HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Wallace F. Janssen

U. S. Food & Drug Administration

and

James Harvey Young

Emory University

Fred L. Lofsvold

Robert G. Porter

U. S. Food & Drug Administration

Rockville, Maryland

January 30-31, 1984

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. The interviews were held with retired F.D.A. employees whose recollections may serve to enrich the written record. It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration.

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.

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TAPE INDEX SHEET

CASSETTE NUMBER(S) 1 to 8

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

DATE: Jan. 30-31, 1984 PLACE: Rockville, Maryland LENGTH: 7 Hrs., 20 Min.

INTERVIEWEE	INTERVIEWER
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FDA SERVICE DATES: FROM 1950 TO: _____ RETIRED? Yes

TITLE: Director, Office of Public Information. Still employed as Historian.
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
1	A	0	1	Autobiography - Early Years.
		4	2	National Grocers Bulletin.
		6	3	Northwestern Miller.
		12	7	The Glass Packer.
		21	10	First Contacts with FDA.
		26	11	Preserve and Jelly Standards.
		30	12	End of Tape 1-A.
	B	0	13	Preserve and Jelly Standards, Continued.
		1	13	"Consumer Activists: They Made A Difference", Consumers Union, January 1983.
		3	14	The "Bred Spred" Case.
		6	16	The Tugwell Bill.
		21	21	J. W. Sale - Preserve Manufacturing Article.
		22	22	Consumers Research, Consumers Reports.
		28	24	F-D-C- Reports (The Pink Sheet).
		30	24	End of Tape 1.
2	A	0	24	F-D-C Reports, Continued.
		6	26	Broadcasting Magazine.
		10	27	F-D-C Reports, Continued.
		15	29	Industry Education
		17	30	FDA Contacts, E. M. Nelson, A. J. Lehman, A.G. Murray.
		20	32	Appointment with FDA, Assistant to the Commissioner, Principal Information Officer, Discussion of Activities.

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
2	A	30	35	End of Tape 2-A
	B	0	36	Trade Press, Trade Associations, Charles Wesley Dunn, Mike Markel, James Hoge.
		5	38	"Read The Label" and Other Information Activities.
		12	41	Milk and Cream, Drug and Pesticide Residues.
		20	45	"Rex Morgan M.D." Comic Strip, Health Fraud.
		30	47	End of Tape 2-B.
3	A	0	47	"Rex Morgan M.D.", Continued.
		2	48	"Dennis The Mennace Takes a Poke at Poison" Comic Book.
		5	49	Accidental Poisoning of Children, "Keep This And All Drugs Out of the Reach of Children", Aspirin Poisoning of Children.
		20	52	Hazardous Substances Labeling Act, "Cracker Balls", "X-33", Fireworks.
		24	53	Public Information and The Statute.
		25	54	"Fraud Fighters" Movie.
		29	55	"The Law Behind The Label", Set of Inspection Slides.
		30	55	End of Tape 3-A.
	B	0	55	"The Law Behind The Label", Continued.
		2	56	The Cardiff Case - Inspection Authority - Colliers Magazine Article.
		7	60	Quackery, Hoxsey Cancer Treatment, Public Warning.
		30	67	End of Tape 3-B.
4	A	0	67	Hoxsey, Continued.
		1	68	Castoria Recall.
		5	70	Grain Sanitation.
		7	71	Quackery Congresses.
		12	73	Quackery - Speech to Chiropractors.
		13	74	Commissioner Goddard's Speech at 3-rd Quackery Congress
		16	75	Shift in FDA Emphasis from Misleading Claims to Pharmaceutical Quality, Kefauver Amendments.
		25	76	Commissioner Goddard, Second Citizens Advisory Committee.
		30	78	End of Tape 4-A.
	B	0	78	Second Citizens Advisory Committee.
		2	79	Dr. Goddard, Second Citizens Advisory Committee.
		3	79	Commissioner George Larrick.
		16	85	Commissioner Charles Crawford.
		19	86	Commissioner Paul Dunbar.
		21	86	Larry Trawick.
		23	87	Winton Rankin.
		24	87	Vivian Boardman.
		27	88	FDA Annual Reports.
		30	89	End of Tape 4.
5	A	0	89	Annual Reports, Continued.
		4	91	Citizens Advisory Committees - Membership.
		7	93	Consumer Advocates.
		11	94	"The Chemical Feast" - James Turner.
		18	96	The Cranberry Episode, HEW Secretary Arthur Flemming.
		28	99	The Role of HEW Secretaries in FDA Matters.
		30	99	End of Tape 5-A.

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
5	B	0	99	Role of HEW Secretaries, Continued.
		2	100	Cranberry Episode, Continued.
		12	105	Charles Wesley Dunn.
		15	106	James Hoge, The Proprietary Association.
		16	106	Dr. Frederick J. Cullen, The Proprietary Association.
		22	108	Carson Frailey, American Drug Manufacturers Association. "The Contact Committee".
		30	110	End of Tape 5-B.
6	A	0	110	Bernard H. Smith, Flavoring Extract Manufacturers Association.
		1	110	John Hall, Flavoring Extract Manufacturers Assn.
		2	111	Gregory Thomas, Toilet Goods Association.
		3	111	S. L. Mayham, Toilet Goods Association.
		6	113	Dr. Bigelow, National Canners Assn.
		7	113	The "Revolving Door" Phenomenon.
		12	115	Trade Associations, Continued.
		22	117	Henry Welch Case.
		30	120	End of Tape 6-A.
	B	0	120	William W. Goodrich.
		3	121	Rufus Miles, Department of HEW - Praeger Pub. Co.
		4	121	Henry Welch, "The Impact of FDA on our Society" - MD Publications Inc.
		7	122	Janssen, "Public Information Under the FD&C Act", Food & Drug Law Journal.
		8	123	Press Releases - General Discussion.
		13	125	" " - Magic Spike.
		15	125	" " - Zerrett Applicator.
		16	126	" " - Fake Olive Oil, Use of Squalene.
		20	127	" " - O-T-C Drugs, Illegal Sales.
		22	128	" " - Appointment of Commissioner Crawford, Diet Quackery.
		30	130	End of Tape 6-B.
7	A	0	130	Press Releases - Black Strap Molasses, Gaylord Hauser, Accompanying Labeling.
		3	131	" " - "Read The Label" Booklet.
		5	132	" " - Durham-Humphrey Act.
		6	132	" " - O-T-C Cases.
		7	133	" " - Bread Standards.
		8	133	" " - General Discussion.
		12	135	" " - Cardiff Case, Inspection Authority, FDA Policy Regarding.
		29	140	" " - Penicillin, Unjustified Prescribing.
		30	140	End of Tape 7-A.
	B	0	140	Press Releases - Chloromycetin, Unjustified Prescribing
		2	142	" " - Ten Day Press-On Nail Polish.
		7	144	" " - Historical Validity of.
		17	147	Commissioner Charles W. Crawford - Expansion of FDA.
		22	149	First Citizens Advisory Committee.

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
7	B	23	150	Congressman John Fogarty - Increased Appropriations.
		23	150	Nelson Rockefeller.
		27	151	Selection of Commissioner - Change to "Outsider".
		30	151	End of Tape 7-B.
8	A	0	151	Change in Selection of Commissioners, Continued.
		3	152	Bradshaw Mintner.
		5	153	Change in Selection of Commissioner, Continued.
		9	154	Possible Successors to Larrick - Malcolm Stephens, John Harvey, Winton Rankin, William Goodrich.
		10	155	Transition to Commissioner Goddard.
		20	158	End of Interview.

ATTACHMENTS

No.	Page Reference	Subject
1	8	"Washington Prepares for new Food, Drug and Cosmetics Act." The Glass Paker, January 1936.
2	13	Speech: "A Case History on Food Standards," March 3, 1952.
3	13	"The Food and Drug Administration and the Consumer": Chapter 10 in "Consumer Activists: They made a Difference," Consumers Union, 1982.
4	33	Dunbar memorandum announcing Janssen appointment, April 20, 1951.
5	38	"Read the Label on Foods, Drugs, Devices,Cosmetics."
6	42	Milk check stuffer, "Federal Law Prohibits Drug and Pesticide Residue in Milk."
7	47	"Warning: Hazardous to Children": article on FDA's child protection activities.
8	48	Comic book: "Dennis the Menace Takes a Poke at Poison."
9	64	Public Warning Against Hoxsey Cancer Treatment.
10	73	Speech: "A Message to Chiropractors"

11	75	Article: "Outline of the History of U.S. Drug Regulation and Labeling," Food, Drug, Cosmetic Law Journal, August 1981.
12	94	"FDA Since 1938," paper at a symposium of the American Historical Assoc., 77th annual convention, Dec. 30, 1962. Jl. of Public Law, V. 13, No. 1, 1964.
13	113	Industry reaction to transfer of the FDA from the Department of Agriculture to the Federal Security Agency, The Glass Packer, April and May 1940.

EDITOR'S NOTE

Readers of this transcript will probably notice some variations in the writing style. These are due to an inherrent problem with oral history--that few individuals have such infallible memories that they can go to press without checking their sources. This writer certainly is not one of them. So, not wishing to rewrite the tape into a book, we compromised by researching and rewriting those sections which seemed to need it.

A few footnotes and attachments have been added to document the text and provide clues on topics not covered by the questions. One of these, for example, is the story of the FDA "Consumer Affairs" program related in Chapter 10 of "Consumer Activists, they made a difference," published in 1982 by Consumers Union. I am proud to have been included as a consumer activist.

It has also been a privilege to have written many articles, press releases and speeches dealing with major happenings in the last half century of FDA history. I would like particularly to include in this transcript my article titled "Toward a New Era in Consumer Protection: The Supreme Court Rulings on Drug Effectiveness." It was in these 1973 decisions that the Court held that FDA has "primary jurisdiction" in all matters covered by the food and drug law, and that its regulations and decisions, if properly prepared, have "administrative finality."

RGP: The date is January 30, 1984. The place is the Commissioner's suite in the Food and Drug Administration Office in Federal Building No. 8, Washington, D.C. We are interviewing today Mr. Wallace F. Janssen, FDA's Director of Public Information from 1951 to 1966 and then becoming the FDA's historian. The others present are Dr. James Harvey Young, Professor of History, Emory University; Fred Lofsvold, retired Director FDA Region 8; Robert G. Porter, FDA retired. Dr. Young, I think I will turn the questioning over to you at this time.

JHY: Wally, you have had a long and glorious career with FDA. Now in these interviews we would like to get the background, what came before. So that, if you wouldn't mind, would you start off by giving us an autobiographical account of when and where you were born, your education and then the kinds of activities you engaged in prior to your coming to FDA.

WFJ: All right. For who's who. I was born in Omaha, Nebraska, February 11, 1905, which I have just learned was the real birthday of George Washington.

JHY: Now, you don't dare tell a lie in the rest of this whole proceeding.

WFJ: My parents stayed in Omaha until 1910 and then moved to St. Paul, Minnesota. I grew up in St. Paul, went to the public schools and eventually to Macalester College. Relative to my subsequent career, my father had been a bookkeeper and

accountant for the Union Pacific Railroad in Omaha. In St. Paul he had various jobs, finally becoming the credit manager of a large retail grocery company. From that he got into trade association work and became Secretary of the St. Paul Retail Grocers Association and then of the Minnesota Retail Grocers Association. Then by the time I was in college he was the Secretary/Manager of the National Association of Retail Grocers. At that time the headquarters could be wherever the Secretary resided, so it was in St. Paul during the time when I was in college.

At Macalester I was very active in the student publications and had a major in English composition. Macalester only had about twelve credit hours in English composition at that time, so I went to the University of Minnesota for additional work in that area. I was...I think, the only person who majored in English composition at Macalester in some time.

I edited a yearbook at Macalester that won the national award as the best in its class - the small colleges. I also edited the student literary magazine and wrote a number of articles and poems that were published in that.

So, my father saw no serious problems of nepotism when he hired me as an editor, without portfolio, on the National Grocers Bulletin. This was a very old fashioned trade paper. It was, however, printed on slick paper and had a colored cover and advertising from big grocery concerns. The paper

was extremely chaotic; badly put together. I believe the first thing I did was to count the number of type styles that were used by the printer who had a free hand in setting material. I found there were 32 different styles and sizes of type being used in the composition of this magazine. So, I developed a style sheet, to cause the magazine to have a fairly decent appearance.

I also began to develop departments and articles that might be helpful to independent retail grocers - like ideas for window displays. We would set up these displays in a warehouse, next door, then photograph them and then we would have an article about a suggested Washington's Birthday Window, for example.

JHY: You are talking about the late 1920's?

WFJ: I am talking about 1928 and '29.

At that time my father and I began to disagree about things. I had ideas for the magazine that sometimes didn't fit in with his ideas and we finally parted company. I answered an ad in the Minneapolis Journal for an editor and found myself working at the Northwestern Miller in Minneapolis.

JHY: Wally, were the conflicts with your father ones that dealt with the nature of the interpretation of the reporting about events in the grocery field, or were they more on technical grounds?

WFJ: Actually neither. My father and I began to have a generation gap, or something, at that time. I was a young man and I was feeling my oats, I guess, and we just began to disagree. It was time for me to be on my own.

At the Northwestern Miller I really lucked out in getting a job with one of the world's greatest trade journals. It had been founded in 1873. Later it was acquired by a young man named William C. Edgar. He was a remarkable person, a showman. He dramatized the milling industry to its members. When I worked there the magazine, really a weekly newspaper, was a big as the Saturday Evening Post. It had four-color covers, all reproductions of old masters that Edgar had collected in Holland and other countries. They showed scenes of grain harvesting and the milling industry and the baking industry from the middle ages on. I could go on for an hour telling about William C. Edger and the Northwestern Miller.

This great worldwide authority on the grain and flour trade was published for one hundred years, to the day, and then closed because the industry had changed so much that it was no longer viable as a publishing property. It was discontinued by the Miller Publishing Company in 1973. I have a copy of the 50th Anniversary issue of the Northwestern Miller, published in 1923. It is a handsome bound book and contains the story of this really remarkable publication.

With the Northwestern Miller I was associated with a man named Carroll K. Michener, who was the managing editor and had been the managing editor of the Minneapolis Tribune.

Mr. Michener was a very skilled editor and I learned a lot from him about the art of copy editing and news reporting, etc.

JHY: What was the spelling?

WFJ: M I C H E N E R.

I don't want to spend too much time on the Northwestern Miller, although that would make a story in itself.

Incidentally, at the time I got the job, my pay with my father had been $18.00 per week and with the Northwestern Miller it was $25.00 per week. I was a junior cub editor and if I had stayed in all probability, I would have eventually received stock in the paper because it was owned by the employees. Mr. Edgar had turned it over to them when he decided to retire. Or rather they bought him out. They had rich friends in the milling industry and they raised the money and bought him out. So, the policy was to give stock to all the employees after they had been there long enough to be sure that they were going to make a career of it. Judging from what happened to my associates there, I would have ended up as Chairman of the Board, eventually.

It was a wonderful place to work - like a blend of a gentlemen's club, an art gallery and museum of the milling

industry, a printing plant and great publishing enterprise and we had advertisers from all over the world. It took two pages, four columns, to list all the advertisers and every flour importer from Rotterdam to Bangkok had at least a little ad in the paper to make him a member of the club.

JHY: In the early days, there were flour problems that the Bureau of Chemistry had to handle. Did you, as a reporter, come in contact with the Bureau of Chemistry and with litigation that involved the condition of flour?

WFJ: No, not at that time, although once in a long while there was something in the paper that did deal with that sort of thing. The paper was a very ethical one. They were four-square behind good food law enforcement and all that sort of thing.

Their main gripes were with food faddists, as a matter of fact. They were very sensitive about what they considered was nutritional nonsense, especially if it concerned flour and bread. They also were very much concerned with U.S. Agricultural policy, the subsidies to the farmer which, under President Hoover, were beginning to be very important politically.

Well, at the time I got my job at the Miller I had answered an ad that appeared in Printers' Ink Magazine. That was the leading organ of the advertising and publishing business. I didn't hear anything from it for over a year and then I learned that there were some inquiries being made about me

by a trade journal in New York City called The Glass Packer. Eventually I met the editor of the The Glass Packer, a man named John T. Ogden. I think I met him at the National Canners Association Convention in Chicago. They didn't invite me to New York; they asked me to meet Ogden in Chicago for an interview. The Northwestern Miller, at that time, was not giving any pay raises because it was beginning to be affected by the depression. They were losing advertising revenue at the rate of a thousand dollars a week, but still prosperous and surviving, and they did survive all the way through the depression. But the prospects for advancement at the Northwestern Miller were very poor at that time. When I talked to Mr. Michener about this offer from New York, he asked me if I planned to get married and he was kind of... Well, he had to be discouraging about the chances for getting more money, or at least not much more. The New York job offered me twice the salary I was getting at Northwestern Miller, $50.00/week, which was rather good pay in 1931.

So, I accepted and I went to New York and arrived there on the 6th of July 1931. The first thing I did was to get on an elevated train, the 6th Avenue Elevated, and ride up to the end of the line and back in order to see what New York looked like. I thought it was very interesting, and it was. From the start I was very welcome as the Assistant to Mr. Ogden. The Glass Packer was a packaging journal that derived its

revenue from the bottle and cap manufacturers and the label manufacturers and the machinery manufacturers.

Mr. Ogden was a Yale man from a wealthy family. He got into publishing as editor of one of the canning trade journals, so one of our big areas of interest was in foods, various kinds of foods, salad dressings, pickles, etc. that were packaged in glass containers.

The magazine was concerned with the technology and marketing of all kinds of products in glass. At that time there were 25-30 glass container companies in the United States, a good source of revenue for this magazine. It averaged 80 pages a month, on glossy paper with lots of pictures.

From the beginning I was an idea man, suggesting subjects and developing articles. There was never any problem about travel expenses so I was able to visit a great many factories and become acquainted with the people who managed the production end of things, because they were the ones who influenced the buying of containers, caps, machinery, etc. So, I became something of an expert on glass packaging. I was also interested in package design and package merchandising. That was how I got to know the food, drug and cosmetic industries. I was able to go to the conventions and reported the trade meetings in some detail. I also got to know the FDA; wrote my first long article about it in 1936 (See attachment).

In 1934 a tragic event happened. There were two

partners in this business, one of them was a man named Cornelius Watney. He was the business partner and the sales manager, whereas Ogden was the editor and publisher. Mr. Watney was on vacation and went swimming one evening and had a heart attack and drowned. Ogden had to reorganize the business, so I became editor of The Glass Packer in 1934 and from then on until '43 I ran The Glass Packer.

Odgen was a very adventurous sort of a person. He had red hair. He had girl friends. He liked to goof off and do things. In the fall of 1941, he enlisted in the American Field Service and went to Egypt. He was in Cairo when the attack on Pearl Harbor took place. I had been given the responsibility of running the paper while he was giving this year of service in the AFS. He never got a chance to drive an ambulance. He was in the headquarters, the management end of it in Cairo, while the war in North Africa went on.

So, I put in a rather rough year running The Glass Packer. I say a rough year because Mrs. Ogden was a constant kibitzer. She was a gal from Mississippi who didn't know much about business and I constantly had to explain things to her and she was always a bit suspicious about how things were going. Finally, when Ogden got back, he was all gung-ho to take over again. He had had his adventurous fling and he was ready to settle down and run the paper again.

But at that time I had an overture - an inquiry from a man

in Washington named Wallace Werble.

JHY: Before you get on to the new stage, can you comment about what you might have learned about the Food and Drug Administration and the problems of your clients whom you visited.

WFJ: Yes, I should cover that before I go into the next phase.

While I was with The Glass Packer, I became very well acquainted with a lot of the leaders, trade association people, company presidents, etc., in the different industries that we covered. We got much of our material from them and we cooperated with them in providing an information service to our readership. Very soon I realized the importance of covering the relations of these industries with the government.

In 1931, shortly after I came to New York, I made my first trip to Washington. Ogden and I flew down in a Ford tri-motor airplane. It was my first flight. I remember looking out the window and seeing the motor rattling around in the supports and it looked like there were loose bolts and that the motor was going to fall out any time. But we made it to Washington, where we stayed at the Washington Hotel and visited the Food and Drug Administration in an old building on Independence Avenue. I don't remember very much about that visit, although I did meet Commissioner Walter Campbell and some other people; for example, I met a man named Sale who was

the head of the fruits and jams and jelly activities.

FLL: J. W. Sale.

WFJ: J. W. Sale, yes. I remember meeting him. Washington was the headquarters of the National Preservers Association which was headed by an attorney named Daniel Forbes. He had been with the FDA before he went into private practice. Actually, he had been in the General Counsel's Office of the USDA.

Then there was a man named Walde, who was the chemist of the association. This association had been very much concerned about standards for preserves and jellies. The leading company in the industry was the American Preserve Company, of Philadelphia, headed by Wayne C. Meschter. Mr. Meschter was a Quaker who believed in making the highest quality of preserves and thought that that was where the future of the industry was. He realized that their main competitor was the housewife and thought the commercial products should be equal to or better than anything the housewife could make.

So, the industry wanted standards for these products and the Food and Drug Administration didn't have any legally enforceable standards. They had had advisory standards for years, but had found that these were not enforceable in court. The FDA had the support of the National Preservers Association in these cases, but the courts held there was no authority in the law to enforce these standards.

The association also did investigations on its own and they had even reported to the Food and Drug Administration about substandard products produced by members of their own board of directors. They were really serious about wanting the industry to put out quality products....

JHY: This developing story could be found in the pages of The Glass Packer? You found these things out and wrote them up?

WFJ: Yes, there were articles in The Glass Packer; every now and then some new development would produce an article. The effort of the National Preservers Association to get standards really summarizes the history of the Food Standards Provision that finally became law in the 1938 Act. That whole story is in a speech I made shortly after I joined the Food and Drug Administration. It was a luncheon talk to the National Preservers Association on the history of the industry and the Association.

JHY: Did that get printed?

WFJ: It never got printed, but I have a copy of it here.

JHY: Could it be made...

WFJ: I will get it out and check the date of it, because I think we'd want to have that date in here.

JHY: Besides having the date in the transcript, don't you think it would be a good idea to have a copy of the manuscript attached to the transcript.

WFJ: Yes. The speech to the National Preservers Association was FDA history as well as Industry history. I find here that in 1978 I sent a copy of it to Commissioner Kennedy, with this message, "This old speech may be worth reading between your labeling hearings. It gives considerable background on the history and relationships of food standards, labeling, freedom of choice, imitations, etc." The title of the speech was "A Case History on Food Standards" and I gave it at the annual convention of the National Preservers Association at Chicago, on March 3, 1952, just about a year after I joined the FDA.

JHY: We will have attached as an exhibit to the transcript a copy of the text of this speech?

WFJ: Yes. I also have a story about that in a chapter I was invited to write for the book called "Consumer Activists: They Made a Difference," published by Consumers Union.

JHY: What date was that?

WFJ: That was published in January 1983, but the chapter was written several years prior to that time.

JHY: This chapter, can we also attach it to the transcript.

WFJ: Yes.

The coverage of the food standards problem not only reflected what was going on in the preserve industry but also in the canning industry. The Glass Packer had reported the passage of the McNary-Mapes Amendment of 1930. The preservers had thought that amendment would give the FDA the authority to

fix standards for almost any packaged food, but the Solicitor of the Department of Agriculture made the decision that it applied only to canned foods, meaning tin-canned foods. So, the Food and Drug Administration did not set any official standards for preserves until after the 1938 Act was passed.

The preserve standards were not the first to come out after the new law was enacted, but very soon afterward in 1940 or '41. It was a model hearing. The National Preservers Association had all the evidence lined up very well and they presented it and there was none of the nit-picking and lawyer opposition that we encounted in later foods standards hearings. Michael F. Markel was the FDA's attorney in this hearing.

JHY: I seem to remember that...

WFJ: It quickly went into effect.

JHY: ...that earlier there had been an almost scandalous situation in connection with a product called "Bred Spred"?

WFJ: Yes, "Bred Spred". The "Bred Spred" case was reported in The Glass Packer. It was possibly the best example of the economic cheating that was going on. It was one of the exhibits in the FDA's famous "Chamber of Horrors" on the weakness of the 1906 Food and Drug Act. Incidentally, this is of interest today because of the fact that it was one phenomena of the Depression. The cheapening of products, the marketing of ersatz products of various kinds, was one of the means

that industry employed in order to cut their costs. The Depression should be called the "Great Deflation", I think. All over industry people were trying to reduce their costs and make things cheaper, to sell for less, and this, of course, resulted in cheapening the quality and cheating the consumer. They called it the "downward spiral." It was one of the main reasons why Congress passed the National Recovery Act allowing industries to set up codes of fair competition.

JHY: And this sort of "Bred Spred" situation was the kind of thing that upset the trade association leaders.

WFJ: That's right. I remember interviewing a little jam and jelly manufacturer in Brooklyn and he said, "You know when I come to the office in the morning I never know how much more I have to cut down on the fruit in order to cut my price another 2 cents a case." So, that is what was going on. "Bred Spred" was about 25% fruit.

FLL: As opposed to approximately 40-50%.

WFJ: Yes. Half as much fruit as it should have had to be what consumers would expect in a "preserve." Now, even then, of course, they called it "Bred Spred," not "strawberry perserve." Do you know who made it? Best Foods.

JHY: So, you were involved in many problems that the Food and Drug Administration was involved in and concerned about the relationships between the industry and the regulators, all through your editing role.

WFJ: Yes. I was also concerned with standards for products like salad dressings, mayonnaise, etc. The Glass Packer was the chief technical organ on the mayonnaise industry, which didn't exist much before 1930 and from that time on developed rather rapidly. We also were very much interested in tomato juice, a new product then, and in catsup, an old product.

I remember when we got a manuscript of a very good article on the processing of catsup to eliminate air from the product. That article came from the Heinz Company. The reason Heinz was giving away their know-how was because they felt that the total market for catsup would increase further if there were fewer poor quality products on the market that turned brown and disappointed the consumer. They wanted their competitors to improve their products because they knew they would get their share in a larger market. So, that was why Fred Heinz sent me that article.

JHY: Now, also mushrooms probably, pickles, olives...?

WFJ: We didn't have much to do with mushrooms. There weren't mushrooms to speak of being packed in glass, but we did have a lot of interest in pickles and olives and things like that.

Well, now while I was with the...this leads to my eventual coming with Food and Drug. While I was with The Glass Packer, in 1933, the "Tugwell Bill" was introduced in Congress. You can't imagine the storm that was stirred up about this New Deal legislation. It was the target of all of those

people who disagreed with Franklin Roosevelt and his New Deal. Of course, it got smeared with the name of Rexford Tugwell who was supposed to be a communist because he had visited Russia. There were hundreds of articles and editorials attacking this legislation. At The Glass Packer, of course, we knew that a new food and drug law was needed and there were a lot of people in industry who wanted changes in the law and saw benefits coming from those changes. So, we were in a position where we had to try editorially to steer a middle course. We deliberately intended to be objective. And we were not sucked in by the rabble-rousers who were out to kill any bill if they possibly could. A lot of those people had not even read it.

So, I got the idea that it would be worthwhile if we had a series of articles on the Tugwell Bill that would tell specifically how it would change things pro and con, for the people who put out foods, drugs and cosmetics. I found a man, a consultant, who worked for the...I forget the name of this consulting firm but it will come back to me in a minute. His name was Philip P. Gray and he worked for a leading firm of technical consultants in New York City, Pease Laboratories. Mr. Gray's assignment was to do three articles: one dealing with foods, one with drugs, one with cosmetics, and we would illustrate these articles with labels showing typical product labeling as it was to be found on the market, and then how it would have to change if the Tugwell Bill passed.

JHY: You mean this was an assignment given to him by The Glass Packer?

WHJ: That's right. I worked with Mr. Gray in developing the concept, the illustrations, and the text. He knew the industry details.

So, we published the first of these articles. Whereupon we received a number of letters, one of them from our largest advertiser, the Owens-Illinois Glass Co. That letter demanded that we not publish the rest of the articles because they were "offensive" to customers of the industry. They threatened the cancellation of their advertising contract, and they were our largest advertiser. They had a contract for twenty-four pages a year, the center spread of the magazine. Well, my publisher was a smart man. He was quite willing to compromise on some things, but he saw that here was a situtation where he really couldn't compromise. It had been announced as a series. If the articles did not appear, it would create a situation that would be untenable. So he backed up his editor and stood up to the big advertiser and they cancelled the space. We continued the series. And in less than a year they came back with a new contract, I think it was for thirty-six pages.

Now, I've had theories about this, since then, and I've never told this before but I have this feeling: The Owens Illinois Glass Co. was the leading manufacturer of what was called "P&P ware" meaning pharmaceutical and proprietary

containers. So, they had heard from their big customer, and then we heard from our big customer. Well, I've always been glad that we did that series, and did not back down.

JHY: Did you yourself do any interviewing with any of the people at the Food and Drug Administration who were developing this bill, in order that that journalism might go forward.

WFJ: We did often communicate with them, but I don't know that we did on this particular series. We handled that series, I think, pretty much on our own.

JHY: I was just talking about the matter of your getting acquainted, personally, with people in the agency. You said you met Mr. Campbell on one of the trips and Mr. Sale and I was just wondering how as time went on...

WFJ: Yes, and Dr. Dunbar and Charles Crawford and George Larrick and Ward White and A. G. Murray and many others. Well, there were a couple of other things that I think I should mention. One of them was in connection with the preserve standards and I think I'll have to refresh my memory a little bit about that, which I will do by referring to my chapter in the Consumers Union book.

JHY: While you are hunting it,did you say, Wally, that there was a complete file of The Glass Packer in the Library of Congress?

WHJ: Yes, right. I have several volumes of it but it's a very scarce thing now. The Owens Illinois Glass Co. library

might possibly have a file and the National Canners Association did have a file in their library, but the last time I checked with them the librarian didn't seem to know about it. That is now the National Food Processors Association.

Suppose I just read into the record a section of my chapter in the Consumer Activists:

> "Officially the FDA declined to advise industry on how to comply. It was seen as industry's responsibility. Certainly FDA could not take on the job of telling so many people how to run their businesses. Besides it was bad policy to give out such information because it could be turned against the agency in the event of litigation.
>
> Such had been the views of Wiley, who had bitterly opposed any approach to compliance save court proceedings, believing this the only method provided by the statute. So keenly did Wiley feel about this, that he made it the theme of his swan song, "The History of a Crime Against the Pure Food Law."
>
> Yet, Wiley himself had been a magnificent educator and his correspondence shows constant use of a strategy of persuasion that produced results.
>
> Whether Food and Drug law enforcement was to be primarily educational, or primarily punitive, was an issue both before and after 1938. As a trade editor I was convinced that both approaches were necessary.
>
> My own publication became a source of information on how to comply with the new law. Month after month we reported on new regulations, labeling of products, food standards and other requirements. We were in effect carrying on an educational program to promote compliance. We got our information from FDA and checked it with our sources to insure its accuracy. The service rendered was appreciated by both readers and the FDA.

How education began to be accepted as a way to compliance was illustrated by a case that came to trial just before the 1938 Act was passed. In this criminal prosecution, the FDA charged deliberate and persistent adulteration of fruit preserves with pectin and water. Notwithstanding strong testimony by industry and consumer witnesses, the jury refused to convict. During the trial, which I reported in The Glass Packer, the FDA had spelled out its not previously published laboratory methods of analysis for fruit content. Industry leaders who wanted enforceable standards saw this testimony as coming close to definite guidance on how to make preserves and jellies that would, on test, be regarded as legal products. I was asked if I could get the FDA to provide an article on the subject. It seemed a reasonable request and on my next trip to Washington I visited the FDA's experts on fruit products and suggested that an interpretive article would be helpful."

Now I'll tell their names: J. W. Sale and a man named Osborn.

FLL: Robert Osborn. Robert T. Osborn.

WFJ: "Knowing these men and their capabilities I did not expect the refusal I got. Clearly agency policy was involved and I would have to go higher. Commissioner Campbell listened to my story and asked a few questions. Then he picked up the phone and called one of the men I had just seen. It strikes me, said Campbell, that Janssen has a good idea. Why not give it a try? That was all that was needed. J. W. Sale of the food laboratory wrote an excellent technical article. Reprinted by the National Preservers Association, it was for some years considered the bible of preserve manufacturing. That is what they called it. It also provided much of the foundation for the standards that were issued in 1941. Later I was to be involved in many FDA-industry compliance projects."

JHY: One further thing, do you remember the name of the case that you referred to there that was lost by the Food and Drug Administration?

WFJ: No, I don't, but I think from the date I could find a notice of judgment and all that.*

JHY: Right, sure.

WFJ: Another thing that happened: Consumer's Research was just getting started and they had an internal struggle there, a labor dispute. Originally it was called Consumer's Research and the two main protagonists of it were Fred J. Schlink and Arthur Kallet. They broke up and so there were two publications, which still exist, Consumer's Research and Consumer Reports.

JHY: My student, Max Cleland, wrote his masters thesis at Emory University about that tussle and that division.

WFJ: That's right.

Well, in industry, generally, there was hostility towards this idea of a consumer organization telling people what to buy, what was good and what wasn't good, etc., and they were constantly finding fault with articles in the publications. The Consumer's Research people had not yet become expert at their job. Some people feel that they still are not always expert at their job. Anyway, back then it was all new, and I was interested when one day a man came in from one of the big PR firms, Batten, Barton, Durstine and Osborn. Fred Smith was his name, and he offered to do a research article about Consumers Research. So, I thought this was interesting and I agreed to look at his article. It turned out to be

* 30405. Alleged adulteration and misbranding of preserves and jams. U. S. v. Fresh Grown Preserve Corporation. Tried to the court and jury. Verdict of not guilty. (F. & D. No. 37033. Sample Nos. 21654-B to 21667-B, inclusive, 43016-B to 43019-B, inclusive, 43023-B, 49913-B to 49917-B, inclusive.)

May 1939

very hard-hitting criticism. It endorsed the idea that there could be and should be an information source for consumers that would enable the consumer to be an intelligent purchasing agent for her family. But the Consumer Research people ought to just get with it and learn how to do research, because they weren't doing research; they were doing some very amateurish product testing and producing some rather misleading and erroneous information. So, we published that series of articles and it was reprinted by the Proprietary Association and circulated by them.

Later, after joining FDA I had reason to be critical of some of the reporting done by Consumers Union and as a result I got to be well acquainted with the editors of Consumers Reports and they began to telephone us and check things, send us copies of manuscripts, and from that developed a very good rapport and as far as Food and Drug was concerned the reporting in Consumers Reports became quite accurate and constructive.

One more story of those years: by 1937 the opposition to the pending food and drug law had largely died down. Some compromises had to be made, but pro-consumer organizations had fought off some of the worst ones. So I was writing editorials urging it was time to pressure Congress to pass the bill S-5 and avoid the risk of more drastic legislation. Then came the shock of the Elixir Sulfanilamide tragedy, and the

beginning of pre-market clearance for new drugs. A high price was paid for that experience, but who would say it was too much?

Well, so much for my years with The Glass Packer. I was there twelve years altogether, from 1931 to 1943.

In 1943 after John Ogden came back from Africa, and we really were in the war, I heard from Wallace Werble who was the founder of a newsletter in Washington called F-D-C Reports. Well, there were really two newsletters; one on the food industry and one on the drug industry and these had been started in 1939, because it was seen then by him and others that there was a real opportunity for a newsletter for companies interested in the problems of compliance with the 1938 Food and Drugs Act.

WFJ: The time was 1943 and Wallace Werble was eligible to be drafted. He was married, but had no children at that time. So, the question was whether the new F-D-C Reports newsletter, also known as The Pink Sheet, was going to be shut down while Werble was in military service or could be kept going. Werble, of course, felt it should be kept going because of its value to the war effort of the drug industry. He looked around the country for somebody who was capable of continuing his publication. I was the number one candidate, the only trade editor in the country who had specialized in the area of the food and drug and cosmetic industries and was already

covering such activities as those of the War Production Board, for example, and other war agencies.

Perhaps I should say a little more about the newsletter business. F-D-C Reports was modeled after another early newsletter; rather there were two of them. While in college Wallace had been an admirer of the reporting of W. M. Kiplinger. He even got Mr. Kiplinger to come to Washington and Lee University and address the journalism department. Werble, I think, very early saw that there was an opportunity for specialized reporting that was not being met by the general media or other trade papers. I also knew this, of course, and that is why The Glass Packer made a special effort, although it was a monthly, to cover Washington in an explicit, detailed way. Werble didn't go to work immediately as a newsletter editor. He had started with the International News Service and you couldn't find a more free-wheeling operation than that. So, his approach was a little different than mine. He told me, more than once, that he didn't hesitate to make predictions, like Kiplinger, even though he didn't have much documentation to back them up. He felt that he could predict when something was likely to happen, and be right so many more times than he was wrong that he ought to do it.

My feeling was a little different - that the business reader didn't want to read speculation unless it was identified as speculation. My philosophy was that in trade report-

ing you had to be very accurate and that it was worthwhile to go back to your sources and check things with them because you always gained more than you would lose by doing this. That philosophy is not practiced or believed in by a great many people who are with the media today. It's the common policy of many publishers, perhaps the majority of publishers, that news writers should get the story right the first time and not take the time to go back to their sources. This often results in inaccurate reporting. But anyway, Werble wanted me to take over the Pink Sheet in the event that he was drafted, and I wanted out from The Glass Packer.

JHY: Why was that, because of the return of the editor?

WFJ: Because of the return of the editor and because I had reached the conclusion that I was never going to get any place with the Ogden Publishing Company. It was a family owned business and I was working to make a success out of something that didn't deserve what I was putting into it. In a way I wish I had left earlier, which would have changed things a great deal.

Anyway I accepted a position with Broadcasting Magazine, which was published by one of the backers of the Pink Sheet. It would be a standby job; when Werble was drafted I would take over the editorship of the newsletter.

So, I reported initially to work on the organ of the radio and television industry, Broadcasting Magazine. It was

a very good paper and in a way it was almost like going back to the Northwestern Miller insofar as the editorial work was concerned because it was a paper that printed a great deal of important news.

I did a couple of things there that I would like to put on record. One, I invented and started the OWI Bulletin, a column that listed the public service announcements to promote the war effort available to the radio stations of the country from the Office of War Information.

At that time there was no television - no T.V. stations or networks - only a few experimental devices with little 6-inch screens. But we all knew T.V. would become a big industry when the war was over. So I wrote an article on "Televising the Package," predicting what television commercials would be like when it got going.

JHY: This was in this journal you're talking about?

WFJ: Yes, in Broadcasting Magazine.

Interestingly enough, it has all turned out very much as predicted. The kinds of advertising, the animated packages, the cosmetics and the pretty girls washing their hair and all that kind of thing. It all came about...

JHY: Wallace Janssen's 1984.

WFJ: Well, after a year Werble was drafted and I was given a choice: stay with Broadcasting or take over the production of the newsletter. Wally was in the service around two years. He

never left Washington and was on hand to advise, and occasionally to write what he called a "think piece." He worked for the Joint Chiefs of Staff and it was one of the instances where the military used a man the right way. He had the job of putting together all kinds of data and information on the beaches in the Pacific for the commanders of landing operations.

Then after the war ended, Wally asked me to stay on as Managing Editor, and we would see if we could expand the newsletter operation and make something big out of it. In fact we even had the idea of going to a weekly printed paper to compete with Drug Trade News and other drug journals.

The other stockholders, however, didn't agree and so we continued the newsletter business and I covered the Food and Drug Administration and the Federal Trade Commission and Werble covered the industry news. I was able to continue writing about what was going on at Food and Drug and got even better acquainted with the FDA. We both also wrote for other journals so together I made more money than just my salary at FDC reports. I wrote for Business Week, for example, and one year I was the leading Washington "stringer" for that publication. It helped to pay off the mortgage on my house.

Well, seven years later, at the end of 1950 I had a phone call from Commissioner Dunbar and he wanted me to come in for a talk. He quickly got to the point. We were very

well acquainted and I already knew his views about the desirability of keeping industry informed about what the FDA expected. He was not like Dr. Wiley; he believed in enforcement but he also believed that FDA could get compliance very often without the turmoil and time and expense of going to court. There were other, better ways of doing things - and so he wanted to know whether I would like to join the Food and Drug Administration and expand its outreach and particularly its trade and consumer education activities. I didn't hesitate. I had thought much earlier that this was the sort of thing I would like to do.

I also knew it was something of importance that needed to be done. Preparing for this oral history interview I located something I wrote in the November 1939 issue of The Glass Packer, ~~which is included with other papers filed with this transcript~~. Quoting just two sentences: "Undoubtedly the Administration has more time for its educational activities, now that the law is starting to work a little more smoothly. A big task facing the FDA is the prevention of mistakes on the part of the manufacturers rather than the prosecution of mistakes after they occur." This was the basic philosophy of the staff memo which Dr. Dunbar issued to announce my appointment 12 years later.

JHY: But before you go on....

WFJ: There is one other thing in connection with this. I

knew that being with the Food and Drug Administration would be tremendously interesting and would be an opportunity to continue doing something that I believed in. I thought to myself, "well, this is something that I can tell my grandchildren about." I was 46 years old and ready to end my 20 year career in the private trade publishing business.

JHY: I wanted to ask, before you get yourself into the government service to think of yourself in that role of a reporter whose sole beat was the Food and Drug Administration. And to think in terms of your sources of information. Now, mention the people who were cooperative and excellent sources of information within the agency at the time and if there were those who weren't so cooperative possibly mention them. There may not have been any like that but think of yourself now still as a journalist from outside covering this as a beat. Talk about the people as sources for what you were trying to do. Your impression of the agency is somewhat suggested by what you've said. Stay outside it yet and talk about your final impression of it before moving into it.

WFJ: Well, FDA was never my sole beat, but if I hadn't believed in what the Food and Drug Administration was doing and the way they were doing it and the people who were running it, I would never have gone into government service. By that time I had become acquainted with a lot of people in the FDA. I remember in 1936, for an example, publishing in The Glass

Packer an article about the FDA and its new laboratories that were just being occupied in the South Building of the Department of Agriculture. That article described not only the new facilities which had been outfitted at the great cost of, I think, a quarter of a million dollars. It also told about such things as the new Vitamin Division under Dr. Nelson.

FLL: That was E. M. Nelson, the Vitamin Division.

WFJ: Then there was also the new Division of Pharmacology under A. J. Lehman. So, I knew most of the top people and I knew Crawford and, of course, Dunbar and Larrick. I knew Larrick quite well. They were all in the top management layer I knew people like Sale, and then there was Mr. ...I can't remember his name. He handled lots of correspondence in the head office.

FLL: On drugs?

WFJ: Yes, on drugs.

FLL: A. G. Murray?

WFJ: A. G. Murray. Yes, he was a legend. I knew A. G. Murray very well. One of the interesting things that happened shortly after I came with Food and Drug was this: I don't remember all the details of it but I think it is worth mentioning.

A. G. Murray called my attention to an action he was handling that involved the destruction of a seized product, and the defect of the product was rather technical. He called my

attention to that. I think maybe he did it on purpose. Anyway, a lot of useable product was going to be destroyed. It struck me that if that information was published, the publicity would certainly not be good for the FDA. I went to Charlie Crawford who had just become Commissioner, (Dunbar had remained as Commissioner only about 6 months after I was sworn in) and told him about my misgivings. He called Murray right away and they reversed the action. It would not have been a good move. So they found some other way to dispose of it. They were serious about making use of my abilities.

JHY: They were quite specific in the definition, the job definition that they had in mind for you when they asked you to come?

WFJ: Yes, they were. And Dr. Dunbar had been careful to discuss the appointment with the Chairman of the House Appropriation's Committee because there was a law against hiring information people without the consent of Congress. And, because of my experience and knowledge they were able to appoint me as a Food and Drug Officer, Grade 14, a high rank. I could not have been hired as an Information Specialist at that grade because I would have had the same rank as the information chief of the Department. So I got my credentials to make inspections, collect samples and so, like any other Food and Drug Officer. My title was Assistant to the Commissioner and they gave me an office in the Commissioner's suite on the

third floor of the Federal Security Building at 330 Independent Avenue SW. It was a familiar place, having been occupied by the War Production Board. Next door was the office of Deputy Commissioner Charles Crawford and across the way was Commissioner Paul Dunbar and George Larrick, who followed Crawford as Commissioner.

An "all hands" memo by Commissioner Dunbar was issued announcing my appointment and broadly describing my duties. (A copy is in the file accompanying this transcript.) This was, in fact, a historic action and document. Dunbar had been severely criticized by ~~Henry~~ Harvey W. Wiley in his book "The History of a Crime Against the Food Law." (You can find it on page 375.) As the head of the enforcement activities he was accused of being soft on industry because he had gone on record in favor of such ideas as education to prevent unintentional violations and warning the trade before starting court actions. Like other FDA leaders he continued to favor such policies, and now he was doing something about it.

One of the things I was supposed to do was to "plan a program." Well, it turned out that the program was already there. The job was already there. I sat down and my phone was connected and I had an in-box and an out-box. Right away I had so damn much business that I didn't have time for anything except to... You see, they had been getting along without a Principal Information Officer and the instant that they had

one, why business that was going all over the agency became concentrated.

One thing that was very fortunate was that after Dr. Dunbar retired, Mrs. Louise Lynch who had been his secretary was interested in writing, public relations and things like that and she wanted to be my secretary. So she was, much to the disappointment of Malcolm Stevens who wanted her for his secretary. Mrs. Lynch was invaluable because she knew a great deal about how the agency did things. She was able to do a lot of mail for me. That brings up my next story.

I found almost right away that FDA was getting a lot of mail from the schools. These school kids and teachers would write in asking about what the FDA did, etc. This mail was all turned over to a messenger who worked for the Commissioner. This man had a big family and they wanted to give him duties that would justify a pay increase, so they made him responsible for this school mail. He would take the incoming letter from the kid or the teacher and mail it back with a copy of the Food and Drug and Cosmetic Act.

I was shocked by that. I thought that, particularly if the teacher or the student had asked a specific question, that they should get a responsive answer. So, we took on this school mail, and Mrs. Lynch wrote most of those letters. That was, of course, the beginning of what is now the Consumer Inquiries Staff - handling around 60,000 inquiries each year.

There were times later when, of course, the backlog got to be very large and not only school mail but other consumer mail. My impression is that they now keep up with it pretty well.

Well, my first weeks with Food and Drug made me think of lightning rod salesman who got caught in a thunder storm with samples.

I had a lot to do right away. Immediately I was involved with the production of press releases and found that very familiar. I had no trouble at all with writing press releases for the FDA.

Now, I am wondering if you are hungry enough to...

RGP: We are just about to the end of the tape anyway.

WFJ: Well, I wonder if we can go on a little bit, perhaps and then go across the street and get something to eat.

RGP: All right.

FLL: One question I'd like to ask.

WFJ: OK.

FLL: At the time that you were still with The Pink Sheet, did you ever feel that FDA people consciously gave you information because they wanted you to distribute it for them? That they used your publication as means of getting information to the trade?

WFJ: Yes, they did tell me when they felt there was a need to get information out to the trade. This ties in with a policy

they followed but was not officially stated. The Food and Drug Administration had this way of going at a problem. Mr. Campbell, particularly, did this. For an example, in a speech or maybe in a TC letter...

FLL: Trade correspondence letter.

WFJ: ...they would, in an informal way, let it be known that the FDA was thinking along this line or that line, or that it disapproved of this or that, or whatever. They would allow maybe six months or a year to go by after giving this signal and then they would make a seizure. They did not, at least the people that I came in contact with, did not believe in clobbering somebody without giving some opportunity for them to shape up. Of course, if it was an emergency or a deliberate violation they would act right away.

JHY: Public warnings?

WFJ: That's right. They did this for Werble too. They would tell Wally what they were thinking about in regard to a particular drug problem. Then on the other hand we would ask FDA too, about what was cooking in a particular area.

As reporters we were an interface between the industry people and the Food and Drug people. We would hear both sides of a topic and then we would write about it and that would help to provide a two-way understanding. For instance, I knew Mr. Dunn - Charles Wesley Dunn, and I sometimes talked to him about a matter or he would make a speech about some subject

and I would be able to quote that.

Another prominent industry lawyer that we knew was Jim Hoge of the Proprietary Association. And Mike Markel who had been the attorney for FDA during the Preserve Standard Hearings and then entered private practice and was connected with different companies and associations after he went into private practice.

JHY: Wally, I met and had some personal impression of Mr. Dunn and you made him vivid in a recent article. I never met Mr. Hoge, who was terribly important on the Proprietary drug side for many years. Would you give a personal vignette of his description and demeanor and manner?

WFJ: I think I can do that to a certain extent. He was a tall, distinguished, graceful, elegant kind of man who expressed himself very well. He had a very strong pro-industry point of view, although I am sure that he was also in favor of good law enforcement, just not too much law enforcement. He, again, was not a trial lawyer type but an industry statesman type like Dunn. From a personal standpoint it is interesting that he was much involved in show business. He was an attorney for theatrical producers in New York City. That was one of his major interests in life, the theatre, Broadway.

JHY: Thank you, that was very good.

WFJ: Where was I?

RGP: About to join Food and Drug.

JHY: Let's join Food and Drug now.

WFJ: Well, I told you already about how I was like the lightning rod salesman in the thunder storm with the samples. I immediately had so much business that I couldn't sit back and act like a bureaucrat and "plan a program." I was immediately operating a program.

One of the things that I found when I got there was the draft manuscript and illustrations for a booklet called Read the Label. This carried out a basic educational theme that the Food and Drug Administration had utilized for many years. The label was the vehicle for a great deal of the consumer protection that the FDA was trying to provide. What it said on the label had to be true and had to correctly describe what was inside the can and what was inside the can had to measure up to what it said on the label. Between those two sides of the same coin was the consumer protection which the law provided - against adulteration and misbranding.

I saw right away that this publication, which was first drafted by an FDA Inspector, met the need for something very simple, understandable and entertaining, even to elementary school children. There were whimsical little pencil cartoons illustrating the various points - nothing distracting from the subject. So, I pushed its final review by the different program people in the agency. You can't imagine what a lot of arguments we had about the simplified language. I had to head

them off from something much too complex. Eventually, we got the final OK's, and saw it through the Government Printing Office. Right away it was a hit. The National Canners Association, for example, bought 10,000 copies from the GPO. They sent them out to the food editors of all the newspapers and to the home economics teachers, dietitians, etc. For the canners, the label was their window to the public. They wanted people to read the label on canned foods. They had opposed the grade labeling provision in the Tugwell Bill, in favor of what they called "descriptive labeling." They felt that this was good for their business and we felt, of course, that it was good for consumer protection, so we had cooperation. It continued in use for many years, being revised a little bit from time to time. What I have here is revision number 4, which came out in 1963, which would have been about 10 years after the first one and it went on for a number of editions after that.

Well, that was an illustration of what I thought the FDA could and should do. The theme, of course, was an old one. It was used when the FDA had its first radio programs on the National Farm and Home Hour, way back in the '20's. I think that it is a theme that ought to be revived. Reminding and teaching the public to read the label is a very good kind of consumer education and one about which there is hardly any argument. You can get cooperation with a topic like that.

Well, without regard to chronology I could talk about a lot of experiences that we had in the information business during the 16 years that I was FDA's Information Chief.

JHY: The "Read The Label" pamphlet is one example of the effort to build up a sort of sound basic plan at reaching the public in an educational way, day in and day out. Maybe you would like to cite other examples.

Then there is the spot news crisis sort of situation, in which public information would be necessary because of some suddenly recognized, possible hazard in the food supply or the drug supply wherein your action required another type of approach. Do you think this is sort of the way to handle these...

WFJ: There are two sides to the basic information job: the activity that I headed was concerned with of both of them. Both were involved in all channels of communication to the public and we were responsible for the press releases, the spot news, the preparation and clearance of speeches, as well as publications to meet specific needs.

JHY: In the basic education job, besides pamphlets such as the "Read the Label" pamphlet, what other approaches did you generate?

WFJ: I could give you examples - without regard to any chronology, except that this one came out of the FDA's experience with the cranberries. We may want to talk about that later.

After the great cranberry recall of 1959, the FDA became aware and alarmed about the frequency of drug and pesticide residues turning up in milk. Having seen what happened in the case of the cranberries, we were very concerned about any replay of that experience in regard to a product as important as milk.

At the same time the dairy industries of the country were also aware of this possibility. They knew what we were finding in milk and they felt that they should do whatever they could to prevent any damaging publicity for the dairy industry and they were also, I think, quite sincerely concerned with keeping milk as just about the purest and safest food product on the market. So, a meeting was called by a man named Joe North, who was the Washington representative of the ice cream manufacturers. He was also the chairman of a Washington group called the Dairy Industry Committee. It represented all the different by-product industries in the dairy field. I attended this meeting with Malcolm Stevens, the Associate Commissioner for Enforcement. After discussing the problem, it was suggested by the industry people that the farmers of the country had to be alerted, but they didn't want to do it in a way that would tend to provoke lay press publicity. At the same time they wanted the farmers to be warned officially, not indirectly from the dairy trade associations, but directly from the government. They wanted an official notice from the United States government that farmers better be careful about

residues of pesticides or drugs in their milk and what they should do to prevent this.

So, we conceived the idea of a little handbill that could be circulated to the farmers. We knew right away what the format of that handbill would be. It would be what they called a "milk check stuffer," in other words, a single sheet that would be put into the same envelope with the farmer's milk check. This could go out without any additional cost for postage and all the cooperating dairies in the country that bought milk from farmers would be able to include it with the milk checks. So, we got up the little folder, "Keep Residues of Drugs and Pesticides Out of Milk." It started out very forthrightly: "Federal law prohibits drug and pesticide residues in milk and cream. Even traces of some chemicals may be injurious to health. Contaminated milk and cream may be seized and shippers prosecuted. Keep milk safe and pure," all in big type. Then, what you the farmer can do when treating mastitis or other infections with antibotic drugs such as penicillin; discard all milk from treated cows for the periods stated on the label of the drug; follow label directions exactly. Or if the drug is administered by a veterinarian follow his advice regarding barn sprays, sprays on pastures and forage crops, and silage etc. Then on the back, information telling the farmer how drug and pesiticide residues get into milk; be careful about feeding cannery wastes, and a word

about guarantees - in other words how much protection you can get or not get from a guarantee. At the bottom it said, "Official Notice of the United States Government."

JHY: Did that ...

WFJ: We made it as strong as we could. Now, just that you'll know what kind of problems you can get into even with something like this: the original version had a reference to residues in citrus pulp, and we right away heard from the Florida people and their Senator about that and I think there were about 500,000 copies that had to be scrapped only because of the way this was worded. Altogether we printed around 2 million copies. They cost the unbelievably low amount of about $2,500. That is all it cost the FDA to reach every dairy farmer in the country.

JHY: Had the Food and Drug Administration run into observable trouble with milk by testing it?

WFJ: Yes indeed, that's how we knew about it.

JHY: It wasn't just the fear...

WFJ: That is what triggered the whole business. We were finding the residues in the milk. We were going to seize milk. I don't know that we had actually seized any then, but we did later. They knew we meant business, and they meant business.

One of the things that came out of this was that the States then climbed on the band-wagon and we had a tremendous

amount of other educational publicity supporting this effort, from the State Departments of Agriculture. They all got up their own versions of our warning and sent it out to the farmers. They saturated the field with preventive education.

JHY: That was in the wake of the cranberries...

WJF: It seemed it worked. Certainly we had far less of a problem after this came out than we thought we were going to have.

FLL: It helped stimulate the states into testing programs, too.

WFJ: Yes.

JHY: That is an example of broad educational approach, in a sort of crisis...

WFJ: And at very low cost. One of the things the present generation of government information people seem to...what I think is a trap that they fall into, is overdoing their publications - printing too fancy publications, spending too much money. The artists and designers seem to think the most expensive way they can to do a job is the most effective when often the least expensive way is the best one.

Well, I was always very well satisfied with that experience and to me it was a very good example of how educational work can be done by the government with very little money. I've always thought that the old USDA farmers bulletins were admirable. Because they came from the government they didn't

have to be fancy. People expected the information to be reliable and it was. So they weren't disappointed.

One of the things that impressed me when I first came with the Food and Drug was the need for public enlightenment about "quackery." The FDA was making a lot of cases that dealt with health frauds of various kinds. Some of the evidence revealed the tragic consequences to people who were deluded, misled into trying treatments that weren't any good. I kept thinking "what can we do about this?" I kept thinking about that.

One day I made the acquaintance of a comic strip, "Rex Morgan, M.D." Here was a doctor who was involved in all kinds of adventures and who had patients, and once in a while there was some educational content to it. It occurred to me that perhaps Rex Morgan could have an experience with a quack. So I found out who was the creator and owner of "Rex Morgan, M.D." It was Dr. Nicholas Dallis, a psychiatrist who lives in Arizona. So I got on the telephone one day and talked to Dr. Dallis. He was interested, very interested. We agreed that I would propose a story line for a series of Rex Morgan comic strips educating the public against quackery. We did that - we got up a story.

JHY: You say 'We' Wally?

WFJ: "I" and "we."

JHY: This is the editorial 'We'?

WFJ: Yes, I got up the story. I talked to the Food and Drug enforcement people and we developed a fictitious but typical case. Eventually there were two of these situations which Dallis developed into scripts.

The first one involved an herb-healer to whom Dallis gave the name of Baru. He wanted, of course, to avoid resemblance to any real person who might claim this was him and sue us. Baru was a herb doctor, who operated out of a trailer. We had him doing this in order to have interstate commerce. He moved around from state to state, prescribing and selling his herbs from the trailer.

One day while the strip was running in the papers I was in it. It was one of the startling experiences of my official life to find myself in the comics. That particular strip is framed and on the wall in my office. Rex telephones "Wallace Janton" at the FDA to ask about this herb doctor. "He calls himself 'Baru.' Does that ring a bell?" And I reply "Does it?!...We've got a file a block long on that sharpie, Rex!" Then I was mentioned again in one of the Sunday strips, in color; I have that at home. I got many letters from people who recognized my name. I got them from all over the country.

During the story our chemist in the script had the unfortunate experience of dropping the official sample and the bottle broke. This was necessary for the plot of the episode. Everybody in FDA was reading Rex Morgan, so the next day one

of the chemists brought me a replacement official sample, which they fixed up in the lab and labeled "Dr. Baru's Medicine." I think I still have that somewhere.

For quite a number of years I was very much interested and concerned with the problem of accidental poisoning of children. That is a long story which I have covered in an article in the March, 1973 issue of FDA Consumer. It occurs to me now because we have been discussing the comics. This was before National Poison Prevention Week got to be a big thing in public health education. Another person very much interested in protecting children from accidental poisoning was Dr. Irvin Kerlan, a pediatrician on FDA's medical staff who at one time was the acting director. I don't recall exactly when it started, but together we drafted the text for a poster, warning parents to keep medicines like aspirin out of the reach of children. It was the right size to go on the back of a standard medicine cabinet door, with spaces to write in the phone number of the nearest hospital emergency room and the family doctor. Dr. Kerlan wrote the first draft and I arranged for some little cartoons like the ones in the "Read the Label" booklet.

Because it was inexpensive we could print a good many of these, but all kinds of other people got interested in reprinting it. The Pink Sheet (F-D-C Reports) for instance, sold a million copies at cost to retail druggists for distri-

bution to their customers. The state health departments also reprinted it. But the biggest circulation came from the national magazines which got up their own versions of this life-saving educational message. Just one of them, Woman's Day, had a 4-million circulation.

The next step, which was inspired by the Rex Morgan experience, was to see if we could get some nationally known cartoonist to improve the drawings. So I got in touch with the syndicate which handles the Rex Morgan series. And from this came a better idea -- a comic book featuring the very popular and lovable character of "Dennis the Menace." It was what you call "a natural." Dennis was just right for the message. A man named Malcolm Ater took our poster script and put all its points in a 16-page, entertaining story book that could be printed for about 2 cents per copy. Again, FDA did not have to be the only source and user; millions of copies were purchased by other organizations. Our distribution was selective; we sent it, for example, to all of the pediatricians in the country, so it would be seen by parents and children in the waiting rooms. "Dennis the Menace Takes a Poke at Poison" is still being published in a new and updated edition.

FDA has long given the highest priority to anything that involves the safety of children. But that was not always true. Throughout society there has been an evolution from

callousness to concern. That is the theme of the article I mentioned previously. For the record I would like to tell what it covers.

First, there is the story of the long crusade of Dr. Chevalier Jackson, the Philadelphia throat surgeon, to get the states and then the Congress (in 1927) to pass laws requiring a poison label on household lye and other dangerous chemicals.

Next, there is the story of another crusader, Homer George, the Missouri pharmacist who got the Congress to establish National Poison Prevention Week. Then come the stories of the voluntary establishment of Poison Control Centers and the Federal Hazardous Substances Labeling Act of 1969, with subsequent amendments -- the Child Safety Act and the Poison Prevention Packaging Act. Finally, there was the Consumer Product Safety Act of 1972, which established the Consumer Product Safety Commission to take over the program pioneered by the FDA.

A major stimulus in all this was the accidental poisoning of young children from ingestion of household products, particularly salicylate drugs such as aspirin. Many FDA people got involved, including myself. I recall particularly when the salesman for a newspaper clipping service called on me to get FDA as a client. He thought we should take the service to see what kind of press we were getting. I was thinking how I would justify the expenditure. But when he offered a one-

month free trial I had the good idea of asking for only one kind of clippings -- news stories on poisoning cases. We got hundreds of them from all over, especially small places where it was news when a baby had to be rushed to the nearest hospital to have its stomach pumped.

Bottles had no safety caps in the 1950's and the only products with enforceable warnings were the acids and alkalis covered by the Caustic Poison Act. The Federal Food and Drug Act had no specific provision for warnings against misuse of drugs. My newspaper clipping survey helped to show the extent of the problem and persuade Commissioner Larrick to "stretch the law," as he put it, to get voluntary compliance in the way of label warnings.

The principal cause of the accidental poisonings and deaths was aspirin left by careless parents where young children could get it. People thought aspirin was the safest drug and paid no attention to where they left it. Well aware of this, the aspirin manufacturers nevertheless objected to putting a warning on their product when virtually no drugs could be considered safe when used improperly. They didn't want to be singled out. Because of the industry's concern for its public relations I was asked to be the FDA's representative in a discussion with the PR firm of Baldwin and Mermey, who represented Bayer. They would go along with FDA, said Mr. Mike Mermey, if we would ask for a warning to "Keep this, and all

drugs, out of the reach of children." I took this message back to Commissioner Larrick and it was agreed to. This was the beginning of the most widely used label warning on drugs and other products.

Commissioner Larrick's doubts concerning the legal authority were resolved in 1967. Requirements for the warnings had been included in amendments to the Food, Drug, and Cosmetic Act and the Hazardous Substances Labeling Act but the House Commitee on Interstate and Foreign Commerce rejected these proposals after hearings, and advised FDA to deal with the matter via its "voluntary conference approach," presumably its rule-making process. Commissioner James B. Goddard then convened a high level scientific advisory committee which recommended regulations as to dosage and labeling of children's aspirin and other salicylate drugs. As issued, the regulations included a mandatory warning on aspirin and a recommended warning on all drugs, to "keep out of the reach of children." (FR March 2, 1967, p. 3340-1 and 21CFR 369.9 and 369.20). To give an idea of the seriousness of this problem, Dr. Goddard told the House Committee at the 1966 hearing that there had been over 16,000 reports of accidental aspirin ingestions in 1965, to the Poison Control Centers, the majority involving baby aspirin. There has been a remarkable change for the better.

JHY: Going on with the warning on aspirin - just by regulation the FDA announced finally what it...

WFJ: That's right. We did not think at the time that Sec. 502(f) authorized that kind of warning, but Commissioner Larrick was ready to "stretch the law," as he put it. But it was obviously needed, and the industry agreed it was needed. But later on Larrick stretched the law again, and that led finally to the action by Dr. Goddard. This came about because of something called "cracker-balls". The Hazardous Substances Labeling Act did not cover articles that had no labeling. There were a number of those that came along.

Well, there were stuffed ducks that had pathogenic organisms in the stuffing. Easter ducks, you know. Then there were the jequirity beans, highly toxic beans from the West Indies that were used in jewelry, not labeled. Above all there were these "cracker-balls," little Fourth of July fireworks torpedoes that looked exactly like candy.

FLL: Jawbreakers?

WFJ: Kids would put them in their mouth and get their teeth blown out. So Larrick, again, decided to stretch the law and seize the "cracker-balls", and that is how we got into the fireworks business.

So we started to make the Hazardous Substances Labeling Act apply to unlabeled articles and then Congress followed up by amending the law so that it would apply to the unlabeled articles. We stopped "cracker-balls" that way. We also... well, it wasn't a labeling matter but we stopped X-33 the

highly flammable waterproofing compound. It was flammable at 40 degrees below zero. It could hardly be used at all by the average consumer without the serious risk of an explosion. The FDA seized it all over the country and went to great expense to stop the sale of it. That story, too, is told in the article I mentioned. Actually, it was FDA's creative enforcement, illustrated by these cases, which produced the effective law and program that was finally transferred to the Consumer Product Safety Commission in 1973.

There are many press releases that deal with the various aspects of this. So, now perhaps we are getting into the press release side of the story.

JHY: This was preventive action by publicity? A major objective that you worked on in the agency?

WFJ: I believed that information from the FDA, public information, ought to ~~be an aid to~~ support the objectives of the statute. We approached it from that standpoint. We should do whatever we could through communications in order to accomplish the objectives of the statutes to protect the consumer. If this detoured the law-enforcement process, why, what if? On the other hand there were times when the law enforcement process was necessary to back up the information process. In the quackery area, for example, you can not very well educate people against quackery without court cases, both to enforce

the law and illustrate what you are talking about.

FLL: In some of the instances you've cited, we couldn't do anything by application of the law; it was purely a matter of publicizing the hazard because our statutes at that particular time did not apply.

WFJ: That is right. And then Congress changed the law.

Which makes me think of something else. Before I get into the press release side of the story, let me talk about another experience that I had that was very gratifying. I wanted to have FDA do something in the way of visual communications, the use of pictures, films etc. We had had a very fine, effective illustration of this in the movie "Fraud Fighters" made in 1947, by RKO Pathe. The initiative for that did not come from Food and Drug, it came from outside. RKO had a newsreel series called "This is America." Many of the episodes were about the activities of different government agencies. So, what they did was to send their newsreel crew into the FDA and they went around shooting footage of the FDA people doing their jobs. Then they wrote a script to fit the pictures, put it together and they had a "March of Time" style documentary that was shown in movie theatres all over the country. Well, the FDA bought prints; every District had a print, and it was used innumerable times in presentations to women's clubs, schools, etc. This went on for many years. It went on even after it became outdated, because it was such a damn good movie.

When I arrived, FDA had nothing else, we had no film strips, no slide show or anything like that. It was not a new idea, of course. I have a slide show that was put together about 1910, on those big glass plate slides and it told about the activities of the Bureau of Chemistry, circa 1910. It even told about Wiley's Poison Squad. But by 1951 there was beginning to be a great interest in color photography, and the FDA inspectors had been issued cameras and were making pictures to document their investigations. It occurred to me that one way to get a good film strip, or slide show, on the FDA's work would be to have a photography contest in the field and get the field people to send in good color shots made during inspections. We got the cooperation of Mr. Rayfield and the unit that we now call EDRO, the field administration organization. They developed a set of assignments to the districts; for example, New York District was asked to submit color slides of import inspection activities. Chicago was asked for food packing, Detroit was asked for drug manufacturing, California for fruit inspection work. Soon we had between 200-300 slides sent in by the Districts. We sorted them out and picked 50 or 60 of the best ones. Based on the instructions, they showed the part of an inspection where the payoff was - the inspector looking at the product at the time when he might see a violation. We called it "The Law Behind the Label." All the Districts got copies for showing to

schools, consumer groups, luncheon clubs and so on.

JHY: Do you think some of those would be good for illustrations, ultimately from the point of view of the way inspections were handled at that time? Are they valuable pictures?

WFH: They were...for the 1950's they were like the pictures that were made between 1910 and 1920 by A. J. Olmstead, the photographer for the Department of Agriculture - the ones that showed John Earnshaw going around; down in the lobby in this building there are over 50 of them showing Inspector Earnshaw.

JHY: Where are the negatives for those? In your files?

WFJ: I have an album of contact prints made from copies of those negatives. So anytime anybody wants a print I can readily order one.

Now, we sent copies of the slides out to the Districts. By that time we had Consumer Consultants in each District. That was another program that I set up. They worked two days a month, for $20.00 a day and every one of them did a week or two weeks of work a month for free. A wonderful group of women.

Then, about that time the FDA lost a very important case. The Cardiff case. A good article could be written about that. Ira Cardiff refused to let the FDA inspectors into his apple products plant and the FDA prosecuted him. It went to the Supreme Court and the court ruled that the factory inspection provision was unconstitutional because it was too vague and

contradictory to stand as criminal law. On the one hand it was a criminal violation to refuse inspection and on the other hand it required the FDA to get permission to inspect. President Eisenhower, who had just been elected, immediately called on Congress to repair this dangerous breach in the law. There was a great deal of press interest in the matter, and of course we prepared a lot of material for news stories and editorials. We could do this because we had Administration support.

One of the writers who contacted us was Ben Merson, a staff writer for FDA's old friend - Collier's Magazine. Merson wanted to do a feature story about the FDA and what its inspectors did for the public. Articles like this were very popular at that time. Journalism was not yet infected with the idea that the only newsworthy stories on government were those exposing some kind of failure or wrong-doing.

There was, of course, investigational reporting. Investigational reporting never died from the time of the muckrakers. But equally popular was the type of article that told about the valuable work done by the Postal Service, or the Food and Drug, or the Secret Service or whatever. Mr. Merson wanted to do an article about the FDA which he felt was too little known to the public. So, he came down to Washington and we gave him a lot of material.

Well, for some reason which I've forgotten, I had to make

a trip to New York City and while there - the afternoon I was leaving in fact - it occurred to me to drop around at Colliers and see how Mr. Merson was getting on with his article, or how they were getting along with the article. I did, and found it was already in galley proof. They showed it to me, and I found a good many errors of fact which I was able to correct right there in the office. When I explained these corrections they were very grateful that I had dropped in and were glad to make the changes. Then I said, "We have a series of color transparencies showing the activities of the FDA inspectors," and offered to send our slides from The Law Behind the Label. They were delighted to have pictures that were exactly right for the article.

Well, I didn't hear anything more until the day when the House debated the Factory Inspection Amendment. I was in the gallery of the House when the debate opened. I was amazed to see 4-5 members of Congress on the floor all wanting to be recognized, and waving copies of Colliers, with an article that told about the FDA's inspection program and giving examples of the value of factory inspection.

JHY: Complete with colored pictues?

WFJ: WITH the colored pictures. Now, you can't imagine how fortuitous this was. If nothing else had ever happened I would have been satisfied to be with Food and Drug just on account of that.

Someone at Colliers had taken the trouble to send advance copies to the members of the House Committee on Interstate and Foreign Commerce, which was handling the bill. Congresswoman Leonore Sullivan of St. Louis had been recognized and was the first to quote Merson's article. Later Congressman Heselton of Massachusetts said this:

> I would like also to read further from the excellent and timely aticle to which the chairman of the committee referred and from which the gentlewoman from Missouri (Mrs. Sullivan) read the first portion. This entire article should be a portion of the record of the debate of this afternoon, and under permission I obtained in the House, it will be included at the conclusion of my remarks. The author of the article, Mr. Ben Merson and Collier's which published it in its July 18 issue are to be congratulated for their fine contribution to the solution of this vitally important problem.
>
> I want to emphasize to you the absolute necessity, as is indicated by the author of the article, of these inspections. They constitute, in fact, the largest portion of the enforcement of this agency.

Mrs. Sullivan, by the way, was a very special friend of the FDA. This had come about through personal friendship with Loretta Johnson, the FDA's consumer consultant at St. Louis. But that's another story.

The factory inspection law, as finally enacted, was something of a disappointment to FDA and I will have more to say about that when we are discussing press releases. (The House debate appears in the Congressional Record of July 15, 1953. Full text of the Merson article is on pages 8919 to 8921.

JHY: You earlier mentioned about the relationship of the campaigns that you've been talking about to the quackery campaign, inasmuch as these were educational campaigns aimed at warning the public about a certain danger that had been discovered to be real by the activities of the inspectors. So, cases were being brought under the law, but you deemed this to be a kind of theme, like some of the others, needed to have an expanded impact upon the public consciousness. Would you talk a little bit about that and how you came to organize the groups that were interested, for the public welfare, in opposing quackery and how you went on to the quackery congress concept, etc.

WFJ: Yes, I think I've already said something about how quackery was one of the areas that needed education and publicity. The FDA was winning lots of cases but we weren't exploiting them, I thought; we weren't using them for public education purposes.

Most of all I was disturbed by what we were hearing in the Commissioner's staff meetings about our difficulties dealing with Harry M. Hoxsey. William W. Goodrich, our Chief Counsel, was reporting developments in the Hoxsey case, and how we had lost in the District Court before Judge Atwell in Dallas, because Atwell was really a friend of Hoxsey, and believed in the treatment even though his wife had died of cancer after receiving it. And even though we finally got the

Court of Appeals to order Judge Atwell to issue an injunction we couldn't expect him to enforce it. The prospect that the litigation would have to go on for years without a decision in favor of the government and the consumer was very distressing. We knew that Hoxsey had about 10,000 people under treatment at that time, people who had come to the clinic and were still getting the medicine, and I personally felt that we ought at least to officially warn the public that a worthless medicine was at large and that it was dangerous because it was worthless. I had the idea at that time that we ought to have something like the FBI's 10 Wanted Criminals list, with one on Hoxsey to alert the public that a criminal drug was at large on the market and that we were not able immediately to stop its distribution. So, I proposed that an official, formal, public warning be issued. It was the first time such a warning had been proposed. The Commissioner, by that time George Larrick, was favorable. But, of course, we knew this would have to have the approval of the Department because of the language of the statute. Section 705 provided for this kind of warning, but the Secretary had not delegated any authority under this Section. At that time the Department was very active in clearance operations. A man named Harvey Bush was the information chief of the department and he was a very professional, capable information officer. Everything that we put out had to go through his office and be approved. So, we

couldn't do it on our own, we had to have the Department's blessing. So, I prepared, with the help of Gilbert Goldhammer and Ken Milstead and Bill Goodrich (I think Goldhammer had as much to do with it as anybody) anyway we prepared a formal public warning and I prepared a justification statement to go with it. We presented that through Larrick to the Secretary's office. Oveta Culp Hobby was the first Secretary of HEW. She had been the commander of the WACS under Eisenhower and had a military style of management. She would not act on anything unless it had been "staffed out." That meant it had to have the initials of her principal subordinates, such as the General Counsel of the Department and the Surgeon General and so on. Our proposed public warning went first to Park Banta, a lame-duck Congressman from Missouri who was the General Counsel. Mr. Banta wrote a memorandum that said, in effect, "this is unquestionably legal but I doubt whether it will work." He thought it would just produce more publicity for Hoxsey and not stop people from going to the Clinic.

Then the memorandum went to Dr. Leonard Sheele, who was the Surgeon General and Dr. Sheele concurred with Mr. Banta. He signed a memorandum which reflected what was then very much the attitude of the Public Health Service about quackery. The general view of the PHS then, and I am not sure but what it still is, was that the best approach to quackery was to ignore it - that you couldn't do anything to help people who were

such fools as to fall for it. In any case it would only advertise and result in more people going to the quacks.

When Larrick got this memorandum back from the Department it looked like my proposal was a dead duck. I remember very well the staff meeting where this was discussed and I told the Commissioner that I thought he ought go to Mrs. Hobby himself and explain it to her and get her concurrence. But he didn't want to do this because of her known ways of doing things. He said a good way to get yourself fired was to go contrary to topside policy. I said I thought that he had a moral obligation, nevertheless. I said that if you were standing on a corner and about to see somebody get run over by a truck, wouldn't you at least shout at them? And Robert Roe said, "'at-a-boy, Wally." Well, we had waited so long, almost two years, for this to come out of the Department.

In a rather short time, however, Mrs. Hobby was replaced by Marion Folsom, the second secretary of the Department. Folsom delegated a lot of his statutory authorities to the different constituent agencies, including FDA and including the authority to issue warnings under Section 705. As soon as that happened, Larrick called me on the phone and said that he would sign out the public warning, which he did. We had it printed like a press release, several pages long, but in extra large type with a heading that said,

PUBLIC WARNING AGAINST HOXSEY CANCER TREATMENT

I can get you a copy of that from the file, too. It was issued April 4, 1956.

We made special arrangements with the Associated Press about this. You see, the AP would be the source of the story reaching most of the newspapers in the country. They have a policy that something of this kind is never put on the wire without first checking with the other side to see what they have to say. Get both sides. That's the standard policy. We knew that if this story were to reach the AP's New York desk, just cold, that they would call Hoxsey right away and we'd get a lot of anti-FDA static out of Hoxsey that would likely turn the story into an argument between FDA and Hoxsey, and lose the impact of the warning.

The AP correspondent in Washington was W. Joynes McFarlane. He was very familiar with the Food and Drug's activities and he went along with this. He talked to the Washington office and they called the New York office and it was decided that they would go with the government's story first before any inquiry was made to Hoxsey. Well, somehow and nevertheless, there was time enough for Hoxsey to get his say in along with our say in most of the papers.

Nevertheless the warning worked. Hoxsey's business took a dive to practically nothing. We knew this because we had the parking lot at the Dallas clinic under surveillance every day and the count of automobiles went to practically zero

after the warning came out. It showed that, at that time at least, the public did pay attention to what the government had to say.

JHY: Beside the broad public warning released through the Associated Press, didn't you pay particular attention to certain categories of magazines?

WFJ: That came later. We had a campaign later on after the warning came out. Now, by the time the warning came out we had litigated two cases in the federal courts. There were three altogether. There was the Pennsylvania case...

JHY: There was also the suit Hoxsey brought against...

WFJ: Well, we had gotten the Court of Appeals decision from New Orleans. What circuit is that?

JHY: The sixth it was.

WFJ: The sixth or seventh? The sixth circuit, I guess it was, in New Orleans had reversed Atwell's decision with a stinging rebuke. They told Atwell in effect... I can almost quote the language, "that a federal judge shouldn't be so deaf, dumb and blind as to ignore the plain evidence that was set before him" and commanded him to issue the injunction. We had asked for a writ of mandamus and they didn't give us that, but we couldn't enforce the injunction because we would have to go to Atwell for enforcement. So, that was all the more reason for the warning.

One of the Dallas' correspondents said this was the big-

gest story since the Korean war. It was big in Dallas, really big.

Then Hoxsey began an effort to rebuild the business. This is where our educational campaign began. Hoxsey hired the editor of the Defender Magazine, Gerald K. Winrod, as his public relations advisor. Winrod was a "hell-and-damnation" preacher who had been a member of the Silver Shirts and the Knights of the White Camelia, both of which were pro-Nazi organizations that were involved in the sedition trials during World War II. Hoxsey paid Winrod to publicize the treatment in his Defender magazine which circulated in the bible belt. He also paid the editor of a sort of forerunner of Playboy called Man's Magazine. It didn't have pretty girl pictures like Playboy; it was a pulp rag,not a slick paper job. Yet it had a lot of news stand circulation. He paid that editor, according to court testimony, $87,000 to publicize the Hoxsey treatment with articles that strongly suggested that it might be very good for some cancer patients - the pro and con type of article that gives a great big ray of hope to a cancer victim.

Well, we had to offset the effectiveness of those articles in Man's Magazine and Defender, and they were effective - the people began to come back to Dallas and the business increased again up to practically the level that it was before. You see, new people keep getting cancer all the time and you

have to keep up with anti-quack education in order to warn and protect them. So, we prepared some new releases about the Hoxsey treatment, renewing the public warning. Some of them were prepared in mat form so that they could go to country weeklys and be put right into type...

JHY: Religious papers?

WFJ: Right, religious papers, lodge papers and farm papers. That got a lot of publicity that seemed to be effective.

One of these religious papers was the Review and Herald, I think it is called, published by the Seventh Day Adventist headquarters here at Tacoma Park, Maryland. Soon I heard from the editor of the Review and Herald that his readers were objecting to the publicity against the Hoxsey treatment. They were supporters of Hoxsey and they felt that Hoxsey wasn't getting a fair shake. Reverend Nichol, the editor, wanted to know what he could do. We gave him some information and on his own Reverend Nichol went on the road for two months doing a personal investigation. He went to Dallas, visited the clinic and then wrote a long article that totally supported the FDA. He told his readers that they were wrong.

JHY: Was this the same campaign that included the posters in the Post Offices?

WFJ: No, I think that came later. We decided that another thing we could do would be to revive the original public warning by putting it out in the form of a poster that could be

put up in the U.S. Post Offices. So when we did that, we not only got the poster in the post offices, but also a lot of newspaper press about the poster. So that helped too.

JHY: Was this the first time that the public warning provision of the law had been used?

WFJ: Yes. Yes, that was the first... Well, there had been, of course, many instances where there had been a need to warn the public, but this time we actually invoked the statute and made it a formal presentation.

FLL: Most of the others, I think, were press releases to the newspapers or occasionally where we pushed a company into a recall situtation.

WFJ: I don't know that we had ever labeled one a "public warning."

FLL: No, I don't believe so. I recall, for instance, when Fletcher's Castoria was recalled, they took large display ads in newspapers to warn people about that.

WFJ: They did do that and I remember writing an editorial about it in The Glass Packer and then, I think, I wrote another one later on about another instance where a drug firm had dealt forthrightly with a recall problem. What I said was that if they had spent a million dollars for advertising, they would not have gotten as much confidence from the public as they did through making lemonade out of this lemon.

FLL: I think that was true. The Fletcher campaign was the

best, I think, we'd ever seen.

WFJ: Yes, that's right. They came right back with a...

FLL: With a revised formula... I think the problem was they had revised the formula that caused the reaction and they went back to the old formula and came out with publicity on that and I don't think they missed a beat from their sales.

JHY: This was roughly when?

FLL: About 1944 or '45, '44 I think. It was still during the war and it was a problem, I think, of sugar content in the preparation.

WFJ: I seem to recall there was some kind of a bacterial...

FLL: Yes, but I think it was the change in formula that triggered the problem. The change was because something was not available during the war.

WFJ: The traditional advertising was something along the line that "babies cry for it." The sub-theme of that was that mothers had confidence in it and, of course, I think they proved that the confidence was not misplaced. Proved to the public...

JHY: This Hoxsey affair, how is it related in time to the broader effort at public education and connection with quackery away from an individual campaign to the more magnified campaign that included the quackery congresses?

WFJ: Well, from that I could go in...maybe should go in two directions. I ought to go back a little bit, as well as forward.

Going back, first, very briefly, when Mrs. Hobby was secretary we also had a campaign on grain sanitation. In this instance the FDA did, I think, what it ought to have done more often - it planned a total strategy. Larrick or maybe it was Crawford, knew that we had a bear by the tail and here were all these farmers and grain elevators, etc. and they were allowing food grain to be defiled by rats and insects. We proposed to enforce a tolerance and there was great opposition because of the great quantity, the economic consequences, etc. The Senate Agriculture Committee had a hearing and Mrs. Hobby ordered a moratorium on enforcement. It lasted 17 months. Then when she left ~~we~~ she took the lid off and let it go again.

Larry Trawick, who later became my Deputy, did most of the preparatory work for that program. He prepared a brochure for the grain industry. We also wrote articles for the farm papers, particularly in those regions where there was a lot of grain production. There is something about that in the talk that I made to the District Directors in 1952. We got lots of publicity and in a way we learned about the possibilities for reaching the rural press etc. So, what we did in the Hoxsey case was something like what we had done in the grain...

JHY: Right.

WFJ: Only we had a totally different objective.

JHY: From the point of view of the sources and the media that you had employed, you'd gotten experience.

WFJ: Yes, right.

Now I am going in the other direction. Tell me again what...

JHY: Well, the broader quackery campaign and the alliances with other groups outside FDA and the quackery congresses.

WFJ: You are reminding me of something that I haven't thought about for a long time. I am going to have to scratch my head and see if I can recall exactly what happened.

Mr. Hoxsey fought us to the last ditch. Well, there were two things he did. One was to have the Reverend Winrod proclaim a "crusade of prayer" against the FDA to make us back down on the Hoxsey treatment. This was a postcard barrage to members of Congress. The members got thousands of these postcards putting the pressure on us but they didn't pay any attention to it. At that time the U.S. Congress was considerably more sophisticated than, I think, it was during the Laetrile affair. Most of them ignored this mail. Later, Hoxsey sued in the U.S. District Court to stop FDA from issuing publicity against his treatment, which he said was destroying his business. The Court ruled we had not only the right, but also the duty, to warn the public against such treatments.

The AMA was concerned; they didn't want to see the FDA get hurt by having our appropriation cut or anything else, as a result of this Hoxsey thing. So, their Washington representative, the head of the AMA's Washington office, conferred

with me. I forget who all was at the meeting, but we did have a conference. The upshot of the meeting was a decision that it would be a very good thing if we could get together with all the people who were against quackery and in favor of rational theraputics. We ought to get together and discuss our mutual interests and we did. Out of that grew the, I think, ... well, various people claim credit for this. I think that I was the first one, but also there was Ken Milstead and also Oliver Field, our ex-inspector, who was then the head of the AMA's Division of Investigation.

JHY: You mean you all three, sort of believe...

WFJ: We all thought along similar lines and we decided that we should have a national educational conference on medical quackery. It was held here in Washington in October, 1961. It was a very impressive meeting with excellent speakers and very well put on and the AMA spent a lot of money doing it. FDA's contribution was in planning the program and providing the exhibits and publicity materials. A printed proceedings was published by the AMA, with all the speeches in full text.

Then we had our Second Congress on Quackery in 1963 with emphasis on educational methods. At that time the National Health Federation decided to fight back. Sensing the well known tendency of the press to publicize controversies, they got themselves some "equal time" in a lot of papers. So, we

saw the beginnings of a "quackery backlash," organized quackery fighting back against the Government.

FLL: They set up a public meeting of their own at the same time...

WFJ: Down the street.

FLL: At the same time that the Congress was meeting.

WFJ: After that we ceased to be a formal sponsor of the meetings, particularly because the AMA wanted to deal with chiropractic and we couldn't see our way clear officially to attack chiropractic. Although we thought it was quackery, it was legal in 46 out of the 48 states at that time. We could not see our being publically involved against a licensed health profession, particularly since we didn't have any statuatory authority to regulate the practice of the healing arts.

JHY: Drugs and devices were are not necessarily involved.

WFJ: Yes. Later on however - this is interesting - later on when we won the Microdynameter case we negotiated with the chiropractors to recall about 1,500 Microdynameters. I got well acquainted with the chiropractic people here at Washington and they invited me to address one of their conventions and I made a speech to the chiropractors. I told them about devices and explained the law to them. I didn't get invited back and I don't know that anybody else from FDA ever did, ~~either~~. (The speech is included with the other papers with this transcript.)

FLL: There was a third quackery conference?

WFJ: Oh, yes. There were four or five of them.

JHY: There were four.

FLL: We were not a party to...

WFJ: We were not officially a party. Dr. Goddard made a speech at the third one. In that speech, this is pertinent, Dr. Goddard as much as said that unproven drugs used by doctors can be quackery too. I think he meant that if a doctor prescribes a drug without informing himself about it, he is acting as a...one of the definitions of quackery is a person who pretends to have medical skill.

JHY: I think he also criticized inadequate work by scientists in the IND and NDA process.

WFJ: Yes. Well...

JHY: You call that quackery.

WFJ: In that, he echoed Larrick. It was in a speech that I remember writing for Larrick, that dealt with "rigged research." Rigged research is certainly quackery.

JHY: I think that Goddard was moving toward a more rigorous reformist perspective and had made up his mind that there were more serious dangers in what he demoninated this form of quackery, than in the common ordinary garden variety of quackery that the conferences had mostly been limited to.

WFJ: The FDA was then making a very distinct change of direction. It ceased to emphasize the problem of criminal activity

by fringe practioners and began to concentrate on making sure that legitimate medicine, or medicines presuming to be legitimate, were effective. Of course, we had at that time the job of implementing the effectiveness provision of the 1962 Drug Amendments which made FDA responsible for compelling the drug manufacturers to authenticate their claims by research before they put the products on the market.

FLL: What was the impetus for that shift away from false and misleading claims and to the quality of pharmaceuticals? Did that come from within FDA or did that come from outside?

WFJ: It came from the thalidomide experience and it came from a lot of other things, Mer 29, for example. It came from a lot of different things. The Kefauver hearings had given us a peek into what was going on. The FDA began to realize it had a very big, much bigger job to do. I think there had been for years a disinclination of the agency to fully exploit its administrative powers to regulate the drug industry. It was the Kefauver hearings that showed the need - although we...for example we had already put out the full disclosure regulations requiring an official brochure with every prescription drug. We had issued those regulations before the Kefauver Amendments were passed. We had reversed the policy which prohibited indications and directions on RX drugs in favor of the full disclosure regulations which required a brochure, a package insert with every prescription drug. The drugs had changed, and

the regulation of drugs had to change.

FLL: Did the Department's interest in the cost of drugs, triggered by their support, their financial support through states and other people in purchase of drugs and emphasis on generics, did that exert any pressure on us that you are aware of?

WFJ: I think that came later. Of course, Kefauver emphasized the cost of drugs and there are provisions in the 1962 Amendments as to labeling with the generic names etc. that flowed from the economic problem. A good deal more happened after that as a result of the huge medical expenses that had to be funded by government. This is an area that requires documentation.

JHY: In connection with this shift from more or less traditional quackery to a much more rigorous appraisal of prescription drugs, following upon the revelations of the Kefauver hearings, there have been suggestions in interviews that we have had - maybe they are guesses more than suggestions - that when Mr. Larrick retired and Dr. Goddard was chosen by this special committee to be the new Commissioner, the first one from outside the agency, that he came not only with his own ideas about what should be done but that he came with directions from the Department, possibly from the committee that selected him,as to a different kind of course for the agency than it had been following. Do you hold with that theory,

that he was carrying out not only his own ideas but some sort of obligation that he assumed, some directions that he had been given when he was chosen?

WFJ: I never heard anything that showed he had that kind of an assignment. My impression is that he had a reputation of being a mover and a shaker, and the top management wanted the Food and Drug Administration shaken up, so they appointed Jim Goddard to do it.

The late Stewart Hunter, who was Director of Information for the Public Health Service, told me that Goddard was a "whirling dervish" - and what did he do at the CDC? Why, he "pulled the tree up by the roots and replanted it and watered it." That was what we could expect at the FDA. He was brought in to shake things up.

Now, Ted Cron wrote most of his speeches and they did have a philosophy, expressed particularly in his earlier speeches, about how there were better ways of doing things than by going to court, and I think in that area he was reflecting very much the general viewpoint of the Public Health Service. George Larrick was aware that the Public Health Service had an altogether different approach to "regulation" than FDA. Although I suppose they wouldn't have called it "regulation." I was aware of this. I knew that when I was with The Pink Sheet, and I had to interview the director of the biologics office and the Director of the National Insti-

tutes of Health, about why they licensed a vaccine for the common cold. I became aware at that time of what I thought was a peculiar attitude about regulation. I can sum it up this way, that once a firm got a license they belonged to "the club" and any problems had to be settled inside, in private rather than in public. It wasn't good to settle things in public. All the people who belonged to the club were good people and they would do the right thing if and when any problems arose. In other words in theory all of them were ethical professionals. Of course, the FDA wasn't that naive. We were policemen, and every now and then a speech by some PHS officer would decry the police approach and be critical of the FDA's way of doing things. They seemed to be unconscious of the fact that terrible problems had arisen and that Congress had enacted legislation to deal with such things and that we had the mission to enforce that legislation.

Now the Second Citizen's Advisory Committee is also pertinent in this regard. The dominant figure on that committee was Dr. George Y. Harvey. He was from the University of Missouri where he had been Lecturer in Political Science and Consultant in Community Development. Previously he had been staff director of the House Appropriations Committee of Congress, from 1948-1955.

Twice in the study report Dr. Harvey quoted with approval the theory of an unnamed "prominent health regulatory offi-

cial" that agencies such as FDA go through three stages --

"The period of police power enforcement.

"The period of health education.

"The period of mandated self-inspection and self-regulation."

Then he said: "FDA has been in the first stage so far. It should proceed to the second and third stages as rapidly as the necessary changes in administrative philosophy can be achieved and a proper climate created within industry."

We in FDA thought Dr. Harvey had gone overboard in adopting this highly theoretical interpretation of enforcement history. Granted there were such trends, practical experience showed he was carrying them to extremes.

Going back to Dr. Goddard, if he had any directive when he came to FDA four years later it might have been to go along and carry out the recommendations of the Second Citizen's Advisory Committee report.* As a matter of fact, the FDA under Larrick had made formal efforts to apply those CAC recommendations, both from the first committee and the second committee. As a result of my recommendations to the first committee they established the Division of Public Information, which I headed, which continued operations until 1964 when the Bureau of Education and Voluntary Compliance (BEVC) was set up as I had recommended to the second committee staff. There was a good reason for that recommendation. I had found that under

* A guess confirmed to some extent by Dr. Goddard's oral history transcript pp. 198-199, which became public in 1985.

Division status I could not offer the salary grades I needed to hire skilled professionals to develop educational program materials. And I did not believe that outside contracting was the way to do this. But for some reason I did not get the job of Bureau Director. Actually the report was critical of FDA for not doing more in the educational area, when we had really done a great deal considering our resources. So the new "BEVC" was headed by Shelby Grey, a former District chief, as the interim director; then by General Fred Delmore, a retired commander of the Army's Edgewood Arsenal, who had once been an FDA inspector. It was staffed largely by FDA people from other Bureaus. And I continued to be FDA's Director of Public Information, reporting to Commissioner Larrick and representing FDA on the Department's information committee.

The second CAC report had stressed the idea that there were better ways to promote industry cooperation and compliance than by court proceedings, and Dr. Goddard echoed that in the speech that I mentioned to the Pharmaceutical Manufacturers Association.

FLL: He made that statement, also, frequently at meetings of the Field Managers that we had here.

WJF: Now we can readily find his speeches... The Center for Drugs Library has a rather complete set of the speeches of the Commissioners beginning with Larrick. The Larrick collection is in separate volumes, year by year, and the first one has a

foreword I wrote which includes his biography.

JHY: That is one thing that we do hope to have in this tape, an appraisal, on your part, of the Commissioners and some of the high level peers of yours, while you were there. It can go together with other similar descriptions and appraisals that we have to provide rounded portraits. You had many ways to be close to George Larrick and be his counselor. Can you sum up what kind of a man he was, what kind of an administrator, his strengths, his weaknesses, his manner of doing business. An incident or two that may be vivid that is revealing of him as Commissioner?

WFJ: Well, I hesitate to do this because I think it would tend to be inadequate. I would say that the best biographical paper would be the article in the Dictionary of American Biography, which I wrote at the request of Mrs. Alice Larrick. Then there would be the eulogy at his funeral and the citation at the 1968 annual meeting by the Association of Food and Drug Officials. We have these in the files of the FDA Commissioners in the Historian's office.

I can only say that from my standpoint everything that was said of him was true. He was a very considerate person. He really knew the business. He trained others, but unfortunately he was not able to train or designate a successor groomed to take over, and established well enough to command support from the department and the administration and the Congress.

Larrick himself was very well entrenched in the Congress even though in his later years he had a very rough time with Senator Humphrey. Humphrey was already campaigning to be President, and his staff undoubtedly had that in mind. The oversight hearings that he held were really very unfair to Larrick and uninformed as to what was really going on and the progress that the agency was making.* Also, this was a time in our national life when it began to be politically profitable to criticize the government. So, there was a combination of circumstances that militated against continuing the line of succession.

Now, you mentioned other people...

JHY: Let me reassert. You may not want to make that appraisal feeling that you have done it elsewhere.

How about anecdotes, incidents that are revealing. Can you think of any, besides the ones that you've given so far, in which you were face-to-face with him involved in a situation? Where he said something, or took some action that is especially revealing. Stories sometimes...

- A few months ago (in 1984) I asked Mrs. Alice Larrick about his reaction to Humphrey's treatment of him, in view of the fact that they had been good friends in the past. Particularly George was hurt by Humphrey's statements to the effect that FDA should be headed by a distinguished scientist and that an ex-inspector was not qualified for the job. Larrick had 'phoned the Senator about that, she said, and found him very apologetic. He told Larrick that he had read only the first page of the statement prepared for him by the staff. A little subsequent research shows that Humphrey later sought to make amends and to correct the record. This appears in Food Chemical News for June 1, 1964, in a report titled "Humphrey-FDA Amity Restored."

WFJ: I don't recall any... At this moment I don't recall anything that had the broader significance, for example, of his decision to stretch the law to get a warning on drugs against the accidental poisoning of children, or to deal with the cracker ball thing. There were lots of things like that, I am sure, that I don't know about. They were rather characteristic of him. If he thought there was something to be gained for the public by taking a chance, he would do it or he would try to figure out some way of accomplishing the same thing.

Now, my dealings with him many times were in regard to speeches. I wrote a great many speeches for him and he liked them. I sensed what he wanted to say himself, and he made few changes. So we had a very satisfactory relationship.* I think he accepted the fact that a lot of people knew that I had written his speeches, but he often added things or suggested something to me and I developed it.

We were able to use the speeches to put on record a lot of factual information about the Food and Drug Administration. Now, I think, the more recent Commissioners have had speech writers who have looked on a speech more as a command performance; something that had to be entertaining, if possible, so he didn't have to say much.

* Mrs. Larrick told me, in the visit previously mentioned, that George would bring home the speech drafts and have her read them aloud so he could hear how they would sound to the audience. She said he was very grateful for my speech writing.

JHY: One of the things that we keep hearing in the interviews, or reading in the interviews, relating to George Larrick is his rapport with so many people.

WFJ: Yes. His funeral eulogy tells about that.

JHY: His knowledge of such a wide band of people within the agency. Knowing their names, knowing what they did and likewise in the regulated industries knowing so many people. This sense of humanity, man-to-man relationship. Anything about that?

WFJ: Right. Well, he was that way with members of Congress and he was that way with the press. Just a couple of weeks ago I heard from Alice Larrick that she had some more things of George's that she wanted me to have. So, Agnes and I went over there one Sunday and took Alice out for dinner and she gave me a couple of things.

One was an envelope full of cartoons, some not very good ones, done by minor cartoonists, but quite a few of them, little sketches that they had done for him, or that he had asked them for. He got lots of mail when he retired.

I was personally acquainted with him years before I came with FDA. We used to go fishing and crabbing at their place at Dahlgren. He and Crawford and Dunbar all were involved in my being appointed, though it was Dunbar who actually recruited me.

JHY: Do you want to take Dr. Dunbar and Mr. Crawford and

think the thrust of my question, my broad question and make comments about them as people?

WFJ: Well, I will try to do the same kind of thing as I did with Larrick.

On Crawford, I wanted to get him an honorary degree; he certainly deserved one. So I communicated with the Oklahoma A&M College and found that they do not give honorary degrees. But they had another idea to offer, and that was an article about him in their alumni magazine. So I got in touch with people, classmates, who had known him in college. Their letters and my information were combined into a profile article about Crawford. I would like to suggest this little biographical tribute to Crawford, as both a portrayal of his character, and his contributions. He was another man of remarkable integrity, ability in writing, and ability in tactics and strategy with people. I think that someday before I finally retire I should write a piece about Crawford for the FDC Law Journal, for example. There should be something about Crawford put on record to tell more about him.

His early life was really very interesting. He lost his mother when he was still a child. She was being operated on on the kitchen table, on a farm where he was a boy. I have forgotten now whether she died in childbirth or whether it was something else, but she had to have an operation under very primitive frontier conditions. He said that he had never

been able to endure the smell of ether since that time. That was one of the episodes. Crawford was a quiet man, with a great sense of truth and fairness. He didn't like what he called "foofaraw," so, like Walter Campbell, he kept his retirement a secret so there would not be any fuss over it.

Then I would like to say something about Dr. Dunbar, just one little thing. Dr. Dunbar has left quite a trail behind him in the things that he wrote. His "Memories of Early Days with the Bureau of Chemistry and the Food and Drug Administration" is a priceless record of how things were in this institution of the government, beginning when he was hired by Dr. Wiley in 1907.

FLL: Was that the article in the Food and Drug Journal?

WFJ: Yes, I reprinted that for the 75th anniversary.

I will just say one more thing, when Dr. Dunbar retired he did not allow them to give him a farewell party. He gave a farewell party, a garden party at his home in Summerset, Maryland for the entire staff. It was a lovely affair. There is also a biography on him that I did for the Dictionary of American Biography.

JHY: You were about to move on to your peers when I asked you about Crawford. I think you were. Wasn't that right?

WFJ: I don't know. I thought you asked me about the different Commissioners and who were my peers?

One of my great friends and close associates was Larry

Trawick. After the Division of Public Information had been created, following CAC 1, I went to John Harvey and told him that I would like to have Trawick as my Deputy. He had been very effective in the educational campaign on grain sanitation. Trawick had been an Inspector in some of our big cases and he knew the business, and knew how to write.

So, I wanted him and Harvey was very pleased because I don't think he knew just where to put Trawick. We worked very well together.

Another person I came to admire for his ability was Winton Rankin. The first thing I remember about Winton was that he had been given the assignment to put the Pesticide Amendment into operation, after it was passed in 1954. Rankin, I felt, did a very skillful job setting up that program. We thought he might be Commissioner some day.

Another person who helped me a great deal was Vivian Boardman. It was a tragic thing that she became seriously addicted to alcohol. But even when she was under the influence she could do certain jobs better than anybody else.
JHY: Would you define the scope of her work, because I don't know that we have had her defined for the records?
WFJ: She was Chief of the Editorial branch when I arrived at Food and Drug. She had been trained as a librarian. She was a good writer, especially about the Food and Drug Administration. She had a great fund of information about many

different FDA activities. She had been very much involved with the annual report from the days when the Commissioners did it largely themselves. I know she helped with the Report during the days of Campbell, and later Dunbar and Crawford. She also did most of the articles for the Yearbook of Agriculture, and many news releases and speeches.

When I came on the scene, the Annual Report was maybe 3/4 by Vivian and 1/4 by me and other people. As time went on, I had to do more and more of it and eventually to keep it going I had to do it all. By the '70s, from 1970 through 1974, this became very difficult.

The FDA's annual report was no longer a chapter in the report of the Department, because the Department had given up the struggle to put one out -- that was in 1970. There were various reasons -- they were always late in coming out, the Secretary (most of them) wasn't interested; there was a lack of cooperation from the agencies -- which did not have the incentive or capability to do their chapters. "Economy" was claimed as a reason, but the only real out-of-pocket expense was the printing. A number of the laws administered by the Department required annual reports to Congress; these, of course, were continued. In FDA, I kept on doing it because there was a need for this annual summary of the important things that happened; statistics and so on, showing what was being accomplished, and how the job has changed. But this

became increasingly difficult. One reason was the lack of any directive from the Department. Another was the FDA's "Quarterly Report," a compilation of management information for internal use. This had been put out for many years for use in monitoring field operations and planning. The trouble with it was that only sophisticated readers, FDA insiders, could interpret and coordinate the material to answer the broad question: "What happened?" Also lacking in these quarterly reports was coverage of major events that made headlines and history but were not reflected in the kinds of data compiled for this report.

Annual reports of the FDA and its predecessors had been coming out for over 100 years -- in fact, since 1862 when Charles Wetherill was appointed by Abraham Lincoln to be the Chemist of the new Bureau of Agriculture. I knew it was a major source of FDA history, and didn't want it to stop. 1974 was the last one I did, completing the 25 years which we put into the compilation published in 1976. After 1974 the planning people took it over and produced it for five more years. And then it "died on the vine," so to speak, for various reasons. I think the demise of the FDA's annual report is very regrettable. It is symptomatic of things that have happened all over the Government and in the private sector as well.

RGP: This is the second day of the interview with Wallace Janssen. The date is January 31, 1984.

JHY: Why were the annual reports stalled, as you were saying at the close of the hour yesterday?

WFJ: Well, I understand that a catch-up report has been prepared covering the last three years through 1982, but this manuscript has not gone to the Government Printing Office because it was stalled in the Department due to the freeze on printing that has been in effect during this Administration. I think it very regretable that the Annual Reports were not continued from 1974 onward in the style that was followed during earlier years. We've lost the continuity of the narrative. It will be tough work for an historian to reconstruct what was happening during those years and since.

JHY: In addition, those earlier reports were prepared from reports sent in from the field, Wally, and from the different Divisions in Washington. The historian has not only the final digested, somewhat succinct and streamlined report, but he has available in the archives at Suitland a whole body of material that was submitted in order that the earlier reports could be compiled and that takes the researcher to a greater level of depth in primary materials, if he is interested in different time periods of the agency's history.

WFJ: Well, I have some doubts about the completeness of the raw material that went into the Annual Reports. For some years, yes, I think it is out there. From perhaps beginning with the '60s, I don't think you will find much out there in

the way of the raw material used in the reports. Also, in more recent years, that is the '60s and '70s up through 1974, less was gotten from the field and more was gotten from the sources here at headquarters.

You also must bear in mind that for various reasons there are certain kinds of information that didn't get into the annual reports. For example, only in the later ones, that is from the mid-'60s onward, did we very often mention the names of companies that were involved in cases. It was a policy not to name names because we felt it was not our function to add to the publicity that had already resulted from litigation.

JHY: Would you think back to yesterday, in following up something that we talked about? In connection with the two Citizens' Advisory Committees, their reports were important and therefore their constitution as committees is important to history. What can you remember about the way in which the membership of those of committees was choosen? How far did the department dictate the membership, how far did the department ratify suggestions that came from within the Food and Drug Administration? Can you remember anything that would be helpful to resolve that problem?

WFJ: Not too much. There were a lot of people considered for a list which was submitted to the Secretary's office. The membership of both committees was supposed to be broadly representive of all walks of life, and to include people from

the industries and professions who had some familarity with the Food and Drug Administration.

JHY: Who made up the list and who did the selection?

WFJ: Well, as I recall, it was a joint effort of the Commissioner and the Secretary's office. The appointments were by the Secretary but, I think, most of the nominations came from the Commissioner. I suggested some of them.

JHY: Did you help the Commissioner compile the list?

WFJ: I made some suggestions of persons. I don't remember much about that. Anyway they were knowledgeable people who were broadly representative of the industries, the scientific professions and the consumer, and their biographies are all available in the records on those committees.

FLL: Was the suggestion of Dr. George Harvey as Chairman, did that, do you think, originate in FDA?

WFJ: No, indeed I am sure it did not. It was a disappointment and a surprise to the Food and Drug Administration that the Second Citizens' Advisory Committee came out with the theories that Dr. Harvey entertained. I've dealt with that in the Johnson Library papers, to some extent.*

* It is important to note that the recommendations and reports were largely the work of the management study firm Cresap, McCormick and Paget, which had the contract to do the staff work for both committees. They were supposed to be critical and to recommend innovative changes. But both committees had individuals who took over leadership roles. In CAC I, it was the industry attorney, Charles Wesley Dunn, who wrote specific recommendations for expanding the FDA into the final report. This was an invaluable contribution. And it was Dr. Harvey who skewed the report of CAC II in the direction of making FDA less of a law enforcement organization and more like the Public Health Service.

JHY: You mentioned consumers as part of these committees. One of the phenomena of considerable importance in the development of the advocacy positions, with regard to Food and Drug Administration policy, that came along was the interest of the group of essentially young people who allied themselves with Ralph Nader, who emerged as a particular kind of consumer advocate. These allies of Nader did take a somewhat different kind of consumer interest and a different stance than earlier consumer groups had tended to do. Do you remember the appearance and the interface between Nader's Raiders and the Food and Drug Administration? Can you speak as to how this began?

WFJ: Well, that is something that came later and is not really related to what we were just talking about, the Citizens' Advisory Committees and their reports.

JHY: That was a mid-'60...

WFJ: That's not really related to that. It came later and I will just say this: that I had a gall bladder operation at the time that the so-called Nader's Raiders were given a free hand to rummage around the Food and Drug Administration. They were able to go into my files, in my absence, to look at anything they wanted to. The Commissioner, I have forgotten which one it was, gave them permission to do this.

One thing they found was the reprint from the Journal of Public Law of the symposium on the Evolution of the Food and Drug Laws that you, Harvey, arranged at the 1962 annual meet-

ing of the American Historical Association.

Now you may recall that in my paper on "FDA Since 1938," I spoke of the attitudes and high moral principles of the Commissioners and their effort to preserve the integrity of the Food and Drug Administration while standing up to Congressional pressure.

I dealt with the famous incident of the beetball machinery developed by a constituent of Congressman Taber, the Chairman of the House Appropriations Committee. I said they (the FDA people) felt that they were in a David and Goliath situation. They stood up to Congressman Taber and I theorized about how that came about -- the psychology of the situation.

Well, the outcome of the Nader investigation by these college students was the book The Chemical Feast, by James Turner. That book was a monstrosity of errors. It was regretable that a fine opportunity was lost to make clear how technology, particularly in the food industry, stimulated by the profit motive, had produced a lot of problems for consumers and for people interested in the public health. It could have been a meaningful analysis of how Wall Street and Madison Avenue had affected the food supply of America a great deal. Instead, it degenerated into an attack on the Food and Drug Administration. Particularly nauseating was the fact that my statements about the way in which the Commissioner stood up to Congressman Taber were twisted around and interpreted as just

JHY: Can you comment on it?

WFJ: But I will say this, that there was a great deal of publicity. And of course, the cranberry industry did engage a public relations firm, one of the biggest in the country -- Batten, Barton, Durstine, & Osborn, in order to fight back against the FDA and save the market for cranberries. This produced a lot of critical editorials. Even the Journal of the American Medical Association poo-pooed FDA's action. They minimized the risk and ignored the fact that the real issue here was whether or not the new Pesticide Amendment was going to be enforced. The Pesticide Amendment provided the law, although we did not use it, while at the same time the Food Additive Amendment had just been passed with the Delaney clause in it.

So, we had an explicit expression from Congress about carcinogens in food. Also, the FDA knew several years prior to the cranberry recall, that aminotriazol was being used. So we had prepared to do something. Eventually, when we found aminotriazol in 7 out of 9 shipments of cranberries from the Pacific Northwest in 1959, we told the Secretary about it. Arthur Flemming wanted to be informed about all of the important developments in the different agencies and then very often he would personally take charge. That is how it happened that Flemming got into the picture.

JHY: Well, in connection with...

WFJ: So, I would like to tell one little aspect of the thing, for the tape here; the rest of it is all on the record in other places.

After we had had a lot of that critical publicity, it occurred to me one day to call the Secretary's office and ask what kind of mail was coming in from the public. They said, "Oh, we're glad you called because we have 1600 letters here and we were just about to send them over for you to answer them." So, we got all this mail that had accumulated in just a few days, and we analyzed it in order to develop three or four or five different form letters that could be used to reply. I was amazed that the mail was about 20 to 1 in favor of the Secretary's action. Notwithstanding the counterpublicity barrage laid down by the cranberry public relations people, the public saw through it and supported the recall action.

JHY: Now, the Secretary's role. It was not only with regard to this episode, which might be regarded as the episode par-excellence, but it was in other things. There were some areas of quackery, possibly weight reduction things, as I recall, where the Secretary also called special conferences and made special announcements. Now, traditionally the Secretaries had not taken such an active role, as I recall. They had left what publicity there was up to the Food and Drug Administration itself and though they had perhaps backed up the Food and

Drug Administration, they hadn't inititated action. I think this episode with Secretary Flemming has been interpreted as a kind of step in the loss of a certain independence that traditionally the Food and Drug Administration had had. The kind of a beginning of a rise of initiatives at the department level, which before had been permitted to remain at the agency level. Do you have any...

WFJ: No, I don't agree with that... For instance, when Oscar Ewing was head of the Federal Security Agency (he had been General Counsel of Merk & Company) he very much occupied himself with Food and Drug matters, to the extent that regulations piled up on his desk and laid there for months because he didn't have time to get around to read all of them and sign them out. He insisted on doing all that.

So, Flemming was certainly not the first of the Secretaries to get involved with the FDA's affairs. Further back, Secretary of Agriculture James Wilson was another who involved himself. It varies with the Secretary as to how much they involved themselves with the affairs of the FDA. Now, Flemming was unique in this respect, that he had taught a college course on American government. He had also been a journalist with the U.S. News and World Report. He had very definite ideas about how the agencies of the U.S. government should function. He had also been chairman of the Civil Service Commission. Flemming had a system. I think he was the

only Secretary who really had a system for running the Department. Briefly, it was like this. First of all, all the constituent agencies had a duty to keep the Secretary fully informed about anything of importance that was going on in their agency. He insisted on that. The Secretary, being the responsible head of the department and the chief spokesman of the department, had a right to know what was going on amongst the bureaucrats. So, this was put on a definite schedule basis, that every agency had to report regularly. I think it was at least once a week.

Well, then Mr. Flemming would personally evaluate this information and if he thought it was necessary for him to get involved, he would call on different people in an agency to provide additional information, in depth. Generally this would be at a meeting in his office. It didn't make any difference whether you were a Grade-9 Inspector or a Grade-11 Chemist, or the FDA Director of Public Information, or the Commissioner, whoever had anything to do with it who could contribute pertinent information, Mr. Flemming wanted to see that person face-to-face and hear whatever he had to say.

JHY: You, I take it, did indeed brief him?

WFJ: Oh, yes, I was in the cranberry meetings and a lot of others. It happened quite often. We had to go over to Flemming's office, Larrick and I and other people in the FDA and we'd sit around the table and Flemming would ask quest-

ions. Sometimes he'd even turn around to his typewriter and type something out. He would analyze the thing and figure out the language that he thought should be used if he were going to make a statement. This is the way that he developed the famous sentence about the Delaney proviso - the one that goes something like: "No one knows how much or how little of a carcinogen is capable of triggering the cancer process in a susceptible indivdual." It was a carefully worked out summary of the situation. Incidentally, after the cranberry thing was pretty well over, Flemming personally reported to Congress in a long detailed statement covering the whole episode, including his recommendation that a Delaney proviso be part of the pending Color Additive Amendment.

FLL: In an interview like this, two years ago, John Kedzior who was the Chief Inspector in Seattle at the time, stated that one of the things that triggered our telling the Secretary about our preliminary results before we had even confirmed them, was the fact that the previous year we had found a similar situation with the Ocean Spray firm in that area. Ocean Spray had voluntarily segregated the affected lot and had voluntarily destroyed it. That voluntary destruction had been reported to Fleming and he was about to make a public statement complimenting the company on their being so responsible. When your Deputy Larry Trawick called Seattle to get more details on the destruction he learned about the fact that

new samples of the current year's crop were now showing indications of the chemical. This was the reason why the preliminary results were passed on to Flemming, perhaps prematurely. We would have preferred to confirm them before we gave him that information, but we had to head him off from making this statement complimenting the company. Do you have any recollection of that sequence of events?

WFJ: Yes, now that you mention it, I can confirm that. When Flemming decided that this information had to be made public, he did so at a press conference. He held press conferences on the average every week or ten days. The manner in which the story was played, and the publicity from it, resulted from the persistence of the Associated Press reporter, Mr. W. Joynes McFarlane. Mr. McFarlane insisted on an answer to the question, "What should a prudent housewife do as regards to serving cranberries at Thanksgiving time," which was only a couple of weeks away. Flemming was somewhat reluctant to answer but he finally said the only advice he could give to the prudent housewife would be to NOT serve cranberries until the Food and Drug Administration had completed its investigation of the crop and approved whatever shipments were free of aminotriazol. So we were off and running a nation-wide recall from that moment.

FLL: There was great consternation, I know, in the field where I was because of the magnitude of the task and the fact

that there were some reservations about how good the method was for analysis.

WFJ: We had a method, of course. We had anticipated this problem enough so that a method had been worked out and disseminated to the field. The labs worked night and day. As fast as lots were released, the industry put stickers on the packages saying that they had been passed by the FDA.

FLL: To test the accuracy of the method at New York, we put a very small amount of aminotriazol into a special sample and gave it to the laboratory without telling them that this was a check sample, and they found it! So we felt somewhat relieved that if we encountered lots that were contaminated that we would find them.

JHY: Well, that was really one of the....

WFJ: The real issue here was, was the Federal food and drug law with regard to pesticides going to be enforced or was it going to be a dead letter? We had, in effect, although it was not in the Pesticide Amendment, we had in effect a directive from Congress that carcincogens should not be permitted to be added to the food supply.

JHY: It was also a "bugle-blow" in bringing the Food and Drug Administration back into headlines, into public awareness. The traditional thing is to say that after Wiley retired it was a very long time before the Food and Drug Administration got as much public awareness through the media as it had dur-

ing Wiley's time. There is a famous story that throughout the whole course of the effort to get the 1938 law, most of that effort made the front page of the New York Times only once and that was when there was a disturbance in the gallery. Even after the law was passed, there was some attention, but the agency kept a fairly low profile. This was 1959, Wally - and big headlines - and Senator Kefauver was waiting in the wings to make even bigger headlines. So, that both from the point of view of media attention and from the point of view of congressional attention this marks an ascending curve for the industry.

WFJ: Well, the cranberry experience had various consequences. Flemming's press release included his intention to seek a Delaney clause in the pending Color Additive Amendment, which he did. It wasn't very long after that that we were delisting colors used in lipsticks. We were also seizing poultry that had DES pellets implanted in the necks that were not dissolved when they reached the consumer, so that it actually was possible for the housewife to be making chicken soup out of chicken necks that were heavily contaminated with DES. Then, of course, there was the reaction of the dairy industry when drugs and pesticides were found in milk. I told you about that yesterday.

So, when the FDA recalled cranberries, just prior to Thanksgiving, it really shocked the public and made them rea-

lize how important the Food and Drug Administration was to every individual in the country.

Now, this is one of the several experiences that I mentioned in the Johnson papers, as events that pushed the FDA in new directions.

Well, what are we going to do now? You want to pause a minute?

JHY: Yesterday, Wally, we were talking about your views of people and you were giving us vignettes of some of the Commissioners and we were also anxious to hear about your awareness of the team under the Commissioners. Your peers and other high administrative officers with whom you worked. Indeed, the rivalries among some of these men. Would you address yourself to that?

WFJ: Well, it just happens that I was not thinking about that. I will talk about that later, if you'll ask me again. I would like to, at this point, say something about some individuals that I was involved with over the years, people outside of FDA.

JHY: Good.

WFJ: A couple years ago I published a biographical paper about Charles Wesley Dunn.

JHY: Where did that appear?

WFJ: That is in the Food, Drug, Cosmetic Law Journal, Vol. 37 (1982) pages 446 to 456. I was always curious about Mr. Dunn

because I wondered, and I think other people did too, about how on earth he got to be general counsel of both the American Pharmaceutical Manufacturers Association and the Grocery Manufacturers of America - the two biggest trade associations in the food and drug field. Here was Dunn, general counsel of both of them and very much the dominating personality in the food and drug bar.

So, I researched Dunn's early career and discovered how he got these jobs and became the senior statesman of the legal profession specializing in food and drug law, and also the founder of the Food and Drug Law Institute.

Now, I also mentioned the other day Mr. Jim Hoge of the Proprietary Association, who was their general counsel. I think there was a kind of a rivalry between these men. Invariably when the two of them were on the same platform, participating in any kind of a discussion like, for example, meetings of the National Drug Trade Conference, Mr. Dunn would always mispronounce Mr. Hoge's name.

It was very noticeable and deliberate. Mr. Hoge was known to be Mr. Hoge to everybody, but Mr. Dunn called him Mr. Hoje, with a soft "G". I think it irked Jim Hoge no end to have him do this, but he never reacted publically to it. In a way it was Dunn's way of putting Hoge in his place, I think.

Another person who was important to me as a trade reporter was Dr. Frederick J. Cullen. Dr. Cullen had been the chief

medical officer of the Food and Drug Administration for many years when he retired from government and became the executive vice-president, or maybe it was president of the Proprietary Association at its office here in Washington.

The Proprietary Association was the trade association of the "patent medicine manufacturers" and very much involved in the history of the 1906 Food and Drug Act. Their lobbying activities had been exposed by...

JHY: Samuel Hopkins Adams.

WFJ: Samuel Hopkins Adams in his famous series The Great American Fraud, which ran in Collier's magazine in 1906 and 1907. When I first became acquainted with the Properietary Association I was not aware of this lurid past, but I soon found out something about it. I came to form the opinion that to a considerable extent, the patent medicine companies, at least those belonging to the Association, had reformed. They had become much more respectable and they were anxious to have a good public image, but they were also very committed to maintaining a low profile. You hardly ever see any public statements coming out of the Proprietary Association.

They had a system of reporting on the legislative doings in all the state legislatures. They had the most effective network of legislative reporters in the country and there were other trade associations that got that service from the Proprietary Association. Every bill and every legislature that

had anything to do, at all, with packaged products, not just proprietary medicines, was reported on by the Proprietary Association service.

JHY: Would you describe Dr. Cullen as a man, the way he looked and spoke, etc.

WFJ: Frederick J. Cullen was a very handsome, white-haired, charming, dignified individual. He was an impressive person. He was greatly beloved. He dedicated himself to persuading and influencing the members of the industry to do scientific research. He was forever after them to do the research that they needed to back up their theraputic claims. That was his constant aim, that products of the home remedy industry should be capable of doing what they were claimed to be good for. So, I had the feeling that Cullen, perhaps, did more to protect the public after he left the Food and Drug Administration than when he was with the FDA.

JHY: They did work hard to limit the restrictions upon proprietary medicines in the 1938 law.

WFJ: That is true. But I think they also allowed a good deal to get into the law that they might have prevented if they had been less public spirited. Cullen and Hoge, I think, should have the credit for that.

Then another person whom I knew and came to respect was Carson Frailey, who was the Washington chief and representative of the American Drug Manufacturers Association. The Amer-

ican Pharmaceutical Manufacturers, in which Dunn had been the prominent figure and the American Drug Manufacturers Association in which Frailey had been the dominant figure, eventually merged and became the present PMA, Pharmaceutical Manufacturers Association.

Mr. Frailey loved to reminisce about the historical beginnings of the pharmaceutical industry in the United States. He gave me a very good picture of how it got started. The major firms that dominated the industry, six or seven of them were, I think, almost all of them started by doctors, beginning after the Civil War. Their aim was products that physicians could depend on. So they were very much interested in working with the Food and Drug Administration and with the United States Pharmacopia in regard to drug standards, testing methods and the like. They had a great deal to do with the development of the USP standards and, of course, these were the official standards under the 1906 Food and Drug Act, and also for an important group of products under the 1938 Food and Drug Act.

This cooperation to insure the integrity of drugs culminated in what was called the "Combined Contact Committee."

This was a group of scientists working for the drug companies, and from both of the major pharmaceutical associations, but not the Proprietary Association. The technical people from the ADMA, and from the APHMA, joined together and

held regular meetings dealing with problems of drug testing and drug standards and the Food and Drug Administration scientists also participated in these meetings.

Any serious history of the Food and Drug Administration's effort to regulate drugs should include something about the Contact Committee, and there are people from whom we can get source material about this.

Other participants in the Contact Committee, of course, were people from the USP and AOAC.

JHY: A word about Frailey as a person.

WFJ: Now, Frailey as a person. He was another very likeable man. A gentlemen of charm and, I think, integrity, and extremely well informed. He was a real pro at association management and I also feel a very public spirited person who worked hard to ensure that the industries that he dealt with were operating in the public interest.

Among other individuals in the trade association field that I knew was Bernard H. Smith. He was another ex-food and drugger. He was President of the Virginia Dare Flavoring Extract Company, of Brooklyn. He was a chemist. Dr. Smith was, again, a big man in every sense, who believed in the food and drug law and supported the Food and Drug Administration. He was President of the Flavoring Extract Manufacturers Association.

Then there was John Hall, an attorney for the FEMA, who

was another good source for me in my days with The Glass Packer. John Hall was a lawyer, a rather crusty individual who was very objective, however, about the membership of his association and who wanted them to tread the straight and narrow path.

JHY: This association was?

WFJ: The Flavoring Extract Manufacturers Association.

Still another one was the Toilet Goods Association. I became acquainted with that organization at the time of the 1933 World's Fair in Chicago and again in New York. There were two men with that association who were good sources of information. One was Gregory Thomas, the President of Bourgeois Inc., the international perfumery house. Thomas was a huge man who had had very interesting experiences during World War II. He spoke French fluently.

He was a terrific gourmet and a very interesting personality. I got acquainted with him because he was the person who, before he became President of Bourgeois, headed the Toliet Goods Association's Board of Standards and also was much involved in the exhibit the industry had at the World's Fair in New York.

Another leader in the Toilet Goods Association was S. L. Mayham. Steve Mayham had been the editor of the American Perfumer Magazine for many years and knew the industry inside and out. When he became the Executive Vice-President, or

maybe it was Secretary of the TGA, he was very well qualified for the job. He was an excellent source of information about what was going on inside the industry, and we had an arrangement with him that proved to be very helpful.

The Glass Packer magazine had a department called "The New in the News." It had four anonymous contributing editors, all in trade positions that made them excellent sources of information.

One chap was with one of the largest food brokerage concerns. He covered developments in the food industry, summarizing each month the important happenings that had gone on.

In the drug and cosmetic area, it was Steve Mayham. Mayham liked this opportunity because he was at heart a journalist and it was a way in which he could communicate with his members and make sure they would hear about things that he wanted them to know and not have to justify his position or get into arguments with them.

JHY: Incognito.

WFJ: It was from Mayham that I learned about the reaction of the drug and cosmetic industry leaders who were dismayed when they heard that President Roosevelt planned to merge FDA into the Federal Security Agency. They were afraid that if this happened the FDA would become a part of the Public Health Service and be dominated by the medical profession and the AMA. So the industry leaders went to Roosevelt and got his

assurance that the FDA would be a separate entity in the new set up, which it continued to be until 1968 when we finally got put into the PHS. (Mayham's story in the April and May 1940 issues of The Glass Packer, pages 223 and 289, is attached to this transcript.)

Maybe I should mention a very early example of FDA involvement with the trade associations and that was the departure of the famous food chief, under Dr. Wiley. What was his name?

JHY: Bigelow!

WFJ: Yes, Dr. Bigelow. Dr. Bigelow was one of the really big people under Dr. Wiley. When he retired from government he became the director of the new laboratories of the National Canners Association. It was very much a pioneering step in the trade asssociation area, at that time, for an association to start a scientific laboratory headed by a man of such eminence as Dr. Bigelow. The work of the FDA benefited greatly over the years from that connection and, I think, it still does. I don't know just what the situation now is. It's now, of course, the National Food Processors Association. They have made important contributions to both the state-of-the-art of canning and to compliance with the food and drug law.

Now, I have mentioned instances of what critics have in recent times been calling the "revolving door," the phenomenon of employment by industry of FDA people after they leave the

government and vice versa. Of course this occurs. I think on the whole that it has been very beneficial to the Food and Drug Administration and to the public. It certainly is important and beneficial that the FDA have access to the industry technology, and that industry know about the law. We learn the technology very largely through our contacts with industry. We would not be able to regulate effectively if we didn't know the technology that industry is using. I regard this as a kind of cross-fertilization, more than a matter of influence. The influence goes both ways. It isn't only a matter of industry benefiting and having an easier time with the government. That is just one part of the total picture. I think there is real cooperation in the public interest here.

Recently there was a small study covering the past 10 or 20 years, of who went where after leaving Food and Drug and the total picture is not what you might suppose from reading some of the critics.

JHY: Do you remember where the article was published?

WFJ: Not published...it was done by somebody in Mr. Meyer's shop. They followed up on a lot of people.

JHY: It would be interesting to keep track of that.

WFJ: ...and statistics on it. In other words it was a deliberate answer to the questions involved in the so-called revolving door accusation.

JHY: Not involved with this particular question, but in

connection with those who were in associations greatly interested in the mission of the Food and Drug Administration, I wanted to ask you about two other persons to see if you happened to have close association with them.

One was Dr. Fischelis of the American Pharmaceutical Association. Did you have much contact with him while he was in the office?

WFJ: Not a great deal, but I was aware that Dr. Fischelis was involved in the...I think the discussions over the 1938 Act.

JHY: Then later on in connection with the Durham-Humphrey Law of 1951, Dargavel of the trade association that involved chain drug stores.

WFJ: No. Not the chain drug stores. Dargavel was with the NARD, the National Association of Retail Druggists, the independent druggists.

JHY: *That's right, retail druggists. Did you have the kind* of association with him that you did with some of these other people you've spoken of?

WFJ: I reported and wrote news articles that involved Dargavel. He was a union boss type, aggressive, pugnacious, a fighter for the rights of the retail druggist. I can't say that I knew him personally as well as I knew some of these other people. For one thing, his headquarters was in Chicago and Frailey was right here in Washington. So, I didn't get to know Dargavel. Also the FDA, except for the problem of ille-

gal sales of prescription drugs, the FDA and the retail pharmacists didn't have too much in common. Later they were recognized to be an important factor in the success of product recalls.

What was the other one? You mentioned Dargavel and... Fischelis?

JHY: He was in Washington.

WFJ: Yes. I didn't know him terribly well. In general I would say that Fischelis had the reputation of being his own man. You couldn't predict what Dr. Fischelis' stance was going to be about something. He was an independent thinker and operator. But very much, of course, a spokesman for the professional side of pharmacy. It is significant that you have in the retail drug industry a dichotomy between those who are more interested in professional pharmacy and those that are more interested in running a drug store. Theoretically they would both be the same people, but actually, I think, there are some differences. This is shown by the fact that organizations have developed in special branches of the retail drug business, such as the hospital pharmacists, for example. They have a professional association of their own.

JHY: Some of these differences came out at the time of the 1951 law that drew the line between between proprietary and prescription drugs.

WFJ: That's right. I wrote a lot of articles and speeches relating to that law.

JHY: Well, how about now within the agency? And your association with others who headed bureaus and divisions?

WFJ: Well, I don't know what I can contribute along that line, except to say that I rarely experienced anything except marvelous cooperation from people of great ability. The food and drug organization, as it was when I joined it in 1951, was a magnificent illustration of the best in the federal career service. There were hundreds of people who knew, not only their own jobs, but a great deal about the total job of the FDA. They worked together as a team. While there were, I suppose, conflicts and problems between individuals, I got excellent cooperation, by and large, from the agency.

JHY: From your perspective, how would you describe the Welch case and its impact upon the agency?

WFJ: It was traumatic. The discovery that Welch had been getting all this money from his outside activities was shocking. At the time I thought of it as like the effect when it is discovered that the trusted employee of a small town bank has been rigging the books for years and getting away with depositor's money. That kind of a reaction. It was unexpected.

Now in retrospect, of course, there were things that perhaps should have been a signal to us that all was not well.

One of these was when the late drug industry reporter Stephens Rippey called my attention to the fact that the sci-

entific symposiums on antibotics that Dr. Welch was putting together included papers that were repetitious of papers previously given, and this sort of suggested that he was not applying a very high standard of quality to these papers. Some of them looked like publicity for the people who gave the papers or for their firms or products. I passed that information on to Commissioner Larrick. He was very interested and concerned about it. It was only a short time before the expose took place.

FLL: Rippey was a reporter for the Drug Trade News.

WFJ: And Drug Topics, Topics publishing company...

JHY: I remember, myself, that certain requirements followed the expose, that all Food and Drug people of different...

WFJ: I can tell you about the aftermath of that. Arthur Flemming was Secretary and he took charge of this matter, Teo. There were two committees or task forces appointed. One was headed by a former top official of the IRS. In this project every FDA employee above a certain grade level (and this was not a very high grade) had to report in great detail about his personal finances.

JHY: A lot of indignation about that.

WFJ: Well, not so much, because we knew it was needed. Not only did you have to tell what stocks you owned, but also what insurance policies you had, when you got them, what real estate you had, endowment policy income or anything of that

kind. Much more than you have to tell on an income tax return. We had to provide all that information.

Then there was another group headed by Dr. Detlev Bronk of the National Science Foundation. Dr. Bronk's panel of scientists reviewed the FDA's scientific decisions over a long period of time to see if they seemed to be tainted by any undue and improper influences. Both of those studies gave the FDA a clean bill of health. It was clear, afterwards, that the Welch case was an aberation, it was confined to Dr. Welch and there was no evidence of anything similar going on throughout the agency.

JHY: Could you describe Dr. Welch as a person?

WFJ: As a person Dr. Welch was a dominating scientist of great capability. He made the Antibiotics Division a very effective instrument for good. He made a great contribution to public protection through the development of the standards and testing methods for antibiotic drugs. He in effect became the czar of the antibiotic drug industry. The industry people respected him and they even feared him. He policed the antibiotic drug industry, I think, in an effective way notwithstanding his accepting this large income from the journals that he edited and the advertising and reprints, etc. I think he made money out of it but I don't think he ever did anything that was contrary to his duty as an enforcing official in FDA. The FBI investigated him for a long time and they were unable

to find any evidence of a law violation on which they could indict him.

Dr. Welch planned and supervised the investigation of improper promotion of chloramphenicol by Parke Davis and its improper use by the medical profession. The outcome of that investigation is covered in one of the press releases that I want to talk about later, if I can find it.

JHY: I do want to talk about the press releases and we did want you to talk about your colleagues but perhaps, do you have any questions in connection with the team under the Commissioners. Explicit questions that you'd want to pose, Wally, before we go on to the press releases?

WFJ: What do you mean the team under the Commissioners?

JHY: Well, I meant your colleagues. You said it was a marvelous organization, very efficient and capable and you didn't note, particularly, that there were rivalries. Some people have sensed rivalries and desires...

WFJ: Well, I'll try to think of some things.

The General Counsel of the Food and Drug Administration during the time when I was Director of Public Information was William W. Goodrich, who had come as a young attorney after service in the Navy. I think in the Navy he had some duties as a public relations officer. Bill Goodrich made a remarkable contribution to the food and drug law and to the U.S. public through his ability to get everything out of the statute that it was capable of doing.

I am sure that there were lobbyists for the food and drug industries who were amazed and surprised at what a strong law it turned out to be. Bill got more out of the law than anybody thought was there, through his ability to interrept it and explain it in briefs and other legal activities. We had years and years of strong enforcement that produced excellent case law to back up what was in the statute.

Then, of course, there were the people who were in charge of the development of cases. People like Goldhammer, Milstead, Stephens, Kneeland and many others who knew the job and performed very much as a team. We had top people who knew the jobs of all the people who were working under them. So, the situation then was, I think... Well, we didn't have a situation where we had newcomers at the head of things. They knew the business all the way from top to bottom.

I think a very good analysis of the management history is in the book by Rufus Miles. Miles was Administrative Officer of the Department of HEW for many years. After he retired he was asked to write a book on the Department for a series on the government agencies published by the Praeger Publishing Company. Miles' analysis of the job of the FDA and its relationship with the Department, I think, is very good and quite accurate.

Another important contribution of Dr. Welch: Dr. Welch was the compiler of the 50th anniversary book "The Impact of

the Food and Drug Administration on our Society," published by MD Publications, Inc. It contains around 70 articles about different phases of the FDA's work. It is a good source of information about what FDA was like in 1956 and how it got that way. In other words, there is a lot of historical background in those articles by people who were with FDA going back to the times of Dr. Wiley. Welch did this on his own, with no input from me. I was asked for a paper but declined because of the way he by-passed the Information Office to arrange for outside publication and funding.

JHY: There is the matter of the press releases, their importance at the time they were issued in publicizing the agency, their importance as historical documents. These had been going for quite a while. When you came in you inherited a sort of system. Did you revamp and revise this system and have a different and broader definition of the role of the press releases?

WFJ: Well, the first FDA "press releases" were the Notices of Judgement beginning in 1908. But the story really begins earlier than that, with the bulletins that Dr. Wiley published, reporting the investigations of the Bureau of Chemistry. In 1957, I wrote a series of four articles under the title "Public Information Under the Federal Food, Drug, and Cosmetic Act." These articles, published in the Food, Drug, Cosmetic Law Journal, were a comprehensive discussion of the informa-

tion function in American government generally, and FDA in particular. They spelled out the law, the policy, and the activities. They were intended to describe our information program, and came out prior to the establishment of the Division of Public Information. This, of course, was one of the actions taken to carry out the recommendation of the first Citizens Advisory Committee that FDA step up its educational effort.

Press releases had been issued by FDA for a long time before I arrived on the scene. The major change that I made in them was to insist on releases that covered the important details of any new regulation in lay language. In other words, I was very concerned that a press release on any FDA policy or new regulation or new law or whatever, be a document that would adequately explain it, not only to consumers, but also to the regulated industries. This came from my background as a trade editor, but it got me into difficulties with the HEW Department quite often, because the press people with the Department were oriented to what the Associated Press (AP) for example, would be willing to put on the wire. They didn't understand that a press release could have various uses, and they would want them edited down to just what the major media would be willing to use.

Today we have the same kind of situation, in a way, because the T V people, for example, only want the very mini-

mum amount of information. If that is going to be the standard, why the agency isn't going to be putting out very much for the people who need guidance.

JHY: You were thinking of the trade press.

WFJ: I was thinking not only of the trade press, but also the trade. I have always thought that if the FDA has a new regulation, it ought to be thoroughly explained for people who might not be subscribers to the Federal Register.

RGP: That is quite a large number of people.

WFJ: Now, I would like to talk about some of the releases that the FDA issued during my tenure as Director of Public Information.

The FDA was not issuing very many releases when I arrived in 1951. But it was not new for them to put out announcements to the press. For one thing, they had a routine monthly summary of enforcement actions. It contained statistics on the number of seizures and the quantities of food removed from the market and the termination of prosecution cases and that sort of thing. It was one means of complying with Section 705 of the Federal Food, Drug and Cosmetics Act, which requires publication of all court actions. It provided a running account of what was happening in the enforcement area that came out regularly every month.

Now, I would like to go through some of the releases and to discuss their significance.

The first one, dated April 26, 1950, announces the conclusion of the famous case against the "Magic Spike." It was typical of numerous releases that we put out when we had important cases against quackery. It is a quite detailed explanation of the Magic Spike fraud. It gives the penalty that was imposed and quotes the message of the judge when he sentenced the defendants. This was Federal Judge Walter LaBuy, of Chicago. He was a very famous Federal Judge. In sentencing he said:

> "The sale of ~~a~~ devices constitutes a gross fraud on the public. You have imposed on the poor sick, who in their anxiety for relief would try anything at any price. You have fooled the trusting, the credulous, and the gullible. The quackery you have employed is the more despicable because those who were deceived into believing in your fake remedy failed to pursue the treatment proven by medical science to be effective in preventing and curing diseases. This credulous belief in the efficacy of a useless product is the greatest danger inherent in quackery. It discourages and prevents those who use it from seeking proper medical treatment and the results of such neglect are often fatal."

I used that quotation in many speeches that I made about quackery.

The next case involved the famous Zerrett Applicator, another gross fraud. It might have been amusing, just merely amusing, if it had not been for the fact that about 5,000 people bought this thing and paid $50.00 for it, and used it for the treatment of all kinds of serious disease conditions.

The inventor, William R. Ferguson, got two years in the penitentiary and his co-defendant Mrs. Mary Stanikus, dis-

tributor, got one year in the federal prison.

The next one, dated June 16, 1950, announced the termination of the famous olive oil racket cases in New York City. The Federal Security Administrator commended the Food and Drug Administration for its success in breaking up a racket which had been flooding the eastern states with fake olive oil blends. It was one of the largest cases of that kind that the FDA ever handled.

Over three years of scientific and legal investigation and litigation were needed to break up the racket. The star of that trial was Dr. Jacob Fitelson, a Food and Drug chemist, who demonstrated in court the adulteration of olive oil with a chemical called squalene which made the fake blend test like genuine olive oil and was done deliberately to prevent the FDA from being able to detect the adulteration.

FLL: That press release, though, didn't tell all the story about how we knew about the added squalene, did it?

WFJ: No, but there is a good deal of it. It was 3 pages of that monthly report, devoted to the squalene case. Further details are in the Food and Drug Review and then, of course, the trial jacket. I think there is a narrative account of that whole case.

JHY: What did you refer to particularly, Fred?

FLL: In order to detect the squalene we had to mark the squalene with another chemical at the source, Eastman Kodak

Company, where the stuff was made and was purchased by these racketeers. It was very difficult...

WFJ: They used another chemical called anthranilic acid to tag the squalene and prove then that it had been purchased in order to adulterate the olive oil.

FLL: Olive oil naturally contains squalene and unless we could mark this added squalene, you could not say for certain that this was some other vegetable oil with added squalene, which is what it was.

WFJ: Then on July 22, 1950, Federal Security Administrator Ewing was quoted in connection with 14 convictions of druggists for selling dangerous medicines without a prescription. Ewing added this plea to drug purchasers; "For your own protection, as well as his, don't ask your druggist to break the law."

Dr. Dunbar then was quoted in detail about the nature of this problem arising from the fact that some drugs are limited to prescription because they are just too dangeous for self treatment.

At that time the FDA was already going strong with its enforcement campaign against pharmacists and doctors for selling dangerous drugs without prescriptions. Eventually it resulted in the Humphrey-Durham law.

WFJ: In most of these monthly reports on FDA actions, the Federal Security Administrator is quoted as the spokesman. At

that time the Department was very much interested in what the FDA was doing. I speak of the Department because the FSA was the forerunner of the present Department. So, Ewing was glad to be the source for publicity on these things.

Now, here is a release dated June 1, 1951, that I wrote. It says, "For immediate release after 10 A.M." We put it out that way in order to be sure that the evening papers would have a chance to cover it on the same day, ~~basis~~. It was on the appointment of Charles Crawford as Commissioner of Food and Drugs. Mr. Crawford and I saw it as an opportunity to make some news and say something that would be educational to the public.

So the release begins, "False teachings of diet quacks are the most troublesome current problem of the Food and Drug Administration, according to Charles W. Crawford, the new Commissioner of Foods and Drugs. Mr. Crawford was sworn in today in the office of Federal Security Administrator, Oscar R. Ewing. He succeeds Dr. Paul Dunbar whose retirement was announced May 14." Ewing said, "Mr. Crawford's appointment recognized not only his outstanding qualifications but was in line with the distinguished tradition of the Food and Drug Administration as one of the career services of the Federal government. Food and drug law enforcement is a highly specialized activity. Today more than ever, the interest of the American consumer requires that this work be kept in experi-

enced hands." Then after the oath taking, Crawford made a statement in which he said, "The purity and truthful labeling of foods, drugs and cosmetics, for which the public now spends more than $50 billion each year, or 1/4 of the total consumer income, is in the hands of a small organization. FDA has about 250 inspectors in the field and a total force of just over 1,000 in its scientific and enforcement work."

Crawford was already very much concerned about the limited resources of the Food and Drug Administration and he wanted to break out of the rut that we had gotten into with Congress giving us less than $5 million dollars a year to run the agency. Later he found a way, the first Citizens' Advisory Committee.

Hitting diet quackery, the release said: "A vigorous campaign of spreading the truth as well as of law enforcement is needed. The truth, Mr. Crawford said, is that America, far from suffering malnutrition has the most abundant and nutrious food supply in the world and is enjoying the best health of any nation in history. Mr. Crawford pointed out that most of the nutrional nostrums now being promoted by food quacks usually do not have any false claims on their labels. This often makes legal action extremely difficult."

Well, by calling for a campaign of public education, the FDA was able to trigger a vast amount of publicity against diet quackery. Right away the national magazines began to come in and want information for articles.

One of the first was Colliers; they did a story that debunked the "5 miracle foods" of Gaylord Hauser. He was the great Hollywood nutrition guru and author of the book called Look Younger, Live Longer.

The national magazines were then the equivalent of the national television networks today. Quite a number of them had articles debunking food quackery. The press was eager to collaborate in public health education on any serious problem, and they jumped at the opportunity to have stories about this kind of fraud.

I've always felt that right away after I got into FDA that I contributed a new dimension by proposing things like this. Crawford was a very willing collaborator.

On June 15, 1951 the monthly report release announced... "that crude black-strap molasses may not be marketed with promises that it will cure or prevent cancer, tuberculosis, heart disease, or a host of other serious disorders, according to Federal Judge Nelson T. McVicker at Pittsburgh. He fined Clinton D. Keagy and John S. Reiley, Jr. of New Castle, Pennsylvania $1,000 each for violating the Federal Food, Drug and Cosmetic Act. Defendents were found to have used a booklet containing false curative claims to promote a mail order business in crude molasses."

August 15, 1951, the monthly report was headed with this paragraph, "Copies of Gaylord Hauser's book, Look Younger,

Live Longer displayed with Plantation Black-strap Molasses in a Rochester, New York retail store, are again under government seizure, the Food and Drug Administration announced today. The original libel against the books was dismissed in April by Judge Harold S. Burke, U.S. District Court of Buffalo, on motion of the publisher that the book did not constitute labeling of the molasses. Judge Burke, however, stayed the dismissal of the book seizure and permitted the government to file an amended libel showing more clearly that the book was used to foster sales of the seized molasses." That was the beginning of a case that we won in which a hard cover book was legally established to be labeling under the Food and Drugs Act if used directly with the product to promote sales.

Then, here is a release announcing the new FDA booklet that I talked about yesterday, Read the Label on Foods, Drugs, Devices and Cosmetics. "Labels can help you get your money's worth and guard your family's health," said Charles W. Crawford, Commissioner of Foods and Drugs, who heads the FDA. "They contain information required by laws which Congress has enacted for your protection but if you do not read the label you are losing the benefits of that protection." We liked to use any opportunity to deliver that message to the American public.

On the 26th of October 1951, we put out a release marked: "Please hold for release until HR 3298 has been signed

by the President". This was the release that explained the Durham Humphrey Law to the public. We had prepared it in advance so that the press could have it, study it, and have plenty of time to write their stories carefully.

The release began, "Refilling of prescriptions for dangerous drugs without specific authorization of the prescribing physician will be a violation of Federal law under the Durham Humphrey Bill which the President signed today, according to Food and Drug Administration officials. At the same time the new law makes it legally permissible for druggists to refill any prescription for a simple home remedy without securing the doctor's approval. Last year more than 389 million prescriptions, of all kinds, were filled by U.S. retail druggists." This release was a rather long one that told in detail the history of this legislation and what it requires.

There was also a companion release for retail drug trade associations and publications. This companion release was a longer one and more detailed for the information of pharmacists.

On December 21, 1951: "The Food and Drug Administration in its monthly report of convictions, released today, stated that the most severe federal penalty yet imposed for illegal sale of prescription drugs is recorded in the November court actions. Judge T. Whitfield Davidson, of the Federal court at Dallas, sentenced a local pharmacist to serve 2 years in the

penitentiary for unauthorized sales of barbituates."

It goes on to tell about a case involving narcotics and a fight amongst defendants in court that broke out during a trial. The judge finally had to continue the narcotic case because most of the defendents appeared to be in a drugged condition.

The next month we announced the conviction of a Jacksonville physician for aiding and abetting the violation of the Food and Drugs Act. He furnished a drug store with signed prescription blanks, which the pharmacist used to cover sales of sulfathiazol and penicillin to persons the doctor did not know and who were not his patients.

Then we had a release on the new bread standards. Mr. Ewing had been very interested in that and had personally reviewed the standards over a long period of time. Finally he got through and signed the regulation. The FDA did not have the authority to issue regulations at that time because it had not been delegated to the agency. Because bread was such an important product we had a fact sheet summarizing the standards in considerable detail.

We felt it was not just a matter of spot news reporting, but that we ought to produce information that would have permanent usefulness.

JHY: That meant that a great deal of effort went into preparation of some of the releases that dealt with complex questions.

WFJ: Yes, that is right. The releases were written to provide a forthright, simple kind of statement that would be readily understandable to people, not just barely enough to justify a wire service type story.

JHY: Did you write most of them yourself?

WFJ: I had difficulties in this because the information staff of the Secretary were people who had gotten into the government information business because of their media experience. They knew just about what the AP would carry on the wire. They didn't see the necessity of having to put out a release that contained any more than that. Later on this problem became more acute and for a time the only way that we could put out an adequate release on a new regulation would be to mark it for release to trade and professional journals. Then they would let us send it out to our appropriate mailing lists. We had more than 40 different mailing lists at that time, to different industries or professional groups.

Later, of course, the lawyers got into the act and we began to publish preambles to Federal regulations that explained them.

JHY: Did you write most of the press releases yourself?

WFJ: I wrote a good many of them.

JHY: What kind of staff did you have supporting you?

WFJ: Well, to begin, Mrs. Boardman wrote some of them. Then we were able to hire other people. I had a several [redacted] press

officers over the years. I'll remember their names as I go through some of these.

Here is a release that was very important. This was the announcement of the Supreme Court's decision in the Cardiff case. It is dated December 24, 1952. It begins:

"Enforceability of the factory inspection provisions of the Federal Food and Drug and Cosmetic Act was nullified by the Supreme Court in a case decided December 8th, the Food and Drug Administration of the Federal Security Agency said today in its monthly report on terminated court actions. Factory inspection is now on a voluntary basis, FDA said. There is no legal compulsion on a plant owner to admit inspectors if he does not want to. The 8-1 decision written by Justice Douglas* held that the Sections of the statue authorizing inspection 'after first making request' and providing criminal penalties for refusing to give consent, were too contradictory and uncertain to stand as criminal law. The court said that the statue as written was not 'fair warning to the factory manager that if he fails to give consent, he is a criminal'."

Commissioner Crawford was quoted, "The Supreme Court decision knocks out the enforceability of the factory inspection provisions of the Food, Drug and Cosemetic Act. By so doing, it also makes impossible enforcement of other vital

* It was Douglas, 21 years later, who wrote the 1973 "drug effectiveness" opinions expanding greatly the FDA's administrative law enforcement powers. Janssen, W. F., "Toward a New Era in Consumer Protection," FDA Consumer, Oct. 1973, p. 19.

sections of act which require evidence obtained by factory inspections." And then it goes on at some length to fully explain the situation. And because it was an emergency, I arranged for a special mailing to editorial writers and there were a lot of editorials calling for action to restore the consumer protection. I have a little scrapbook somewhere containing about 20 of those editorials.

President Eisenhower, who had just been elected, gave it top priority in his first message to Congress. He said it was imperative that they quickly restore the factory inspection powers of the food and drugs act. So Congress proceeded to consider the legislation that the FDA drafted for this purpose and in due course they got around to passing what we thought was a strong bill.

I told you yesterday about the experience we had when the bill was being debated in the House and the members were flourishing the copies of Colliers magazine that told all the important things that the inspectors did to protect the public. Well, later when they had the final debate, various members arose and qualified what their intent was in certain provisions of the bill. They said they didn't mean that the manufacturers had to open their complaint files, or their formula files or personnel records - things that were quite important. So, we found that we had won a pyrric victory because we had lost authority that we thought we had. The

amendment was passed in August 1953, and on August 27th we issued a release that we had to slug: "For release to trade and professional journals."

JHY: Didn't you really send those out to the regular wire service people as well?

WFJ: Yes, they went to the wire services as well because the wire service people had given notice to the Department that they wanted everything we put out, no matter what it was. So, this release was what I prepared after I had sized up the situation. Everybody around the FDA and in the Commissioner's office was down-at-the-mouth. We had gotten our factory inspection powers back, but they were so circumscribed, particularly in the drug area, that it seemed nothing had been gained. Congress had let us down. Members who had important drug constituents and food constitutents had yielded to the lobbyists and proceeded to construe the legislation before they enacted it, so that it could not be applied in various situations. The lobbyists had out-smarted us. The law is what Congress means, not necessarily what it says.

So, it occurred to me to produce this release, which Commissioner Crawford was glad to approve. It spelled out, first, how the FDA inspectors would proceed under the new law — serving notice, presenting their credentials, leaving reports and so on. And then it said:

> "Modern production and distribution are carried on to a large extent through the medium of written

instructions and records. The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files, within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis. Accordingly, Inspectors have been instructed to ask permission to see such records or files whenever there is any need or reason to examine them or to obtain information contained in them. The Inspector may state reasons for asking to examine a particular record or file, but will not otherwise press the owner, operator, or agent for permission to see it. The Food and Drug Administration will not attempt to predetermine what action may be appropriate in future situations which seem to necessitate inspection of records but will endeavor to resolve these problems as they arise, keeping in mind the health, safety and interest of consumers and the congressional intent in the statute, as a whole, to protect public health."

JHY: That was really... Reading it...

WFJ: We put the responsibility back on industry.

JHY: As liberally as you...

WFJ: We made lemonade out of the lemon, by putting the responsibility on industry to cooperate in any situation that affected the public health.

RPG: But that responsibility only went on the back of the ones that didn't have real smart lawyers to tell them exactly how far we went. We used to go to...

WFJ: Well, as I recall the reaction to this, the real smart lawyers and lobbyists were somewhat enraged.

RPG: I can imagine.

WFJ: But I think the real smart lawyers knew that if there were a situation that involved the public health and there was

no cooperation, their clients would be in a very serious situation.

JHY: Do you remember any situations in which the public health was involved seriously and you asked and were refused permission to see the proper records?

WFJ: I don't recall any. Another thing I think I should say, was that beside the industry lawyers, I think, there were some people in Food and Drug that were not enthusiastic about this.

JHY: About that stance, about the release?

WFJ: About this release. Yes.

Commisisoner Crawford was all for it. I had the impression at the time that Allan Rayfield was not for it. I don't know why, but I don't think he liked it. Anyway...

RPG: It left inspectors in a peculiar position, really, because to inspectors that in effect said you haven't got any right to get this information but, by gosh, we want you to try to get it.

WFJ: Yes. If we had any good reason for asking for it, we should ask. That was our feeling about it. Also I think the intention of the Commissioner was that if there was any question they could ask Washington and if there was any need to put on pressure for the voluntary submission of any kind of a record, that we could back them up. But, as was said in the release, we would not insist on it. In other words there is a

moral obligation on the manufacturer. He has a moral obligation to protect his customers and the public in case of any situation that requires it.

JHY: If there was a case and he refused and you believed there was a public obligation that he should, could you use publicity against him? Probably not.

WFJ: I think at the time we would have said "No." I think today we would view it somewhat differently. It would depend on the circumstances.

JHY: Are the laws essentially the same from the point-of-view of what you can get today?

WFJ: No, we have gotten back some of the power. The 1962 Drug Amendments gave us authority to require records on prescription drugs, especially adverse reaction reports.

FLL: The Kefauver-Harris Drug Amendments of '62 gave us some authority to look at formulas and that sort of thing in prescription drug plants, that we never had had.

WFJ: Indiscriminate prescribing of drugs was one of our most serious public health problems when I joined FDA in 1951. Penicillin was being prescribed for all sorts of things, often simply because patients demanded it. This was still going on even though reports of fatal reactions to penicillin had been appearing in medical journals as early as 1945.

There were several press releases on this. Unjustified prescribing of chloromycetin was particularly serious. Detail

men for Parke-Davis were encouraging doctors to prescribe it prophylactically for minor infections, particularly in children, even though the possible benefits did not justify the very serious risks.

FDA was on the horns of a dilemma: chloromycetin was the only really effective drug for typhoid and resistant staph infections, but it was causing a high incidence of aplastic anemia and other serious blood disorders, with fatalities in up to 50 percent of reported cases. To assess the risk, FDA did a nation-wide survey of hospitals to get case reports. Then it asked for an evaluation by the National Research Council. A medical panel was set up. Following its advice, FDA concluded that chloromycetin "should continue to be available for careful use by the medical profession in those serious and sometimes fatal diseases in which its use is necessary." Our press release went on to explain that "FDA's decision was similar in principle to one made every day by thousands of doctors who weigh the need for a potent drug against the possibility of harm to the patient."

Label changes warned that the drug should not be used indiscriminately or for minor infections, and that blood studies were necessary to monitor intermittent or prolonged use. Nevertheless, nine years later (in 1961), we still had the problem and another NRC panel came up with essentially the same recommendations, which the FDA adopted. The only difference

was that the warnings were made stronger and our medical advisors stressed the need for "continuing education of physicians in the proper use of drugs." But this, they said, "is a responsibility of the leaders of medicine and not of the Food and Drug Administration."

The chloramphenicol experience was a dramatic early example of a risk-benefit decision by the FDA. It was also one of many which caused the changes made by the 1962 drug Amendments requiring prescription drug labeling and advertising to provide full information on adverse effects, and putting prescription drug advertising under FDA control.

Indiscriminate prescribing is still a serious problem; probably it always will be, though continuing medical education is helping to reduce it. Today, fortunately, we have direct communication with prescribers through the "FDA Drug Bulletin." And, hopefully, detail men are becoming more professional in their role as medical educators.

Here is a release dated February 26, 1958 about a product called 10-Day Press-on Nail Polish. It came in the form of colored plastic strips of different sizes to stick on the nails without the mess of painting them with regular nail polish. By that time there had been about 32 million applications of the product. FDA approval, of course, was not required. It had been rushed on the market and the business expanded very rapidly. The release starts out, "Disfiguring

and sometimes painful injuries to the nails can occur to users of a new cosmetic product known as 10-Day Press-on Nail Polish. Action is being taken to get the product off the market. The company, Harrison Laboratories of New Rochelle, New York, is cooperating with the government in this effort. Dealers are being asked to immediately return unsold stocks. Users should remove the plastic coverings with extreme care to avoid peeling, splitting, or breaking off of the nails. Approximately 700 women have complained to the manufacturer and FDA of injury to their nails after using the product."

I recall very distinctly the visit I had from their attorney, a former FDA lawyer named Michael F. Markel. After reading the release in my office, he agreed that in view of the situation it was, as he said, "fair enough." We then issued it.

Before the day was over the chairman of the board of the company had repudiated it and had given the press a statement to the effect that the FDA was excited over nothing and that we had misrepresented the situtation.

The result of that was a lot of phone calls and some letters from women who had used it and thought it was great, and why were we interferring with a legitimate business?

But I remember one call from a women here in the Washington area. I said, "Well, Mrs. so-and-so, you are entitled to your opinion, and you are entitled to use this product at your

own risk, but I would like to ask just one thing: would you please give me a call if you continue to use this as you say you will. Give me a call and let me know if you have any reason to change your mind." In a few days I got the phone call and she said, "Oh, I wish I had listened to you. I have had the awfulest time with my nails; they are sluffing off and it is just terrible."

So, that is the kind of situation that we can run into in the case of a public warning. A lot of people are contrary-minded. They believe in something and they think the government is just pushing somebody around. There can be a great change of views after the experience of being injured.

I have heard there are again products of this kind on the market but apparently without the same consequences - YET.

JHY: Would you talk about press releases from the point of view of their historical validity - the value they would have to the researcher from the point of view of a document representing the agency's viewpoint on the issue covered.

WFJ: Yes, I would like to talk about that. There is a too common misconception about government press releases or "handouts" as they are sometimes called. Roughly it is to the effect that a government handout is necessarily self-serving and therefore suspect because some agency puts it out. And the press very generally has rules, editors have rules, requiring that all releases be rewritten. The wire services are

very strict about it. There is a theory or feeling that the freedom of the press and the function of the press are involved. At any rate it is a fact that the government does not have much of an opportunity to communicate with the public except through the mass media. The media have the responsibility and the last word in determining whether something is news and important enough to be passed on to the public or what should be passed on to the public.

Well, the facts about government press releases are, I think, rather different from the concept that they are merely self-serving propaganda documents of the bureaucracy. In the case of the FDA press releases, I can say without any equivocation that they are most carefully prepared to ensure truth and accuracy. To be sure they do present the facts and the views of the agency, as the agency knows the facts. They do represent the policies and views of the agency and they are thoroughly checked and there has to be concurrence by the top management of the agency and their legal advisors. For such reasons I think the FDA press releases, as contemporary records of the actions it has taken, should be considered very important historical sources, which can be relied on with a high degree of confidence.

Now, one other thing in connection with this. I recall very distinctly talking to a former Records Officer of the FDA, one who came from outside the agency. I was asking this

lady about what the FDA was doing to preserve the press releases. She astounded me, set me back on my heels as a matter of fact, by saying that a press release was not a record. She didn't think that there was any obligation on them to preserve this kind of thing because a press release was not a record. I am still in the dark about this attitude on the part of a Records Officer.

JHY: In fact, in the early days when the decimal filing system began, there was a decimal file that did preserve the press releases and for the period the teens, late teens and 20's and 30's, I have seen press releases filed in the files out at Suitland, Wally. Now I don't know about this situation later on. It is your intention to take your complete master file, which covers the years in which you were responsible for issuing these press releases, and see to it that these documents are preserved in a library, likely one of the libraries in the Food and Drug Administration. Is that not true?

WFJ: Yes, I would like to do that. I think it would be very useful for future researchers and writers of history to have hard copy on what happened during these years. We have them on microfilm, but it can be difficult to read because the quality of the microfilming has not always been good.

Here is a release issued April 1, 1958. "The Food and Drug Administration today reported an ingredient in poultry feed as the probable cause of outbreaks of a mysterious

poultry disease estimated to have taken the lives of several million birds between October 1957 and October 1958." It goes on to tell about the outbreaks in Alabama, Delaware, Georgia, Indiana, Illinois, Kentucky, Maryland, North Carolina, Ohio and Virginia. The most prominent symptom of the affected birds was the accumulation of fluid in the heart sack and the abdominal cavity, commonly referred to by poultrymen as "water-belly." The disease was attributed to a feed additive, fatty material in the poultry feed. All kinds of emergencies and problems are recorded in the FDA press releases.

JHY: Do you suppose we have a fair sample, now for the record?

WFJ: Yes, I rather think so. They certainly show what the FDA was coping with in its day-to-day activities.

JHY: They did help, along with the crises, in making the agency recognized for its day-by-day importance, in contrast with a lag of interest in the '20s, '30s and even to some degree in the '40s.

WFJ: Well, they keep the agency on the record. The electronic media, of course, is not a very satisfactory means of doing that. Print is still the best medium for a continuing record.

FLL: One of the early press releases you spoke of involved Mr. Crawford as Commissioner, and you alluded to his being foreward looking. Now, shortly after he left office, the agency started to expand greatly. Get larger appropriations

and larger staff. Was that something that Crawford instigated?

WFJ: Very much so. Before he became Commissioner, as a matter of fact, Mr. Crawford was trying to find some solution to the poverty of the Food and Drug Administration - its lack of sufficient finances and resources to do the kind of a job that needed to be done.

During World War II, Commissioner Dunbar had been very patriotic and had not even asked for any increase in appropriations to cover the cost of the war work that the FDA was doing. He had not done what other agencies of the government had done and had absorbed these costs by having the FDA discontinue some of its routine protection of the public in order to carry on the testing of drugs, and foods, for the armed services. Some food and druggers felt that had been a mistake; the FDA should have been able to expand because it was doing necessary war work.

Well, Crawford was quite aware of that. Year after year Congress would appropriate about the same amount of money that they had the year before, and yet the FDA's work load was growing. So, one of Crawford's very important ideas was that a blue ribbon committee be named to investigate the adequacy of enforcement. He sprang this on me and other people in FDA and we all concurred that it was a good idea. At that time, of course, the Eisenhower administration was appointing commit-

tees to investigate various subjects and see what should be done. They were not, by any means, going ahead and just throwing money at a problem without finding out whether there was any need to do something.

So Charlie wrote a very comprehensive memorandum to the Secretary about the financial situtation at FDA and comparing the resources, for example, of the Food and Drug Administration to insure the safety of foods in general with, for instance, the amount of money appropriated for the USDA to ensure that meat products were safe. It was a very carefully constructed letter that went to Secretary Hobby.

Well, that letter was answered by Under-Secretary Nelson Rockefeller. He went along with Crawford and this resulted in the appointment of the 1st Citizens' Advisory Committee on the Food and Drug Administration.

The committee reviewed all the activities of the agency. They hired a management consulting firm, Cresap, McCormick and Padgett, to do the staff work and to write the report, which contained about 100 different recommendations which the committee adopted. Then very fortunately Mr. Charles Wesley Dunn, who was on the committee but not the chairman, noticed that it did not contain any explicit recommendations in the way of an amount of money. It didn't set any goal. And it was Dunn who wrote in a very imporant paragraph stating that the FDA resources ought to be greatly expanded, and he sug-

gested a 3 to 4 fold increase in the amount of money and an increase in the number of inspectors to 1000.

This provided a concrete objective and Congressman John Fogarty of Rhode Island, who was on the Appropriations Committee, took that seriously. Fogarty was the Congress' expert on the programs of the HEW Department. His recommendations and leadership were accepted by the other members, and so he was instrumental in securing the beginning of increased appropriations. It was the start of some great changes.

This is related in several papers I have written, including my American Historial Association paper on "FDA Since 1938." I think it is also in a paper that I had in the 75th Anniversary issue of the FDA Consumer in June 1981.

JHY: Wasn't Nelson Rockefeller, earlier in the first years of consideration of the law that was to become the 1938 Law, a member of the public relations and publicity staff in the Department of Agriculture?

WFJ: Nelson Rockefeller? I don't know. I never heard that.

JHY: I think that is true. So he too, I believe, had an earlier reason for interest in the activities of the Food and Drug Administration.

WFJ: I recall that Milton Eisenhower had such a job. I met Mr. Rockefeller a couple of times while he was Under-Secretary. I don't remember just what the occasions were. He was a very able administrator. He knew how to go about problem solving. I came to have a high regard for his ability.

JHY: Your tenure in the Food and Drug Administration ran across one of the most important events in its whole history. That was the change in the mode of choosing the Commissioner. Mr. Larrick retired in late 1965 and instead of following the long standing procedure of naming as Commissioner someone who had grown up in the Agency, a change occurred and at the recommendation of a committee that was set up by the Secretary, a Commissioner was brought in from outside the agency, Dr. James Goddard. The "why" of this has been talked about and your conjectures and reflections would make an important addition to the consideration of this important transition.

WFJ: I am not sure how important my observations may be about this, but it is something that I was very conscious of during the time when the transition occurred and before it occurred and of course afterward. I think many people in FDA and outside it believed that the line of succession, so to speak, was going to run out. For 40 years the Food and Drug Administration had been headed by people who came up from the ranks, so to speak. It was one of the glories of the agency that it was a civil service from top to bottom and that even a new inspector could say that he had the Commissioner's "baton in his knapsack," if you want to go back to a famous remark attributed to Napoleon. Certainly Dunbar, who was a cub-chemist under Dr. Wiley, and Campbell, who was one of the first inspectors hired by Wiley, and Crawford and Larrick were all

people who had started at the bottom, so to speak. So, for all that long time the FDA had been headed by people who had learned the business from a great deal of experience before they got to be Commissioner. It had been possible for retiring Commissioners to recommend their successsors to the Secretary and see them appointed.

There was a very close call in 1954 when Larrick became Commissioner. At that time a man named Bradshaw Mintener, an attorney for Pillsbury Company in Minneapolis, had been approached by the White House to be the Commissioner of Food and Drugs.

Mr. Mintener had sparked the Minnesota write-in campaign for Eisenhower's nomination. He was a lawyer who was an expert on food and drug law and quite friendly to FDA. He had been much involved in the development of the 1938 Food and Drug Act. By present day standards, I think, Mr. Mintener would have been an excellent candidate, but Mintener thought otherwise. He advised the White House that he should not be Commissioner of Food and Drugs because he did not have the experience and expertise in the job that he thought was necessary. Knowing the agency so well he believed it should be headed by a professional in food and drug law enforcement. And he wanted George Larrick to be the Commissioner. Ultimately the thing was resolved by the appointment of George Larrick to head FDA and the designation of Mr. Mintener as an

Assistant Secretary of the Department. It was a very admirable solution because we had our expert Mr. Larrick as Commissioner and then we had a real friend in the top eschelon of the deparment who understood what FDA was all about and was able to represent us at the highest level.

Now, Larrick was Commissioner for over 10 years, before finally retiring.

FLL: It was about 11 years.

WFJ: During that time, however, there was not the same kind of triumvirate, you might say, that had existed after Mr. Campbell's retirement.

All that time, from Campbell's retirement on, it had been generally understood that after Dunbar got through, then Crawford could take over and after Crawford got through then Larrick could take over. I think it was taken for granted by the FDA people, even though they had no assurance, of course, that the department or the administration would go along on this. Also, I think, the industries felt the same way about it. They knew the views of Dunbar, Crawford and Larrick and they felt comfortable about it, and that there would be continuity. Of all things that are wanted by a businessman from a regulatory agency, even if the regulatory agency is a tough one to deal with, they prefer continuity. They like to know what to expect. Knowing what to expect, they can prepare for it, which is better than having the unexpected happen.

But when Larrick became Commissioner there was also an awareness that the Civil Service dynasty might run out. Also Larrick did not succeed in grooming anybody to be his successor, to the point where there was an acceptance of that individual, whoever it might be, as Commissioner timber.

JHY: Do you think he tried and didn't succeed or do you think he didn't try?

WFJ: I think he tried but perhaps not very hard. There were two persons who I believed might have been regarded as a successor but he didn't want them. One was Malcolm Stephens and one was John Harvey. People thought of them but I don't think Larrick felt that he could favor them. I don't know why. One he did consider at one time, according to Alice Larrick, was Winton Rankin. Larrick and I never talked about this to any extent. We did talk about it in this way - that he saw, down the road, that things were going to be different. He had a feeling that political realities and the growth of the agency, the size of the agency and soon militated against the continuation of the old system. I think he may have even believed that it would be a good idea to have some new blood from outside.

Another person who certainly would have been a very capable candidate was William Goodrich. But Bill Goodrich may have been too successful as FDA's lawyer to be acceptable to the food and drug industries. I think it is regretable. He

would have made an excellent Commissioner.

JHY: You talked about Mr. Larrick seeing change ahead with regard to the size of the agency, etc. There also was great change underway in connection with the nature of the problems with which the agency was dealing. Later on, the next Commissioner got a good deal of credit for launching a number of initiatives that dealt with these new problems, when in fact a great many of these initiatives had been begun during Mr. Larrick's tenure but had perhaps not been pushed as hard as they might have been. That is to say, some of the aftermath of the Kefauver investigation and law, ways that had been begun to look at pharmaceutical advertising. Plans that had begun to be launched to try to figure out how the efficacy provision with regard earlier drugs could be instituted. There was some sort of feeling that Mr. Larrick didn't work as hard as he might have at establishing the new machinery for the regulation of things that were involved in this great change. Do you think this is a fair criticism or...?

WFJ: I concur about the idea that there were changes in the works, at the time that Goddard arrived, and that he got credit for things started before he got there. On the other hand, there were also some serious rejections of things that were in the works when he arrived.

For instance, we had a wonderful museum ready to be opened to the public dealing with the problems of health frauds

and misinformation, and we felt it would be a great asset in the FDA's educational efforts to promote rational therapeutics. But apparently Dr. Goddard went along with his new information chief in rejecting that resource.

Later, when they decided to use the museum space for computers, we were told to get rid of the entire collection of fake medical devices and other educational exhibits, and the expensive fixtures built to display it. Gifford Hampshire, who had been my audio-visual expert, and who had designed and supervised the development of the museum, was broken-hearted. But he went to work and found a home for most of it at the St. Louis Medical Society where they already had a small medical museum. It became the major attraction of that museum until recently when the Medical Society turned over their entire collection to a new St. Louis science museum that is still under construction. I doubt that the FDA will ever again have such an exhibit. I have always felt there was something fishy about the explanation that it was "inappropriate in a building devoted to science." After all, one of the best ways to teach about science is to show what is <u>not</u> science, and to warn people against it.

We also had a roomful of quack devices and old lab equipment in the sub-basement of the Washington building that we were ordered to dispose of. I well remember the afternoon we spent packing up things that we shipped to the Districts. The

larger devices went to the Smithsonian. It was a traumatic experience, parting with these historical artifacts.

There were other things that were scrubbed because apparently they didn't like anything that was started before they got there. They wanted the appearance that the FDA had been turned around by Dr. Goddard.

JHY: Do you think the pressure of the criticism and the time it took, the magnified nature of the task that FDA faced, implementing the 1962 law and soon, coming when they did with Mr. Larrick having had periods of illness - do you think that this meant that the agency didn't push forward with the new problems as rapidly as at least some in the overall government structure and the department and the health establishment felt FDA ought to be moving?

WFJ: Well, there is no question that Larrick had prolonged periods of illness during the later part of his tenure. He was running out of gas, so to speak, he was tired. And other people in the agency were not taking over.

As to implementing the 1962 Drug Amendments, we did indeed try various ways of doing that. We called on the industry to produce their evidence of effectiveness. We got truck loads of data but it proved to be largely testimonials - not scientifically substantial evidence from controlled investigations.

I think, however, that we had to proceed as we did before we could try something else. It would be desirable to find out to what extent the Drug Effectiveness Implementation Study, the so-called DESI study, had been conceived before Dr. Goddard arrived on the scene. He is credited and perhaps deserves credit for setting the DESI machinery in motion. Goddard's oral history claims credit for recognizing that the assignment was an obvious one for the National Academy of Sciences. Whoever it was, I believe the launching of the DESI project will come to be regarded as one of the great landmarks of the history of medicine. And credit should also go to the FDA attorneys who won the court decisions that have upheld the findings and legality of the project.

RGP: Well, Mr. Janssen, you've indicated to me off the record that you have finished for the afternoon and I want to thank you very much for this recording and Dr. Young, and Fred. You know that you will receive a rough draft of it and have a chance to make some additions and corrections, as you see fit, before we make the final copy. This will be the end of the tape. Thank you very much.

Post Script

Reviewing this transcript, I recall several things I would like to add for the record.

First, I want to mention the times I was given a "detail" to handle projects for the Secretary's office. The first of these came in 1966, after I had been relieved of my duties as FDA's information director, thus making me available for other work. I was asked to determine what should be done with an incomplete collection of "fact sheets" on the activities of the different agencies of the Department. The outcome was a 374-page book: "Programs and Services, U.S. Department of Health, Education and Welfare." Its production was a unique experience. Getting some of the bureaucrats to tell in simple language what they were doing was like pulling teeth. Others cooperated wonderfully. Then came the translation job, and finally getting concurrence that the end product was accurate as well as readable.

"Programs" turned out to be a GPO best seller. At $4.00 a copy, it was a bargain to thousands who needed to know, explicitly, how the programs worked. The foreword, by Secretary John W. Gardner, was revealing:

> "The Department of Health, Education, and Welfare now operates more than two hundred separate programs to help people. Few of these programs are carried out entirely by the Federal Government. Most are partnerships which depend on the active cooperation and initiative of state and local governments, non-governmental organizations, and individual Americans.

"For these programs to produce the full benefit intended by the Congress, people must know what they are and how they can be used. That is the purpose of this volume: to provide basic information on current HEW programs to other participants in the Federal-State-local partnership."

This was what they were calling "the new Federalism."

My second detail came several years later when Congress passed the Freedom of Information Act. At that time I was asked to select and assemble the basic reference documents to be included in the Department's "Information Center." This no longer exists, the function being carried on by the separate agency information offices.

Pub. 2

Nowhere in this interview have I mentioned the work done revising and updating the FDA's "Pub. 2" - a unique publication titled "Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration." This lay language translation of the requirements for specific products was first issued in 1947. I have had a hand in supervising six revisions, beginning in 1958, the latest in 1985. A more detailed history of the publication appears in the foreword of the 1985 edition.

Consumer Consultants

On page 56 of this transcript, there is a brief mention of the Consumer Consultant Program, which I helped to establish in

1952. A more complete history of this pioneer consumer outreach program, started 10 years before President Kennedy's historic message on consumer rights, is in my "Consumer Activists" chapter (Attachment No. 3 with the transcript).

Johnson Library Papers

Finally, I should particularly call attention to the FDA history contained in the Johnson Library Papers, mentioned on page 105. When Lyndon Johnson announced his decision not to run for re-election he commanded all the Federal agencies to prepare histories of their activities during his administration. These are now on file in the Johnson Library at Austin, Texas. FDA's contribution, titled "The Food and Drug Administration during the Presidency of Lyndon Baines Johnson," actually covers both the Kennedy and Johnson Administrations -- a complex and difficult period. The White House directive included a list of topics to insure completeness of the agency reports. This was explained in greater detail in the instructions from the Department and at meetings with Ralph K. Huitt, Assistant Secretary for Legislation, who had been designated as coordinator. Otherwise, there were no constraints whatever; we were given to understand that we should write it the way we saw it. For FDA, the result was a series of papers by officials familiar with the assigned topics, prepared under my direction, and a narrative overview paper which I wrote. Several top FDA people read the final draft, including Kenneth Kirk and Winton Rankin.

President Johnson insisted that every day of his administration be covered so I also prepared a supplement, covering significant developments in November and December 1968. In this I reported on the incorporation of the FDA into the ill-advised and ill-fated "Consumer Protection and Environmental Health Service" and its impending demise as recommended by a task force of the incoming Nixon Administration.

Reproduced below are the concluding paragraphs of the Johnson papers narrative "supplement":

Questions for a New Secretary

The CPE statement of Organization, issued so near the end of President Johnson's Administration, raised important questions for the new Secretary of Health, Education, and Welfare:

Should FDA's traditional independence as a non-political law enforcement agency, responsible only to the Secretary, be restored and maintained?

Should FDA operations be centrally controlled, or decentralized in accordance with the HEW policy to "regionalize" its activities?

Should FDA planning and budgeting be from the top, down - based on the changing ideas of a succession of public health administrators, or from the bottom up - based on enacted laws, incidence of violations, program experience and known needs for consumer protection?

Should FDA continue to be managed by professionals in the food and drug field? And, if not, how could food and drug law enforcement continue to offer career opportunities in Government service?

In 1960, an "employee attitude survey" was made in FDA to provide guidance for personnel policy. If such a study had been made in 1968, it would have presented a disturbing picture. Morale was at a low ebb. More than six years of almost

continuous reorganizations had left employees confused, frustrated and uncerain concerning the future. With 500 fewer court cases in the fiscal year 1968, compared with 1967, they saw all the talk about "consumer protection" as mostly window dressing. While acknowledging the good sense of some of the organizational changes made by the new management they wanted, more than anything else, a chance to get on with their job of protecting the American consumer in the fashion set out by the law.

The regulated industries were likewise concerned about the changes which had taken place in FDA. Continuity of policy, and uniformity of enforcement are necessities of life to the management of a regulated business. The food and drug law, and its amendments, had in general been written to reflect the best practices of the industries involved. Contrary to popular belief, the most effective advocates of firm enforcement were the leaders of the regulated industries. More than once in the past, when there was a change of administration, industry leadership had stepped in to keep the FDA Commissionership out of politics. This had saved Commissioner Crawford's job in 1952 and helped to assure Commissioner Larrick's appointment in 1954.

At the end of 1968, the situation was different. The continuity of the FDA itself was at stake. When a task force of the incoming Nixon Administration examined the reorganized FDA in the 1st days of the Johnson Administration, it found cause to strongly recommend a restoration of the agency's independence.

January 6, 1969

If I were asked what single event in my 50 plus years as an observer of FDA history has had the greatest significance it could well be the Supreme Court decisions in the 1973 "drug effectiveness" cases. It was in these opinions that the Court ruled that FDA has "primary jurisdiction" in questions arising under the Federal food and drug law and that its decisions in such matters have "administrative finality." My article summarizing the opinions is included in the attachments on file with the transcript.