned those patents. So they were in favor of some kind of control and the companies were in favor. The possibility was that insulin would be put out without any certification, so that's what gave that urgency to it, and that's why it passed with such a fast go.

FL: There was no opposition of any kind.

WG: No. As a matter of fact, everybody was much in favor of it, and as a result, the legislation passed, and the regulations were put out within a very few days. I worked on both of those and that set the stage for later legislation on antibiotics, but that was the first of the . . . Well, we'd had certification of colors before, and we kind of patterned that to some extent on certification of colors.

I have talked about the prescription drug legislation. I want to go back, now, to the early days and take up new drugs. The revision of the Food, Drug, and Cosmetic Act passed both houses of Congress in 1936. But there was a dispute that held up final enactment about who should have control over advertising. Chairman Davis of the Federal Trade Commission had been a member of Congress before, and he had great influence up there. He was able to get that authority passed over to the Federal Trade, and Food and Drug then objected. So the bill died in conference committee because of inability to resolve that issue.

In the next Congress, Davis made a fast move and got the Wheeler-Lea Amendment passed in about April of '38, and that made it fait accompli of them having



control over advertising before our law was ready for passage in June of that year. So the act passed in June. But in November or in the fall of 1937, the elixir of sulfanilamide episode arose. That was after both houses had passed the bill and nobody had said anything about new drugs, and the whole idea was just brand new. When that episode occurred, the first thing Congress did was ask the department for a report on what there was in the new law that would deal with that problem. And, of course, the answer had to be, very little. So the department sent up a report and sent up a proposal on new drugs in '37. It turned out to be controversial because the drug industry was very much opposed to licensing, and they considered this to be a licensing bill.

Nonetheless, that was a bill whose time had come. Before that, there were very few, if any, drugs that had any real importance as curative agents. Sulfanilamide was the beginning of an era. That was in 1936. The New Drug Provision came in just at the dawn of the era of rational therapeutics. Sulfanilamide itself was exempt because it was on the market before 1938. But most of the important drugs came along after that time.

Now, in the beginning, I'm not sure any of us had a very good idea about what that New Drug Provision was all about. The New Drug unit was headed by Dr. Durrett. He was a pretty powerful, opinionated, sort of a fellow, and he had as his deputies, Ted Klumpp and Robert Herwig. I guess before Durrett came, Larrick was the first head of that unit. And then Durrett came in as the first M. D. and started working at that. The first I became involved with New Drugs was soon after the passage of the act. There was a provision there that if the application wasn't acted on within sixty days, it would become automatically effective. So we, then, held a series of hearings, most of them uncontested-- I believe all of them; maybe one was contested--to go through the formal steps of denying approval of the new drug before the sixty days passed.

The real eye-opener on new drugs, though, came in about 1941 when there was a mixup of the sulfathiazole-phenobarbital tablets at Merck, Sharpe, Dohm. That made us begin to realize that the effective New Drug Application (NDA) had some lasting

duration to it. We were arguing that because of a failure of the controls, that was a basis for revoking that application. But you had to do it on the ground that the application contained an untrue statement of material fact. The untrue statement was a representation the firm had made about these controls that would be exercised. We took that to be a continuing promise and proceeded on that basis to take action on that application. That was the first time that it was clear to us that the New Drug Application would be considered as a continuing document, making a commitment to the firm both as to their reports of clinical experience and their reports on controls.

The New Drug operation was kept separate from antibiotics primarily because the antibiotics were considered to be a kind of a laboratory problem rather than a labeling and control problem, and that we had in effect control over the quality of those products through certification and not under New Drugs. So they were allowed to grow in parallel, but on two different routes. The New Drug operation was not supported by fees, and it suffered from financial neglect during those years of its early being. It suffered from that plus, I think, not a complete understanding on anyone's part about the importance of making the New Drug Application a commitment of continuing viability on the part of the manufacturer.

They took the view, once they got the New Drug Application passed, that that was the end of it, and they didn't really have to tell us if they made any changes in the thing, and they didn't tell, by and large. If we learned that a new drug was causing problems, we had the authority to withdraw that, but the original thoughts were that the New Drug Application dealt with safety only. Now, I don't know how we ever got that way, because none of these drugs were really all that safe. I remember Dr. Moskey, who was the head of our veterinary group, used to say, "Well, if it's safe for the chickens, it's okay. But without looking at it beyond that, a man has a right to kill his chickens and his cow. Therefore, it really doesn't make very much difference about whether the drugs do harm to animals."

In the human area, there just wasn't enough of a medical component to Food and Drug to be really in there on that operation, although we did have Durrett, and we did have Klumpp, and we did have Herwig. Durrett quit soon after that and went over to Federal Trade. Klumpp resigned and became president of one of the drug companies. Herwig stayed for a while and ultimately went with American Home Products. So the New Drug operation became somewhat of a paper-shuffling deal, and suffered from neglect. That is, Dr. Nelson was head for a while and Ralph Smith was head several times. We didn't really have any strong medical input to that. Both Doctor Arthur Nelson and Smith were pharmacologists--they were not clinicians--and they were more concerned with the pharmacology of the drug and its behavior than they were of how it was promoted and what was happening out there in clinical experience.

So the new drug thing gradually got out of control. When the budget became tighter and tighter, there were more and more rulings by the New Drug Division. Products were no longer new drugs; that relieved them from having to deal with supplements, and in effect, let other people introduce that same drug without clearance, although we never said that to them. That became the drug companies' understanding of it.

From those years in the '40s after the war was over, when the drugs began to be introduced and promoted in large volume, that grew, and it grew continually through the end of the '40s and up into the '50s. And up into the '50s we began to get these first real problems with new drugs, that is, having to withdraw some of them from the market because they turned out to be dangerous. That led into a lot of investigations by the Fountain Committee and by the Nader Group. They began to ask questions about these drugs and what sort of controls were available, and what the agency was really doing about a lot of them. We took, of course, one step in the Durham-Humphrey Amendment by insisting that at the time of the New Drug Approval, the drug be classified prescription

or not and labeled accordingly, and there had to be an official brochure. But there wasn't really any insistence that that brochure be used as the basis for promotion.

Along about 1960, and I'm not dead sure of my date here, but I'm pretty sure, we amended the drug labeling regulations, the 502 f(1) regulations, to require a better pattern of labeling for all drugs, that is, to require that all the promotional material be substantially the same as the official brochure, and that there be full disclosure in this promotion. The biggest basis for promotion, I guess, at that time was the PDR (Physician's Desk Reference), and it was being used, really, as a promotional piece rather than as a source of reliable information. If you look at the 1960-61 PDR, you'd be shocked when you compare that with the next year, which is when we first put in the full disclosure and required essentially a full rewrite of that.

So the 1960 regulations were designed to require that all over-the-counter drugs have adequate directions for use--and it was spelled out what that had to include--and that prescription drugs would be exempt from that only if they had full disclosure to the medical profession. That was the first really important step taken by the agency to improve the quality of promotion of prescription drugs, primarily. We had been concerned with a lot of these cats and dogs drugs like Mrs. Alberty's and some of the others, and even with some unorthodox drugs, but the 1960 regulations were moved in that direction.

From there, we went to the Drug Amendments of 1962. The beginning of the Drug Amendments of 1962 was way back in '59, when they were trying to put the '60 regulations in setting. The first of the Kefauver hearings on prescription drug promotions was December 7, 1959. That's the day the whole thing really started to build. The drug companies came to the hearings saying that everything was hunky-dory, that is, that new drugs were being honestly promoted, not exaggerated, and so forth.

Well, Kefauver started off with an anti-trust investigation, that these prescription drugs were too high, and that "he who orders doesn't pay and he who pays can't order."

That was the theme of the investigation. First, the pharmaceutical industry responded to that by bringing in some of their big guns, presidents of companies--Frederick Brown from Schering and what's his name from Parke Davis, and Eli Lilly and those companies all sent their big presidents down here to testify. Their testimony was that drugs were high because it cost a lot of money to do the clinical research, it cost a lot of money to promote, it cost a lot of money to advertise, and that they were under an obligation to follow the experience with them and they had a short life .

Well, of course, they stepped right into the bear trap when they did that. That just focused attention on these various phases of new drug development and promotion. First of all, was it really all that expensive? Were they really doing all that kind of research? And anyone who had looked at any of the New Drug Applications knew, as I knew, that that was all baloney, and what they were saying to us in those early days was essentially a bunch of testimonials. The way drugs were investigated, a physician from the company would go out in the community with some samples and say to the doctor, "I've got this new drug for so-and-so. Here's some samples. Try it out and let us know how you like it." And they would get back a letter from him: "I tried it out on eight patients and they all got along fine." That's the kind of stuff that was coming in for the science. Of course, that was completely unsatisfactory, and as soon as people focused on that, that raised the problem.

Then, on promotion, they said that the promotion was educational; they were providing a service to the medical profession. They later took the opposite position, saying none of it was educational--nobody believed it, and therefore, it was no reason to require such a hard line on honesty with it. But the defense that they made--the cost of research, the cost of promotion, the promotion to a limited audience, the doctors' responsibility to choose for the patient and make an economic choice for the patient, and the follow-up--all those things were brought up.

Well, the next year, in '60, the committee focused on Henry Welch and his relationship to Ibanez and his collecting money for reprints for various articles that were used in promotion for the drugs. And also, it had something to do with those antibiotic conferences that had been held during the late '50s, particularly with respect to the unprecedented growth of antibiotic combinations. The idea was that if you had one antibiotic and you added another one, you got a broader spectrum, and it was like a shotgun therapy, starting, really, from the combination of penicillin and streptomycin. The triple sulfas, I guess, were the first of those, and then the combinations of the various antibiotics pressed particularly when tetracyclines came along. When Henry was called to testify, he was not able to testify; he had a heart attack. So they, then, introduced the evidence about his relationship with the drug industry, and it was very bad. Henry about that time retired.

Larrick and Rankin and myself went up on what was wrong with the new drug thing and what needed to be done. Now this was not the first time we had urged Congress to deal with the effectiveness of new drugs. We had asked them to do that before. But we had a pretty well-thought-out idea about all that needed to be done, not completely as it ultimately came out, but a pretty good idea about that. So we presented that.

Then, of course, came the testimony of Dr. Moulton, and about that same time, the people over in pharmacology were publicizing the cyclamate thing. The upshot of it was that the hearings continued through 1960. I'm not sure when Morton Mintz's story came out, but I believe it was either in late '61 or in '62. Maybe it was up in the summer of '62. Because once that came out, the drive to have a New Drug Amendment of '62 was unstoppable.

We first tried to compromise with the committee and made a bad choice on it. That became publicized, and when the amendments were finally passed, they were much better than what we had gone in with, and much better than what we could have hoped for. But we did do the drafting on those amendments and did work with the committee,

particularly the House Committee on Interstate and Foreign Commerce, in working up a bill. Kefauver had a bill, too, but it wasn't like the one we ultimately came down with. It was somewhat like it, but not completely. And so out of that arose the Drug Amendments of 1962.

FL: The department was involved in this negotiation too?

WG: Yes. Wilbur Cohen was the assistant secretary for legislation, and Abe Ribicoff was our secretary. Abe Ribicoff testified on this bill in '62 favoring a bill. Then Jerry Sinosky, who was Cohen's assistant on legislative matters, tried to work out a compromise with the Senate staff and did work out one; there was a committee report. But it really didn't come down hard on real proof of effectiveness; it in effect bought their argument that it was impossible to prove absolute effectiveness, and therefore relative effectiveness was about the best you could do, and that they would have a right to claim usefulness of the drug provided they put enough qualifiers in there about the thing. Well, that wasn't very good.

The AMA (American Medical Association) had testified against the bill; they didn't see anything good in the bill. And Austin Smith, who was then president of the PMA (Pharmaceutical Manufacturers Association), finally testified and said that all their drugs were safe and all of them were effective, and that they were strongly in favor of a strong science. So we took him up on that and came up with the provisions in the '62 amendment, the most important of which was the requirement that drugs be proven effective by adequate and well-controlled studies and by new regulations on new drugs, new regulations on record keeping and recording, and the other aspects of the '62 amendment.

FL: Was there any White House involvement?

WG: Yes. John F. Kennedy was president and Ribicoff was very close to him. Kennedy was very conscious of the *Washington Post* stories. This was just a few months before he died. This was in June of '62, and he was murdered roughly Thanksgiving time of '62. But he was strongly in support of this, and that's why we got such a good bill out of the thing in the final go-around. That is, both Ribicoff, who had been relatively lukewarm originally, and Kennedy, who had not been directly involved until after it became a big public affair, and he gave an award to Frances (Kelsey) for the thalidomide episode . . .

(Interruption)

WG: . . . from the administration, and that influenced Kefauver and his associates, although they wanted to take the credit themselves rather than give any credit to the administration. And then in the House, Oren Harris was chairman of the House Committee on Interstate and Foreign Commerce, and through the work of that committee and with the help of Kurt Borchardt, their staff man, and Jim Menger, who was then in the Legislative Counsel's Office, we worked up all those provisions and the committee reports, and the bill passed with a very strong endorsement.

FL: Did you have an active part in actually drafting language?

WG: Yes, as I indicated, we worked with the committee staff and with the Legislative Counsel's office. They were the expert draftsmen, but we would tell them what really needed to be done. A lot of those ideas, though, were picked up from the testimony. You know, Dowling testified and others testified about you couldn't prove effectiveness without adequate and well-controlled studies, and so that became a part of the law. The industry was arguing that clinical experience was worth at least as much as a well-



controlled study, and in the first committee report, we put in a provision that clinical experience adequately documented would be considered along with adequate and well-controlled studies, but not as a sole basis. That part was the sticking point of the controversy about the first report and the withdrawal of that report and the ultimate adoption of a stronger bill by the Senate, and yet a stronger one than that in the House. The bill passed in October and from there we adopted the regulations that were necessary.

RO: Bill, going back to antibiotic certification and the fact that the agency was able to keep the fees rather than going to Treasury, do you know what prompted that? Usually in things like that, fees go to Treasury rather than the agency.

WG: By putting a provision in the Appropriations Act to make sure that was so, and we got that done because the agency was so short on funds; we couldn't do it without that money, and they weren't going to appropriate anything for it. So the fees became the support for the thing and also became kind of a sticking point in the agency, that is, Henry took the view that he was supporting everybody else and that they should consider him as having been a financial benefactor. Well, that was part of our troubles.

RO: That was really user fees that have resurfaced since then.

FL: Yes, the current administration would like to do that more broadly.

WG: Well, but that sort of fee was based on a laboratory study. It wasn't like the user fees that they're talking about now, of taking a big fee out of the capital of the new drug to get it approved. That part has never worked; that is, they tried that once with TV licensing and it failed, and I don't think they've ever put that back in. They may have, but

I don't think so. If any group can afford it, the television stations can. But the user fee provision just never did work that well.

FL: Bill, in talking about the 1962 amendments, in an interview Winton Rankin told us that he was surprised that the requirement for effectiveness of drugs survived in the final act; he thought that in the beginning, everybody that was involved in that thought this was probably not going to fly, that maybe we would get the authority to inspect records and things like that, but we might have to give away the effectiveness in the final crunch before the thing was enacted.

WG: I wouldn't go that far, but as I said, we did give in that first committee report to the extent that we would have authorized the use of claims to some extent based upon clinical experience. And if you go back and look at that committee report, the first one that came out, that was some give on our part to the effectiveness claim. But that resulted in everybody focusing on, how do you really approve a new drug claim? And that was the adequate and well-controlled studies. I believe that came, in part, from Austin Smith's testimony. They did this by adequate and well-controlled studies, and we adopted that and put that language in, that effectiveness would have to be proved, and we defined what was inadequate in well-controlled studies by regulations thereafter. Now, we'll get into those regulations in a minute or two, but I ought to take a break.

FL: This sort of all became moot as soon as thalidomide got the publicity. Congress was about to enact almost anything that was before them.

WG: Well that was really what turned things around.

(Interruption)

WG: Having had lunch we are now going to talk about cancer cases that were a major focus of my time here. When I returned from World War 11 in 1946 I worked on my first big cancer case. It involved William H. Koch an M.D. from Detroit, Michigan. Dr. Koch was both an M.D. and a biochemist. He had an unorthodox cancer treatment he called Glyoxylide. As near as the agency could find out Glyoxylide was nothing but distilled water. According to the formula that Koch published it was a  $10^{-12}$  dilution, so it had nothing in it. It was quite dilute. Koch, because of his professional claims, etc., had a following and he had a theory about how his product worked. The agency tried Koch twice, both times ending up with a hung jury and were prepared to try him again when Koch left the United States.

My first experience with Koch came in the spring of 1946 when I went out to Detroit to help Al Loverud with the trial of the case. FDA set this case up with the idea that it should be pretty simple. That is, by proving the extreme dilution of the drug that any jury would surely find that there was really nothing to it. Koch was represented by a lawyer who was also a scientist and who had worked for Dow Chemical Co. and who was trained by a chemist too. So the way the case proceeded it was almost assured in a hung jury. The government relied first, on the dilution second, expert witnesses who would testify that the product didn't work, and third, a so-called clinical trial of the product.

Essential to Koch's business was secrecy about the product, what was in there. He claimed that it was an oxygen uptake product of some kind. The formula was  $O = C = C = O$ , which means nothing, really. That's the way he described what it was. In order to make the case, the Department of Food and Drug, maybe the lawyers' offices, decided it would be important to try the drug out on some patients. In order to do that, they obtained a sample from a return shipment that came in through customs from

Canada, which was picked up and in effect commandeered by the government, and then subjected to clinical trial.

Now the dilution that came in was  $10^{-6}$ , so the agency then made it  $10^{-12}$ . That was the first big bad mistake. You see, it wasn't really his product that was tested. And second, as with any of these cancer cases, trying to prove by limited clinical trial that the product is no good, when the defense relies upon actual human experience, it is a bound-to-lose situation in court. And third, the theory that Koch had was one in which he equated the dilution of his product to enzymes in the blood. The enzyme in the blood would be about that same dilution and this was how he rationalized what was going on.

The case got started and the government first undertook to prove what the product was. We had no factory inspection--he would never allow an inspection--so it had to rely upon the formula. Well, the formula didn't mean anything, so they then had to have a theory on what that must have meant, and with the dilution that it would end up with either nothing in there or an ingredient so small that it would amount to nothing. Then with the ampuls that they made from this one shipment, they got immediately into a hell of a big argument about that, first, on whether the government had the right to commandeer that product which was being returned to him from someone in Canada and was picked up by customs as it came in; and second, whether it was logical to dilute that further and then use that for a clinical trial, rather than come to him and have him give you some samples. Of course, he wouldn't give you the sample, but that was the way the case went.

Koch had, as all cancer quacks have, a number of patients who apparently had received some benefit. Cancer is, as we all know, a capricious disease and doesn't behave at all in a normal function. And from experience of several years, which was what Koch had, he could draw from that experience patients that either were much better now as a result of some other therapy, or who had never had cancer in the first place, or who had a misdiagnosis or things of that kind. So it was a typical problem with that case.

The long trial was made necessary by bringing in witnesses from various places. There always was a delay. It was a jury trial, all right, and the judge tried to move ahead with it, but there was a constant problem of having witnesses available, having them ready to testify. And so the case dragged on and on and on. The lawyers for Koch, Sheridan and Goodow, were able to draw this doubt through the difficulties with the sample, the dilution made by the government, and with the experience that they'd had. We put on a case that was, we would have thought at that time, entirely adequate. But we know now it was really not adequate. So the case, even though we had leading experts from the Cancer Institute from the main hospitals in Detroit--Henry Ford and the other hospitals in Detroit--and other places there, there was simply enough doubt thrown onto it where the jury couldn't agree. Finally, one of them got sick during the deliberations and the court had to declare a mistrial.

So with that, Food and Drug had invested a tremendous investigational effort in this. Walt Simmons in Chicago had spent months both in the first trial and preparing for the second trial. He was anxious as hell to go ahead with the thing again. Soon after the trial, we conceived the idea of really this time making an absolute investigation to find out what it was all about. So we got John Cain, who as you probably remember, is a very hard-nosed, bird-dog-type inspector who really would just hang in there. No matter how much insulting the guy did to him, he would never turn loose. So we sent John out there to make an inspection, and by that time or soon after he got there, William H. Koch left, went to South America.

Louie Koch, his brother, was the one who was running the business and who essentially made the drug. Louie then hemmed and hawed about he didn't have any available or he wasn't going to make any for a while, and this, that, and the other. But ultimately, by staying with him long enough, it was possible to prove how the thing was made. And essentially what he observed was Louie Koch, a non-M.D. at all, just an ordinary person, distilling this water. It was in the summertime, and it was at this attic of

Louie's house in Detroit. He was distilling and distilling and distilling for days on end and never would get right down to what active ingredient was ever put in there. He used every conceivable way to avoid that, but ultimately that inspection showed that that's what it was, distilled water.

But the case was never retried, because that Koch treatment lost all favor after that and became a small operation. But at one time in the early '40s and up through the time of that trial, it was the leading unorthodox cancer treatment in the United States. That's what it was and what the agency had to do to get to the bottom of it was to hang in there and prove just that there was nothing to it, that you couldn't really take it into a trial basis without getting equivocal results. You know, if you used it on some patients, every one of them's going to react somewhat differently. And, of course, in a trial, he was able to pull out that this patient did this, had less fever and so forth, just enough to show a shadow of a doubt.

So this taught us that in dealing with cancer treatment, it was essential to not go on a theoretical basis, or not go on a basis of just because we don't think there's anything in there, that that's enough to make the thing go. So that case ended about 1946, and then Walt Simmons and Brandenburg spent another two years really working up the inspection with Cain and getting ready for another trial. Then the issue came up about spending a hell of a lot of money--those cases do cost a tremendous amount of money, as you know-whether it was justified in spending it. The decision was made that it really wasn't worth that.

FL: Did Koch ever return to the United States?

WG: Not that I know of, but if he did, the treatment has never been a big factor since then, that having been tried twice in the criminal courts, I think he had enough and decided that he'd been lucky to get out that well.

FL: He at one time had a reputation as a legitimate practitioner, didn't he?

WG: Yes, he was an M.D. and a Ph.D. in biochemistry. So in the cross examination of our medical witnesses, he'd bring out this Krebs's Theory and the enzyme theory and the dilutions there. The doctor would say it's too dilute to do anything, and then you'd ask him about biological processes in which you had the same minuscule active ingredient. Of course, they would really not know very much. It proved to us, too, that using an M.D. witness is treacherous business because the most honest ones there are would say, "Did you ever have any reason to believe that this product would have any effect on any type of cancer?" He'd say, "I know of no evidence that it would," instead of saying, "Absolutely not; there's nothing to that." That's the way you'd get the answer.

My next experience with the cancer problems was with Harry Hoxsey. Harry Hoxsey, at the time I came into the business, had a clinic in Dallas, Texas. Hoxsey had had a background of conflict with the Medical Practices office up in Missouri, I believe, and one of the other Central states there. Excelsior Springs or someplace up there in Missouri. And so he went down to Texas and organized this clinic and was giving out this Hoxsey cancer treatment. In the early '40s, he was involved in a libel suit with the AMA. The AMA had taken a point of view and said publicly that Hoxsey's treatment was no good, was a fraud, and they'd all put out word about him from the Medical Practice Act. He then sued the AMA for libel. There was a trial in Texas.

Hoxsey won, but he got a \$1 judgment, like the recent football thing. They held that he had been libeled, but his damages were only one dollar. But that was enough for him. He then could contend with his patients that he had proven the AMA had libeled him and that they were wrong in saying that he did not have a proper treatment. So with that background, the AMA took a somewhat less stringent view. Just as a matter of history, the man that they sent to investigate the Hoxsey treatment was Andy Ivey, who

later became involved with Krebiozen. Andy Ivey did a report on Hoxsey and reported that the product was not effective for anything.

When we got ready to go into the thing, we sued him for an injunction in Texas. It was pretty well known that Judge Atwell, who was the federal judge there, who had been in the AMA trial and in effect was all for Hoxsey, was going to be our judge. So we knew from the start that we had a tough time going for us. What Hoxsey was giving out was a black medicine, kind of a tonic, and also a bunch of vitamins and herbs and preparations of that kind, just a lot of pills and this liquid medicine that he had. So we got busy on that, analyzed it.

Hoxsey claimed that he'd gotten this treatment from his father, that his father had an old white horse that had a sore on its leg which was a cancer. The horse went down to a certain corner of the farm each day and walked around there, and ultimately that thing cured up. So he reasoned that there was something down there that had caused that sore to heal and that therefore, this was the basis for his treatment, the herbs that he had picked up there. Well, of course, there wasn't any such white horse or anything like that, so the analysis of the product proved that potassium iodide was the active ingredient. The rest of it was vitamins and minerals and things that didn't amount to anything.

Well, we tried this case with more care. We were able this time to put on the same type of case that we had with Koch, that is, the analysis of the product, what it was, what it was recommended for, and the different people who it had been recommended for. But our problem was to prove that none of these people that Hoxsey brought in as his witnesses . . . We, of course, brought in our evidence some people had taken the drug and died, but not enough, and we didn't try any clinical trials on it because we didn't think that was justified. So the case was tried at considerable length--much shorter than the Koch case, though. It was tried in Texas with a very good assistant U. S. attorney. And the upshot of it was that when it was all over, Judge Atwell ruled that we had failed to



prove our case, that is, that Hoxsey's medicine sometimes failed, sometimes worked, sometimes it helped some people somewhat, kind of a very equivocal sort of a judgment.

So we had to appeal. We then appealed and took the view that the undisputed evidence showed that none of these people that had been put up for the cure had actually been cured, and that every one of them had another explanation, and that therefore there was no evidence that . . . Our evidence was that it didn't work, and the evidence he put on was of no value in showing that it did. And the court of appeals held for us.

Then we went back down to have the judgment entered, and Judge Atwell ruled the same damn way. He said, "You know, I'm just not convinced." So he then ruled that Hoxsey could continue to market the product as long as he said there was a difference of medical opinion about the claim. We went down there moving for judgment on the mandate from the court of appeals, and Atwell then didn't do that. So we had to appeal again, and this time the court of appeals ruled with us again, and ordered him to be enjoined from making these representations.

Then Hoxsey hooked up with John Hluska, who was a state senator in Pennsylvania. John Hluska was the Democratic leader of the state senate in Pennsylvania. He came from a place in Cambria County, which is over in the coal mining area near Johnstown-Portage is the name of the town. Hoxsey then organized, through Hluska . . . I'm getting ahead of myself. After Hoxsey was enjoined, he then brought in an osteopath to run the thing there in Dallas. This man claimed that he was practicing medicine and wasn't really selling the Hoxsey treatment, which, of course, he was. Then in Portage, Hluska and the osteopath converted a garage into a clinic and set up to market this product through people who would come there. Their idea was that if people came there and they didn't ship anything in interstate commerce, that they would not be in violation.

So they put in the clinic there, and we decided to make a large seizure that would seize everything they had, and would in effect put them out of business. Rather than sue them for an injunction, we'd give ourselves an injunction by having a big seizure and that

would get everything they had at the clinic, all the medicines available there, and that would in effect close them down. Well, we made the seizure.

The Scripps-Howard newspapers in Pittsburgh were very interested in it, as were all the local television media. So they were alerted by the U. S. attorney or someone there that this seizure was about to take place, and they were on hand when the marshals arrived there to seize the material. Well, this Hluska being a public character, he had to kind of hang in there with it, so he contended that the drug was good and so forth, and that he was going to contest the case. The first thing we did was take a whole bunch of depositions, and Hluska and the doctor there and everybody else involved pleaded the Fifth Amendment and wouldn't answer anything at all. So the discovery didn't bring anything, but the seizure of the pills did in effect put them out of business for a while. They got some more pills from other sources, and they went away from the liquid black medicine to a tablet for the potassium iodide, and the whole thing was a bag of pills, now, this time around, rather than that liquid that cured the old white horse. We then seized and they contested, and after the discovery we had a jury trial.

FL: We seized a lot. of credit material, too, didn't we?

WG: Right. And our seizure was based this time not only on the case I have described, but there was a pamphlet, a leaflet, that had the story of ten people who allegedly had been cured. We alleged that all those were false, and we proved in our case the story about each one of these people. For example, one of them was a little boy who was operated on in Cameron, Texas. He had a young surgeon from Waco open him up there who had never operated on a kid that young before and never seen anything like what he saw in his belly. He closed him right up and told him that he didn't know what would happen. The guy went to Hoxsey and the kid recovered. Well, it turned out that he had what's called a neuroblastoma, which is a special tumor of neural tissue that comes with

an aberration of birth processes. So we learned through an expert in that disease up in New York at Kettering, and another one at one of the main hospitals in Pittsburgh, that that condition had been seen in about twenty people, and that each one of them had had this remission after an operation just like this. So that was one of them.

Then he had a great, big guy, a big, tall Texan, that had a terrible condition of melanoma. This guy explained that he had a rising on his butt, and that he didn't know what was the matter. He went to the doctor and the doctor told him that he had a melanoma and told him it was a deadly disease. He said, "Doc, what can you do for me?" The doctor said, "There's not very much I can do except to offer to cut you off right at the base of" his ass, you know--a hemipelvectomy was what it was called, a hemi across the pelvis. That, he said, was the only thing he had to offer, and that didn't offer a very good result. So that's all the guy heard. But the doctor told him that he wouldn't do anything about it if these things were come and go, and that it wasn't any reason to go and take that operation when the possibilities of success weren't all that great. What he would recommend that he do would be to wait and see what happens.

Well, he went to Hoxsey and took the treatment and he got better. So when he was there to testify, he swore that he had this thing. Well, while he was testifying about this hemipelvectomy, one of the jurors fainted. (Laughter) Of course, it was so bad. But the doctor that testified before us and was a very personable guy, he helped the juror up. You know, he was on the witness stand. (Laughter) So those two cases, and then the others-- we were able to take each one of those cases apart and show that there really wasn't any belief there that the drug had done any good.

Well, the trial went on for about a couple of months, and then the jury returned a verdict for us, holding that the product was misbranded. That, in effect, closed that clinic down. Hoxsey testified in the case, and before he testified, I took his deposition and asked him about the old white horse. And he was so damned embarrassed. We asked him about it on the stand, and he just, you know, mumble, mumble.

But Hoxsey testified that he didn't make any money out of the cancer treatment, that that was all a pro bono publico thing, that he made all his money out of oil and gas. Well, we had his income tax and it showed that he had made about eleven million dollars in the last year off the drugs and that he'd lost most of it in the oil. (Laughter) We wanted to put that in evidence and Judge Miller looked at it and he says, "No, I'm not going to let you do that. If you put that in, it'll surely result in a verdict for you. I'm going to let you take a chance of getting a verdict with what you already have." (Laughter) And of course, we did; we got the verdict.

After that, there were a few more rumblings about that, but Hoxsey pretty much withdrew from the cancer business, and I understand he later died of cancer. So that was the end of the Hoxsey cancer.

FL: Didn't we have to bring another proceeding against the osteopath that was a successor to him to get . . .

WG: No, it was all in the same thing. He was down in Texas.

FL: At about the same time as Portage, didn't he also try to start a second one in Salt Lake City?

WG: I don't think so. There was a lot of talk that he was going to do that.

FL: But it never did gel.

WG: The talk that he had after the injunction was issued in Texas, was that he was going to offer these clinics at various locations where people would come there, and he would not be introducing drug into interstate commerce in violation. We told him that

would be a violation, anyhow. But in sum and substance, the Hoxsey cancer thing was proven to be false, and we got a jury verdict and the seizure case. I guess he never did have a criminal trial because of the difficulty of proving beyond a reasonable doubt in these emotional cases.

FL: In the investigation of that case, we went to considerable lengths. Didn't we send a couple of inspectors as prospective patients to Dallas and they went through the clinic?

WG: I'm sure we did. We had all kinds of evidence there of what the drug was. Yes, we did that.

FL: And made sure that he was really sending it to patients who lived outside the state.

WG: Well, that was more involved in the Krebiozen case, which was the next one I was going to talk about. The Krebiozen case was one of the most difficult that we had. It was complicated by the fact that Andy Ivey, an M.D., at one time a very distinguished member of the American Medical Association, and very distinguished in cancer research, became a supporter of Krebiozen. Krebiozen was brought into the United States by a couple of Yugoslav brothers, the Durovics. According to their story, they escaped from the Nazi underground during World War II and took with them from Yugoslavia to Argentina, this drug Krebiozen. They called it Krebiozen because cancer is a Kreb-like disease, and that's why they gave it that name.

Some time soon after the war, Stevan Durovic, the doctor brother, came into the United States from Argentina, and he said he brought with him the basic Krebiozen powder that he had made in Argentina. He claimed that Krebiozen was a product of actinomyces bovis. By injecting this actinomyces in a horse and then letting him develop that in his blood for a while, then bleeding the horse, and then taking the active

material out of that blood plasma . . . That is, he'd take the blood and then take off the red cells and then get the plasma distilled down, and he'd come out with a white powder. He claimed that he brought that white powder with him. When he came into the United States, he brought it in a suitcase, he says, and he did not declare it at customs because there was no reason to declare it, he said, and it was not a noticeable thing; it was a small vile.

Well, he began to tout this material as a treatment for cancer, claiming that he had this treatment, and he organized a so-called Krebiozen Research Foundation. He enlisted Ivey to help him. The AMA conducted an investigation in which they developed a lot of evidence, and they took the view that there was nothing there but mineral oil, that there was no active ingredient. I'm getting a little ahead of myself, but when people asked Durovic for some of the powder after he got here, he said, "Unfortunately, I can't give it to you because it was all dissolved in mineral oil. Therefore, I don't have the powder and I can't supply the sample." That was his story for a long time.

But through the years, he continued to sell the thing, and it kind of fell between the cracks between Food and Drug and the Biologics people. Durovic claiming it had been a product of horse's blood, that classified it as a biologic, according to Food and Drug; and if it was a biologic, it was exempt from the New Drug provision, provided it was licensed in the Biologics group. Well, it wasn't licensed there, and it wasn't exempt, but anyhow, between those two, he did not apply for any kind of approval or any kind of clearance and continued to sell Krebiozen.

He was investigated a couple of times, and he filed a New Drug Application at one stage and claimed that it became effective. Well, when the New Drug Application was filed, we wrote him a letter and said that the application was incomplete and was not approvable and in effect turned it down. "If you want a hearing, you can ask for a hearing," which he didn't do. He then contended that, due to the operation of law, the New Drug Application had become effective, and that he didn't have to apply. That's the

way the thing kind of went on for several years, up until the passage of the '62 Amendments. Come the '62 Amendments, it was necessary for him to either have an IND or a New Drug Application, one or the other. We claimed that he didn't have either one.

So we started work investigating Krebiozen. Ivey enlisted Senator Douglas in helping defend the thing. Senator Douglas put a big statement in the Congressional record about the Durovics, that they had all this work and that they had a proven cancer treatment, the AMA was abusing them--the whole schmeer. He had strong political and strong medical support there. And the department equivocated on it. Food and Drug didn't want to get involved with it because it was biological, they thought, and sure as hell, the Biologic group didn't want to get into it because it would involve some money and some work.

The thing kind of drifted along there until after the passage of the new law. And then we decided to bring the thing to a head. That caused all kinds of troubles. First of all, Douglas appealed to Ribicoff, and then to Celebrezze, and then to Kennedy. Then Ivey came down to Washington with the Durovics two or three times. And Ivey, having been such an outstanding man in cancer research, had doors opened all the way through, I mean right up to the top of the department. He could go right to the surgeon general or to the assistant secretary for Health and get an audience. We just finally said, "Absolutely not. We're not going to give an inch. We're going to bring this thing to a head."

We wrote him and told him he'd have to have one or the other, a New Drug Application or an IND, and to sell was illegal without that. Well, he was contending first, that he had a New Drug Application; second, that he wasn't introducing anything in interstate commerce. People had to come to Chicago, Illinois to get the thing. Those were essentially his defenses.

As we tightened down on him and wrote these letters, he then did two things. First, he went to Douglas and from there again to Kennedy, to pull us off, and they called on Celebrezze to find out what it was all about. Celebrezze kind of equivocated with us at

first, but then we wrote a written report to him of what it was all about, and from that point on, he stood very fast with us; we could go right ahead with it. He wasn't very happy with it, because the next thing done was bringing all those patients in. They were brought in to Celebrezze's outer office and into the auditorium there at the HEW. All of them were in effect protesting.

His pitch was that he wanted . . . This was Ivey's pitch at this stage, Ivey having been discredited in the medical profession. He was hell-bent on vindicating his reputation, at least by getting the thing subjected to a clinical trial. He didn't care how it came out at that stage, as long as he could say, "Well, all I wanted was a clinical trial, and the trial is underway." He would have been rehabilitated in the medical profession and would have been satisfied with that.

One time, Ken Endicott, who was then the head of the National Cancer Institute, was committed to buying some of this stuff. He asked them to give him a price on ten kilograms for some God-awful amount, and the price came back at eight billion dollars or something awful. They could have it anyhow, but the price that they put on that was prohibitive. We told him that it wasn't going to do a bit of good to buy that stuff and subject it to a trial at the National Cancer Institute, because proving that the drug is ineffective on lung cancer, on breast cancer, there would always be enough other cancers that he would never get to the endpoint, that the clinical trial not only would cost him twenty million dollars to buy the product, but also would cost him millions of dollars in going through these trials, and that the trials would be inconclusive.

And then we said, "This product has had a trial; it's been given to hundreds of patients, many of them under very careful medical control, that is, with a biopsy and with a medical treatment and so forth." We'd seen enough of those reports to know that the drug just was not working. So we then said to him, "You produce the 200 best cases you have," and then we would have those reviewed by the National Cancer Institute to see whether there was any basis whatever for believing the product might have an impact, or



for setting up a trial. Well, they hemmed and hawed about that, but finally did identify these patients.

We collected all the medical records, that is, the Food and Drug Administration's field force went out and either got the patients' consent or went to the doctors and got the hospital records--all the records available so each one of these cases could be reviewed. And they were reviewed. We built up that way a very reliable medical history of every one of those cases, and the fact that instead of us having a trial on some kind of an unknown product on a single disease, we had a nationwide trial of Krebiozen's own stuff on these patients who actually had cancer and that either then died or so forth. In addition to that, we put the pressure on them through inspectional means to produce some of this material. That is, "He said he didn't have any, that he put it all in mineral oil. Well, we got to the bottom of that, that he had bought ten barrels of mineral oil. We asked what came of it and he said he spilled it. (Laughter)

Pressing on, though, we finally got him to the point where he said he didn't have any more available. He would have to make some more if he was going to continue in business. Either he was out of the product or he would have to make another batch. So he went to the president of Quaker Oats, through Ivey, and made a deal with him which allowed him to treat some horses out at Rockford, Illinois, where Quaker has a dog food factory. They had these horses out there to make dog food out of them. So he let Durovic inject and bleed these horses. And like all con artists, Durovic did it in high style; that is, he put on a white coat and he got a syringe to inject these horses. He had a big tube on it so it would show up in the picture--you know, everything that a con artist would do. He had his picture taken out with these horses; he was going to give them the shots and so forth.

Well, he gave the horses the shots, and then the horses were bled. Then the problem came of what happened to the plasma? We were right on his tail at that time. We had Bob Palmer out there and other inspectors around from Chicago keeping absolute

contact all the time. One Friday afternoon, they went out there to get some samples. When they got there, he had just left; that is, the Durovics had taken the material into Chicago. Then they had rented an old used firehouse which was their so-called manufacturing place. When we got pressing in on that, we learned that they had poured the plasma out in the city sewer.

We kept on with that, in effect, having a statement out that they didn't really have anything to sell, so they kind of had to go out of business, at least temporarily. Then came the trial. We got them indicted and went to trial with them. And again, the thing was drawn out forever. We overtried our side and they overtried their side. But the upshot of that was that they were all acquitted, that one of the jurors was fixed, and that guy was later prosecuted and convicted for manipulating the jury. Ivey was first acquitted, and then the Durovics were acquitted. Then after the trial we had gotten enough records of financial transactions and shown them to the IRS to where they were prepared to go ahead and do some action on them under the income tax law. But Steven Durovic left the United States and while Marco Durovic stayed here, that product died a death just like that.

So all these three cases show you the grave difficulty of proving the ineffectiveness of a cancer treatment, and the cost and the efforts that go into it, and the pitfalls that you face, even where you have all the evidence on your side in proving that the thing never fails. People somehow want to believe that. I saw a lot of those people face to face that came to testify.

For example, one woman was a nurse in a major hospital in Chicago. She had taken her husband to Portage. The place was a revamped garage. Now, she should have known--and she did know--by looking at it that it was not the kind of place that her husband should be. But she couldn't bring herself to blame herself for that. She thought that they were offering a ray of hope when she didn't have any ray of hope for him, and that therefore, she was really doing what was right. Well, after he died and we talked to

her again, she conceded that she'd made a terrible mistake. But having gotten into it, there was no backing out on it. People want to believe that there's something there, and when the doctor tells them, "You've got a melanoma on your butt and this is the only treatment that's available," they're going to go and believe these people who are bound by the truth but will tell them anything to take their money. And, of course, they weren't making a lot of money. All three of these cases that I have illustrated to you involved millions of dollars and they were all scientifically proven to be worthless, and even in the end, the treatments were all defunct.

RO: Did we ever examine or analyze the Krebiozen to find out really . . .

WG: Yes, we got the powder, and it was . . . Durovic, finally being pressed hard enough, supplied us some powder, and Joe Carol, Joe Levine and Danny Banes analyzed it, and it was creatine, that you could make from hamburger meat.

FL: In at least two of those cases, too, Bill, if my recollection is correct, there was a lot of public sentiment generated in favor of those . . . Hoxsey and Ivey both.

WG: That's what I had in mind about the patients, that they, of course, got a lot of publicity when they came down to HEW and showed up in the Secretary's Office claiming that this was the only thing that was saving their life: "Here's my daughter; here's my son. He's got a fatal disease. I want to give him the medicine."

That's what else. They got laetrile back on the market and caused those state legislatures to pass those laws, making the product available. In each case, they were motivated by a patient's coming there and appealing to their sympathy: "If we have any hope, let us do this," and that's a very, very persuasive thing, only you've got to look at it

in terms of to offer hope where there isn't any hope is one of the worst things you could possibly do to those people.

FL: Well, I remember in the case of Krebiozen, they set up an organization nationally, the Ivy League, with chapters in various cities.

WG: That never made any big splash.

FL: They tried to generate local publicity in the newspapers.

WG: That didn't work out. What worked out was gathering together a nucleus of twenty, thirty hardcore believers, and they were the ones who came and boycotted the offices and put on this show of support. They didn't show up at the trial; we didn't have any of that sort of thing at any of the trials. But that's what the politics of it was.

FL: Were you going to go into laetrile at all, the early years of it?

WG: No, I don't think so. I was going to leave that for somebody else because when I was dealing with laetrile, it was not a factor. After I left the agency, it became a factor as a result of the state actions that allowed it to be so notwithstanding the Food and Drug's lack of approval. My experience with laetrile, we had these lawsuits and we won all the lawsuits.

FL: With Krebs out in San Francisco before he went to Canada.

WG: Right. And there was another one down in Oklahoma, too, wasn't it?

FL: That was the one that I think was the second go-around we had, that generated all the problems. That was later.

WG: Okay, that's the three cancer cases.

FL: With the one from Detroit, Dr. Koch, it seems to me there was a story about his complaining to us after he had gone to Brazil that his product was being purveyed down in Mexico.

WG: That may have happened; I don't know.

FL: He wrote to us complaining bitterly that we should do something about it because that was not his own product. (Laughter)

WG: I have a vague recollection that that did happen.

RO: Were you going to mention anything about the Scientology case, Bill? You were still here, I think, when that was . . .

WG: I hadn't planned to. Joe McGuire handled that case, and . . . Oh, Scientology. I was thinking about Reich. The Reich case was handled by Joe McGuire who was my deputy in the General Counsel's Office. Wilhelm Reich had an orgone energy generator, which was supported by his writings, which explained that it was a source of drawing life rays or something, a new life force, into the patient. It was a plywood type of box, and it was lined with some sort of metal. The patient was to sit in that and it would regenerate the life processes through this orgone energy which was accumulated in the device and then delivered to the patient. Reich had a place up at Rangely, Maine, and Reich was a

psychiatrist author of some international repute, and he had written widely on the orgone energy accumulator.

We brought an action--I forget whether it was an injunction or a seizure--in Maine against the product. Joe went up there and tried the case with the assistant U. S. attorney, and they were successful in proving that it was not effective for the conditions for which it had been written, and he received an order requiring the destruction of the so-called labeling. Well, these were the writings of Reich, and that raised all this business of the specter of book burning and so forth, and he was able to accumulate a lot of support from civil libertarians claiming that we were in effect engaging in book burning when actually the decree provided that the books would not be used again with the machine. Some were destroyed. But that case was handled, tried successfully, and the main upshot of it was publicity that continues even to this day, contending that what we were doing was interfering with free expression and not dealing with a commercial product.

With Scientology, our experience here was that they established a place of business in downtown Washington in a row house towards the center of town. In Hubbard's early writings, in *Dianetics* and other things, he had espoused this psychological theory and later hit on the idea that by making a church, they would be exempt from any regulations, hoping that they'd be exempt from Food and Drug and from tax regulation. We sent inspectors; Taylor Quinn enrolled in that in Washington and went there as a student to learn all there was to be known about it. He stayed in there with it for quite some time. I was just congratulating him yesterday on the risk that was involved in that. It takes quite a bit of courage to go and get that deeply involved with those people.

But he did, and he brought back all the material. We then did an analysis of it and what they were claiming, and proved that they were selling their services for money and that they were doing harm. We won in the district court. Then when it went up on appeal, the court of appeals held that we were challenging a religious belief and that that was

exempt from seizure under the Food and Drugs Act. So we were way ahead of our time on that, and we were not successful because of the religious overtones that were put on it.

FL: The device is still used, do we know?

WG: I imagine so. I think we've just stayed out of that since we were told that it was not our . . . The device, you remember, was a couple of juice cans the E-Meter, that you'd hold in your hands, and the sweat would generate this electrical charge between, and it would show on a little gauge. If you were being monitored and the gauge flipped around, you were either lying or you were clear. You would not be clear until that gauge stopped moving around. But it was a physical operation with the person holding the machine.

Another area of enforcement that was new under the 1938 Act involved economic frauds. This proved to be one of the most difficult areas that we had all across the board. You'll remember that in the 1938 Act, food was declared to be adulterated if it was made to appear better or of greater value than it was. This was the basis for actions that we took, or if any substance had been substituted . . . I believe in the act of 1906, substitution of one product for another was an adulteration, but the new thing in the '38 Act was that if the product has been made to appear better or of greater value than it is, then that would be the basis for an action.

Although adulterating products with water and cheaper ingredients is one of the oldest adulterations known to man, we had plenty of problems with that. For example, proving that a juice product was not what it appeared to be was one of the major operations in two large cases: one, the Bireley Orange beverage product, and the other, the Cal-Tex case in Houston, Texas.

In Bireley, the product was in a wide-mouthed, soda-type bottle. It had some suspended material in it; it was made cloudy; it was orange; and it was promoted as containing some Valencia orange juice. Well, we made a charge that this product had

been colored and packed to make it appear better or of greater value than it was, i.e., that it contained more orange juice than it actually contained.

In the trial, that was proven several ways. First, before the jury, to simply bleach out the added color, and the product looked like it really was. Then they analyzed for the amount of juice in there, and it came to less than six percent. In those ways, the charge was, in effect, that the product was made to appear to have more orange juice than it actually had, i.e., at least twenty-five percent when it had only six percent. So we won that case in the district court. We proved what the product purported to be by opinion survey, that people did think it contained a substantial amount of juice.

The judgment was in our favor, and then that was appealed. One of the judges in the court of appeals was Judge Hastie, who was one of the most intelligent federal judges around, ruled that we couldn't make a case like that where the jury would have to guess what level of orange juice the customer would expect. That is, that would put the manufacturer at risk; if he put in six and the jury expected twenty-five, he would be held to adulteration on some unexpected thing. The court held that the only way you could go at that would be first to establish a standard for that kind of a product where everybody would agree that the proper level is fifteen percent or twenty percent, and if you established the level, then everybody would know what that level was, they would have to comply with the standards. But under the general language law, made to appear better or of greater value than it is, it would have to appear to be some defined, superior product, in this case, 100% orange juice. It wasn't enough that it appeared to be a product containing greater concentration of orange juice than it is. So that was one of the problems.

In Cal-Tex, these people were treating orange juice with citric acid, and water, and artificial flavor, and sugar and selling it as a reconstituted orange juice. The surveillance by the inspectors clearly showed that they had these ingredients delivered there, and they observed the materials being delivered to the manufacturing plant, and photographed it



all, and showed that this product was in all likelihood being fabricated from these non-orange-juice products, and it was not what it purported to be. It was not a reconstituted orange juice. But the difficulty was in defining what was a reconstituted orange juice? How much water and how much citric acid and the other things are normal in this product? And it has such a range of actions that when you prove that it was anywhere near that range, you'd failed to prove your case.

And that's the same thing that was involved in the oyster case. If you have a standard for oysters that calls for a certain amount of solids, and the oyster being such a variable product in terms of water content, it simply was impossible to prove that this was not a natural product and was in violation of the standards. That's what those cases were all about.

As the Food, Drug, and Cosmetic Amendments were proposed in the mid '30s, devices were not separately regulated. But it was the intent of that revision to place the same kinds of controls over devices that applied to drugs. There wasn't any definition of device, but the definition of drug was made to include estimates, apparatus, and contrivances, which were devices. And in the legislative history, it was plainly shown that it was the intent of the act to cover devices for weight reduction, arch support repair, and other things like that. But the opponents of the bill really took that as a laughing matter; they claimed to classify a crutch as a drug just violated all common sense, and therefore it didn't make any sense to have that under the drug definition.

So that controversy continued all the way through. When the New Drug Provision was put in, they did not say anything about new devices, because new devices would have been covered under new drug as long as devices were drugs. But at the last minute there, to get away from this claim that the act was claiming a crutch was a drug, the new definition of device, quite parallel to the drug definition, as you know, was inserted and the regulation of devices proceeded on that basis.

My first real experience with the device was in the Urbeteit case, in which this naturopath down in Tampa, Florida had a device which was represented for treatment of every kind of a possible disease. It was a simple little shocking machine; that is, it had a little battery in it, and you'd take hold of it and it would give you a little shock and you'd feel that. These off and on currents, he claimed, would cause the tissue contraction and therefore would help treat a large variety of diseases.

In that case, we first used experts in physical medicine to testify about device claims, that is, to prove that a device was simply a modality for having some physiological effect, and that what was happening with this machine was well understood, and that that action couldn't possibly have anything to do with high blood pressure or some of the other diseases that were known. That case turned on the labeling issue, whether or not the promotional material used by Urbeteit was actually labeling or whether it was advertising subject to the control of the Federal Trade Commission.

We brought several other device cases, and we learned from the Urbeteit case how to put those on pretty well: by using experts in physical medicine, and by explaining to the jury and to the courts that this device is a barrier of some physical force, things of that kind. Physically, what is it doing? And make your case from there. So we never really had any great problems with that.

Now, some devices like bandages and prophylactics were under the drug provisions, but with the new definition, devices were separately regulated and were not under the New Drug provision. They were not under the new drug simply as an operation of its history. When the device definition was put in, the new drug definition was not changed to accommodate that. And so for years, we had no real new-drug-type approval over devices that were newly being introduced into the medical profession.

Most of the device cases that we brought during those early years were over simple things like Urbeteits and things, or a belt, or Dinshah Ghadiali's Spectochrome, which was just a showing of light through various colored glass--things of that kind

which were relatively easy to explain. The devices came into the real world with us in connection with two cases. One was the suturing device put out by A.M.P., and the other one was the antibiotic disc case involving Difco in Detroit.

First, when the suturing case came up, what A.M.P. had was a new method of tying these sutures. It was a plastic, kind of a little button on the thing that you'd tie on the suture, and then that was inserted into the wound. The thing was alarming to surgeons on what would be the fate of that little button left there, and what the material would really hold with this kind of a suture as against a sewn suture that was used by surgeons. So they became alarmed, and we became concerned. Then A.M.P. asked us what we thought, and we told them that we thought it was a new drug. They then demurred, and I've forgotten whether they filed suit. I believe A.M.P. filed suit against us for a declaratory judgment.

Being able to show that sutures have long been drugs by recognition in the USP and by other ways, it wasn't such an illogical step to classify them as new drugs, particularly for something that was put in the body and left in the body. That was kind of the compelling feature of that case. It enabled us to get a ruling by the Second Circuit Court of Appeals that the A.M.P. suturing device was actually a new drug and was subject to new drug controls.

That was followed by Bacto Unidisk relatively soon. The Bacto Unidisk, those antibiotic disks--they've been around for quite some time--the Antibiotic Division had tested a lot of them and approved a lot of them, but never had certified any of them. Difco was the first big promoter, I might guess. Others were kind of put out as an auxiliary to a drug by the company selling the drug, just as a way to test for . . . We had a seizure; we tried to get Difco to get those things certified, and they wouldn't, and finally called our hands. We had to initiate a case to proceed against them. I'm not sure whether we won in the court of appeals or not; I guess not. But we did win in a big way in the Supreme Court by being able to show that because the risk of misdiagnosis was so great, and because

these things had such a powerful influence on the choice of the antibiotic for treatment, there was a major risk there. That's what carried that case for us through the Supreme Court. We got a quote from Goodman and Gilman on them that clearly showed the role of the things in medicine. This is what worked for us in that.

Having had these two cases classifying the Bacto Unidisk as an antibiotic drug and the suturing device as a new drug, then it became important to see where we were going with various devices, and to draw the line between drugs and devices. I guess our idea was to have a new device law similar to the new drug law, and we made that kind of proposal for several years to the Congress--to deaf ears, I might say; they were not at all interested in doing that.

So finally the Secretary, I believe Ribicoff, decided to set up a committee to study what ought to be done about devices, that is, whether we needed legislation, and if so, how to go about it. So he appointed a committee headed by Ted Cooper, then the director of the National Heart and Lung Institute. I was on the committee. I believe Wetherell from Food and Drug was on the committee. He was either on the committee or was an alternate. Then we had the deputy director of the National Cancer Institute, a man from the Dental Institute, and others drawn from the department, on the committee.

Ted Cooper was a remarkable man in terms of running a committee of that kind. He just wouldn't let you get by without doing something. He organized the committee to where we had to have a meeting every Monday morning at the National Institutes of Health at 8:30 or something like that in the morning. And he wouldn't take no for an answer. You know, "I can't get out; I can't get any parking places." No, he answered all those, "Use my parking place." So we met and went over the problem.

Then Ted invited in representatives from a lot of different places. First was people that were involved in inventing and promoting these things, people that made artificial hearts and things of that kind. They were inventors; they were just good mechanics that would put these things together. Then he had a survey done of the literature over device

accidents, a great many device accidents happening in hospitals, many of them electrical in nature. He collected all that information. Then he brought in people from the various branches of medicine: what devices were they using, what did they know about the devices, how did they test them to be sure they were working as they were supposed to, how did they know they were getting the result that was being read out--all those questions that really no one could answer satisfactorily. He went through this operation for several months in the early '70s.

The committee then issued the report, recommending that the regulation of devices be in four level stages: those that were generally recognized as safe and effective have no control other than their own professed standards of quality of performance; those that required standardization, like electrical equipment, just to be sure that it operated right; those that required some kind of a pre-clearance. That's three classes, I believe. So we recommended that a law be enacted along those lines that would set up a new device control that would enable the department to survey the whole field of device use, specify those devices that were so common in use that they required nothing beyond attention to their labeling and whether they were what they purported to be and operated as they purported to operate; second, that they then provide a list of those devices that required standards, and what those standards ought to be; and next, what devices ought to be subject to the regular pre-clearance, pre-clinical, and full-scale production rules that were apropos to drugs. And that's what was recommended.

When the thing got up to Congress, they really got messed up with it and came up with a very elaborate bill. I was gone then, and the department lost all control of the legislative process, all input into the legislative process. I'm not sure they lost all control into it, but anyhow, Congressman Rogers, who was the chairman of the Subcommittee on Health, and his people, got up the device bill. And it was something that they'd never administered and never understood, really, the complexities of.

So they came out with a bill that was terribly, terribly complex to deal with this problem. It follows, in general, the lines of the Cooper Committee Report, but because it's so complex, the department's never been able to do very much with it. They claim that there are several hundred devices that need standards, but they don't know how to proceed. Well, you know, all you've got to do is find out what their professed standard is. All of them have standards, or else they are irrational. Every device out there has got some kind of a standard, and why they can't get on with that and decide that, it's just beyond me. I've told those guys that: "When you say you don't know what the standard is, you can't even read the literature, because that's what the standard is, that's what it purports to be. If you want to exempt them from standards, go ahead and exempt them; you've got that authority." But the device bill just became way too complex, and that's the source of the problem with it.

FL: In your discussion of the suture device and the Bacto Unidisk, where we didn't have any specific authority on that kind of new device, and we brought it under the New Drug section which was available--isn't that sort of a typical way that we've handled problems over the years?

WG: Well, you know, when I was General Counsel, people used to accuse me of selecting cases to make law up as we went along, but I always denied that. We did try to take advantage of any case that had a useful, factual situation and a real need for some regulation, as was the case with the Unidisk. In the case of the A.M.P., they sued us; they wrote us and we wrote them a letter back, and then they sued us. So they initiated that action. And then, in recent years, more of the law has been made through people suing us than us suing them. Years ago, you couldn't bring a declaratory judgment against the government; that was only possible after the toilet goods series of cases, Abbott against Celebrezze. So we did have a selection to make, but even in the cases we chose, we

couldn't be sure they'd contest. We would bring the case with the idea that if they contested, we were ready to go to trial with them and that we were ready to prove that we were right. It was pretty much a big bluff--not a bluff. You know, industry, when it costs money to contest those cases, are reluctant to come on in and go to bat when they know you're prepared to go all the way with them to prove your point.

FL: I would agree with what you said. What I was really trying to get at was that when we perceived some kind of public health problem that no one else was doing anything about or had no authority to, we then looked in our statutes and deliberately tried to find some way to do something. The over-the-counter sale of dangerous drugs is a good example.

WG: That's absolutely true, Fred. Food and Drug's history--I don't know whether it's true now or not--but I know when I was there, it was a can-do organization; it would not try to make excuses of why they were not doing it. They use all kinds of excuses now: they don't have people, they don't have money, they don't have this, they don't have that. They've got more of that than we ever had way back there, and they just will not do things like that. Doing something, particularly a hard case, involves work and it involves money and it involves effort, and they just won't do that anymore. But we did that for years and years. How did we get into the hazardous substance business? How did we get into the firecracker business? How did we get into a lot of other things there? The turtles. Everything that came along nobody else would do it. We would end up doing it.

For example, once on poultry inspection. Nobody was inspecting poultry. So the union came to us and said, "Agriculture won't do it because it costs too much money. Let's amend the Food and Drugs Act." And we were gung ho to go ahead and do that. Secretary Folsom said to us, "You know, if you take that responsibility and you start inspecting those chickens, that's going to take priority over everything else you've got.

You don't have any money now." That was in the '50s. He said, "How can you undertake to do something like that without being assured that it's not going to take away from the rest of your operations?" So there was some of that to it, too.

But in terms of the child protection, we took the poison center idea and that was run by PHS (Public Health Service) on kind of a voluntary basis. We tried to make that something that was really good, and I believe we did. But that is the history of the thing. Now maybe some time, like in the case that Folsom was talking about, we would take on something that was at the expense of something else. The vitamins, which I was going to talk about next, was one of those big examples. One, it cost us millions of dollars and ended up unhappily for us by the court saying, "These things are not dangerous; let them go ahead and sell them without any restraint, even though it's a gigantic fraud." You just can't be sure how some of those issues are going to hit people.

(Interruption)

FL: This is a continuation of the interview with Mr. William W. Goodrich, retired general counsel of FDA. The date is October 16, 1986.

WG: Earlier in our interview, we were talking about food standards, and I mentioned the ones that were very important in the early days, that is, the standard for enriched flour and enriched bread, and the standard for canned fruits. I didn't follow up on that. There were, of course, other very important standards adopted about that time: standards for cheese, standards for frozen desserts, standards for milk products, standards for other foods. But before I leave that subject, I think I must take up the much-disputed, much-mooted issue of the peanut butter standard, because it has been so misrepresented and so desecrated as a bad example of government in operation that I have to come to its defense, even though I was involved only at the beginning and, of course, in the court of appeals with that case.



The standard for peanut butter came about in this fashion. At the beginning, the leaders in the business were Skippy from Best Foods and Peter Pan from Swift. Those were the leading brands. Proctor and Gamble decided to come into the market with its product, JIF, which is now, of course, one of the major, if not the major brand. The original proposal on JIF was that it would contain more emulsifier than had been involved in the other products. And that was regarded by the people in food administration as a bad departure. That is, putting a non-peanut fat in that product to make it more spreadable just didn't seem to them to make sense, and was a typical type of what they would regard as an economic adulteration.

Proctor and Gamble was represented by a man who later became secretary of Commerce, whose name escapes me at the moment. He came in and talked with Malcolm Stephens, who was then the associate commissioner for enforcement. An inspection was made at the plant, and while the inspectors were out there, someone mentioned that the additive they were using was Crisco base. Well, that, of course, raised everybody's eyebrows about what was going on in there. They visualized it as adding Crisco shortening into the product. That's not exactly what happened, but that's the way it was reacted to by the enforcement people at Food and Drug.

So it was proposed that a peanut butter standard be adopted which would hold the product to essentially all ground peanuts with a little salt and sugar; that is, it would be essentially just ground-up peanuts with salt and a little flavoring. Two or three proposals were made. One I believe was for essentially all peanuts, then 95 percent, and then it got down to about 90 percent. That's when the hearing got underway.

The reason the hearing became so protracted was that Proctor and Gamble, CPC, and Swift were all very well represented there, and the proposal to adopt a standard just simply couldn't accommodate all those products. JIF, of course, was proposing more of the emulsifier; the CPC product had a partially hydrogenated peanut oil which was built into the product and was flavored with sucrose, as I recall--that or Peter Pan. So the

difference was that the Proctor and Gamble product would have had more emulsifier than the Best Foods product, which was the best selling at that time, and the Best Foods product would have had a higher percentage of emulsifier than the Swift product would. And so, it was trying to reconcile those numbers of where the proper point lay for an appropriate level of peanuts in the product without allowing the adulterations by the emulsifiers of the flavorings or the seasonings and the oil.

So that's why the hearing was held, and that's how the hearing came out, that when the standard was ultimately adopted, a level of peanuts was insisted upon, and the added optional ingredients were held to essentially what was deemed to be a practical level. The upshot of it was that the fifteen percent emulsifier, which was requested by Proctor and Gamble, was not allowed, and the amount was increased somewhat to accommodate the Skippy product. But in the ultimate solution of the thing, the existing products which had the total market would not be within the standard, and the standard was trying to make a step forward in being sure to protect the integrity of those foods. This is what caused the great, protracted hearing. And while it's been said that is an example of Food and Drugs' abusing the administrative process, that's not at all what happened.

The lawyers involved were Tommy Austern, who was the leading light at the bar from Covington and Burling. He was representing Proctor and Gamble. Kleinfeld and his firm were representing Best Foods. And so they simply hung in there day after day. The hearing examiner was the one who was really at fault in allowing the thing to go on so long that the record became very, very protracted, and it was an example of a massive record over a pretty straightforward issue, that is, how much peanuts should be in peanut butter. Even though the law had been amended earlier than that to try to simplify the establishment of food standards to eliminate hearings to a certain extent, that original amendment only eliminated hearings on non-controversial items, and there was nothing it did at all when this controversy arose.

I was into the case at the start, discussing it with Malcolm Stephens on how to set the thing up and whether or not we could establish a standard which would insist upon a level of peanuts in the product that was what we considered to be in the consumers' interests, which may not necessarily conform with what the existing product was. The query was, are we bound in the standard to adopt the market leader as the standard, and are we prohibited from making changes in those market-leading products that we believe would be an appropriate step in coming to a good standard? Well, the hearing was held and after much debate back and forth and decisions and not decisions and kind of decisions like Ken Kirk and others who were in the food part of Food and Drug at that time, the ultimate standard came out.

Of course, I know very well that CPC appealed, Best Foods appealed. So I got the case to take it to the court of appeals. And the issue there was whether or not the standard could call for this product which was a new item, new in the sense that it fixed a level on peanuts and on emulsifiers and accommodated both partially hydrogenated peanut oil and fully hydrogenated peanut oil and the fixed product which was used by some, which was the fully hydrogenated rapeseed oil. All those products could be put in there, but because they were so different, the level for one wasn't necessarily the right level for the other. This is why we had to adopt a level which, as I remember, was somewhere between 90 and 95 percent, which was a good compromise.

As a matter of afterthought in history, if one looks today at JIF, it has met with the standard and is probably now the leading product. Whether it would have been a better spreading product with more emulsifier in it is a question, but we're not embarrassed by that standard. As a matter of fact, we think that standard was pretty good, and just like many of the other standards, has been terribly misunderstood by people who were not involved in these standards.

Remember, they were products of the Depression, and were products of economics in keeping up the food supply. Today, the interest is in all these new products

with new names, but that was one of the things that the standards were supposed to get away from. To think of repealing the standards provisions, keeping in mind the great benefit achieved by enrichment of flour and bread, which was only possible through that standard, and the accommodation of canned fruits through these sweeteners that have come through the years, I say that that was a pretty far-reaching and pretty knowledgeable operation. And maybe today the economics are not what they were then, and the standards were too stringent. But I don't go along with this business that it's an appropriate idea to put a whole bunch of stuff on the label and think people can make a judgment on that product from those label statements.

As a matter of fact, once I talked with George about the label statements and talked with Charlie about the label statements, that is, Dr. Edwards and Mr. Larrick. I told them these label statements are a joke. They're so small and so poorly understood that we really ought to go for some sort of a label thing that would explain what they were and how they performed in a food. Well, both of them thought that that was something that was really not of enough interest to go into; it would cause problems. Even though they recognized that the label statements were obscure and not fully understood, they were not in favor of that. After I left, of course, we had a big to-do about labeling, and I guess nothing really ever came out of it. But it maybe proved that Charlie and George were right in the first place. (Laughter)

FL: The court did uphold the peanut butter standard.

WG: Yes, it did, in spite of the fact that both the market leaders did not comply, as they were then formulated. But it was easy for all of them to reformulate and come into the market. They're all in the market now; they're all very fine products; peanut butter is a better product as a result of that standard and has never been downgraded as a result of steps that were in the offing at the time the standard was adopted.

Well, going from there, I think the next thing we ought to do is pick up the sequence of events in terms of the commissioners who were here, because in history, that seems to be the most logical way to do this. We have talked earlier about Mr. Campbell, who was the long-time chief of the Food and Drug Administration, from the '20s up till the end of the war, about '45. And then P. B. D., P. B. Dunbar was put in as Commissioner. P. B. D. had been here since Wiley. He was one of the first employees of Wiley and worked with Wiley in the lab. P. B. D. was a chemist by training, and he had been pretty much out of the lab for quite some time, but he was a very fine administrator. He supplemented Campbell quite well in handling the budget and all those things. Campbell was kind of a philosopher king, and P. B. D. was the man who made the railroad run.

That same relationship arose between Charlie and Dr. Dunbar. That is, Charlie Crawford was, I think, probably our best thinker of the ones I knew best, in terms of looking forward to what was down the road. Charlie, of course, as I said earlier, was concerned with the food standards at first. He became interested in the issue of chemicals in foods in the late '40s. Really, after World War II there was an introduction into the bread supply of a new emulsifier which had been discovered by R. K. Vanderbilt Company, but produced by Atlas Powder Company. It was a polyoxyethylene monostearate, that type of product, called spans and tweens, and it was introduced into the bread supply to make the bread stay fresh longer. Those who were not involved in World War II and the economics of that probably have no recollection of stale bread and the habit of people squeezing bread to see whether it was fresh. Everybody that went into the store in those days would squeeze the bread to see how many days it had been there. So it was important in the business to have a bread softener, one that would make it softer to the touch.

Well, mono and diglycerides had been allowed in bread and part of the shortening for a long time and were popular items in the shortenings available to bakers. Swift made them, Proctor and Gamble made them, other companies made them. Indeed, during the

bread hearing, back earlier than that, the issue of emulsifiers had been involved through lecithin. The American Lecithin Company was wanting to get lecithin in practically everything you can think of; they considered it both a health godsend and an emulsifier godsend. But anyway, they were basically interested in getting it as an ingredient in a widely used food like bread.

But to get back to where we were, when this new emulsifier was introduced, it was viewed with alarm by the competitors. The competitors then went to the American Institute of Baking, and to the American Medical Association, with concerns about the product both from a functional standpoint and from a biological standpoint. This was not a chemical substitute in the ordinary sense; it was a reaction product made from reacting alcohol with a fat. It had peculiar properties in that it really did make the bread feel softer to the touch.

So the bread standard took up after the war, and one of the major controversies about that was whether or not these new emulsifiers should be allowed. You'd think of standards in terms of promoting honesty and fair dealing in the interest of consumers. That's an economic concern. But the whole issue turned on the safety of the product. That is, the people concerned, both the American Medical Association and the Institute of Baking, of course urged on by Swift and Proctor and Gamble and others, were raising issues about the safety of the thing. So when the hearing got underway, it went on for weeks and weeks and months and a couple of years, all dealing with the safety of this product, whether or not it was safe to put this thing in there.

Again, like in the peanut butter case, these companies were very well represented. As a matter of fact, Potter Stewart, who later was on the Supreme Court of the United States, was the lawyer for Proctor and Gamble and the Institute of Shortening. And Swift had their general counsel down here. And Atlas had their people here. So the hearing went on and on. What made it more protracted than ever was Atlas's proposal to admit not just one ingredient, Myrj-45, but a whole series of spans and tweens which varied by

how far the reaction was carried with these various items. They wanted all of them introduced. So the evidence on any one of them was fairly thin.

That hearing went on and on, and ultimately the Myrj-45 was not allowed on the ground that its safety was in question, and that it offered the possibility of deception of a practice called "bread-rolling," in which bread would be picked up at one outlet and turned over to the next customer there as fresh bread, even though it was several days old. Now, whether or not you could tell any difference was a debatable fight. But that controversy was the first one really focusing on Food and Drug's ability to deal with a new food additive of unknown safety.

(Interruption)

WG: When the '38 Act was passed, Congress did undertake to deal with substances that they described as poisonous and deleterious substances. Under the 1906 Act, a food was adulterated if it bore any added poisonous or deleterious substance which may render the food injurious to health. And the old Lexington Mill and Elevator case had held that if by any possibility an additive of a particular food would make that particular food possibly injurious to health, then it was adulterated. But each food had to be considered on its own.

So one of the great flaws that FDA saw in the 1906 Act was the inability to cope with a variety of additives that may individually be poisonous but had come together in the total food supply, but none of which individually would be up to a level that would permit the proof that they would be injurious to health. And even though the Coca Cola case had held that all substances and ingredients in foods were added, that strength of the law there simply didn't get to the issue of poisonous and deleterious substances across the board.

Well, in '38, Congress undertook to deal with what I characterized earlier as the per se rule, which provided simply that if any added poisonous or deleterious substance was in food, it was per se illegal, and thus there was a tolerance for it. And then there was a tolerance authorized for those additives that were required in production or unavoidable in good manufacturing practices. That was to accommodate pesticide residues on growing crops and other unavoidable, environment hazards, is what the legislative history indicates.

But that was the state of the law dealing with those substances, and here we had in the Atlas case an entirely new issue: that is, here's a substance that is greatly suspect, but no one knows enough about it to classify it as an added poisonous or deleterious substance. Whether it was poisonous or not, you really didn't know. They had always had trouble from the very beginning of dealing with a poisonous substance, because you'd have to rely on animal studies and you'd get in court and the guy says, "We don't sell this to rats, and therefore this is all irrelevant." It did involve an extrapolation of the judge or the jury from animal studies over into the human experience. So that was another problem with the early law.

Crawford saw this and his interest was greatly promoted by what he was seeing in the bread softener things. So he became interested in getting either the agency, but he thought primarily getting the Congress, to concern itself with this issue, looking way down the line, as he did, to some kind of law that would cope with these new items. He didn't really fully understand the difference between a poisonous and deleterious substance and one of unknown or uncertain toxicity. In his thinking, he talked about chemicals in foods and added and poisonous and deleterious substances.

He was able to talk with Frank Keefe, who was then a congressman from Milwaukee, I believe, somewhere in Wisconsin--maybe from Madison. Congressman Keefe, in the Eightieth Congress, had created the special committee to investigate the safety of chemicals in foods. That started in about '48 or thereabouts.



I'm not sure exactly of the year, but by the time the Democrats came back in control of Congress, in 1951, that committee was changed over to the chairmanship of Congressman Delaney, and that's where the big drive for the addition of legislation came. Alvin Gottlieb, who still works for Food and Drug, Vince Kleinfeld, who was at the Department of Justice, were counsel there, and, of course, they knew quite a lot about this. Charlie provided them with a list of some 700 items that were, in his judgment, suspect, and so forth. They held very extensive hearings in '50-'51.

In 1952, the Atlas case was decided in our favor, in the court of appeals in Philadelphia. I took that case up; I argued the case, and we won on that issue that they had the authority to exclude under a food standard an item of unknown, uncertain toxicity. But the record was real good for me, and it elucidated all that was really wrong then about food investigations, and problems that still arise today.

Most of Atlas's problem arose in proving the safety of the thing out of first, failing to identify specifically what the additive was and what they wanted it in. In terms of overreaching, trying to get a whole class of items in there, they outsmarted themselves. Second, the research done had all kinds of problems with it. For example, they tested it in rats, and Dr. Krantz at Johns Hopkins was their investigator. The Swift and Potter Stewart cross-examination of that stuff made a joke out of it. Some of the rats got out of the cages over the weekend and were not accounted for. They had all problems--you've all seen yourselves in terms of accounting for every one of these rats every day.

And then they did some tests on rabbits, and the rabbits had cannibalism in the thing. Rabbits are normally a vegetarian animal, and these animals ate each other up. Then some doctor, Rene Dubois up in Rockefeller Institute, had raised the issue about whether surfactines in the diet might exacerbate tuberculosis. They had four monkeys, and one of these got tuberculosis and died. So everything went wrong, and that's why the evidence was inconclusive.

When the Atlas case was decided, that gave Food and Drug a strong hand in terms of calling the shots on what might happen. About that same time, the pesticides had really blown up. After World War II and when DDT came along and was followed by aldrin and dieldrin, and there was a regular flood of those things. There were a great many pesticides coming along, and people who were using them in agriculture were asking more and more questions of the manufacturers: "How the hell do I know this stuff is okay?" The manufacturers would have just as soon gone along with saying, "Well, it's registered by USDA," and no question of concern. But that wasn't an acceptable answer, so they began putting some steam on the pesticide manufacturers to come up with an approval.

We had had a hearing in the early '50s over insecticide spray residues. As you can see, under the law as it was then, the hearing had to prove what pesticides were being used on what crops, which ones were necessary in terms of food, and which were only convenient. Of the ones that were necessary, then, what's known about their toxicity and what would be a safe tolerance. Well, that hearing went on for months. People testified from USDA, from the state experiment stations, from Food and Drug--from everybody. The upshot of it was that the record was inconclusive. You couldn't do anything with it; you couldn't make a single judgment there that would fit what the law was requiring you to do.

So by 1954, we had our first movement in terms of congressional control over these additives, and the Pesticide Chemicals Amendment of 1954 was enacted in that year. It was promoted by the pesticide manufacturers. The one that came through wasn't exactly what they had in mind, (Laughter) but they did get enough pressure from the so-called farm groups to interest the Congress in taking this up as an urgent item. We never could have gotten them to do that, but as a result of the pesticide manufacturers going to the farm users and getting the farm groups to support that, the House committee took up the bill.

The bill they proposed was really pretty damn bad, fundamentally because it would have required the agency to establish a tolerance for each one of these pesticides that were in use within a short period of time--sixty days, ninety days, something. That was the concept. So we said we couldn't live with that at all; we'd have to have some way to turn down a tolerance; we'd have to have authority. Well, they wouldn't give us that, but we proposed that a language up there in the legislative thing, that the tolerance may be affixed to zero level, unless a higher level is justified by the evidence. That gave us the control over the things, and in effect, we would have been the same without that in that of the absence of a tolerance was zero. This confirmed that we had that authority. And so the Pesticide Chemical Amendment was passed.

You'll remember that at that time the registration of pesticides was still in USDA, and the fixing of tolerances was in Food and Drug, and the enforcement of tolerances was in Food and Drug. But there were a great many things registered and in use for which there were no tolerances.

The pesticide amendment was a complicated thing; it had all kinds of committees and all kinds of reports from the secretary of Agriculture to the secretary of HEW and so forth, but it did accomplish the goal of moving that thing along. This was 1954. And from 1954 over the next few years, a great many of those tolerances were regularized and were put into place. I'm going to mention how the procedure came to play on aminotriazole in just a few minutes.

Maybe I should go to aminotriazole now and then come back to food additives after that. No, I think I'm going to have to go to food additives first, because that's where the Delaney clause was, and the pesticide chemical didn't have the Delaney clause in it, and because of that, I've almost got to go to food additives.

When Atlas was decided in '52, as I said earlier, the food industry and Food and Drug began taking a harder look at these things. The urgency on the food industry wasn't fully understood by them because they hadn't had any pressure against the use of these

new things; nobody knew anything about them being poisonous, and they assumed they were safe. So they were using them. But people began asking Food and Drug, "What do you think about this?" Dr. Lehman set up kind of an informal adjudication procedure in which he would give opinions on this. That procedure was publicized in the *AOAC Journal* and was followed for quite some long time.

Charlie then drafted this legislation--he and I did--and it was kind of like the new drug approach. None of the people in the food industry liked that worth a damn; they didn't want to have to have a pesticide guy come and show the safety of food. The pesticide guy wasn't making food, they were making food. So it was a question of who had the responsibility. The pesticide guy had the responsibility, but the food manufacturer wanted the assurance that these substances were safe.

Rule making at that time was a relatively new technique--it wasn't a new technique, but it came in a wider use in the administrative process as a means of settling in advance rules for behavior and let the agencies fill in details from legislation that had binding force and effect of law. Before, there was a great dispute always about whether regulations were binding or whether they were just advisory. We, of course, had that same problem we took up into the court in the Abbott Laboratories case on what rules were binding and what were not. Congress, in '38, clearly thought that the ones that were fully binding, that is, the formal rule making, would be fully binding.

We drafted a food additive amendment which provided for the food additive manufacturer to apply for approval and to obtain a rule that would specify the conditions which they would use. Now, in order to get that through, of course, we had to have a grandfather clause, and that was where the famous GRAS list came along. The "generally recognized as safe" came from the new drug approach. Nobody liked it--we didn't like it, Congress didn't like it--but nobody could think of a better thing to do. So we had to deal with products generally recognized as safe, and then we had to deal with products that

were generally recognized as safe like salt and pepper which had never been subjected to any formal procedures.

That's where that part of the grandfather clause came from. Substances generally recognized as safe on the basis of either scientific procedures, or if they were in common use prior to 1958, the date of enactment, and were generally recognized on the basis of long-continued common use, would be approved. After much controversy, the Senate passed the bill. Senator Hill was the chairman of that committee at the time. He pressed a bill that did not have the Delaney clause in it. Jim Delaney, of course, was not on the House Interstate and Foreign Commerce Committee. We went to that committee and asked them to adopt the same thing the Senate had done, but without the Delaney clause.

Delaney wanted them to put the Delaney clause in, and they reported it out that way. But it soon became obvious that we weren't going to get the thing through the Rules Committee, on which Mr. Delaney was a member, unless we had something to deal with the Delaney clause. So we first tried writing into the committee report a statement that the law would be the same with or without it; that is, if a food additive caused any serious condition—a cancer or blood disease or anything else—it obviously wouldn't be approved, and therefore the thing was unnecessary. But it turned out it was necessary for us to get the thing through Congress. So we drafted the Delaney clause down in the department. John Harvey, who was then deputy commissioner, and I talked with Delaney and Senator Hill and got them to agree.

So with that, the food additive law was passed. The first thing that was done was to set up the procedures and set up the GRAS list. I don't suppose there's any reason to go into that; the historical records of that GRAS list are good enough, I think, without me talking about it. Quite briefly, what we did was we obtained from Dr. Lehman's group a list of additives that he would regard as generally safe for use in food, and we publicized that and asked for comment from the scientific community. We sent it out to people he had on his mailing list and we published it in the *Federal Register* and a few objections

came back. And we took off some things like carbon black and a few others that were objected to. But in essence, that rule was adopted.

So we started off with that in '58. Not much controversy about it. Putting it into effect was smooth. That is, Lehman had already had some things done and the GRAS list took off a lot of the pressure. We were able to move into that a lot differently than the way it's run now. "Tillie" Checchi, who was Harvey's special assistant, got together the GRAS list; Winton Rankin, who was Larrick's special assistant at that time, worked on the regulations with me. So we got that thing in operation fairly quick, and without any to-do. We thought the food additive law was the same with or without; it didn't make any difference.

Well, that came to a test in 1959, not under the food additive, but under the pesticide law. Our secretary at that time was Arthur Flemming. Arthur Flemming was a man of great public relations skills: he enjoyed meeting with the press; he enjoyed encouraging the press to come and ask him questions; he enjoyed having press conferences. He was a very good publicist and got a lot of mileage for the department and for himself out of that.

But the way the thing came into a real crisis in Thanksgiving of 1959 was over aminotriazole as an additive for cranberries. It was a weed killer that was used on cranberry bogs, and the idea was to apply it in the spring when the weeds were coming up. And in the fall, when the cranberries were harvested, there wouldn't be any there. So you didn't really have any problems with it, and it would be assured of a zero tolerance. Well, according to the way the pesticide amendment worked, if anybody was seeking even a zero tolerance or a minimal tolerance or a freedom from a tolerance, they would have to apply first for registration, and then when the registration was filed, that was publicized. Then, after a certain length of time, that was studied and the tolerance was granted.

In the normal timing of events, the application for this pesticide was filed and publicized in the spring. So the growers there thought that come fall, it would surely be granted, and therefore, they went on and used the thing with the idea that by the time the cranberries were ready to go, there would either be a tolerance or a freedom from a tolerance. Well, it didn't turn out that way. As the registration process moved along, it was discovered that aminotriazole was a tumor producer to the thyroid in animals. So the tolerance was refused. A lot of cranberries had been treated, and they were put in storage for a year's time. I guess all this registration was earlier than that, around '58. Some enterprising photographer took a picture out in Oregon or Seattle, where these cranberries . . .

RO: It was in the state of Washington.

WG: In Washington. Took a picture of one of those beautiful forests and these red berries and this yellow Caterpillar that was burying the berries. It was really a striking picture. So one of the reporters asked Flemming, "What's this all about?" He said, "I don't know; we'll have to look into that." He came back and he then reported that these berries were being buried because there was not any tolerance and they had had some aminotriazole on them. That explanation was okay for the moment, but it raised the other question, "What about all the other cranberry sauce that's around? Has it been used in New Jersey and Massachusetts?" He said, "I don't know." Of course, the upshot of all that was that he wasn't sure which cranberries had the aminotriazole on them and which didn't.

Just before Thanksgiving--all this occurred in early November--the public started rejecting them. Well, their whole sales crop is about Thanksgiving time. So they were understandably alarmed. Ocean Spray, as you know, was at that time--it may still be--a co-op, and there were other co-ops involved in growing and marketing cranberries. So

they were alarmed, and a congressman from Massachusetts, Hastings Keith, was on the committee that we were dealing with, that is, the House Interstate and Foreign Commerce Committee. He came down with fire in his eyes. They were going to really get after Secretary Flemming.

Well, Flemming was a master of public affairs, so instead of meeting all of them individually in his office, he held a big hearing down in the auditorium at HEW. He was the defendant and the judge of that. (Laughter) He invited them all to come down and he heard what they had to say. So the hearing was held, and at the end of it, he didn't really say very much of anything. If any of you ever knew L. D. Elliott, who used to be assistant commissioner for Food and Drug, you could talk to L. D. for an hour, and he never would give any inklings whatever that he'd heard you or agreed with you or didn't agree with you or what.

So Flemming held the hearing; he was very cordial to them, but really gave them no hint of what he was going to do. It was obvious to him, though, that he had to do something. So after the hearing was over, we adjourned up to his office and he inquired about what might be done. There were two courses: one was for the USDA to buy up this cranberry sauce and put it in storage until the safety was determined; the other, which we did, was for Food and Drug and the others to establish that crash inspection program, in which, within a very few days, we inspected, and we then inspected laboratories who inspected and certified that this cranberry sauce was free of aminotriazole. And that way, the crisis was avoided for Thanksgiving and the aminotriazole was over.

Now in the course of that, the issue came up, what is all this about? And Flemming said, "Well, aminotriazole is a tumor producer to the livers of these animals." They said, "So what? I brought an expert in liver tumorigenesis from Tufts University who said that thyroid cancer is really not seen in any significant degree in humans, and this is really not any reason for alarm, and in any event, the amount there is so small that it wouldn't make any difference." So that really raised the issue of allowing an animal



carcinogen into the food. When Flemming said that's what the basis was, people said to him, "The Delaney clause doesn't apply to pesticides." He said, "Well, the principle does." And that's when the whole rationale for the action was developed. This was in about Thanksgiving of '59. I'm pretty sure of the year of that. That's about a year after the food additive law became effective.

Meanwhile, the color problem had come up for settling, and we had won the case on that problem in the Supreme Court, dealing with the color used in coloring Florida oranges. A new law having to do with color additives along the lines of the food additive law was under consideration.

(Interruption)

WG: Under the '38 Act, colors had to be harmless and suitable for use. We had taken the view that *harmless* meant absolutely harmless, and that any animal injury from it was justification enough to outlaw these products. We had no authority to establish a tolerance for them. This is what we went to the Supreme Court on and won.

Since we won that case, the color manufacturers had a certain urgency to try to get a new law into effect, as did Food and Drug. That is, Food and Drug was not interested in outlawing all colors, but they were very much interested in doing something about the safety. Here again, Charlie (Crawford) was responsible for this. He had become concerned about colors back in the mid '50s, '56 or thereabouts, and had told Lehman's group and others to begin investigating some of these things. We had a report on Violet No. 1; we had a report on one or two others. They had to be withdrawn. So Charlie told Lehman's group to begin work to do this. They did, and it turned out that the colors, particularly Orange No. 1, Orange No. 2, and Red No. 32 all had significant toxicity when fed in any appreciable amount. That meant that we had to have some sort of a law if we were going to have artificial colors for soda water and all the other things, to say

nothing of cosmetics. In many foods, of course, artificial color is a factor in acceptance of . . .

That change in the law had been proposed in the fall of '59. We had won that case about the same time the pesticide thing was coming to a head. We had a bill up before the committee, but the committee took that as a reason to really get Flemming up there and give him the hazing that he'd given them.

We went up to testify about the color additive bill, and of course, they wanted to know what the Delaney clause was all about, and then they had all this squeal about you'd have to eat 90 million pounds of this stuff in order to do any harm and so forth--the same old argument. The committee heard Flemming. Flemming made a stirring defense of the Delaney clause which I helped write, and in effect, that's where he says, "No one knows how much or how little of it causes cancer, and until we know that, we have to be safe." And that was the theme song. We said to them that the rallying point against the Delaney clause was, it took away your scientific judgment. We said, "No, that's not true. There's plenty of judgment in deciding whether or not the item is a carcinogen. Once it's decided that it's a carcinogen, then there's a little room for judgment because nobody knows how to fix the same tolerance."

That was the first time that we really rationalized the Delaney clause in the sense of any size. That rationalization today is what's being used by the public interest groups to stymie all change in the Delaney clause up at the Capitol. Every time, they quote that language that we wrote for Flemming at that hearing in 1960 as the reason why we still don't know. Flemming said that whenever science makes a breakthrough, we'll make the change. The upshot of all that was that the Delaney clause stood and the Food Additive Amendment was passed and it has a provision kind of like the Delaney clause but not exactly like it in the color additive. So that is where that went.

I believe that pretty much summarizes the legislation on these things and the shift from the old per se rule to the rule-making type procedure, which would set up

specifications in regulations on conditions of use of first pesticides and food additives, and ultimately color additives. All of them were treated by rule making, but under somewhat different procedures, depending on who all was involved.

For example, in food additive, there wasn't any advisory committee on the cancer thing. In color additives, there was. The food industry didn't want the advisory committee and the color people did, and was put in that. We were willing to have an advisory committee in pesticides which we used several times. Those advisory committees pretty much all came out with where we were, that is, the evidence is inconclusive; you can't make any judgment on that. (Laughter) Heptachlorepoxyde was one, aramite was another of those pesticides that went to the advisory committees and came back accepting what we had done. Now, let me see where I go from here.

As I've indicated, Charlie Crawford was the philosopher king that did think of all these things. He became commissioner in 1951 when Dr. Dunbar retired, and he himself retired in 1954. He was actually at the head of the agency a relatively short time. But he was a major influence both on Walter Campbell in the legislative process, and on Paul Dunbar and his operation of the agency. And in terms of legislation and setting the stage for this material that I've just covered, he ordered the investigations of the colors which resulted in the Color Additive Amendment; he pressed for the Delaney-type investigation; and in all was the one who was thinking ahead. Equally important, Charlie was responsible for reorganizing the agency. That, I think, was about 1948. I guess he was a deputy at that time. Before that time, the field had been divided into both districts and regions, I guess they called them.

FL: Districts and stations.

WG: Right. The districts were the three districts, East, Central, and West, and headed up by three strong field people: John Harvey in the West, J. O. Clarke in Chicago, and I

forget the name of the one in New York. Charlie decided to abolish all that extra layer of review in those district offices and make each one of what had been stations who were reporting through the district organization report directly to headquarters. He brought to headquarters a lot of the field people: John Harvey, J. O. Clarke, Malcolm Stephens, Ken Milstead, and others. I believe there were about fifty that came in. Bob Roe was also in that group. He started organizing it maybe before, but almost all the people were here by about 1950. So this was another major thing that Charlie did.

Now George Larrick became commissioner in 1954, and he continued to be commissioner for a very long period of time, retiring in 1966, maybe at the end of '65. Larrick came from the inspection part of the agency. He was at one time chief inspector--that's what they called him--he was head of the Bureau of Drugs at one time, and he had spent his life essentially in inspection and in administration involving drugs.

The administration involving foods were L. D. Elliott and Ken Kirk. Kirk was Elliott's associate. But Crawford was the thinker behind that. L. D. Elliott was the enforcement-type person on foods. Larrick came to the commissionership without any real substantial exposure to food problems. As we've seen, his first several years were devoted to the major problems in the food business which had been set up by Crawford to set the stage for the new legislation. And of course, Larrick was involved in handling the aminotriazole and the other episodes which we have talked about, from 1954 up through about 1960--that's with pesticides in '54, food additive in '58, and color additive in 1960.

But during all that time, he still maintained an interest in drugs. The Kefauver investigations had begun in December of 1959. Larrick was a long-time supporter of improving the New Drug law to require proof of effectiveness as well as safety, and he recognized some other problems. But beginning about 1960, Larrick became a victim or a necessary actor in a tremendous number of investigations by congressional groups in terms of how well we were really operating the New Drug procedures, and the answer was, not very well up to that time.

The first thing Larrick did in an important way was to recover our economic health. Crawford just was not a compromiser; he wouldn't make any peace with anybody on a matter of principle. If he felt a matter of principle, he stood on the matter of principle. If it cost him all of his appropriations, so be it. But he would not compromise under any circumstance. Larrick, on the other hand, was a very jovial, well-met person. He was very friendly with the people on the Appropriations Committee, particularly the congressman from Rhode Island, Fogarty. Fogarty introduced Larrick to other people there that could help him.

About that time, the Citizen's Advisory Committee, which Crawford had been instrumental in setting up, came up with their first reports about improving the appropriations, and Larrick, to his credit, did get that done. He got the ball rolling of increasing substantially over a period of two or three years, and he got that done. He also started the rebuilding of the field stations. I don't know how many of them have been built, but that was one of his first and major accomplishments. This was his line of interest: the inspection, the field, and the appropriations he knew and he did well and got along with the Congress. While he was not a tremendous compromiser, he was a pragmatist and would be able to get along with Fogarty and the Bureau of Budget people and others where Crawford did not.

Larrick, having spent the first few years on these pressing problems of food additives and others which were rather foreign to him, really got caught in the ringer by the investigations on drugs. He was a supporter of Henry Welch's, although I'm sure he knew nothing about what Henry was actually doing. Henry was kind of secretive about where he was making money. He told everybody he was selling reprints, but it wasn't clear that people buying them were just storing them away and in effect giving Henry money. So the Kefauver hearings put him really to the first test. We testified up there, Larrick, myself, Rankin, and the others, in terms of what ought to be done. I think we presented a rather good statement. That statement's in the record, so everybody can look

at what we did and said when we went up to testify, which was some time in 1960, as I remember. It could have been '61, in terms of how long before they got around to us.

But about that same time, there came more and more questions about various drugs, particularly the tranquilizers. Valium and Librium were widely prescribed and widely used and widely abused. This was an alarming development in drugs, and this led both the House Interstate Committee and the Government Operations Committee in the House, as well as the Humphrey Committee in the Senate, to begin these various investigations. They took a tremendous amount of Larrick's time and effort for a good period of time.

During all this time, he had really no one running the Bureau of New Drugs. Ralph Smith was in and out as a substitute; Arthur Nelson did it for a while. The money to hire new physicians didn't come until after the '50s when the budget started to improve. So they were very short-handed over there. As a result, a lot of those drug problems simply got out of hand. So when the Government Operations Committee began investigating the thing, they would call for the files and they would find in there that some of the employees had made certain recommendations that were not followed up on. In other words, it was a failure of real follow up on problems that were fairly well recognized by the department itself. So he had a lot of that.

He finally got Joe Sadusk as his medical director. I don't know exactly what year that was, but it was before the '62 Amendments were passed. Joe came from George Washington University. He was a very personable man, but very close to the PMA (Pharmaceutical Manufacturer's Association) and responded a lot to the PMA's desires. The role of Sadusk and Larrick in these things really came to a sharp head in connection with the Parnate case. That was a tranquilizer put out by Smith, Kline, and French, and very widely prescribed in the early '60s. All these tranquilizers were widely prescribed. But this one was widely prescribed, and then it turned out to have a very unique hazard to

it. If it was taken with cheese and other products of that kind, it caused these reactions, and was a source of causing strokes. So it was a life-threatening kind of thing.

The agency proposed to take the product off the market, and Smith, Kline, and French demurred and came in with a lot of arguments. During the unfolding of that case, Sadusk became our medical director. He, instead of recommending that Parnate be taken off the market, recommended that it be severely restricted in labeling and continued on, which was what was done. That was probably the right thing to do, but it still didn't sit very well with the Congressional people who thought that there just weren't any adequate and well-controlled studies to justify the continued marketing of Parnate.

Then there was a row about the meclazine, cyclazine sort of thing, and there was kind of an uprising in the Bureau of Drugs by Barbara Moulton and John Nestor and others who were bad-mouthing the thing. All these things contributed to the investigation. So Larrick spent a tremendous amount of time with that in his last few years. The major thing that he had to do was Krebiozen, to put the money there and to put the effort there that was necessary to push that case. That took a lot of money and a lot of field effort to do that. Secondly, he had to get the food additive, color and pesticide amendments going, to equip the field to cope with those new kinds of problems in terms of scientific abilities and people. And thirdly, for the agency to grow with this new appropriation money. He did those things.

But with the enactment of the 1962 Amendments, indeed, even before the enactment of the 1962 Amendments, after the expose in June of 1962, I believe it was, of the Kelsey Krebiozen episode . . .

FL: Krebiozen or thalidomide?

WG: Thalidomide. When the Congress looked at thalidomide, it was obvious that we weren't doing enough on investigational new drugs. So even before the enactment of the

thing, we pulled out these regulations that we'd been trying to get the Bureau of Drugs to adopt for a long time and put in the new regulations. We couldn't get any consensus from our medical people on what ought to be done about investigational new drugs. Before '62, all a person had to do was certificate himself as an investigator and sign a statement that he would use the drug for experimental use only and that he would make reports back to the sponsor. Nothing to us, no obligation to report, even to tell us he was an investigator.

So a whole new era came out of the thalidomide episode. That case showed that the companies were spreading these investigational new drugs very widely, that they were using investigations as a pre-marketing opening of a lot of access to a lot of doctors who were really not investigators in any sense of the word, and that they were not keeping close track on either what was happening abroad with the drug or what was happening here with the drug. So all those things merged into the investigational new drug regulations.

Essentially what those regulations require is that there be an orderly and rational investigational plan executed with respect to these drugs. First, you have to identify what the thing is, how it's standardized, what's known about it from pre-clinical studies, and what's known about it in terms of possibility to introduce in demand. Then the investigation for man involved three stages: one, the initial introduction of the drug to see how it's metabolized and handled by man; two, to wider patient population to get kind of a handle on toxicity; and three, the definitive clinical trial. It was recommended to us that we have a phase four, which we rejected. That would have been a more widespread clinical trial. We thought that the requirement for reporting and the ability to withdraw the application if anything came up there was an adequate substitute for phase four, and we didn't want the investigation to be commercialized like that phase would have been. So that wasn't adopted.

Those regulations were proposed in August, I guess, before the October enactment of the Kefauver-Harris Drug Amendments. We got tremendous opposition on the thing.



Every organized piece of medicine came here arguing that they were responsible people, that they didn't need any government supervision, and that the record keeping and reporting was onerous and would cut down the development of new drugs. We had a deaf ear to all that. We did provide that an investigator would have some access to inspectors that were scientifically trained. That was one sop that was put in there. But essentially, those regulations were proposed in August and were finalized in October, right about the time of the enactment of the '62 Amendments, and were put into effect with Krebiozen almost immediately, and with a lot of other people along the same time.

The next thing that had to be implemented was deciding what to do about reviewing the drugs that had been introduced through these years without any proof of effectiveness. There was a big argument between us and the industry over the right to do that. They thought that the grandfather clause was absolute; we insisted that it was not absolute, and that we were not going to go along with that, which we did not. We put out this regulation in '62 or '63 on record keeping and reporting to try to make a requirement of every company that had a New Drug Application any time in the past was to do a self-audit and report to us whether the drug was marketed, whether it was still marketed, what changes had been made, what the basis for the changes were, whether they'd been reported to Food and Drug, whether any changes in the labeling had been made, and this was to update the whole thing.

Of course, we got a lawsuit immediately from the drug industry about that, they didn't want to have anything to do with that. That went along for a while until it became pretty much moot after the developments on Panalba and that group of drugs. But that lawsuit did slow down the influx of those reports, but having put those regulations out, it put the drug industry on notice that it was their responsibility to come up with the evidence of effectiveness.

Next was the record-keeping provisions, how to handle an immediate report, how to handle a routine report, how often to report--all that was covered by the record keeping

and reporting. And then the business of the clinical trial. As I've indicated, most of these regulations were put out under Larrick's regime. The drug advertising regulations, for example, were put in at that time. All the regulations to implement the '62 Drug Amendments were enacted within a relatively short time, that is, promptly taken care of. But there again, we did not follow through on that, and Larrick got an awful lot of static about what was happening with these various regulations. And the answer was that we had our hands full with litigation with the drug industry about the regulations, and that was what was holding things up.

Larrick retired in 1965, and then for the first time, we had an outside commissioner--the first time in my experience, and my experience goes back almost to the beginning. But this was the first time from the beginning that the agency had had an outside commissioner. This commissioner was Jim Goddard, who was at that time director of the Center for Disease Control, I think they called it, down in Atlanta. He was a public health officer. He was a colorful person. He came in in about February of '66, as I remember. It was while the Krebiozen case was under trial or about to go to trial in Chicago. He came in with a real stir of activity. He had a speech writer named Ted Cron who was a very gung-ho sort of a person, somewhat influenced by the public interest movement and somewhat anti-PMA certainly.

About the first thing that happened when Goddard got in was the retirement of several of the top people: Malcolm Stephens, Ken Milstead, and others who considered that they were not being consulted or brought into the decision making, that Goddard was kind of going his own way with Cron's advice, and was just being his own man, and indeed he was.

FL: Didn't several of those people actually retire before Goddard came? Steve (Stephens) and Allan (Rayfield) and a number of those, recognizing that a commissioner was going to come from outside?

WG: I don't know. I know that Milstead was around for a while. I'm not sure about Malcolm.

FL: Steve said he announced his retirement before the commissioner did.

WG: Did he?

FL: Yes.

WG: Well, in any event, I think the reason Steve did was that he had expected to get to be commissioner, and he'd been told he was not going to get it. As soon as he was told he was not going to get it, he retired. Now the atmosphere there was such that all these investigations had drawn the credibility of the top leadership of the agency into question. That's why it was decided to go to the outside and to put Goddard in there. Goddard was a colorful, public affairs type; he got along well with the newspapers and was prepared to beat on the industry a little bit, which was what the agency wanted done at that time.

FL: Could anyone from within FDA have taken over the job and done what needed to be done at that time?

WG: Oh, yes, I think so. But that wasn't an option. The option was that they were going to go to the outside. They wanted to go to a physician, and they wanted to go to someone who would have a break with the past and would give a new urgency to the program. That's why they brought Goddard in there.

FL: There was some speculation at the time in the *Trade Press* that a man named Goodrich might be named for it. Was there ever any formal approach to you?

WG: No. I talked with the Secretary, and what he said to me was what I've just said to you: that they wanted a new person, they wanted it to be a medical doctor that they hadn't had before, and they wanted it to be an aggressive person that would really shake the agency up somewhat, and that Goddard had caught their attention through some of the actions at CDC. So that's why they got him.

Soon after he came in, about his first step was to make a bunch of speeches to the various industry groups. They were hard-hitting, mean-spirited speeches. I mean, he in effect called them crooks and in effect said that they were a sick industry and that they needed to heal themselves and a lot of things needed to be done. He went through the whole rigamarole, and that, of course, interested Fountain in holding a series of hearings on what he was going to do in various areas. This made him concentrate his effort, his attention, early on to these rules. He came in here with the idea that he would rewrite all those rules and all that stuff, but he became convinced fairly early on that he couldn't ever improve on that, and that he would have to go along with what was on.

But the first thing he decided he had to do was get on with the effectiveness review, and coming from the PHS, he was able to put a latch on a bunch of PHS physicians, that is, people who had been educated at PHS expense and were serving out their time with PHS to keep from going into the army. So he was able to draw on 100 people to undertake the review. At the same time, he was able to get the National Academy of Sciences to be interested in this, which Larrick had tried and had not been able to. I mean, they just wouldn't have anything to do with it. As a matter of fact, Crawford tried to get them to become interested in this, and they wouldn't do it. But when Goddard came on and got all this publicity and got these doctors around, the National Academy did organize the Efficacy Review Study.

Goddard had the standing and the public attention to this problem to a degree that meant that he could begin moving that along. So that review started in '66, soon after he got here. Again, the call was for the data to be submitted, and that to be turned over to these panels, and the panels then to make a report back on what they found about this.

The panels were independent beings, if I may put it that way; that is, they were volunteer consultants by and large drawn from the Academy and were serving on panels as consultants. I guess they were paid like regular consultants, but there were several panels organized. The young doctors who were on temporary assignment had the responsibility of drawing together from the files what was in the New Drug Application, what the company had submitted, and then the panel would take all that data and then would make a recommendation on what ought to be done. Their procedures were certainly not due-process-like; they were doctor-like. That is, they would meet around a table and one of them would say, "Well, I think this about this drug," or that "so and so is an expert in this drug," and he would give his view of it. That way, the thing got underway.

One of the first ones they reported on was the bioflavonoids, which we'd always considered to be inert substances. But they were on sale, and that was the first sign that we were going to have a big upheaval in the marketplace with this. Rutin and other bioflavonoids were selected. But the thing really came to a splash when the committee made its report in 1968 on the antibiotic-sulfonamides combinations, and from there to the antibiotic combinations. They reported that all those combinations were irrational. We knew that; everybody that knew anything about medicine at all knew that. But the idea that we could roll back that much of common wisdom in the medical profession--it just didn't seem like it was going to take place.

We did put out, though, a statement of policy on combination drugs, which we were able to get the Bureau of Medicine to agree on. The Bureau of Medicine was just like the AMA on this. They didn't think that you could tell doctors that they ought not to

use these combinations, that the doctors already knew that, but they were going to use them anyhow. They may do some good, and the kind of harm they would do was not fully documented, and therefore, they would tend to go along with that.

The first of those reports from the panels came back in early '68, and then the problem was, how were we going to implement them? We put out a statement on what we would do: we would send them to the company and ask the company to comment; and then we would classify the drugs in one or the other of these categories. If they were classified ineffective, we would begin the steps to take them off the market; if they were possibly effective, they'd have so much time; if they were probably effective, they would have so much time. The way the mechanism was set up was to relieve the immediate pressure but keep the ultimate pressure on them to come up with a medical justification for the claim.

Several of these very important items were publicized and the time for action came due sometime, as I remember, in about January or February of 1969. About that same time, there was a hearing up on the Hill about, "How are they doing?" and, "Are you damn sure you're going to go ahead with . . ." In other words, the pressure was on us to really hang in there with that. And of course, Goddard and the others testified they were going to hang in there, and "we're going to do the deed."

Herb Ley was brought in as director of the Bureau of Medicine by Goddard, and he was the one that was down in the lines there with the responsibility for seeing the thing through. We publicized that, announced that these drugs were irrational, and that they were to be taken off the market. Of course, that precipitated a whole series of lawsuits, all of which I defended. The first ones that went to court were the sulfonamide-penicillin mixtures up in Delaware. It seems like we had another one there before that one. But anyhow, there was a series of these cases in which they filed suit, alleging that they had been denied opportunity for a hearing and a right to defend these drugs--in any

event, that our regulations weren't clear, these panel things had been ex parte, and they'd not been able to have a hearing--all that whole stuff.

Well, we worked our way out of that, but the major case that came along was Panalba. That, through a series of events, took root. We decided that instead of going ahead without any hearings whatever, we would try this shortened procedure of really saying, "Now, we'll give you a hearing. You come in and I'll tell you what I think about your presentation, what you've presented. Present your written stuff, then we'll decide whether there's any issue of fact." And when they would present the written stuff, we then decided we would have a hearing in which Herb (Ley) would preside, and he would have a doctor-to-doctor discussion with the Upjohn's doctors. And Stan Timko, their lawyer, and I would be the bystanders. (Laughter)

In preparation for that, we prepared an analysis of their filing, and it was the first time I think that Food and Drug really put its mind to analyzing the documentation for these drugs, what it really consisted of, and how it measured up to the new standard of adequate and well-controlled studies. So we decided in the Panalba case to go ahead and have that hearing, which we did. And then we put out a tentative order explaining our reaction to what their paper presentation was and what their oral presentation was, and in ordering the product be taken off the market by X date. We were pressed in all this, again, by the committee up at the Hill to go ahead and take the action--don't delay--and we didn't.

So that case moved pretty rapidly. The first notice was published in '68, and they had some time to come in, and it went to the hearing in early '69, and the order to withdraw it from the market was in about May of '69. Then it went to the court of appeals, and it was argued in October of '69 and decided in January or February of 1970. So we moved that along pretty fast, and that made it possible to see the end of the tunnel, that is, that we were going to be able to go through this thing without getting involved in a thousand and one hearings which would have kept us forever.

During the consideration of Upjohn's product, it became necessary for us to articulate where we stood on adequate and well-controlled studies. That order on Upjohn did explain that, and the court of appeals sustained it. But then PMA filed suit in Wilmington, Delaware, on the ground that we didn't have any regulation on that and we were trying to proceed without . . . We'd put out a regulation without asking comment, consistent with what we'd done in Upjohn. And the judge, Judge Latchum, took a dim view of this. He was pretty hard on me on that and on the sulfonamide-sulfathiazole, but he never really went over the cliff on it. He looked like he was going to jump out of the traces two or three times, but he didn't.

What he ruled was that we didn't give notice and that, therefore, the thing was not legal. When I decided to withdraw it and have a hearing, he was tickled to death. He was afraid I was going to go on to the court of appeals and reverse him there. He thought we were right on what we were doing, but that we hadn't been through this. But in order to get these new rules out, first of all, we had presented an affidavit in support of the rule we issued without a hearing, explaining how we got there.

Bill Devers, who is a teacher down in Georgetown University and was a part-time consultant for us, and may still be, was working here, and he is quite a student--he's a teacher kind of a fellow, and he's one of the world's leading experts on analgesia. He was on the National Academy of Science's panel on analgesia. Even in those days, he was really a very well controlled expert in working on analgesia. He was really put to the test on how to devise a study and how to make the results be equal. So he gave us an affidavit.

So when we came back down to go through the administrative process again, to put these rules out after notice and opportunity to comment, we filed that affidavit with it and explained this was where we were, and that we wanted people to comment on whether we were right or wrong on that. The comments that came back were, "Well, those are probably right"--of course they were all taken right out of the scientific



literature--"but they're too stringent; it should be applied with some rule of reason." Well, we put in that it would have to have an adequate and well-controlled study by those rules or explain why your thing was the equivalent. "What you're telling me is that what I've in effect saved that day." Then we went back to Judge Latchum and he upheld us in the rules. From that stage on, the pattern of reviewing for effectiveness was set. That's the story on that.

On the advertising regulations, this, too, was a matter of considerable interest to Goddard and was a matter of considerable publicity, which he was also interested in. After the '62 Amendments were passed, this was of course our first experience with drug advertising, particularly prescription drug advertising. That had always been the role of Federal Trade Commission; we'd never done anything about it. One of the proposals in the legislation was to hand that over to them, but we held our lines and we acquired jurisdiction over the prescription drug advertising.

Well, the first thing we had to do was to put out the advertising regulations after notice of public hearing, which we did. We put out a proposal. We got ready for a hearing, and in getting ready for the hearing, we used a lot of the stuff that had been put in the testimony of the Kefauver hearings--about what advertising was all about, how it was being carried out, what there was to support it, why it was lacking in support by and large, why it was unbalanced, and why it needed major improvement.

Dr. Dowling was one of the major spokesmen who elucidated that point of view before the Kefauver hearings, and of course, he was a consultant to us. I believe he was teaching in Chicago at that time.

FL: That's Harry Dowling?

WG: Harry Dowling, right. When we had the pre-hearing conference on the prescription drug advertising, the industry was represented by Gary Gesell who is now a

district judge here in the District of Columbia. He was with Covington-Burling and was their chief counsel. He was prepared for a hard fight until he began looking at the advertising. As a matter of fact, we put in the record what we had and sent the inspectors out to get additional advertising from the companies. Well, he told them all not to give us anything, so that came to a crunching halt with us. We were going to put that in evidence, that he had refused to allow the collection of the samples, and that therefore we were right.

To make a long story short, he decided fairly soon that he would compromise with us on those regulations rather than go to a hearing where it would give them more and more bad publicity about their advertising. They'd already had plenty of bad publicity from Kefauver, and they didn't want any more bad publicity about this. This was before Goddard's time, but this was a matter that was being followed rather closely by the press; they were very much aware of what Kefauver had done. Morton Mintz was still very active in writing all this stuff. So we were getting a lot of publicity out of it.

The law provided that any prescription drug advertising should contain a brief summary, a statement of effectiveness, side effects, counter indications, warnings, etc.--a brief summary, in accordance with regulations published by the Secretary. So we had the choice of trying to do this class by class, specify just what claims could be made for what drugs, how they'd be made, and what kind of counter indications, warnings, and other things that would have to accompany them. We decided that that would take too long and wouldn't really get us there with the speed that we had in mind. So we adopted an alternative that said that any prescription drug advertising had to have a brief summary that was consistent with, not contrary to, the official brochure. It would have to give in fair balance a statement of effectiveness, side effects, counter indications, and so forth.

Well, the fair balance, of course, really didn't tell them anything in the way they wanted, but it told them one thing: they could not leave out or minimize these various things. And that's what we were explaining at the hearing, that we weren't against

graphics, we weren't against photographs, we weren't against any of the advertising techniques that were being used there, unless they misled or put a different slant on this. We thought they could determine what the message was, but we knew damn well we couldn't determine what the message was. Therefore, we were going to hold them to a fair presentation of that official brochure.

We'd already had full disclosure under the 1960 regulations, and that was in effect in the PDR. So the PDR had already begun to improve by '62. I guess '61 was the last time it was really bad. By '62, they'd begun to improve. So they first tried to ridicule the regulations, saying that we wanted them to make all advertising closely-knit and single-spaced that you had to read with a magnifying glass. They brought up some ads that had been in use back in the early days in which that technique was used in the medical journals and so forth. But with the onset of modern advertising, the advertising was an entirely different breed of cat.

So we did try to accommodate that and were able, through that accommodation, to get the thing into effect. In order to get them to agree, they brought in a series of ads that they had, and asked us to react to that in terms of fair balance. Bob McCleary was the head of advertising at that time, and he and I went through each one of those ads for them, saying, give them an idea of what it is we thought was wrong, and how we thought they might comply. Well, having heard that on the record, they decided that they could live with that and that they could do without all the other publicity, so the advertising regulations were placed into effect.

Before Goddard came here, McCleary was already in the process of making some advertising cases; that is, he was picking out ads that were not satisfactory in his way, and he was a very, very intelligent physician who had a background in advertising on Madison Avenue. So he knew how they were developed and he knew what went on about these ads and who was calling the shots, who was doing the layout, the storyboard, and that they fully understood what they were trying to put across there. But McCleary was

also a stickler for detail, so he brought in some of his early ad cases, details about the ads that were kind of--he was right, but they were kind of hard to explain to a judge and to a jury. So we didn't have very much luck getting the Department of Justice to file those cases. So that had pretty much disillusioned him.

When Goddard got here, he was quite interested in the advertising. And McCleary presented to him some of these cases. Goddard was a man of direct action. He'd call up the president of the company. He'd say, "I've got this ad. I want you to come down here with your scientific people and I want to go over it with you." And when he got here, he would present to him what McCleary said about it and say, "What have you got to say about it?" Well, of course, many times the company president didn't know anything about that, and he was embarrassed by what he heard, and his medical people were embarrassed because they'd been called on the pan in the presence of the president getting a lecture. So that worked very, very well. We told them that we had taken a sample of the drug and if they wanted to talk with us, we would withhold the seizure until we could talk, but otherwise we were going to file a seizure of the product. So that's how the drug advertising regulations moved ahead.

Well, through a lot of what we said on the record at the hearing, through a lot of experience over the next year or two, it became obvious that we needed to be more specific in the regulations. So we proposed and ultimately adopted a new series of regulations, this time specifying those kinds of claims that were absolutely forbidden, and those kinds of claims that were allowed, and those kinds of claims that had to be qualified. We dealt with such things as use of statistics, use of animal studies, use of all other techniques that we saw that were contributing to an unbalancing of the ad and getting across a bad story.

We got the attention of the companies right away, and we got the attention of the advertising, the creative people. So they invited us up there to New York to speak to the New York Advertising Club. McCleary and I both spoke. I had obtained from Dr. Jean

Lockhart, who was then in the Bureau of Drugs, and another doctor who worked with her who is now dead, gave me the ads for the ten drugs introduced within the last year that had become best sellers in their first year in the marketplace, and gave me an analysis of the ads' follow up, and every one of them was misleading. So I took that as the theme. I said, "I want to show you what's going on, how we look at it, and it'll tell you what we think of what you're doing here." That was a blockbuster, too. They had ads for avental, which was a new tranquilizer; they had two for birth control pills--they were very much promoted at that time; they had one for Enovid, one for one of the other competitors; there was one for a combination antibiotic-pediatric formulation; there was one for a very widely prescribed tranquilizer. But to make a long story short, each one of those ads had a gross exaggeration of what it was for.

For example, the one on the combination antibiotic for pediatric use showed a picture of a pediatrician at 9:00, 10:00, 11:00, 12:00, 1:00 with different patients. He was giving them all the same shot. (Laughter) We said, "Now, you've got to understand we're not fools; we can read what you're saying." The avental was a new tranquilizer by Lilly, and they were really embarrassed. They had picked up the old saw that then was used for promoting tranquilizers--sadness, crying--just a bunch of symptoms that are ordinary frustrations of daily living. They equated that with a reason to prescribe avental. Oh, they were adamant that all they were presenting was a galaxy of symptoms that added up to depression and that they were not recommending it for the everyday frustrations of living, but only for serious depression.

But this did get the attention of the advertising people, and the advertising improved substantially. It's still got a long way to go; you're still seeing these same issues, but anytime the agency wants to do anything with that, the rules are out there. It's tempting for the agency to treat that as, "Oh, hell, that's not important. You know, doctors don't really go by advertising." My answer to that was--I got this from Jean--"you can be assured that if the advertisement doesn't sell, it will not continue to run." (Laughter) So I

said that to them. "We take the view that if it doesn't sell, if it's not being persuasive, we won't be seeing it again. If it disappears, why, that'll suit us fine. But as long as it continues to run and we've got this to say about it, we think it is doing these things."

The agency was tempted like others to consider advertising as a part really outside of the practice of medicine. It was a necessary part, all right, but it wouldn't really have any health consequences. We became convinced that by selling all these drugs with a lot of advertising, it was a major factor in why people were choosing the drug. It was a competitive selling thing, particularly in the case of the birth control pills, for example, where they were sold against one another as more effective--all were 100% effective, so none of them was more effective; better safety--they were all the same safety. And they all had the same brochure. It was this kind of advertising that was leading doctors to shift their patients from drug to drug and was confusing their understanding of what the drug was all about. And in the case of tranquilizers which were being used very, very widely, they were encouraged to prescribe these things for these minor conditions which led to the over-prescribing that we were seeing with Valium and Librium.

We have talked about the advertising regulations and why I thought that some regulatory action in the heel of prescription drug advertising made a lot more sense than regulatory action in other ways, my reason being that prescription drug advertising is a very high-intensity operation, and it must sell drugs or it wouldn't really be anything under the order of magnitude it is now. I think that because it's giving a direct message to the prescribers, the agency ought to spend a lot more effort in watching that. And particularly one thing I recommended--I don't know what they're doing now--was to watch the advertising of a drug soon after it's approved to make sure it gets off on the right foot. If it does get off on the right foot, then without any exaggeration, the chances are it's going to be all right from there in.

Having talked about the adequate and well-controlled clinical study regulations, I want to be sure I attribute to Herb Ley full credit for that. While it's true I made some

suggestions about the Panalba shortened procedure and suggested to the Bureau of Drugs, the Bureau of Medicine, that they study this situation to get the affidavit which we got from Devers, it was Herb Ley who really put that thing through and gave it some scientific stature that it otherwise wouldn't have had. Paradoxically, Herb was doing this, which is one of the greatest things that ever happened to Food and Drug, yet at the same time he was losing his job over cyclamates.

I don't see any real reason to go into that whole cyclamates thing, because the history of that is so well developed in that court case. Every scrap of paper that had to do with cyclamates is in that court case, and as you know, the court of claims first ruled against us and ultimately ruled for us that everything we did in that case was right, and that the other side had no claims for damages. For that reason, I would simply defer the cyclamate discussion to that as a better source of history than anything else. While I testified in the case, I helped the Department of Justice identify the people who were really involved in it, and the history of that is very well laid out there.

FL: Does that go into the part of the story of how much the department's involvement was, superseding any decisions that were being made in FDA?

WG: Yes, that's what I mean. The whole case is laid out there. Now, it's true that in testifying about the case, ex-Secretary Finch had a very poor recollection of what happened, as did some of the others. But in the final analysis, when everybody was questioned, everything was said and done, the whole picture did emerge, and it's all documented to the last piece of evidence right in that case. So if anyone studying the history of this becomes concerned about that, I strongly recommend that they go to that case, and that the documentation is there.

FL: That was the claim by some of those canners?

WG: By the California Packers and Growers against the department.

There are two or three other classes of drugs that you wanted me to discuss. First, of course, the oral contraceptives. The history of these drugs is really rather unbelievable. This class of drugs was introduced before they were ever available as oral contraceptives for female disorders--menstrual difficulties and so forth. So they were around. The idea of having these as oral contraceptives came to the department and was strongly pressed on the department by the Planned Parenthood Association, who had done some studies in Puerto Rico where there was a real need for population control and where they were giving the drugs to people down there.

The population control group, as I remember the file, urged the department to approve it first for a limited study down there, and then to expand the study. Whoever it was that was responsible for approving the drug--and I don't know who it was; I'd have to look back--made a rather simplistic decision. They made the decision that enough was known about the drug and its safety to justify its being approved for use by a limited population group over a short period of time--six months.

Well, anyone should have looked forward beyond that to say that once you approve something like that, it's going to grow like wildfire; and that's exactly what happened. After the initial approval, the department was pressed almost constantly to expand that, and the use of it expanded, I'm sure, beyond what we had approved. So it first started out with a single drug, Enovid, and before or about the time the Drug Amendments of '62 were operational, there were several of them on the market, all different kinds, and they were all essentially the same.

While there were some differences in theoretical risk, depending on the strength of the active ingredients, the experience with the drugs was such that the agency fairly early on settled on a uniform pattern of labeling to try to control the different competitive pressures that were building in the marketplace about one as against the other, both in



confusing the physician and convincing women to shift from one to the other. Some of those early shifts were due to the possibility of getting off one in six months. Some of those early labelings still carried forward that limited idea, and people would simply shift to another drug.

The department, as long as I was there, and maybe they still are, was concerned about the very long range effect of these drugs. I know I was concerned about it, and I know that the experience we had didn't begin to answer what might happen when we were deeply involved in approving those drugs. One thing we did in the '60s was to constantly refer that whole issue to an advisory committee to be sure that there was pressure on us to gather up all the data and get from the advisory committee all the data they had and all the leads they had that would tell us where we should be looking for possible untoward effects from those drugs. So that advisory committee was quite active.

We used the advisory committee to develop the uniform pattern of labeling for them. We used them to help assay the experience that was coming in. Much of it was of statistical nature and wasn't really all that good. You know, you're dealing with an epidemiological problem by then. And there wasn't any way, really, to subject these drugs to a long-term study of the type that would be required to give you reasonable assurance of safety. Using a small patient population in Puerto Rico even for a year's time would give you only the vaguest idea of what might happen with the drugs.

But nonetheless, I think we were lucky in the long run that they haven't turned out to be any more problems than they are. I know Larrick was there when this was approved, and he was concerned, and I know I was concerned, and I know that the Bureau of Medicine was concerned. But it was one of those situations that here was a drug whose time had come, and there wasn't any holding it back from the marketplace. About the best you could do was follow the experience as closely as you could and put out the word on them at very frequent intervals just to keep attention on them and keep attention on the fact that the last word in their safety had not been written.

FL: Was that the first time we'd approved a drug for non-therapeutic use?

WG: I'll be damned if I know, Fred.

FL: I think that statement was made in the press at the time that we approved it. I was just wondering.

WG: I'm sure we had some prophylactic drugs before that, some vaccine and things like that were used for prophylactics long before that.

FL: But those would be aimed at a disease other than a condition.

WG: Right. But these were unique drugs all the way across the board, and as I said, all I can say is that we're quite lucky that we came out as well as we did.

The next group of drugs you asked me to talk about were the so-called drug-abuse drugs. Quite early in the '50s, maybe before that, maybe as far back as the early post-war days, the agency became concerned with the excessive prescribing of barbiturates. The people who were studying narcotic addiction at Lexington, Kentucky made a movie early in those years showing the withdrawal symptoms from barbiturates. It was a very striking film. They were interested in having the barbiturates recognized as a serious habit-former, and in putting them in some kind of a classification like narcotics.

Harry Anslinger was the commissioner of Narcotics at that time, and was absolutely adamant about not getting into any other business on drugs other than narcotics. He was an old-time Narco agent, and he wanted to deal with heroin and the other products of that kind and to have nothing to do with anything like barbiturates. This film was shown in and around the Public Health Service, and ultimately was shown to the

House Committee on Ways and Means, which had jurisdiction over narcotic legislation. The chairman of that subcommittee on narcotics, Hale Boggs, who later became majority leader and was killed in an airplane accident up in Alaska, instructed us . . . Well, first we went up there to hear the testimony, and Anslinger testified that he didn't want to do anything about it. So Boggs, recognizing he didn't have any jurisdiction legislatively over Food and Drug, nonetheless pressed Larrick to get together some kind of legislation on barbiturates, and to make them subject to closer control. And this is where the dangerous drug business really began.

We proposed a barbiturate bill. My memory is vague on what happened to it. But meanwhile, we were gaining increasing knowledge about other drug uses outside the medical parameters, particularly amphetamines. Amphetamines were in use on the truck routes and among other drivers, and among entertainment people to a substantial degree. But we had no idea it was anything like what it ultimately turned out to be. Again, Charlie Crawford was concerned about these two classes of drugs doing great danger, and he and Larrick both put in programs to start trying to control the distribution of these drugs outside the drugstores, and to some extent, in the drugstores.

In those years, we spent a very substantial amount of our field effort in running down sales of these drugs, and they were everywhere. For example, Scotty, a black man, who was a messenger in Larrick's office, was one of the most effective guys we had in going out and really making buys. He went out to Detroit and he could make a buy almost anywhere around. I mean, he wasn't suspected, and he could make them anywhere. Now some of the other people that worked in the inspection force were quite good at making those buys. The Atlanta district office went all out on it. John Sanders was really convinced that it was all down through there.

As a matter just of curiosity, I was down in South Carolina fairly recently, and drove through a place called Society Hill. Society Hill was one of the places that had figured largely in those early investigations. That's where this chiropractor-osteopath was

that was weighing out the amphetamines on a baby scale, that we caught and prosecuted. But there were a lot of them down there, and when I drove through Society Hill, I remembered that. I don't know what's happened with that since, but those two classes of drugs were in great abuse. Now, the amphetamines, I guess, are off the market, and the barbiturates are under somewhat closer control that restricts their abuse somewhat.

In addition to those, we had a problem after the Drug Abuse Amendments were passed about what to do about some of the drugs that were of use in medicine but were being overprescribed, particularly meprobamate, Librium, and Valium. We had the job to list those drugs as dangerous drugs and subject to all the limitations of the Drug Abuse Amendments. The meprobamate was the hardest because it's probably the least habit-forming of that class, but nonetheless was habit-forming. The physicians who testified in the hearing really classified it as habituating rather than habit-forming, as just a drug that really wasn't quite up to that. But nonetheless, the hearing was held, and we did put meprobamate on the list, and they argued that case to the court of appeals for the fourth circuit in Richmond, where they upheld that. So we were able to move with those drugs to keep them going.

Now, after that, when that problem became large, we did organize a drug abuse division, and transferred some of our people to it and recruited others. That operation, I guess, was later shifted over to the Department of Justice. It's still there and has grown substantially since we had it. But we were the ones who started that, and the whole thing goes back to the barbiturate beginnings.

FL: Before the Drug Abuse Amendments were adopted, we just had to use the general provisions in the statute.

WG: We used the sale without prescription. After the Durham-Humphrey Amendment in '50, of course, they were in violation of that. Before that, we charged that they were

sold without adequate directions for use. Of course they were, so there wasn't any great problem. We learned in the course of that where all those drugs were made. We developed a capability through microscopic techniques of identifying those drugs, even with no labeling and them being outside the containers of original sale. Our people became quite good at proving interstate commerce by proving where they were made. If they were found in a state where they were not made, that would do the trick on interstate commerce. That incidentally led to a good deal of litigation on whether that was adequate proof of interstate commerce, but it turned out to be.

FL: Were the Drug Abuse Amendments drafted in FDA?

WG: Yes.

FL: With you involved?

WG: Yes. The whole thing started with the barbiturate and amphetamine bill and was expanded into the Drug Abuse Amendments. Then we had the Bureau of Drug Abuse Control. So that came into being after that law was passed. Then the whole thing was transferred to Justice.

FL: Now the Drug Abuse Amendments also included the . . . That was the statute which includes counterfeit drugs?

WG: That may have been a part of it, but counterfeit drugs was another problem with us. In the early days, Food and Drug didn't give much truck to counterfeit drugs. We considered that to be a competitive problem and a problem for the owners of the copyright to protect their property rights. What was involved was imitation in

appearance, and if the drugs had essentially the same strength, we didn't really get involved. But at one stage, Larrick did become concerned about the widespread abuse-- and that's when the first counterfeit drug provisions were put into the law.

FL: They also were drafted by FDA?

WG: Yes. Next you asked me about DMSO (Dimethylsulfoxide). This drug was, of course, a solvent, and readily available as a solvent for non-drug use around. We began to hear stories about it that I'm sure everyone else has heard, that people were having these remarkable recoveries from arthritis and other serious diseases by buying this product and painting it on themselves. One characteristic was, if you painted it on your skin, you could taste it in your mouth almost immediately, which convinced them that it was quite a drug to move through the body. We became interested in that, first as its being used as a commercial product for a drug with all the attendant risks that were involved there; and secondly, we were interested in if it was that good a solvent, did it have any potentiality for being combined with other drugs that would translocate those drugs from the point of intake to the point of need for the tissue of drug therapy.

We brought some actions based on seizing DMSO that was being offered by chiropractors and others who had been diverting it from industrial use. And then we ran into the problem of Dr. Jacob at the University of Oregon. Dr. Jacob was a very strong supporter of DMSO, and he had the credibility of the University of Oregon Medical School to that and gave it some semblance of scientific development.

We were not convinced that the drug was being handled as an investigational drug; indeed, we were convinced that it was being promoted way beyond any acceptable investigational use, and that Dr. Jacob was the one responsible for that. He was cited, and of course, that drew the Food and Drug in controversy with the university medical school. The case was very, very difficult to deal with. No criminal case, as far as I know, ever

came out of that. But he was cited for diversion of the drug. He and his supporters made a lot of efforts to get legislation passed that would guarantee the continued use of that drug. We resisted that legislation and it was really never passed.

Next, the vitamins. The agency's experience with the vitamins goes back many, many years. Earlier in this discussion, I talked about the introduction of vitamins and minerals in flour and bread. That was a unique experience in using a common food item to increase the use of a nutrient that was health-oriented. The Vitamin B complex had been found to be involved in the prevention of pellagra, and that disease was fairly common in the southeastern part of the United States back in the '30s, but since that time has essentially disappeared, and there are no frank vitamin deficiencies in the United States. But as a result of the enrichment of flour and bread and the popularity that the vitamins got there, combined with a lot of enthusiasm for these products made available when we classified them as special dietary foods rather than as drugs, that made them available to a lot of outlets that otherwise wouldn't have had them. The sale of vitamins mushroomed beyond belief, and the first large reason for the growth was the adaptation of . . .

(Interruption)

WG: The adaptation of house-to-house direct selling sales combined with the pyramid-type method of distribution that was feeding that direct sales technique led to the first big confrontation we had with this problem. Mytinger and Casselberry was the firm involved. Mytinger was a sales-type person and Casselberry was a psychologist or the other way around. One of them was a psychologist and the other one was a salesman. They hit on the idea of creating this pyramid-type distribution pattern and selling a product they called Nutrilite, which was a combination of vitamins and minerals in a base of alfalfa, parsely, and watercress. They put those vegetables in there to make it unique from other

products so that they would have a very special product. And they sold the material in strength and double strength at about \$19, \$20 a month. Now, that was back in the '50s and that was a good deal of money at that time.

But they were very, very successful, first as a result of a book which they wrote called *How to Get Well and Stay Well* which uses all the psychology techniques; that is, that everybody wants to be well, and if you're sick, first, it hurts, and second, it costs you money. Therefore you want to be well. And the way to get well and stay well is to feed your body right. And if you feed your body right, you take these vitamins and minerals. And if you do that, then you're not going to have these diseases. And if you have the diseases, the vitamins and minerals are going to restore the so-called balance in your body to where the disease can't exist in that kind of an environment. Well, you know the old spiel.

The agency was quite alert to the initial distribution of this product, and they had a citation of Mytinger and Casselberry in Los Angeles on the basis of their first book, *How to Get Well and Stay Well*. Now, it was a book that didn't pull any punches. That is, it went on and told you that if you had epilepsy or if you had heart disease, this was for you. It didn't make any ifs, ands, or buts about it. It had a lot of testimonials in it. One page had a list of all the diseases you could think of. All those, of course, were supposed to be amenable to Nutrilite Food Supplement.

When they were cited, they hired a lawyer in El Monte, California who was active in representing proprietary medicine people out there. He immediately recommended to them that they come in and say that they were going to rewrite the book, that they understood what the charges were and had no intentions of violating the law, and that they were going to rewrite it. Well, Food and Drug nonetheless went on with the citation, but meanwhile, they perfected the other book. First they had a 48-page book or something like that. And then they pulled out what they called the last part, which had the



most exaggerated claims, and replaced that with what they called an epilogue. So they had three or four editions of the book.

After the citation and with the appearance of the new book, Mr. Murray, who was the regulatory person in Food Division, or in the Bureau of Enforcement, I guess they called it then, began citing them right and left for multiple seizures, and began to make seizures. We made some seizures, and his plan was to make enough seizures to where they would have to either do something about the thing, correct the violation, or go to trial. He thought that they were simply dodging. Well, instead of that, they filed suit against the agency for these multiple seizures, and to enjoin FDA from making multiple seizures claiming that they were proceeding in good faith and that the agency was harrasing them and making these seizures to run them out of business before they could have any chance to make the necessary corrections.

They were represented by a lawyer named Charlie Rhyne, who was and, is a prominent Washington lawyer, and was a good lawyer. They sued us for an injunction, and they got a judge over in the district court, Judge Goldsborough, who was very much against Food and Drug to start with. So he issued a temporary restraining order. Then we had a trial. We lost very, very badly, because Goldsborough was adamantly against us, and all he did was adopt Charlie Rhyne's findings verbatim, and that really made it tough on us.

But what I learned in this case was the way people looked at vitamins somewhat differently from other products. We had a physician from Cincinnati Medical School who had written on this subject in the medical journals. His evaluation of it, which I think is right, was that Americans want to believe in tonics; they always have believed in tonics. And the vitamins should be considered as a tonic and are considered as a tonic because they're non-toxic and they're readily available, and if people feel like if they take them, they're doing them some good, whether or not they are, then they really weren't doing an

awful lot of harm. And that has made it hard on us on regulating vitamins all the way through.

After that trial that we lost in the district court before a three-judge court--this was a suit to enjoin the enforcement of the law claiming that the multiple seizures were unconstitutional--we then went to the Supreme Court twice. First, we went up before the trial for a writ of prohibition alleging that the three-judge court had no jurisdiction. Although the Supreme Court accepted that case for argument, we lost almost the very first day. I mean, we had the argument one afternoon and got word the next day that we'd lost.

So we had to go to trial, and at the trial, the three-judge court took every slant possible against us, and every piece of evidence that was interpretable any other way, they interpreted it against us. They interpreted things that Crawford, Larrick, and Dunbar had all arbitrarily made these judgments without listening to the facts, and that Murray had a sinister motive in trying to put them out of business and so forth. So we lost.

We then appealed to the Supreme Court both on the jurisdictional grounds which we'd previously lost, and second on the factual matter that these findings had absolutely no support whatever in the record, that they were made up out of whole cloth, and that they should be reversed. Well, it would have been in our interest, I think, if the Supreme Court had gone into that. But they decided this time that the court had no jurisdiction. Now Justice Douglas who had dissented when we went up the first time--we lost 8-1--was the majority judge this time. So we won in that case despite having taken a hell of a beating on the facts in the trial court.

After that, we pursued the investigation of Mytinger and Casselberry. We were able to prove in two ways, one of which was through recordings like this that were put in people's houses just to hear what the house-to-house sellers were saying . . . And they were going wild; they were making every kind of a claim you could possibly make. We knew that was so, and Mytinger and Casselberry denied it under oath and on their word

to God that it wasn't happening, but we knew it was. So we did a lot of recordings. We entered people into the sales organization. You know, any pyramid thing like that will take anybody and everybody. In order to make those sales systems work, you've got to have quite a cheerleading operation going on. So they ran a Nutrilite News and they ran a lot of meetings at which they had these inspirational speakers and a lot of prizes. The way you'd make money in that, of course, as in any pyramid, is you would make money not only on what you did, but on the business that the people you sponsored did, and you would become a key representative.

After that was done, after the case was reversed by the Supreme Court, we entered into an injunction with Mytinger and Casselberry which curtailed essentially all those things, but for the first time made us recognize that there were certain claims that were being made and could be made for vitamins that we had to accept, notwithstanding we understood that that was going to be probably misused in the direct selling. That was the flaw in that case, in the final settlement. I believe, though, that the pyramid thing died and that the thing has never been the success that it was at one time. There were a lot of other people that were coming into this direct selling, following the example of Mytinger and Casselberry, and Food and Drug developed out of that its so-called quackery program that Milstead has talked about with you in terms of the various people that were going into these schemes and how they were doing it.

At that time it generated in my mind, and several years later, having lost the case involving dextra-sugar in which vitamins were added, and having problems with the vitamin mineral soda water and other things, I hit on the idea of trying to have a standard for dietary food supplements, and to make the dietary food supplements that had the vitamins in it reasonably complete in all vitamins for which there was any reasonable likelihood that supplementation would have any benefit, and then make all others that were not in that category either irrational supplements, because they were not complete, or drugs, and make them have adequate directions for use.

We had a hearing on that and the biggest problem was we wanted a requirement put on the label that most Americans didn't need this; they could get all the vitamins and minerals from foods and they don't really need it, which was a truthful statement. The hearing went okay and we were able to go ahead with the standard, but the legislature intervened, and through Senator Proxmire and others, put in a statute that took jurisdiction away from us on that. So the vitamins are being terribly abused still, but as a tonic, and I guess that's something that we'll have to learn to live with in spite of the fact that from an economic standpoint, it's a very substantial fraud and a very substantial taking of resources from health budget that could very well be put to better use than some other things.

FL: That legislation, too, was engendered by a massive propaganda campaign by the health industry.

WG: Right. Well, it was started by Clint Miller's outfit. It was a group sponsored by people that were in this area of quackery, and they promoted letter-writing to people who were interested in these tonics, and they flooded the legislature with the proposals to deprive us of jurisdiction. Proxmire got onto it and was adamant about it and put the thing through. There was nothing we could really do to resist it.

FL: Wasn't their attorney, Charles Rhyne, very prominent later?

WG: He was president of the American Bar Association.

FL: Yes, that was my recollection, that he was well-connected politically.

WG: He was a roommate of Richard Nixon at Duke University and very well hooked up with Richard Nixon. And in addition to that, he was active in the American Bar Association and became president. He was a good lawyer, and he did lick us in a big way in the district court. He fortunately had three judges that were really awful from our standpoint. Bennett Champ Clark has been one of our major opponents when the bill was going through Congress; Goldsborough was a long-time Eastern shore Maryland judge that kicked us around all through the years; and Eddie Tamm was just an ex-FBIer and thought the agency had misbehaved.

FL: I always thought, though, that the speed with which we got the review in the Supreme Court was remarkable.

WG: Well, it was. And more remarkable is that we failed there and won on the same grounds when it was heard completely on the merits soon after that. But you've got to expect that. Anything that goes up to the Supreme Court on an extraordinary, expedited appeal basis is likely to be thought out, bounced back, and reserved for another day when they have more time to do it, and you might win the second time around, which we did.

FL: I guess because the attorney general was one of the defendants in the injunction. That probably helped expedite it.

WG: Yes. You asked me about the Abbott and toilet goods cases that led to the current situation with suits against the agency early on as programs are being developed. Historically, all through my early years here, it was a matter of well-recognized law that a person couldn't sue to enjoin a prospective enforcement action. It was premature, and the courts just wouldn't take jurisdiction over that. This is a principle that had very few exceptions. We were sued several times, you'll remember, over artificially colored poppy

seed, Elko Products against McNutt. We won that on jurisdictional grounds. We lost an old case, National Remedy against Hyde, way back under the original act, where multiple seizures had been initiated after the government had lost its first case. That was a case of deemed arbitrary action. We thought that was a kind of a legal sport--by that I mean one of a kind. But through the years, we had always been baffled about the difference between 701(a) regulations and 701(e) regulations. The former regulations were promulgated after a formal rule-making and after a hearing. The question of whether they had binding force and effect of law was one of those obscure things, because if you looked into the legislative history, it looked like the people up on the Hill were saying that even after you went through that formal procedure, there'd still be a chance to contest the regulations when it was put into force in the district court. But we took the view right along that those regulations promulgated through the formal procedures would have force and effect of law.

About the time that the toilet goods and Abbott cases were decided, the swing in administrative law tended toward making a difference in these rules. That is, the conventional wisdom up to that time was that if the agency issued an order under its general rule-making authority, that that would be entitled to persuasive effect, but not binding on the court. The court could reverse that if they concluded that it was wrong or was arbitrary--anyhow, was subject to de novo review when it became a factor in enforcement.

But there were two cases primarily coming out--one from the Federal Power Commission and one from the Federal Communications Commission--that led me to believe that that part of the law was changing. One of them, the Federal Power Commission, put out some rules on accounting applicable to natural gas which disallowed automatic escalation for increased costs and gathering costs. In other words, they put in a rule that when the gas pipeline came in for a rate increase, it couldn't automatically take advantage of an escalation in a contract it had with one of the

suppliers who were beyond their jurisdiction. And the court held in that case that that rule, having been promulgated after notice and opportunity for comment, had the force and effect of law and was binding.

About that same time, the Federal Communications Commission put out a rule that no company could have more than six television stations. That was the limit. If you had six, you couldn't apply for another one no matter how good you were, how much money you had, or where it was. Six was the limit, and that's all you were going to get. And the Supreme Court upheld that, holding that that was a reasonable thing to do.

So when the drug amendments were passed and the color amendments were passed, we put out some what we called interpretive rules, 701(a) rules. We put them out after opportunity of comment. One of them was--and it's the one involved in Abbott--that wherever a trade name of a drug was used, the generic name would have to be presented in half size in immediate conjunction with that. And that's pretty clearly what Kefauver had in mind. It says in the legislation that wherever the trade name appears, the generic name and so forth. And we said that *wherever* means everywhere. That was the bone of contention. They contended that the rule was that it didn't have to be everywhere, that it had to be in such conjunction with the trade name that would be noticeable, and it wasn't necessary to do it every time.

Well, our regulation was challenged by them, and in the district court in Delaware, we lost. And we appealed. And in the court of appeals in Philadelphia, they agreed with us that the regulation was an interpretive regulation and didn't have binding effect and would not be subject to injunction prior to enforcement. If we tried to enforce that against a piece of literature, then the company could challenge that. In arguing this case in Wilmington before the judge, he said to me, "You adopted this as a binding rule, and you have every intention to enforce it?" I said, "Yes, that's true." And he says, "Sounds like it has the force and effect of law." I said, "Judge, if you'll rule that, I'll take my hat, leave, thank you, and be satisfied with it." Well, he then hemmed and hawed, and so did the

other side. That was a case which I had nothing to lose. If I got a ruling that the 701(a) rules were binding force and effect of law, it was beyond my wildest dream. And so, having said that to the judge--and Judge Gesell was their lawyer again--they about flipped that I would say that. But anyhow, he ruled against me, and didn't touch that issue.

It went up to the court of appeals. The solicitor general was Archibald Cox, who you may remember was the one fired in the Watergate episode. He was a teacher of administrative law at Harvard Law School, and went by the conventional wisdom that we did. And when we recommended the appeal, he said, "Well, I agree with you. That interpretive regulation is subject to these other things, and they have to be challenged in the enforcement." So we appealed and we won there. As a matter of fact, when I argued that case in the court of appeals, I said to him first, "I'm going to argue this case in a kind of a backward way. First, I'm going to argue the merits of the regulation because I think we're clearly right on that, that this is what the law says, this is what it requires, and therefore it's valid no matter how you look at it. Second, I said, that will make it much easier for you to decide the jurisdictional issue. You won't feel like you've let me get off the hook on a jurisdictional issue where I had no merit to my case." So we argued that way, and sure enough, they went with me on the jurisdiction. That agreed with Cox.

Then it went to the Supreme Court, and we argued all these issues: rightness, eminent threat--all the things that would make for those early resolutions. Again, we really had more to win by that by making those regulations a binding regulation than we had to lose. You know, it wouldn't really help us much to open the rules up for challenge at some undefined time, when we could get it all settled and have it as force and effect of law. So I consider the Abbott and toilet goods case, which was on the same principle, as cases that gave us a very strong leg up on making our general regulations have force and effect of law. And as things turned out later, that, of course, has been an important development in administration of the law. And that's how that came about.



FL: By losing, we really won.

WG: By losing, we won. And we knew that from the start and said that to the district judge. That's the way we argued it in the district court. (Laughter) So it didn't come as a great surprise to us.

You asked me about turning the files over to Turner and the other Nader people who came in. The public affairs situation was such at that time as a result of Nader's expose of laziness and poor actions over at Federal Trade Commission, that you really couldn't deny them access to anything without it being implied that you were a bad bureaucrat. So a judgment was made to tell them what we had. I mean, I don't think we really lost anything much by that. Turner's book may have been the thing that saved us. It was so bad, had so many mistakes in it, that it was a joke. We wrote a critique of the book and sent that out, and the book never amounted to anything because of that. You know, he just jumped to all kinds of wild conclusions and cited all kinds of half-truths. That didn't hurt us.

Now, this Mark Green, who's running for Senator in New York now, was one of the investigators who came in. Mark was a bright guy then, and he is now. And he was focusing in on how we were enforcing the new drug and the advertising regulations. He had talked with McCleary, and he knew where those records were of a justice turning down some of the early advertising cases. That's what he was interested in. He was trying to show that somebody or other had let these drug companies off when we had an airtight case against them. It really wasn't quite that simple, so he never did very much with it. But that's why we let him have it. Larrick was under a lot of pressure then, and he was trying to dispel the idea that he was trying to hide something. I felt like, "The hell with it; let them see it."

The way I felt about it, I wouldn't say anything inside here that I wouldn't be willing for people to see. I just don't think we do business like that, and sometimes you'd rather they wouldn't see anything that would tip off something in a case or something like that, or if you've got a going argument about some policy that hasn't been settled. But once it's settled, I don't see any problem with where people were and what the arguments were. I mean, it was all done as far as I was concerned out here; it was all done above board and with no sinister motives. I mean, some of us were more adamant than the others, and some of us were more pressureful than others. But that's why I didn't think there was any great problem there.

FL: At the same time, Agriculture took entirely the opposite tact and . . .

WG: And they've never recovered from it. The implication was that they were an old-line, FTC-type operation and that they were trying to hide something. And they weren't trying to hide anything. And the meat inspection people have never recovered from that.

One of two other items that Fred was interested in was how we got into various cases that ended up by giving us expanded inspectional authority into what were essentially local operations. Of course, with the amendment of the seizure provision after losing Phelps-Dodge, and with the broad scope of a seizure then being the equivalent of the criminal authority under the original act, particularly as amended to cover adulterations as well as misbrandings which occurred while the products were held for sale, those provisions themselves were what expanded our authority, and the upholding of that in Sullivan was the most far-reaching decision that we ever had. That is, it gave the agency the authority to follow a prescription drug down to a package or lack of a package in the hands of the individual user. Now, that is the principle on which all that expanded authority went. The reason we had to get into that is that that was the point of diversion of the drugs, and that was what was causing the difficulty.

In the food field, the Pinocchio Oil case and the Allbrook Frozen Foods cases were cases where the raw material was of interstate origin, and the end product was locally produced. All we were saying there was that if the adulterated raw materials in these frozen strawberries was converted or transformed from a fresh to a frozen product, that didn't do away with our jurisdiction to follow those berries into the food. And that's what the court held. In the case of Pinocchio, the situation was somewhat different. Those were products properly labeled in interstate commerce, and then commingled locally to make a product that was labeled as a major olive oil which had no olive oil. That case, in a sense, is somewhat broader than Allbrook, by dealing with a purely local step that resulted in misbrandings, as against Allbrook, which was a purely local step just changing the physical form of an adulterated product that had been in interstate commerce.

FL: The reason I was interested was that I remember some early cases soon after the first years of the '38 Act where field recommendations for action under circumstances like that were disapproved, and they seemed to be following the old, original packages doctrine.

WG: That's true. The Food and Drug Administration in 1938, and for several years after that, really wasn't all that sophisticated about interstate commerce and how far they could go, and neither were many other federal agencies. I mean, the Supreme Court itself had not really been long since in deciding where the limits of interstate commerce were. Remember the Schechter Chicken case and the other cases there all had thrown some kind of question on it. The original package doctrine was, of course, an old myth or an old arbitrary rule to try to draw a line between where interstate commerce stopped and where it didn't. So there was a lot of feeling in Food and Drug about that. But in terms of the legislation, it had nothing about that; indeed, it had a definition of interstate

commerce that was as broad as any possibly could be. That's what led us into these later developments. That, combined with the "held for sale" idea. Again, that was Charlie's idea. He developed that "held for sale" after his shipment in interstate commerce idea on the criminal part, and then didn't put it into the seizure, and we later had to put it into the seizure.

Ron asked me about the GMP (Good Manufacturing Practices) regulations for foods. We didn't have them for a long, long time. We brought a case once involving the Smith Canning Company, which you may remember. Smith Canning Company was a part-time operation out in Utah. By that I mean Smith Canning had this cannery, and the local growers grew the tomatoes around there, and they brought in wetback-type workers to work during the season there, peeling and processing the tomatoes. Then the cannery would close down. I guess it would be open maybe a couple of months during the tomato season.

The conditions at that plant were quite bad; I mean, they were terrible. (Laughter) It was an old, open-air operation out in countryside Utah. In the hot summertime, you had all the problems of that kind of an operation. Not only that, the temporary workers were living around there in camps, and they lived in the most despicable unsanitary conditions that you could think of. They used an old bus for a latrine, and it was open to flies going back and forth. So the conditions were really reprehensible.

We brought a seizure against it. Smith was a very prominent Mormon and later became president of the National Cannery Association. So they contested, and they had a state inspector who testified against us in the case. In sum and substance, the case got down to a difference of what our inspector said about it and what he said about it. And the court ruled against us. In terms of deciding that case, the court said that there weren't any provisions for screens, and there weren't any other . . . So the court didn't know what would be better and what would not, and he suggested that the agency would be much

more likely to receive the support of the court if we first had regulations which specified what . . . Well, that was an open invitation to us.

But Milstead was in that regulatory staff at the time, and I talked with him about general regulations. He demurred; he thought that there were too many different conditions and different types of operation where it wouldn't be possible to develop GMPs. Well, when we finally did it, we had the Smith dictum to go back on, and it turned out they were a good deal easier to do than we thought. They were just rudimentary things like clean water, and screens, and things like that. So that's where the GMP rules originated, and that's why we took the view that we could adopt them as implementation for a(4) as specifying what would be sanitary conditions as a minimum.

RO: To begin with, we were going to have the general regulations, but later they were going to go back and make specific recommendations.

WG: Well, they abandoned that because it was too much like work. You know, that was following up with what Milstead had said, that there were a lot of individual conditions. But when we got to looking at that, that was more like going into a project that had no end and no real outcome to it, and the best we could do was leave that case by case, and add on those GMPs for the basic rudiments of sanitary conditions.

FL: Even without regulations of that sort, we did, in selecting those cases we went to court with, take into consideration what good manufacturing practices were.

WG: Right, and that was the rule, that either that case or the other case on the seizure said that they were more likely to equate the conditions to the average conditions than . . . Well, that was right down our alley. You know, we knew what the average conditions were better than anybody on earth, and anybody we were going after was a hell of a lot

below average. So that was our meat, too. So that part of the opinion didn't bother me at all.

You wanted me to say something about CPEHS (Consumer Protection and Environmental Health Service). Back just before Nixon came into the presidency, as I remember the timing. I'm not sure; do you know the years on that?

FL: Yes. At least, from what I know, in April of 1968 at a meeting that I went to in . . .

WG: Right. That would be when Nixon came in, after Johnson.

FL: No, it was before his election.

WG: That's right, it was just before that.

FL: Yes, that's right.

WG: Okay, that's what I'm talking about. Just before Nixon was elected in the late years of Johnson, I guess, Wilbur Cohen was assistant secretary, and there was a great upheaval on environmental stuff. You know, the Clean Air Act was passed in 1970, and the whole department was kind of gung-ho on environmental things, and consumer activities were very much in the news. About that time, we had had Hazardous Substances Labeling Acts and other consumer acts. So Wilbur hit upon the idea that we should have a consumer protection unit in the Public Health Service, that is, that they had a quarantine, they had a clinical, and they should have a consumer and environmental health protection agency. So he created that. He put in charge of it C. C. Johnson who was a PHS sanitary engineer, a black man. He had risen high in the PHS organization as a sanitary engineer, and was very well thought of. So Wilbur picked him to head the agency. He put in the agency

Food and Drug; the Air Pollution Control Administration, which was part of PHS; the Drinking Water operation in PHS . . .

FL: Solid Wastes?

WG: Solid Wastes.

FL: Pesticides?

WG: No, Pesticide was Food and Drug. He put us in there. Let me see. There were one or two others from various parts of PHS.

FL: Radiological Health.

WG: Radiological Health is what I was trying to think of. We were based out here at the Rock. I think all of the agencies were either here or over on Twinbrook, which is fairly close to here. C. C. Johnson had the role of being the head of that agency. Well, he could never quite really get control over those independent people. They had been independent too long. John Middleton, who was the Air guy, and Herb Ley, who was Food and Drug, and the others just simply took it as a necessary evil and never did give full support to it.

Well, it didn't last all that long--I think about a couple of years--and when the new administration came in, one of the first things that Charlie Edwards and the other people did was to take Food and Drug out of CPEHS, and CPEHS very soon died. That is, the Air program and the Solid Waste went to EPA, and the CPEHS died a natural death as a result of that. But it never did really become very functional or very operational.

C. C. (Johnson) tried, but he wasn't a line man; he didn't really have any line authority. All he could do was by persuading these people that really had the authority to send everything up through him, and that way he would have a say as it went to the Secretary's office. Now, that may have been the start of taking away from Food and Drug the authority I got for them a long, long time ago to issue regulations without having to go through the Secretary's office. I got that authority from either Folsom or maybe as far back as Ewing. Because they were looking at a lot of papers, primarily antibiotic papers; all the antibiotic regulations had to clear through there. And so, every time a new Secretary would come in, he'd get one of these damn antibiotic documents which were all graphs or parts of paragraphs that they couldn't make head or tail out of. He'd ring me up on the phone: "Come around and explain this thing." I said, "Geez, I can't explain the damn thing. It's an antibiotic laboratory procedure."

Anyhow, whichever one it was said, "I don't see any reason why I should see these things." And I said, "I don't see any reason why you should, either. I don't see any reason why you should see things like these records." For example, when the Willapoint case was through the administrative process, the record was long and involved, and the Secretary had to read that; he had to be prepared to make a judgment. Well, it took Ewing days. He was a lawyer, and he sat down with that thing and didn't do anything else for two or three days. So when he got through, he was inclined to go along. So I got them to put that regulation in that said Food and Drug would have the authority.

One of the considerations there was whether or not they should have a further provision on there that it be subject to approval by the Secretary. I said, "There's no use putting that in there. If you don't trust these guys to do the job and let them do it, then there's no reason to buck it up here automatically; you'll simply have to go through the review whether you need it or not. Why don't you put out a directive to them, and say, 'I've given you this authority. I want to be damn sure that anything that involves any



policy thing is explained and alerted to me." And I said, "That's really all that's needed." So they agreed.

It went that way until when Flemming got involved with the aminotriazole. He wondered why he hadn't seen some of these documents before, and I explained it to him. He then wanted to put in the same thing. I said, "You don't want to do that. It just invites a political intervention in things that are not political, and it doesn't assure you anything you can't get through proper management of these people that are employees of the Secretary and that won't respond. I know from having worked here a long time and knowing the people, if you tell them to do certain things, they're going to do it. And you can rely just as well on that." And I don't know why they haven't been able to put that across down there now. But anyhow, I had problems with it, but I was always able to hang onto that.

RO: Bill, were you chief counsel for CPEHS?

WG: Yes.

FL: Did you have any contact with Winton Rankin in that particular year before he made his speech to FDLI in which he invited the regulated industry to object to the FDA being submerged under CPEHS?

WG: Oh, I'm sure I talked to him a lot of times on it. I talked to Winton every day. I would never do anything like that because it didn't do any good. You've got to go to Wilbur Cohen or somebody who was responsible for the thing to get it . . .

FL: It cost Winton his career.

WG: Yes, well, you can't invite nonparticipants to go and raise hell with your boss on something that you can't convince him on. But CPEHS really never grew into anything, and it disintegrated when the Environmental Protection Agency got those authorities.

FL: Of course, Goddard expected to get that job that Johnson got, didn't he?

WG: I don't think so.

RO: I was going to ask whether it was coincidental that Goddard left almost the same day that we became a part of CPEHS?

WG: I don't know. I know Goddard got in trouble over that speech he made about marijuana. That was a funny thing, and he should have known better than that. Ted Cron kind of agitated him on that, that marijuana wasn't all that dangerous and people were going ape on it. So Goddard made that statement about his daughter and marijuana and his daughter and a martini several times around. I told him, "You're nuts to talk that way. That's not your concern; why the hell do you want to get involved in it?" But he did. Then he made the statement once out in some university--I forget where.

FL: Minneapolis.

WG: Minneapolis. Some stringer picked it up, and from there on, he had bad press. Up until that point, he had excellent press. And from that point, people began to question his judgment if he talked that way.

FL: Well, then the other statement about the demise of the corner drugstore being something that was probably going to happen was widely quoted and got him into further difficulty.

WG: He was an outspoken enough person to where he could make a lot of powerful enemies in the pharmaceutical industry. He called them a sick industry; I mean, he didn't pull any punches on any of that stuff.

Well, Fred, I think that pretty much covers what I've got to say. If you identify other areas that I might be able to contribute on, let me know. Ron wants me to talk about the role as general counsel, and about all I can say about that--I wouldn't want to be critical of what goes on down there. All I can say is what happened with me. When I first came here, and P. D. Cronin was the general solicitor in charge of the work, the Solicitor's Office was not very active in anything Food and Drug was doing because it didn't have any regulations that amounted to anything. They were having some cases in the courts. They were referred to the Department of Justice and handled by the Justice Department without any further intervention. So about all the office was doing was processing those cases and notices of judgment.

Well, that whole scope changed with the '38 Amendment. As I've indicated in the talk here, there was a large operation of administrative hearings with standards and with regulations and so forth which necessarily got them into that. So the role changed. Then, when we were transferred to Federal Security, Paul McNutt was the administrator of that and Fowler V. Harper was the general counsel. They were both from Indiana and both very close friends. So McNutt began to rely on Fowler Harper in helping him understand and cope with a lot of these things, such as the corn sugar issue. So from that point on, the general counsel became more involved in dealing with the top.

Now, as long as you were in the Department of Agriculture, I guess you know that that is a hydra-headed, complex agency. If you deal there from Food and Drug over

in the south building, when you went over to the north building, you were in some really different, foreign territory. Campbell dealt with Wallace and Tugwell, and Crawford did to some extent, but not anybody else much. Now, Mastin White did. He was brought in by those people to have a stronger say in the legal part. They had a weak general counsel, and Mastin did have a say there. But he didn't involve the division in direct operations.

We got involved in direct operations through working with Charlie (Crawford) on these administrative things. Then when we began to have court cases, it was clear to me that we were going to lose a lot of them if we didn't get out there and argue them ourselves. If we left that up to an assistant U. S. attorney to argue, it didn't do the briefs, and we were going to hurt for that. Because every time you lost a case, it was like losing an amendment to the law. That's something you had to live with a long time, and there was no way to get out of that, other than to get Congress to change it. So it became important to me to kick in there. So from the very first--the Cordell-Urbeteit cases were very early on, the Atlas case--we wrote all the briefs and argued all those cases. And then we became more and more involved with Food and Drug as these things have unfolded.

I've explained to you what I did in legislation and how I got there. That is, Charlie had handled it early on, and then I began to handle it through contacts he made for me through the House legislative counsel, and through the committee counsel. So we became involved with the legislation both as a persuasive matter with Charlie and as having experience working with the committees. So that's the court business and the legislative business and the administrative business.

Then the Division of Regulatory Management came in and they encouraged more and more assistant U. S. attorneys to request aid, so we came more into that. Then, as we got into cases like Hoxsey and Koch and Krebiozen, those became cases in which you had to be an actor; you couldn't just pass the cases over to the Department of Justice and expect anything good to happen. What happened wasn't all that good, but at least we had a going chance.

Now, we had a staff of about fifteen lawyers, I guess, when I first came back after World War II. That grew up to about thirty, maybe. Then, when the cutback came, we lost several, had some RIFs in our own . . . Some of the best lawyers we had--like Selma Levine and Les Uritz--we lost them. So we were cut back. Then we got to where we were handling a lot of business without all those protracted delays. As a matter of fact, I handled all the regulations that came through. I never farmed those out to anybody, unless there was really someone there to do it. I'd either approve them or buck them back with little buck slips saying this was what was wrong with it. So there wasn't any big delay there. Then I wrote all those beginning regulations, at least an outline of what needed to be in the food additive. And then between Rankin and Checci and myself and Wulfsberg and the others working on that, I would give them an outline of what needed to be done, then they would write them up, and then between the two of us, we would get up a draft and send that on up the process. That's the way it worked. So the number of people we had was smaller than they now have.

When Hutt came in, he brought in a lot more money and lot more people, but to keep them busy, they had to put in all these multiple reviews, and when they got involved with all that labeling business, that fell outside of any Food and Drug's real interest. So they became the principal actors in that, I guess. I don't know anybody in Food and Drug that was very much interested in all those regulations and the freedom of information business like Hutt was. So that's why it changed that much.

FL: Well, in your time, too, you recognized that a lot of cases you did not have to be involved in, the regular, routine insanitation cases . . .

WG: You ought to have some judgment on when to get in and when not. That's what I'm talking about. I came to the conclusion that all those appeal cases had such a risk for it that we would argue every one of them and write the brief. If we were not going to

argue it, we would insist on writing a brief, go sit down with the guy that was going to argue it, be damn sure he knew what he was doing, be sure he was prepared. But, sure, there were a lot of over-the-counter cases, sanitation cases--we wrote trial briefs, provided trial briefs for all that stuff. Just routinely, all the district would have all those briefs that outlined what the issues were; they could give it to the judge. So a lot of stuff was handled there without being individually tailored for each and every case.

(Interruption)

FL: Do you think we need to wind it up now?

WG: I don't have anything more in my notes, Fred, but after you go through the draft, if there's anything that needs clarification, let me know. Or if you find areas that we haven't covered that I could contribute on, I'll try my best. But I've probably told you more than I really know already. (Laughter)

FL: We would appreciate your sort of leaving the record open, Bill, because I'm sure that all of us, when we have a chance to look at the transcript, will think of things that might be embellished, or at other subjects that we might also discuss. Certainly this has been an enjoyable and informative session with you, and we greatly appreciate your taking the time to help us out for this project.

WG: Thank you Fred, it's a pleasure to work with Food and Drug again.