History

of the

U. S. Food and Drug Administration

Interviewee: David J. Miller

Interviewer: Ronald T. Ottes

Date: March 28, 1990

Place: Washington, D.C.

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

DAVID J. MILLER

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INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold and Ronald T. Ottes, retired employees of the U.S. Food and Drug Administration. The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source along with written and pictorial source materials, for present and future researchers. The tapes and transcripts will become a part of the collection of the National Library of Medicine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1,2

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

DATE: March 28, 1990 PLACE: Washington, D.C. LENGTH: 90 min

INTERVIEWEE	INTERVIEWER
NAME: David J. Miller	NAME: Ronald T. Ottes
ADDRESS: [redacted]	ADDRESS: [redacted]

FDA SERVICE DATES: FROM 1934 TO 1969 RETIRED? Yes

TITLE: Deputy Director, Division of Color and Cosmetics
(If retired, title of last FDA position)

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RO: This is another in a series of FDA oral history recordings. Today we're interviewing Mr. David J. Miller, a retired FDA official. The recording is being made in Mr. Miller's office in Washington D.C. The date is March 28, 1990. I am Ronald Ottes.

Dave, we'd like to start with a brief sketch of your background, when and where you were born, where you went to school, what brought you into the government service, and some of the positions you held during your FDA career. As we go along, it would be of value for you to recount some of the interesting assignments or cases you worked on and give us some insight into some of your bosses and some of your peers, that is if you had any peers. Dave, with that, why . . .

DM: Thanks, Ron. My name as was just mentioned is David Miller. I was born in St. Louis, Missouri, September 20, 1910. I attended the public schools in St. Louis and graduated from Washington University in St. Louis with a degree in Chemical Engineering. That was in 1931. In 1932 I went to Paris and was a student at the Sorbonne, and my most vivid recollection of that period--which I unfortunately because of a health problem had to leave in March or April of 1933--was that one of my professors was Madame Curie, who died some three years later.

RO: Dave, what were you studying at the Sorbonne?

DM: It was a program in advanced inorganic chemistry. And the radioactivity course was just one of a number of courses, but it was, to me at least, very interesting that the professor was Madame Curie.

This being right in the middle of the Depression, one can readily recognize that jobs were scarce. I had a number of part-time jobs, one with the St. Louis Public Health Department.

And my original entry into the Food and Drug Administration was a telegram inquiring if I was interested in a position as a seafood inspector. I had previously taken civil service examinations for chemical engineer and chemist with the United States government. I was interviewed, because I happened to be in Washington at that time, by Dr. Dunbar, who at that time was the deputy chief of the Food and

Drug Administration as I recall then. Campbell was the chief. I spoke both to Mr. Campbell--he was an attorney--and Dr. Dunbar. And I believe that the only reason I was accepted by Dr. Dunbar, who was very small as I am, is that I gave him a talk on the psychology of the small man. And it must have impressed him enough to be willing to accept me.

In October of 1934, after the passage of an amendment to the Food and Drug Act--the old 1906 Act was in force at that time--there were positions open for resident inspectors at each of the plants that was interested in participating in the program. That was processing shrimp. Although the general term was seafood, the only seafood then under inspection, and apparently until years later, was shrimp.

RO: Was it a voluntary program?

DM: It was a voluntary program, and the canners had to pay certain small fees--well, it's small now--it was a sum to cover the cost of the seafood inspection. In return for this particular inspection service--which meant that all shrimp was supervised from the beginning, from the catch to the unloading at the dock of the cannery, to the processing, all the way through the canning process and so on--if accepted by the inspector after viewing the processing as well as examination of the cans after processing, the manufacturer or the processor was permitted to place on the label of his product the statement (I don't remember it exactly), "Processed under supervision of the United States Food and Drug Administration."

I am reminded now as we're talking that one of the responsibilities of the inspector was to be certain that the labelling was correct, and the rules required that only a very small percentage of broken shrimp were allowed to be in a can just labeled "shrimp." And one processor to whom I as inspector told his pack was unsatisfactory because he had too many broken shrimp decided that if he had to obey the law that he would have to have another label, whereupon he labeled his product Miller's Brand Broken Shrimp. And I still have a label dating back to that time.

RO: Dave, when you came into this service were you given any kind of a training program? You surely had no experience.

DM: Yes, we had I think it was a one-day training program. It might have been one week. But what it essentially amounted to was somebody who had had experience with shrimp from the New Orleans district, or station it was called at that time, stood by the side of the shrimp boat as they unloaded and looked at the shrimp as they were being unloaded, and that was the first inspection. If they did not meet the criteria then in use, which involved principally odor and an examination of the color of the shrimp . . . Shrimp, when they decompose--at least those from Gulf Coast--will turn an orange color. And they may even be orange without an objectionable odor. But that was our criteria at that time. If they had any color at all, even a tiny spot, the shrimp were rejected forthwith. They were not allowed into the cannery, and since the shrimp boat captain had no place else to dispose of it, he had to dump it up in one of the bayous. And needless to say, initially there was considerable friction between the inspector and the shrimp boat captain.

At one time, I felt that this friction was being carried a little bit too far when I was in the middle of a plank between the boat and the dock, and suddenly the boat moved out and I fell into the water. And the only reason, I believe now, that it was accidental was because somebody did throw me a rope. And I couldn't swim, and after that I began to take some swimming lessons.

RO: Dave, were you assigned to one particular plant or did you have a number of different plants that you had to inspect?

DM: Actually, and purposefully on the part of the Food and Drug Administration who were very, very concerned that there be no favoritism and no relationship between the inspector and the canner, the inspectors were moved fairly frequently, usually about every six weeks. You didn't know where you were going. The supervisor would come driving up in the car, tell you to get packed and would go on to the next plant. Since at that time all but I think two or three of the inspectors were single, it was no big deal to do that. But for those who were married, it is possible they gave them a little more time than I know I got. At any rate, I moved twenty-seven times during a three-year period as a seafood inspector.

It's interesting in light of current concern about relationship between the Food and Drug employee and the industry how concerned the supervisors and the administration as a whole was that there be no, *no* signs of favoritism. We were told not to accept a Coca-Cola or a cup of coffee or anything from a canner. To the best of my knowledge, this was a strictly observed rule, which gave us some trouble because the canners didn't quite understand why we were so aloof when we had no tension. Hours were extremely bad sometimes, like twenty hours a day was not unusual at the height of the shrimp season.

There were, as I mentioned before, considerable times when there was conflict between the inspector and the boat captain. And there was one occasion when I condemned a whole boat load immediately, because it obviously had been held out without ice for too long, where the boat captain threatened me physically and took swings at me, but being agile enough, I didn't get hit. It also is perhaps a tribute to the underground that this episode occurred in the morning and I was sixty miles down the Mississippi River from headquarters, but that afternoon I got a call from the New Orleans station wanting to know what happened. I still have no idea how they found out.

Life was crude and there was no such thing as bathrooms or anything like that. Most of the places you stayed, they were all out in the country. Outhouses were the rule. One particular place I stayed at in a little town called Empire, Louisiana, the only place you could board was to board at a couple where the husband was an oyster tonger. I had oysters every day, three meals a day, for a month, because that was the cheapest way to feed the inspector. Prices of course were cheap. A dollar a day was the standard for room and board. Your pay was also not as high, but proportionately it was much better than, I think, nowadays.

RO: Was this pretty much supervised out of New Orleans?

DM: Yes. That was initially supervised out of New Orleans, and then later on, canneries on the East Coast, or on the Gulf of Mexico towards the East entered the program, and people like Rayfield and others who later became quite prominent in the FDA activity first came in from that area. Others went to work in the canneries

in Texas. But the majority, at least initially, worked on the Gulf Coast from New Orleans to Bayou La Batre and Gulf Port and Pascagoula and places like that.

RO: At the height of the program, do you remember how many inspectors there were?

DM: Actually, I don't. I think it was over twenty anyway. I can't remember the number of plants under inspection. For a while they considered and maybe even put into practice having one inspector for two canneries, but for the most part in the early days of the shrimp program, an inspector was on duty at one plant whenever it was open. And as I said before, since they were open when the shrimp were running, that meant that you could start to work at 2:00 in the morning and work until 10:00 p.m. that evening, and then start to work again at 2:00 in the morning and so on for a week. To compensate for that kind of overwork, when a hurricane came up, the shrimp boats couldn't get out, and so that's how I learned to play poker, because there would be as long as a week when you had no activity. So I guess it averaged itself out.

You were able to see then things which you couldn't comment on, like the poverty of the workers, probably underpaying of the cannery workers. The lowest people in the group were the so-called shrimp peelers who took the shells off the shrimp. And they were paid something like ten cents for a three-pound container of peeled shrimp, which took them about a half an hour to do.

RO: Had there been a serious health problem from eating shrmip that had caused this inspection to start?

DM: There had not been a health problem, but the New Orleans station at that time got interested in, as a result of some activity in other parts of the country, in the quality of the shrimp. They had developed procedures for detecting decomposed shrimp by actually decomposing the shrimp under controlled conditions and observing the color and the odor and so on, which was one way we were trained. As a result, the Food and Drug started to seize the packs of the canners and it got to be so bad that--remember this was again right in the middle of the Depression--the

banks would not loan the canners any money at all on the packs which they had put up, which was the usual practice. So initially it was an attempt to put the shrimp canning business on a sound financial basis, and it could only be on a sound financial basis if the quality was of a kind that the FDA would not seize it for being decomposed. So this, in my opinion, was one of the best programs where both the consumer got better quality and the packer didn't lose his business--as a number of them initially did.

RO: I think you mentioned earlier that you were with the program for about three years. Was it discontinued then, or did you just go on to other assignments?

DM: No, I went on to other assignments. At that time, it was, well, not a positive program. It was the thought of the supervisory people in the Food and Drug Administration that having had a chance to evaluate a chemist or a possible inspector while he was a seafood inspector, they would be better able to choose somebody for what we called the permanent staff of the Food and Drug Administration. So, at the end of three years I was offered a job as a bench chemist at Buffalo, New York, and accepted that.

RO: When you took this seafood inspection assignment, it was understood that the program was temporary?

DM: Yes, originally it was understood it was temporary. Actually, it lasted I guess close to twenty years before it came to a point where there was really no need for supervision. The canners learned their lesson, and there was enough supervision by the ordinary inspection procedures now in use for all foods that the canners knew better than to try to start going back to the old days of packing decomposed shrimp. There were consultants in the area who would for a fee look over the canning procedures and so on. So this was, again in my opinion, a perfect example of a program which had considerable utility, as I said before, both for the consumer and the canner initially and when it served its purpose was discontinued.

RO: Then you were assigned as a chemist in Buffalo?

DM: Yes. As I said before, you desperately wanted to get out of seafood. After all, it was sort of a dead end. So I took the opportunity that was offered and went to Buffalo, and I started off in looking at canned tomatoes or flour or food that had a history of poor sanitation, and after a couple of years of that went over to the drug area. When I first arrived at . . . I'm sorry, I said Buffalo; I meant Baltimore.

RO: Oh, Baltimore.

DM: Not Buffalo but Baltimore. When I first arrived at Baltimore the first assignment I had was in connection with the sulfanilamide situation. As you may recall, the elixir of sulfanilamide tragedy was in 1937. People were dying from the use of the ethylene glycol, I believe it was. I can't remember. At that time, part of my job was identifying qualitatively the constituents of the elixirs that had been collected by the inspectors. This was towards the tail end of it, and after that then I went over into doing a lot of sanitation and examination of foods, and then went over into doing more to the drug side of it. Then after three years at Baltimore, from 1937 to 1940, I was transferred to Buffalo, where again I did some sanitation and then went over to drug area.

At one time I don't believe I was quite as respectful of the purposes of the Food and Drug Administration as I might have been, and I remember writing a skit for one of the annual meetings in Washington, where they found an individual dead in his home. And nobody could figure out what he had died from until the Food and Drug inspector came in and looked at a can of tomatoes that was on the table and determined by a very quick examination that he had eaten tomatoes with 1 1/10 square inches of peel per pound, whereas the regulation only permitted one square inch of peel per pound. I don't think the skit went over very well, but I can still recall it after some forty years.

RO: Was there much difference in the enforcement philosophy of the management in Baltimore as compared to Buffalo?

DM: No, I don't think there was a difference in that. I always had the impression that Food and Drug was very serious about its enforcement responsibilities. I never got suspicious. I never got skeptical of our function. I was really proud I was a Food and Drugger, and I think this held for many, many years by the great majority of Food and Drug employees. Obviously, we're talking now, as I said before, forty and fifty years ago. And even then, of course, there was always a problem.

As we were chatting before this interview, I remember the situation one time when a canner of beets was making what he called "baby beets" by using a little device to scoop out small round beet balls and labelling them as baby beets, and the FDA--this was in Buffalo--took a dim view of that and seized it. I remember this because I happened to be the analyst of it, and I remember reporting that they were obviously not baby beets, and it was so obvious that I didn't think the consumer would really be mislead, except perhaps by the label. But on a glass jar, that wouldn't have meant a great deal of deception. At any rate, we seized it, and I assume--I can't remember right now--that it was condemned by the court.

The canner complained to his congressman named Taber about this. Taber, who headed up the appropriations committee of which the Food and Drug was a part, was so incensed that at one of the hearings said, "If the Food and Drug Administration has that much time to spend on things like this, they have too much money." So they reduced the budget of the Food and Drug, which at that time was around $4 million for the entire agency as I recall, to something like $3 million. And that resulted in a RIF (Reduction in Force), and the loss of employment by a certain number of employees. This was in the early forties. And the word Taber became a verb at that time as a synonym for RIF, be Taberized. If an agent said he'd been Taberized . . .

(Interruption)

DM: At least within the Food and Drug that was used as a verb, and I don't know whatever happened to it, whether it ever went into more common use or not, but it's probably something William Saffire couldn't find the origin of (Laughter) if he ever heard it.

During the period in Buffalo, obviously some cases were interesting; some analyses were interesting, some meaningful, many of them routine. You always have a memory of some of the kind of oddball ones, like one where I had examined a product called Herring Roe. It was seized because it was filthy, and the filth consisted of some entrails, perhaps some skin and so on, enough of it so that it very obviously had not really been cleaned properly. Well, I went down to where the person who canned it contested the seizure, and I went down to testify as the analyst. The judge said he wanted to see a can of this stuff. So we had a can. He opened it up. He looked at it, and he dipped his hand into the can and pulled out some of the roe, looked at it and ate it, and he said, "Boy, that tastes good. I don't see anything wrong with this stuff," and promptly found for the canner, which is not the usual kind of a case that one thinks of as a Food and Drug case.

Another case I participated in was a dog food. You must remember in those days the Food and Drug never really got somebody who went to jail, and the fines were minimal: fifty dollars, a hundred dollars, and so on. Well, I went down to testify on that case, and the judge was indignant. It happened to be low protein dog food, and it isn't something that the Food and Drug got very excited about usually, but for some reason or other this came up. But at any rate, the judge points his finger at the defendant--this was a criminal prosecution we had of the guy and he had done it before, and I guess Buffalo was getting tired of this situation--at any rate it was a criminal prosecution, and the judge pointed his finger at the defendant and said, "It's guys like you that make my dog sick." And he sentenced him to a week in jail, which was the first jail sentence that I think Buffalo had ever had. So, to give you an example of how personal some judges take these cases! (Laughter)

I was an analyst at one time on one of the cancer cures. I can't remember what the . . . I don't think it was Hoxey, but it was one of the cancer cure people. And we won the case. I don't remember what the penalty was or anything. But I felt rather happy with our winning the case, because I had at that time no idea what was in there and was able to detect by various organoleptic means as well as by chemical means what the composition of the material was, which we hadn't had before, and therefore we were able to bring enough evidence to show that that material would not cure cancer.

RO: You didn't have very sophisticated instrumentation at that time?

DM: No, we had nothing like that, nor did we have any inspection of the firm, obviously, to know what they were using.

RO: Was it Wilhelm Reich?

DM: It was a well known one. As I think about it now, it was a salve, something that you applied externally for curing cancers of the skin, I believe. Under the example of where experience is important and sometimes critical to an analyst, and in one of the tests I was making I took the material and dried it to see how much of it was solid and how much of it was volatile, and in the drying of it I detected an odor, which I said, "That's a familiar odor." I said, "That smells just like something or other that I had run an analysis on years ago." At that time, my memory being better than it is now, I was able to check for the presence of that particular substance or chemical, and it turned out to be the active ingredient of the substance.

RO: As active as the ingredient could have been.

DM: Well, actually, it wouldn't cure cancer, but it would serve in some ways for treating a breaking out of the skin or something. I don't remember what the substance is now.

From being an analyst I became the assistant to the director of the district, which involved the common duties of an assistant director at that time, which meant drawing up citation papers, presiding at hearings when somebody came in to answer a citation, serving as acting chief chemist, serving as acting director. I had the unusual experience one time, at least to me it was always amusing, of serving as acting chief chemist, because the chief chemist happened to be away at that time, and putting down the analytical conclusions of the laboratory. The next week the director was away, so I was serving as acting director and had to review the conclusion of the laboratory, which I promptly endorsed as being quite satisfactory. And then by one of the strangest coincidences was given a temporary assignment in Washington the following week where I was working for the assistant commissioner

for enforcement who looked over all the recommendations of the district, and there appearing in my box was my recommendation for action on that particular product. I can't remember what it was.

RO: You didn't happen to disapprove of it then?

DM: No, I thought that showed exemplary foresight on the part of the acting chief chemist and the acting director of Buffalo district.

RO: Do you remember who the district director was?

DM: Pappe. Theodore Pappe.

RO: P-A-P-P-E?

DM: Yes. Pappe had at one time been a chief chemist at Baltimore and then became director of Buffalo. And I still remember his sage advice--I'm not so sure what people would think now--he said, "David, more people get into trouble insisting on their rights than any other way." (Laughter) I don't guess that would go over very well nowadays, but that was his philosophy. But nevertheless, it's an example also though of how people tend to exaggerate their own importance. Mr. Pappe had a heart problem, treated it the way I'm afraid too many smokers do; when he had been told by his doctor to limit his smoking to one cigarette a day. I don't know where he got the paper, but he used to roll a cigarette that was as big as a cigar and would limit it. But Mr. Pappe died, had a heart attack one morning, carried him off to the funeral hall or the morgue that morning. The afternoon someone was sitting as his desk signing papers, getting . . . And you wonder about the . . .

RO: The overall importance of one individual.

DM: Yes, business goes on, but in a way it speaks well for the government that we are not dependent on individuals so critically that we can't do the job with other people. At any rate, I left Buffalo district, was transferred to Washington.

RO: Do you remember what year that was?

DM: In 1958, I was transferred as an assistant to the director of the Division of Field Operations, which was the division responsible for all of the operations in the field. The director of the division was Allen Rayfield. The assistant to the director for chemistry was Fred Garfield. I can't quite remember who the assistant director for inspectors was, but there was one at that time.

RO: Lennington?

DM: I think it was before Lennington. It was a different name; I can't remember exactly who it was. It might have been Frank Clark, but I'm not quite sure. At any rate I worked there for several years and then was transferred to the assistant commissioner for regulation who was Mr. Kirk at that time, Ken Kirk, who assigned me to review the comments on the regulations which had issued for color additives. This was a law that was passed in '60. Regulations of a sort were written in '61 and were promulgated not finally but a draft of the regulations was published in the Federal Register for comment. This presents an interesting comment on the procedures then in use for promulgating regulations. First of all, there was absolutely no preliminary discussion. What do we call the before the actual regulation?

(Interruption)

DM: There was no such thing as a preamble. Everybody put in their two cents worth in a memo to whomever had the final say so on approval of a regulation. But none of this was ever put into the publication itself. There was no comment on the comments to the regulation and so on. This went on for quite a while before I think it was Peter Hutt . . .

RO: That's right.

DM: . . . who originated the concept that people ought to know what was going on before a regulation was promulgated--one of the best things I think that was ever done for the Food and Drug Administration. At that time there was no such thing, and it was my job to assemble all the comments, to make comments on these comments--there were many, many comments--to propose either the acceptance of the regulation as originally drafted or to propose a change. Then, all of my comments were again circulated for comments by interested parties. By interested parties we mean both the working groups, that is people who worked in the food area and the drug area and in the color certification area, as well as those who worked in the legal area and the regulatory area. There were a fair number of people who looked at it.

RO: Was this published then in the Federal Register for comments or were these kept in the agency?

DM: No, none of this material the second time around was ever published either. To the best of my knowledge, the work that I did to assemble all the comments and to comment on the comments was available. I'm not sure anybody knew where they were. In those days--we're talking now '61 or '62; the final regulations were published in 1963--in those days everything was secret. There was no such thing as freedom of information at that time. And so while they might have been available in a file, if you knew where the file was and knew who to talk to, you might as an FDA employee review it, but I had never heard of anybody outside the FDA ever seeing them, although I don't think they were entitled to any secrecy. My comments did result in a fair number of changes in the regulations.

Probably two items were the most controversial. One of them was an original regulation which proposed that cosmetics which contained colors could of themselves be considered as color additives, because they colored the human body. This was a regulation which was promulgated both in draft form, and while I objected to it, was nevertheless promulgated in final form. It was then subject to appeal to the court, where it went first to the Supreme Court on the basis of whether it could be challenged at this particular time before it was "ripe." The Supreme Court ruled that it could be that it was ripe enough so it went back again for a decision on the

merits. A court of appeal held that the Food and Drug regulation was not an authorized interpretation of the color additive amendments. So it was deleted from the regulations. From that time on, only the color additive per se became subject to inquiry.

In the color additive per se approach, the subject of safety of course was paramount. The law required it; regulations required it, and so on. And the question of what constitutes safety obviously became very important, and equally important was the fact that the Delaney Clause--which I don't think I need explain here right now--was part of the original act and became part of the regulations. And the subject came up, where does the Delaney Clause . . . When I say the subject came up, this was a question discussed among Food and Drug employees.

RO: Dave, let me ask you though for the record just to briefly say what the Delaney Clause is.

DM: There are two aspects of the Delaney Clause. One of them deals with an ingested product, food, where the regulation says that if a color additive produces--and the word was if the color additive produces--cancer, either in man or in a test animal, that it may not be used; and it didn't say how much. The question of risk is avoided. There's another second part of the Delaney Clause that deals with products which are not ingested; in other words, cosmetics would have fallen in that class. There again, the regulation doesn't read quite the same. But essentially, if the color additive produced cancer, then it was not permitted. Now producing cancer by something which was a topical preparation didn't mean that you could only produce cancer by rubbing it on the skin. If it could produce cancer systemically and it was shown to be permeable to the skin so it did get into the system, then it was felt that the Delaney Clause applied.

Well this is the Delaney Clause. Well, initially, the question came up in the original draft of the regulations about whether or not we're talking about the color additive or about a constituent, an impurity which might produce cancer? And this is not an unexpected or unanticipated situation. Arsenic and lead are common impurities of color additives. They can produce cancer under certain circumstances. Does this mean that if it had a lead or arsenic impurity in it you couldn't approve

the color additive? My concept of the industry, too, was that Congress didn't mean that if an impurity in the color additive could produce cancer, that the color additive could not be listed. The industry said the cancer clause meant that if the color additive as a whole could produce cancer, then, only then, did the Delaney Clause apply.

And I concurred fully in industry's position. Many in the FDA did not. When I say many, I should say a number did not. But I think I was able to rewrite the regulation, which made clear that we were talking about a color additive as a whole--whether or not *it* produced cancer. Now the FDA--when I say FDA I meant George Larrick at the time, who was commissioner; and John Harvey, the deputy commissioner; and the general counsel, Bill Goodrich, and so on--all bought that at that time. Initially I was a little uncertain that we were doing right by taking it out, because I thought industry might use the fact that we didn't say anything about that impurity in a wrong way.

But I finally ended up by saying--I happen to still have my original comments--I said, "I think this section now makes clear we consider the color additive actually tested *including* any non-color components or impurities as one whose carcinogenesis we are evaluating. I do not think the section implies that if a color additive contains any impurity which is a known carcinogen, the color additive must be rejected. Division of Cosmetics interprets the section in the law to mean this, and therefore recommends we delete the words 'or any of its components or impurities,' etc." I revised the regulation to say that if the color additive *including its components or impurities induced cancer* when ingested and so on that only then does the cancer clause become in effect.

Well, strangely enough the FDA bought this at that time, and yet for many years afterwards continued to consider an impurity, particularly impurities resulting from unknown impurities in the components of the color additive reacting with each other, to be subject to the Delaney Clause even though the color additive itself did not induce cancer.

But finally--I can't remember how many years ago, ten years, a little less than ten years--in a case involving D & C Green 5 or 6, the FDA comes out forthrightably, if there is such a word, and says, "No, if the color additive itself doesn't produce cancer, we don't care if there is an impurity in there, which when it is tested by itself produces cancer, as long as the color additive as a whole . . ." And

they have used that policy, and I think correctly, since then. But to be very current, in the recent action on F D & C Red No. 3, they were not able to use any argument of that sort. They use a risk assessment, but they could not use the argument, because according to the tests the color additive itself was a carcinogen. Now they have other problems--is it a secondary carcinogen?--which don't relate to the question that was initially the subject.

RO: Dave, how reasonable do you think that this whole Delaney Clause is?

DM: Well, I don't think the Delaney Clause allows the use of sound scientific judgment. I have gone over the hearing records time and again. And at that time, 1956 and so on, the knowledge of carcinogens, how a substance became a carcinogen, was really not very well known. There were many scientists of excellent reputation who held to the one molecule theory. If you've got one molecule of a carcinogen, that's enough to produce cancer, sometime or other, maybe thirty years later, but you would sooner or later get cancer.

So it doesn't allow for the concept of risk assessment, which I think we have to allow for now in everything we have, whether it be a drug which certainly is always a risk assessment, because as a drug analyst I used to read--even though it wasn't part of the analytical process--I was interested in it enough to read whatever I could about the particular drug whether it was a USP aspirin or whether it was a complicated thyroid-type preparation, and I never knew of a drug . . .

(Interruption)

DM: . . . that didn't have an adverse reaction of some sort, and I still know of no drug that you will not find some people adversely affected. And so I think risk assessment is critical in that. It's critical I think in foods, because again, the Red 3 is again a good example of where other safety factors which make Red 3 a better color than a permitted color which has some unsafe characteristics worse than that of being a carcinogen. Because the carcinogenicity of Red 3 is, even as measured and forgetting about the secondary mechanism, the risks of it are very, very low. If I'm

going to have the color at all, if I'm going to have to take risks in using it, I would rather have one with less risks due to its being a carcinogen than one with greater risks because of other types of toxicity. My chances of dying or getting ill could be worse with the other toxicity aspects of the substance.

And we're not talking about a color only which is one of the most . . . I know of no food additive or drug which has been tested more than color additives. It's so obvious when you have a colored products. Since 1859 when Perkins first discovered the coaltar colors, there have been more studies made of colors than any other substance used in foods, drugs, or cosmetics.

Which kind of reminds me of a little story. Back in 1913 there was a chemist who on contract with the Department of Agriculture, which was then supervising the Food and Drug Administration, prepared a book listing all that was known about colors at that time. And most of the time at that time all they did was take a color and feed it to two dogs, and they would feed it for a certain number of months. If the dog got ill or died, you didn't want the color. If the dog survived and didn't seem to get ill, the color was used. And remember this is 1913, but even then there was enough of that testing going on. But I recall reading--I have a copy actually of the page--one write-up of a color showed that the color was tested with one dog for three months and they gave the results of the test; and then another dog was fed for one month, and then the rest of the months are blank. And there's a little asterisk at the one month entry. You look down at the footnote, down at the bottom of the page, and it reads, "This dog ran away," which is not the kind of comment you would see in a scientific paper these days.

RO: There's a lot of testing of colors. Is there an association doing most of the testing?

DM: Oh, yes. There are a number of groups doing testing--they used to call them the Certified Color Industry Committee; now it's called the National Color Association, something like that. I should know it; I've forgotten. The Cosmetic Toiletry and Fragrance Association (CTFA) has certainly sponsored a great number of testing. I mean financially sponsored; the testing, of course, is done by laboratories outside. The FDA did considerable testing of its own back in the fifties, prior

to 1956, probably did some of its own testing in their own laboratories, but not to any really big extent. I can't remember right now, even though I was deeply involved in the color administration.

Well, essentially, I wanted to bring in this facet because it's so important to the concept now of "Do we keep the Delaney Clause or not?" that I talked about.

RO: What do you think the prospects of the Delaney Clause being--well, it won't be scrapped entirely, but do you think it will be amended so that it will allow for some scientific judgment?

DM: Yes, I think there's enough . . . It's going to take a while, quite a while, but I think eventually there will be enough brave people willing to--I'm talking about Congress, because the FDA has brought the concept up more than once in discussions with congressmen--but more and more the understanding that there is a risk concept in everything that we'll have to do something about the Delaney Clause. I think maybe not in my lifetime, but I think it's going to eventually be amended to bring in the risk assessment, but don't look for it next week or next year.

After I did various other assignments while working for the assistant commissioner for Regulations, some troubleshooting at the various bureaus at that time. With the stabilization, let's say, of the color regulations, I was appointed a deputy director of a division called the Division of Color Additives I believe was the name of it. The responsibilities were the administration of the color additive regulations and research and review petitions for the approval of both the "coaltar-type" colors and the "noncoaltar-type" colors.

Something which was very frequently misunderstood, and still is misunderstood even today, and never been clearly understood either by industry or by the public as a whole, is a difference between the so-called certified colors and the noncertified colors. This has nothing to do whatsoever with safety. Both have to be proven safe. This establishment of safety either by actual testing with animals or by history of use or by testing of a noncoaltar-type color, that had nothing whatsoever to do with certification. Certification merely is required when it is possible for the manufacturer of the color to end up with unknown impurities or with more of an impurity than is permitted by specifications.

Now this is more likely in the organic type of colors, which are commonly called the coaltar colors, than in the others. In order to be reasonably certain that the end product will indeed conform to the established specifications--and the specifications can be very, very tough, sometimes measured in parts per million of an impurity--then the regulations require that a sample be examined by a division in the Food and Drug Administration, a scientific and analytical division. But it does not mean that a "natural" color could not be required to have certification.

For example, carotene. At one time the question came up whether beta carotene should be certified or not, and it is not now certified. Or beta apo 8 prime carotenal, which is another carotenoid, or others common in foods should be certified, because the great majority of these carotenoid colors are synthetically manufactured. We were convinced by the data supplied by the manufacturers of those where they are synthetically produced--let's say beta carotene by Roche--that they could produce consistently a beta carotene that did not have defined impurities and that there was no need for the Food and Drug to examine each batch any more than to examine each batch of every drug manufactured or every food additive manufactured and so on.

Now it turns out--and this may be fortuitous or it may be that we are living in a dream world--it turns out that at present there are no "natural" colors that are certified, no "inorganic" colors that are certified. The only ones that are certified are the old-type coaltar colors.

At one time there was considered--and my memory's vague on this time--the need for certification of a noncoaltar-type color. But the use of it was so minor that they concluded a batch that was produced--I think it might have been used in a lens color--was so minor and so small that the amount that was manufactured in order to test it would have lasted for twenty years or something. So they did test the color, but it was a question "Did it need certification?" And it was probably one of the coaltar types, now that I think about it, but the need to test it was so unimportant that I think it was exempt from certification. It's one of these rare unusual kinds of situations.

But I just want to make clear, certified colors or uncertified colors both need to be safe; both types must be listed before they are allowed to be used in foods, drugs, cosmetics or devices. And the only difference is a batch of one type must be

examined, whereas you don't have to examine batches of the other. I know even as late as this year that this question was confused with . . .

RO: What about provisional listing? You were probably involved in the division responsible for recommending whether they be listed unequivocally or provisionally listed.

DM: Well, the law is fairly explicit on what could be provisionally listed and what isn't, and essentially, what it says was you had to establish that the color additive was safe if it was going to be listed. But Congress recognized you couldn't do all this testing immediately. The testing obviously couldn't be done very quickly, right away, and some tests involved obviously two-year feeding studies, to say nothing of the results having to be looked at, slides looked and so on. But I can't say industry was exactly breaking their neck to get this done, but the Food and Drug consistently postponed what is called the closing date. A color additive is provisionally listed up to a certain date. If by that date FDA did not have enough data to come to a conclusion that it was good or bad, but that work was still in progress or contemplated or some effort was being made to eventually get around to really testing this color, then the closing date would be postponed. And so it got postponed from sometime in 1960 to '63 to '65 to '70 to '75 to '80 to '85. And the last one, Red 3, was the last one that was provisionally listed.

And yet that is not the end, because all lakes except one are still provisionally listed, which is a temporary listing. A lake is a form of color where the original color is mixed with a material which makes it more pigmentlike than it is originally. In other words, a color might be water soluble and you don't want a water soluble color, so you make an aluminum lake, it's called. And you'll make the aluminum salt of the color which is sort of absorbed on aluminum hydroxide and dried, and that will give you more of a pigment than it will of a soluble color.

Well, originally, under the old section of the regulations prior to the passage of the color additive amendments in 1958, there was a regulation dealing with lakes. It said what impurities they could have in terms of lead and arsenic and other aspects of it, and they were considered as much a regulated color as the original color, the unlaked color. But with the passage of the color additive amendments,

the Food and Drug Administration adopted the policy that they were not going to write a general regulation. And from I would say 1963 on, if my memory serves me, until the present date, no regulation has yet been written by the Food and Drug for general applicability to lakes. So all of the lakes except one still have this provisional listing. And when FDA will come around to it is still uncertain; there have been a number of occasions they have talked about it, but it's still no permanent listing.

A question came up: Should there be a lake paragraph for each color or should there be a general lake regulation applicable to all colors? Originally, I think it was the general counsel opposed the applicability of a general regulation for lakes, felt that it should be specific for each color. The only one that I know of that is specific to a color is F D & C Red No. 40, which has a specific paragraph in it about the lake. But other than that, all of the others--and we're talking not only about the so-called F D & C colors, which used to refer to use in foods, drugs, and cosmetics (not necessarily applicable now), to ingested colors called D & C colors, to externally used colors called external D & C colors--none of those currently have a regulation permanently listing a lake.

After Color Division was created (by dividing Division of Cosmetics) the divisions were recombined. It's certainly not unusual in the Food and Drug Administration to combine and separate divisions. Originally there was a Division of Cosmetics which handled colors also. Then there was a Division of Colors Additives and a Division of Cosmetics, separate divisions. Then they were put together in a Division of Cosmetics. Then they were separated again into a Division of Cosmetics and a Division of Colors. And then they were put together in a Division of Colors and Cosmetics. Then they were not separated but they essentially resulted in deputy directors on each end of them. So during my tenure, we've had them all. I ended up as deputy director of the Division of Colors and Cosmetics when at that time they had only one deputy director.

During that time I guess if I thought hard I can think of a lot of things that happened, but . . .

RO: When did you retire?

DM: I left the Food and Drug in November 1969 but have been associated with the food, drug and cosmetic industry since that time as a consultant.

RO: You left right after Dr. Goddard had been commissioner and he had left.

DM: Yes, the commissioner when I left was Dr. Herbert Ley. I may really end this interview, unless you have questions, by saying I still have the highest regard and respect for the Food and Drug Administration. I still think it is one of the best both in the operation as well as in the purpose of the organization that we have in the government. It's obviously regrettable for those of us who are old-timers to be aware of unethical conduct that has occurred in recent years. And I can honestly say in some thirty-five years with the Food and Drug Administration, I cannot recall a single instance during the period I was there when I felt that somebody was doing something that was not ethical.

RO: Dave, I have a couple questions, because you were here at a time when it marked the end really of the career ladder to the commissioner.

DM: Yes.

RO: When Larrick left and Goddard came in, a lot of the old-timers thought, "Well that's the end of the old Food and Drug Administration when you're going to start to bring outsiders in as commissioner." And of course, Goddard came in to turn things around a lot. You were in the commissioner's office.

DM: Actually, my office was right next door to Larrick's at that time. You raise a very good point there, and it illustrates what happens when we don't have a career ladder. We lose what I call and others have called institutional memory. People who have started off at a journeyman's level and have worked their way up to commissioner . . . Larrick started out that way; Dunbar started out that way. They were workers out in the field and they remembered things; they knew what were the concepts of the Food and Drug at that time. It may be that some of the policies were wrong, but at least they had a memory of them, and they knew what would have

been done before. There was a degree of continuity in philosophy and in action. I'd certainly be the last to say, "No change!" That's ridiculous. But it has resulted sometimes in having people who make decisions, policymakers, not knowing that this identical subject was discussed at length and that there were files on the subject and that it had been kicked around, and people knew why it had been rejected as a policy or why it had been accepted. And that is lost when you don't have the career ladder approach.

RO: Now the other question I had I think you've already answered, because I was going to ask you since you were in the consulting business for the last twenty years if you had a different view of the Food and Drug Administration than you did all the time that you were employed, and you told me that you still had the highest regard for it. But I'm sure in the last twenty years there have been times when you've differed with agency policy.

DM: Of course, but let's put it this way. I have never asked a Food and Drugger to give me information which I thought was confidential. What I have succeeded in doing--and this was more so obviously in the earlier days when I knew more of them--was to get information faster than I would have by writing a letter. The same information; there'd be no change in it, but a telephone call might have gotten the information that I would have had to have written a letter before.

I never asked for and never got what I thought was secret information from a Food and Drugger. I wasn't going to jeopardize my--and I think it's true of most consultants--my relationship with the organization by divulging secrets. I think it's a mistake for any consultant to try and get information that is really secret. And you're putting what used to be a friend of yours maybe on the spot by asking the question in the first place, and that's very unfair. But no, I can honestly say I'm not worried about the Food and Drug as a whole, and I'm not worried about consultants or otherwise.

RO: Well, Dave, I want to thank you an awful lot for this interview.

DM: You're welcome.

RO: You'll have an opportunity, as I said, to review this.

DM: Yes, well, this is almost two hours of talking. That makes for an awful lot of sheets of paper.

RO: Thank you.