HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Transcription of the Recording of

a Meeting to Discuss the History

of Science in the Food and Drug

Administration.

Rockville, Maryland, Dec. 7, 1979

Present:

Dr. Oral Lee Kline
Dr. Henry Fischbach
Dr. Glenn G. Slocum
Robert S. Roe
Dr. Bert J. Vos
Dr. Edwin Laug
L. L. Ramsey
Retired FDA Scientists

Fred L. Lofsvold
U. S. Food & Drug Administration

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Room 500 U.S. Customhouse
721 19th Street
Denver, Colorado 80202
303-837-4915

TAPE INDEX SHEET

CASSETTE NUMBERS 1,and 2

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

DATE: Dec. 7, 1979 PLACE: Rockville, Maryland LENGTH 102 Min.

INTERVIEWEES	INTERVIEWERS
Dr. Oral Lee Kline	Fred L. Lofsvold
Dr. Henry Fischbach	U. s. Food and Drug Admin.
Dr. Glenn G. Slocum	
Robert S. Roe	
(Also Present)	
Dr. Bert J. Vos	
Dr. Edwin Laug	
L. L. Ramsey	

All are retired scientists from the Food and Drug Administration.

CASS. NO.	SIDE NO.	EST.MIN. ON TAPE	PAGE NO.	SUBJECT
1	A	0	1	Introductory Remarks. (On the rest of side A and 5 minutes of side B, Dr. Kline discussed the history of the Vitamin Division. He later expanded and rewrote this. His paper is attached to this transcript.)
1	B	5	2	Bleached flour toxic to dogs.
		6	3	Aflatoxin Problem: Cooperation with U. K. authorities.
		13	6	FDA analytical methods research.
		20	9	FDA role in establishing identity of aflatoxin.
		22	10	Division of Microbiology role in aflatoxin work.

(cont.)

TAPE INDEX SHEET (PAGE 2)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
1	B	27	12	FDA work on decomposed food, canned salmon.
		29	13	Tomato products.
2	A	0	14	Frozen and dried eggs.
		4	16	Fishery products.
		8	18	Bacterial contamination of food, botulism in canned food.
		10	19	Crab meat.
		14	21	Staphylococcus poisoning.
		18	23	Salmonella in food.
		20	25	Botulism in marine products.
		23	26	Detecting filth in foods.
		25	27	Ballistic identification of drugs.
		28	28	Worms in tomato products.
2	B	0	29	Role of laboratory research in FDA.
		3	30	End of Recording

"Recalling Early History of Vitamin Division"
by O. L. Kline

1	Early organization and staff (ca. 1935)
2	Early analytical methods.
6	Research on Vitamin B_6.
7	Vitamin B_6 deficiency case.
11	Standards and labeling for special dietary foods.
12	FDA and NRC/NAS.
Attachment:	Curricula vitarum.

This recording is being made at the headquarters of the Food and Drug Administration in Rockville, Maryland on December 7, 1979. Present are a group of retired FDA scientists who will discuss some of the scientific achievements of the agency. Each of the participants will now introduce himself.

O. L. Kline: I served in the Food and Drug Administration in the Nutrition Division for several years.

Henry Fischbach: Completed a doctorate in chemistry at Indiana University. Joined the Food and Drug Administration September 25, 1939.

Edwin Laug: I joined the Food and Drug Administration in 1935, having graduated from the University of Pennsylvania with a Ph.D. in biochemistry.

Bert Vos: I came to the Food and Drug Administration in 1939, retired in 1970.

Robert S. Roe: I joined the Food and Drug Administration in the old Bureau of Chemistry in Chicago, September, 1925. Served in various assignments until July 1967.

Glenn G. Slocum: I joined the Food and Drug Administration as a Junior Bacteriologist in 1930 and retired as Director, Division of Microbiology at the end of 1965.

L. L. Ramsey: I joined the Food and Drug Administration as a Junior Chemist in 1942, retired in 1973 as the

Assistant Director of the Office of Compliance of the Bureau of Foods.

Fred Lofsvold: I joined the Food and Drug Administration in 1939 and I am still employed by the agency. My present assignment is Regional Director of the Denver Field Office.

Lofsvold: For a good many years the agency has been involved in vitamins and nutritional problems. As of this date they are still one of the big programs of FDA. Perhaps we should start back a way and see just where we've come from in that area. Dr. Kline would you care to kick it off?

Kline: Yes I'd be glad to. (At this point in the recording Dr. Kline talked about the work of the Vitamin Division. He later amplified these remarks in a paper entitled "Recalling Early History of FDA Vitamin Division" which is attached to this transcript.)

Roe: I don't recall the exact year, but during the period of my assignment in Los Angeles (1943-1952) I recall that a woman telephoned the office and complained about a dog food that she said was causing "running fits" in dogs. She coined the term "vitapepitis"--to designate the effects of that particular dog food. We did investigate. We found that the product was being prepared in a clean plant

using sound raw materials, including a good grade of bleached flour but the caller was persistent in her complaint. We were slow to respond because it was presented in a way that wasn't very convincing. Our own investigation did not indicate careless practices on the part of the manufacturer. Our investigator happened to be a veterinarian whose experience had been that this condition in dogs occurred from time to time from eating garbage and other questionable products. He was inclined to dismiss the idea that this product was involved. However, we sent in samples and after some delay it was found that consumption of the dog food did cause "running fits". About the time we started getting into it, the scientific literature contained a report from England indicating that a bleaching agent used in flour was the cause of this condition. The upshot then was that we reexamined our standards for flour. New hearings were held and the flour standards were revised to delete the particular bleaching agent.

Fischbach: This sort of contamination of animal feed brings to mind a problem that initially was brought to our attention by the British. About 1960 they were confronted with a serious problem. About 100,000 turkey poults had been lost in England.

Slocum: 200,000

Fischbach: Correct 200,000 turkey poults and later I believe they estimated about 1,100 or so cattle were lost. This information was brought to us through the British scientific attache here in the United States, a Dr. Hiscocks. He came to my office and arranged for a meeting with a Dr. Desmond Raymond from the Tropical Products Institute of England to discuss this problem. Dr. Raymond, indicated that they had started some work in their animal laboratories in Weybridge, outside of London. Their early work indicated that the source of the toxin was groundnut meal imported from Brazil and used as a protein supplement in feed. The British do not have an ample animal food supply and import protein feed supplements. Peanut meal is an important one.

The toxin was named aflatoxin after the organism that produces it, Aspergillus flavus. The Tropical Products Institute in London had done some preliminary work on methodology, but the known methodology was very poor at that point. There was discussion of cooperative work between England and the United States.

I think it was late in 1961 when Dr. Raymond came to our offices. Before Raymond left we discussed the problem with the Director of the Bureau of Biological and Physical Sciences, Bob Roe. Roe, Slocum, and I were convinced that

aflatoxin had serious implications. One must remember that this was a time when total FDA personnel was about 900 and the budget little more than $5,000,000. Positions were scarce. The full impact of the Food Additive Amendment was just beginning to be felt by the scientific bureau. Roe presented strong and convincing arguments to Commissioner Larrick for immediate FDA involvement in aflatoxin work. Five additional positions were assigned to the Division of Food but there was no laboratory space available in Washington, D.C. Boston District had just moved into new space and we acquired a few of the old laboratories there. In retrospect it is remarkable how quickly we became operational in the aflatoxin field.

In 1962 Dr. Slocum and I attended the first International Congress on Food Science and Technology. We had an opportunity to visit the Tropical Products Institute in London. Dr. Hiscocks was now heading the Institute and Dr. Raymond was in charge of aflatoxin methodology. We visited the Weybridge Laboratories (Ministry of Agriculture) where considerable animal toxicology and microbiological work was in progress. The microbiologists had found that only 10% of the 147 strains of A. flavus tested had produced aflatoxin. The pharmacologists and veterinarians felt that aflatoxin was toxic to most warm-blooded animals except

the sheep. Since then it has been found that even sheep, although more resistant, finally succumb. They were convinced that aflatoxin is a strong hepatocarcinogen. We came away more firmly convinced that FDA must build its expertise in the field of mycotoxins and aflatoxin in particular.

By 1964 aflatoxin was affecting international trade in peanut meal to the extent that the International Union of Pure and Applied Chemistry (IUPAC) invited me to chair the Trace Substances Commission under its Food Section. Among other obligations the commission was asked to focus on fostering and harmonizing the developing methods for aflatoxin to avert disputes in international trade.

In the meantime progress was being made in the FDA. I should hasten to say that the skills and expertness that had been developed in the FDA to cope with pesticide and antibiotic methodology came to the fore. These abilities provided the solid ground on which to build adequate methodology for aflatoxin. By '64 or '65 we had begun to acquaint our field districts with the methodology for determining the aflatoxins. This involved thin layer chromatography, another variation of paper chromatography but a more powerful tool. With this methodology the FDA began to monitor the presence of aflatoxin in peanuts.

Initially it was thought that the mold Aspergillus flavus would produce aflatoxin only at tropical temperatures and humidities. Later aflatoxin was found in temperate climates as well. By recognizing the optimum conditions under which A. flavus would produce aflatoxins we could advise changes in certain storage practices which helped materially in alleviating some of the problem. For example, in Belem, Brazil, the Brazil nuts brought down the Amazon River frequently were stored in single storied warehouses with one large door. The warehouse was filled by starting from the rear and continuing until the warehouse was full. Consequently those nuts in the rear were often exposed to the high temperatures and humidities for a considerably longer time than those in front next to the door. Higher incidence of aflatoxin was evident in those stored for the longer time at the rear of the warehouse. The recommended remedy was simple; namely, a rear door. The first nuts that went into storage now could be the first ones removed.

As complex as the pesticide residue problem is, the mycotoxin challenge presents an added dimension of difficulty. In the case of pesticides the chemical structure was generally known since man had synthesized the compound or mixture of compounds. Some methodology and some toxi-

cology was available, particularly after passage of the Pesticide Amendment of 1956. Mycotoxins are naturally occurring toxicants. The private sector generally has had no incentive to spend much effort in this area. The burden rests squarely on the regulatory scientists and those in academia. The aflatoxin problem is a good example. The FDA scientists brought to bear techniques and skills which they had developed in dealing with pesticides, antibiotics, and other problems, bacteriological means for producing high yields of toxicants, and physico-chemical skills for isolating, purifying, and assisting in characterizing the structure. Also pure material was provided for the toxicological studies.

In the early years FDA was the sole source internationally for the pure aflatoxin B_1, standard; later this obligation was taken over by the Southern Regional Laboratory of USDA. Concurrently intense analytical development within FDA, along with active cooperation with the Tropical Products Institute of London, England and the Southern Regional Laboratory of USDA led to accepted procedures for monitoring aflatoxin in food channels. The FDA exercised considerable national and international leadership in fostering and developing the analytical methodology for the aflatoxins through chairmanships and memberships on

the joint committee of the Association of Official Analytical Chemists, the American Oil Chemists Society, and the American Association of Cereal Chemists for Aflatoxin, and the Trace Substances Commission of the International Union of Pure and Applied Chemistry. In keeping with a philosophy stimulated in FDA in earlier work on antibiotics and pesticides efforts were initiated to develop multi residue techniques for mycotoxins. The ability to determine several toxicants in one analysis is uniquely suited to regulatory work.

Roe: In the work on aflatoxin, including the efforts to identify the substance, our Divisions of Food and Microbiology and others in the Bureau had prepared solutions of the material to study. At the same time M.I.T. had been working on the problem and had consulted with us. We had supplied them with some of the material that had been prepared in our laboratories which they had requested of us because ours apparently was in better shape for the purpose of the studies than what they'd been able to prepare. As a result of our collaboration and the work done by both of the laboratories, the M.I.T. people were able to identify the material ahead of our scientists, probably because they had better instrumentation equipment than we had at that time. This is not to denigrate their work, but simply to

point out that our people were in contact with other laboratories and leading universities on this problem, and we were recognized as participants, and we were able to supply the material that helped them a great deal in their studies.

Another aspect of this that is worth commenting on is the trip of Drs. Fischbach and Slocum that enabled them to visit some of the laboratories and workers in England. It was if not the first, at least among the first, international trips that we had been authorized to arrange for the scientists of the Food and Drug Administration. Since then there have been many others and this has been important in the cooperative contacts and scientific recognition that has been accorded our people at least in those years that we're talking about now.

Slocum: I think the project on aflatoxin and other mycotoxins represents an excellent sample of inter-divisional cooperative research. Our initial attempts in the Division of Microbiology were to grow and produce the toxin. I believe we started with cultures for Aspergillus flavus and Aspergillus parasiticus we got from England, from Weybridge or from the Tropical Products Institute. At any rate, we found it quite simple to sterilize peanuts with small amounts of moisture added, grow the molds on them,

and produce substantial amounts of toxin. This was expanded later to show what kinds of grains and oil seed crops would support growth and toxin formation. This showed for example that corn, rice, and several other cereal grains were excellent media, and would support growth and toxin formation. Soy beans on the other hand were very resistant and we got very little if any toxin. We also found out what conditions of time and temperature and humidity and so on were involved. But ultimately we developed a very simple medium, using commercial shredded wheat biscuits, moistening it and sterilizing it, and we could produce very large amounts of the aflatoxin. We soon developed a cooperative program where we in a pilot plant so to speak--produced as much as we could in laboratory flasks and turned it over to the Division of Food to separate out and concentrate the toxin. The pharmacologists took it and did their toxicological studies. It was this material which we produced in gram quantities that was supplied by Division of Food to Dr. Wogan at M.I.T. for his identification work.

Another aspect of it, which we were rather pleased about, was that FDA really almost from its beginnings had programs to prohibit the use of moldy food products in the human food supply of the country. Dr. B. J. Howard, back

I think not too long after FDA was formed as an operating unit, worked on his Howard Mold Count to prevent the use of rotten, moldy tomatoes from going into concentrates like catsup and paste and things of this sort. That continued to be the objective of FDA for a great many years so that all kinds of dry products such as spices and seeds of various kinds, fruits and vegetables which became moldy were excluded from the human food supply. Many times we were asked if molds were harmful. As far as we could determine from our own studies, or from the scientific literature of the world, there was very little indication that molds were harmful per se. This view changed right away when aflatoxin was shown to be definitely toxic to several of the food animals and very greatly justified the efforts that had been made to hold to an absolute minimum the amount of moldy foodstuffs going into the market.

The programs of FDA to prevent the packing or distribution of spoiled or decomposed foods has a very long regulatory history. The man I replaced as head of the Division of Microbiology, Dr. Albert C. Hunter, was trained as a specialist in fishery microbiology, joined FDA around 1918. His first assignment was to go to the West Coast; both in Alaska and in the Pacific Northwest to study the basic causes of spoilage of salmon. During the war years

literally millions and millions of cans of rotten salmon were packed, but of course, sterlized in the can. This was a major scandal in and after World War I. He and his colleagues made extensive studies of the bacterial causes of spoilage in raw salmon arriving at canneries. More particularly they correlated the signs, organoleptic if you think in terms of using the senses of odor and sight of spoilage in the raw salmon before canning with the appearance, the odors, and other changes in the salmon in the canned state. Then by examination of the canned products they could determine whether it was sound or decomposed at the time of packing. This resulted in literally dozens and dozens of massive seizures of rotten canned salmon and, perhaps hundreds of court cases in which Dr. Hunter testified for the government and became known as an expert court witness.

I mentioned earlier that Dr. Howard had used the mold count procedure which he developed to detect the use of moldy, rotten tomatoes in the processed products where it wouldn't be obvious to the naked eye as you used the product. You couldn't taste it or see it. He developed this procedure to detect the use of unfit raw tomatoes.

Later on I think beginning in the '30's, but extending certainly through the '40's and '50's a great deal of

attention was devoted to methods for the detection of decomposition of a wide variety of foods. Some of these involved very extensive cooperation between microbiologists and chemists to develop the sound indices of decomposition which could be used in case of court contest, and to support the regulatory program for removing such products from the market by seizure. Two good examples, I believe, would be the development of the frozen and dried egg industry which I think became extensive perhaps just before and during the early part of World War II. The quality of eggs broken out to produce both the frozen and dried products frequently left a great deal to be desired. Some were storage products that had been held too long to be used in the fresh market. All kinds of materials actually went into these sorts of by-products of the fresh egg industry. Two scientists, particularly Dr. M. T. Bartram with the Division of Microbiology, and Mr. Henry Lepper and his staff in the Division of Food collaborated in several sections of the country in the packing out of frozen and dried eggs where the amounts and types of spoilage were very carefully listed prior to the processing into the finished product. The direct microscopic count of bacteria which were associated with the spoilage of the decomposed eggs and the chemical indices of decomposition as

indicated by the volatile acids and perhaps other by-products of decomposition were found to be indicative of spoilage in eggs. Methods were developed for their detection. By applying both of these measures to the products in question, the Administration succeeded in eliminating a very large traffic, sometimes an underground traffic, in the use and distribution of spoiled egg products.

This approach was also employed for a wide variety canned fishery products. Spoilage of canned shrimp was extremely prevalent in the '30's and early '40's. Canned salmon I've already mentioned, represented a similar problem. Almost every variety of fish that goes into commerce and was canned so that the product is sterile in the can even though it may have been prepared from spoiled material was subjected to this kind of investigation. Where chemical indices of decomposition could be found and developed, they were applied to the control of decomposition in these products. The so-called fresh products, the unprocessed products, were controlled largely by making experimental packs by FDA chemists, microbiologists, inspectors in the field, who by participating in putting up the experimental packs--developed the signs and obvious indices of decomposition which could be applied by the

examining chemists to detect and identify lots of such products which contained decomposed material unfit for food.

The individuals who participated in the experimental packs and established the bases for detecting decomposition in turn trained field scientists who applied these tests to goods in interstate commerce, and thus applied the same index of decomposition for control of traffic in decomposed fishery products throughout the nation.

Roe: Dr. Slocum has described the background of the development of procedures for detecting decomposition in canned salmon and other products. In the field our field examiners, inspectors and some of the laboratory people went through training of that sort; that is putting up experimental packs which they then examined in order to train their organoleptic senses in evaluating samples from the market. That is they would actually go to a cannery and pick out fish from a fresh delivery, examine and view the fresh fish, watch some of that canned, and take samples of the cans. Some of the fresh fish in the delivery would be set aside and allowed to gradually spoil over a period of some days. From time to time fish would be taken, examined, and canned under supervision of the examiners. Later, samples of the canned material would be examined

organoleptically and observations related to the condition of the raw fish observed before canning. That way we trained the organoleptic examiners. This procedure also was followed by the industry examiners. In the Northwest it was the laboratory of the National Canners Association that did work for the salmon industry and other industries in that area. In their control activities for the canneries, their examiners adopted the procedures that we had developed. It often happened that a contested case in court, where we'd had a seizure of a shipment of salmon, charging it was in part decomposed, or a prosecution of the shipper of such salmon, the industry examiners would appear as witnesses for the defendant in opposition to our examiners. Well, of course, in an examination of this kind there's a leeway of judgement and there are differences between samples. The problem then is presented when the experts disagree, how's the jury going to make a decision? This is one of the reasons why our people were anxious to get some objective chemical tests, if possible, to back up the subjective organoleptic procedures. It became important in fishery products, in egg products, and in some dairy products to have available chemical assays that are reproducible to back up the expert testimony of the organoleptic examiners.

Slocum: Another aspect of decomposition which I neglected, and wanted to mention, is that when I joined FDA in 1930, we were just beginning a new decade following one which was notable for rather widespread outbreaks of botulism from commercially canned foods. They involved a variety of products, but principally canned olives and canned spinach from California, and certain other foods. The National Canners Association, which had been formed well before this period had been working diligently to develop adequate heat processes for canning foods and had already published recommended processes for use by their members for processing, especially the non-acid canned foods which are now subject to a special regulation. The canning industry was somewhat slow to adopt these recommendations and consequently for the decade of the 30's outbreaks of active microbial spoilage of a wide variety of canned foods were not uncommon; so much so that sometimes we would have thousands of cans of a particular commodity awaiting bacteriological examination. Fortunately, in that period we had no further cases of botulism from commercially canned foods; that is canned in the United States. We did have one imported product. But this was such a burden that essentially all of the microbiologists--there were only five of us at the time--had to devote pretty much full

time to canned foods. There had been a fairly substantial microbiological program in the Bureau of Chemistry from which the Food, Drug and Insecticide Administration was formed in 1927, but as far as I know the new microbiology laboratory started in 1927 with Dr. Hunter as director, and one of his colleagues from the Bureau of Chemistry. I was number five bacteriologist to come on board in July 1930.

Early in that decade, I believe 1931, possibly as late as '32, we began to have reports of outbreaks of food poisoning, sometimes fairly serious from a product highly prized on the East Coast: fresh crab meat, in which the crabs are first cooked and then the meat picked out by individual workers, packed in cans, and held under ice refrigeration until it's consumed. Now one use of the product is crab salad in which the product is not further treated or heated before it's eaten. It was this type of product which led to most of the outbreaks. Well to make a long story short, our studies of the industry showed literally horrible sanitary conditions existed in that industry. Some of the buildings weren't buildings at all, but posts holding up the roof, exposed completely to flies, vermin, dogs, cats, children, you name it. The crabs were cooked, dumped to cool before they could be handled, and many

times they were left overnight and rats had full access to them. There were many, many sources of serious contamination representing health hazards.[1]. A rather comprehensive study of plants, particularly on the East Coast in Maryland and Virginia, and later on the lower East Coast and Gulf Coast showed that we could use certain types of coliform bacteria which are found regularly in the feces of man and other warm-blooded animals as a good index of insanitary conditions of production. These bacteria could be traced directly to human misbehavior, filth from privies and things of this sort, flies, roaches, and other sources of pollution. The essential requirement was developed that this organism be absent from the fresh product as it is produced and distributed on the market ready to eat. A program of detailed sanitary inspections and microbiological testing of the product throughout the industry, first in the East Coast area, later in the Gulf Coast, and Florida, and other parts of the country where this type of product is produced, and also cooperative programs by some of the public health or Food and Drug agencies of the producing states resulted in a remarkable cleanup of that industry, and almost complete cessation of outbreaks of illness. A flare-up in the early 1940's showed a new spot

of difficulty in the Gulf Coast area which was cleaned up very rapidly. It has since been discovered a very unusual type of organism, Vibrio parahaemolyticus, which causes widespread food poisoning in Japan, actually is the causative agent, and that the methods that we were using in those days would not even detect this organism. But, nevertheless, the sanitary requirements were sufficient to eliminate the problems and prevent outbreaks of food poisoning.

Another problem of great concern to us, and you must remember that the top priority about Food and Drug regulation is protection of the public health, was concerned with a form of food poisoning caused by a rather common organism; the staphlycoccus. It was rediscovered at the University of Chicago in 1930 that this organism could produce a very severe gastrointestinal poison or enterotoxin which when eaten in susceptible food, produced very rapid symptoms of gastrointestinal illness, vomiting, diarrhea and frequently prostration. It has been said that at first you think you're going to die, then you're afraid you won't. But when it became evident on careful studies that this organism was responsible for perhaps as much as one-third of all the food-borne disease in the United States it became a primary object for our research.

A project under the direction of Dr. Ezra Casman succeeded in developing a definitive method to detect enterotoxins directly in the foods. Before this was accomplished, we could only produce indirect evidence of the involvement of staphylococcus in outbreaks. Humans are vastly more susceptible to the toxin than any other animal. Monkeys require perhaps 50 to 100 times the dose to produce gastrointestinal illness and few other animals react at all. So what we had to do was to look at the food, try to isolate the organisms, then grow them in a pure culture and produce a poison, and then try either monkey feeding, or in the case of the University of Chicago, they used human volunteers to try to reproduce the illness. But it still left us short of direct evidence that the food was responsible for illness. In some cases this resulted in tremendous losses of food supply. In one case a plant had somewhere close to six million pounds of cheese, some of which we knew was toxic, but had no way to sort out the good from the bad. So it all had to be destroyed. In the early 1960's in another episode involving toxic cheese, industry scientists trained to apply the Casman method were able to salvage more than 90% of several million pounds of good normal cheese from the bad portion. There are other episodes of the same kind where the need

for this method was extremely critical. This method now serves as the reference method for scientists all over the world for the detection and identification of staphylococcus enterotoxin.[2. 3.]

Another problem that came up about the same time, but particularly became more critical in the early 1950's was the development of good methods for the isolation of salmonella from the food supply. These organisms are another of the major causes of food-borne disease and produce from perhaps one-third to one-half of all the outbreaks and cases of food-borne illness in the country. While prior to 1950 it was felt that food produced and consumed locally was largely responsible for salmonellosis, it became evident to us from small outbreaks involving dried egg yolk in one case, dried yeast products in another, (later several other foods were implicated) that salmonellae could survive the processes applied during manufacture or could reinfect the product after processing. It was evident that the cells for salmonellae which survive in small numbers were somewhat injured by the processes and frequently could not be recovered by ordinary methods. Scientists in the Division of Microbiology made two major contributions to the improved recovery of salmonellae. Number one, Mr. William

North, developed a selective medium which was much less toxic for the injured salmonellae than other normal cells and with this new medium we were readily able to isolate the damaged strains from a variety of food products.[4] Secondly, he and his colleagues found that to isolate damaged salmonellae cells from food products, a period in which they and other organisms associated with them in the product were allowed to grow for a few hours in a good nutritional broth before they were subjected to the selective chemical procedures greatly facilitated the recovery of salmonellae.[5] His pre-enrichment procedure has been adopted everywhere for the examination of practically all kinds of dried foods and many other food products, and has made the control of salmonellae by direct microbiological examination a practical answer to the problem.

Lofsvold: That was really a piece of basic research although it was applied to a problem that we had, but it was really a fundamental change in the way of analyzing--

Slocum: That's right. He took the one test culture medium practically apart to find out what each ingredient contributed to recovery of the bacteria and found he could avoid injury to the damaged cells while retaining the ability to select the salmonellae from the other competing bacteria by adding one critical ingredient.

But when you come right down to it all we are talking about are studies designed to answer a regulatory problem, and in that sense they are certainly applied research, but some of it gets pretty fundamental. A variety of other foods including dry milk have been implicated and are now widely controlled. Products such as frozen and dried eggs are now required to be subjected to a pasteurizing process to destroy salmonellae before they are generally used in other food if shipped in interstate commerce and a variety of other regulatory actions designed to reduce the salmonellae problem have evolved.

Another case which I think shows foresight on the part of the scientists in the Division of Microbiology came about around 1960. They learned of an isolated outbreak of botulism from a sealed package of smoked fish which had been carried literally in the trunk of a car for several days prior to use. They also knew that a variety of fishery products, mainly home processed, had been involved in outbreaks caused by a relatively new type, Type E Clostridium botulinum. Only one prior case involving a commercial product had occurred to our knowledge at the time. One of the scientists, Dr. A. P. Dunnigan, said, "Let's produce a large amount of antisera and develop our methods for detection of this organism." From that start he went on

with the development of critical antiserum, which at one time was the only source of supply in the United States, and a series of methods for detection and isolation of Type E Clostridium botulinum[6].

Again, the key to a whole control program which has resulted largely in the elimination of this form of food poisoning. Another branch of the division, Microanalytical Branch, was concerned with the application of the optical microscope for the detection and identification of ingredients or foreign materials which find their way into food and drugs. A group of scientists, largely from the biological sciences, were recruited in the late '30's, and early 1940's to devise a variety of systems for the separation of contaminants resulting from rodent or insect infestation from all kinds of foods, spices, processed, unprocessed, dried, almost any class of food product. In one case back in the late '30's they actually isolated and reassembled a corn ear worm which was removed from a can of tomato products packed in one of our western states, and were able to exhibit it in a court case. These procedures were used to prevent the use of raw materials which the ordinary, prudent housewife would refuse or discard rather than put into her processed food products. They were applied individually to almost every segment of the food producing

industry, and resulted in a vast improvement in the quality of the materials manufacturers were using and putting into human food supply.

Another development in microscopic methods quite distinctive from this was the use of the histology, in the case of plant and animal tissues of the cell structures from which they are derived, or in the case of chemical substances, of their chemical properties, or their optical crystallographic indices to identify materials found in our foods and drugs. The ultimate refinement of this was that the manufacturing source of drugs was established primarily by these techniques. When drug abuse programs were first established by FDA, and underground traffic in potent drugs made it impossible through ordinary records to establish proof of interstate commerce, an expert analyst by determining the active ingredients and the other fillers or excipient materials used was characteristic of a given firm or manufacturer could prove its interstate origin. By this technique he identified the drug firm manufacturing the product in another state. By using what we called the ballistics approach, and using imperfections on tablets, and capsules, and things of that sort caused by the punches and dies used to make these objects, he was also able to establish at what plant the product was made, and thus

indirectly establish that it had obviously moved interstate commerce. By dies I mean the punches used to form tablets or dosage forms used in the manufacturing process.

Roe: When I was assigned to the San Francisco office as Assistant Chief, I recall one time when I went out to make some tomato cannery inspections. One of the East Bay canneries was in the process of making tomato catsup or tomato puree, tomato sauces of that type, and I observed that they were carefully trimming the tomatoes with respect to mold, but they were paying no attention to the worm infestation which did exist--corn ear worms. I remonstrated with the cannery superintendent and the cannery chemist, and he said, "Oh, we're getting the mold out. To hell with the worms, you can't find them when we get them all ground up." Well, he was perhaps sorry for that neglect before the year was over because our laboratories had been in the process of developing the procedure. I recall that we did have a number of seizures of shipments from that plant because of the worm contamination.

The Food and Drug Administration is primarily a law enforcement agency responsible for administration of the Federal Food, Drug and Cosmetic Act and other consumer protection statutes. However, the FDA would not be able

adequately and intelligently to carry out its responsibilities without appropriate laboratory research programs to develop methods of analysis, data to interpret results of analysis and information to enable appraisal and evaluation of petitions seeking regulations for pesticide tolerances, food additive uses, food standards, etc.

Examples:

1). Studies of the composition of foods, including seasonal and geographical variations in natural constituents; and studies to develop methods of analysis and data to enable detection and measurement of adulteration, such as the watering of fruit products or the substitution of sugar for fruit solids.

2). Studies of the decomposition of foods to identify and measure products of decomposition to provide analytical procedures for detecting spoilage, decomposition.

3). Development of methods to detect and identify contaminants in food products due to insect or other types of filth.

4). Among the important responsibilities of the Bureau of Biological and Physical Sciences was the review of pesticide and food additive petitions proposing residue

tolerances or regulations with respect to the use of such materials. This involved review of the information submitted by the petitioner with respect to the chemistry of the substances, identity of residues, analytical methods; and with respect to the toxicity data to evaluate and make judgments as to the adequacy and reliability in establishing safety of the proposed tolerances or uses.

We thought it essential that the reviewing scientists have experience and involvement in research programs in these areas to be able to adequately to appraise the reasonableness of data submitted by petitioners.

Ideally, we thought it desirable that our review scientists be engaged in research in their areas of expertise. This was not always possible. Some good research scientists were not interested in review work; others preferred the review work. Many did participate in both types of work. In any event the reviews in both the chemistry and pharmacology areas were the responsibility of Division Directors or Branch Chiefs who had immediate access to, if not actual direction of the related research activities.

Often questions would be raised by Accounts people, and Budget Bureau reviewers as to use of appropriations in research programs. Sometimes long and hard arguments were

involved in convincing critics of the appropriateness and indeed, the necessity of these types of research in this law enforcement agency.

Actually, the work done in our laboratories in development of methods of analysis, methods of appraisal and data with respect to toxicity of substances provided the scientific bases for enforcement programs.

Lofsvold: Thank you gentlemen for taking part in this recording.

FOOTNOTES

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5. Lactose Pre-enrichment of Salmonella from Dried Egg Albumin. W. R. North. Applied Microbiology 9: 188-195, 1961.

6. Problems of Isolation and Identification of C. botulimum. Glenn G. Slocum, Proceedings of a Syposium. U. S. Department of Health, Education and Welfare. Public Health Service, Publication No. 999-F.P.-1, 1964, pp. 83-88.

RECALLING EARLY HISTORY OF F.D.A.

VITAMIN DIVISION

by O. L. KLINE

I joined the FDA in 1936, coming from the University of Wisconsin, where I was awarded the Ph.D degree in 1934. I was involved there in nutrition research from 1929 to 1936, an exciting period in the discovery and identification of vitamins. Dr. E. M. Nelson, Director of the Vitamin Division of FDA, was a Ph.D from U.W., where he had worked with Dr. Harry Steenbock and Professor E. B. Hart on Vitamins A and D. He joined the FDA as head of the newly established Vitamin Division in 1930.

In 1936 the Vitamin Division was involved mainly in the testing of vitamin products in interstate commerce for their vitamin content, with Dr. C. D. Tolle in charge of the laboratory. The staff was small, and little time could be devoted to the improvement of methods for this purpose. The methods used were animal tests, and were time-consuming, but accurate. With a newly developing industry in this area, there were a number of actions taken against products that were falsely labeled.

It was obvious to us in the Vitamin Division that in a regulatory organization there was a need to have a continuing effort in improvement of the methods used for determination of the claimed ingredient of the food or drug in question. With the rapid development of information in the vitamin field, this was of particular importance.

My effort was devoted in part to the improvement of our methods, to attain greater accuracy and to reduce the time needed for a test. Our staff was enlarged gradually, so that both routine testing and methodology were dealt with effectively. Our animal laboratory was large, well-equipped, and air-conditioned, the only air-conditioned space in the large Department of Agrculture building, which housed us at that time. (During mid-summer we had many visitors "sauntering" through our air-conditioned hallway.)

The vitamins known, and available, in the 1930's were A, D, B_1, B_2, C, and E. We now know B_1 and B_2 as thiamine and riboflavin. The vitamin content in marketed products was determined by measuring growth rate of young rats during a period of 3 to 4 weeks, one group receiving a specified amount of the standard vitamin, the second an equal amount of the test product, as indicated in the labeling. In the case of vitamin D, after the test period, animals were killed, a leg bone removed and photographed,

to show amount of bone-calcification. These methods were reasonably accurate and effective, but quite time-consuming. We recognized that improvements were much needed. A part of my time from 1936-38 was devoted to various procedures that would reduce test time, and possibly improve accuracy. We acquired additional knowledgeable personnel for this purpose, and in 1938 our first publication (Kline, Tolle & Nelson,[1] appeared in the Journal of Official Agricultural Chemists (AOAC) entitled "Vitamin B_1 Assay by a rat curative procedure." The basal diet had been compounded to include the then recently described factors of the vitamin B complex. This diet, when fed to rats, produced polyneuritis in a relatively short period. The curative response to standard and test material was made in the same animal, eliminating individual variation. Also, in preparation of standard diet, devoid of B_1, we used a treatment of the diet constituents with sodium bisulfite, which destroyed completely any thiamin present in the dietary constituents.[2]

By 1941 this method was well established and accepted by the Association of Official Agricultural Chemists (AOAC). I served that organization as Associate Referee of thiamin methodology from 1938-58.

By 1942 chemical methods for thiamin had been developed for use in pharmaceutical products. As early as 1935 it

was observed by Professor Peters at Oxford University that a fluorescent compound, thiochrome, was formed when the thiamin was oxidized in alkaline solution with potassium ferricyanide. The fluorescence developed was compared with that of a standard thiochrome solution. My Associate Referee report of November 1944 reviewed the progress with use of this method, and requested the AOAC to collaborate with Dr. Fullerton Cook, of the U. S. Pharmacopoeia (USP) in a trial of the method. The results encouraged the AOAC to adopt the USP method for cereal and vegetable products.

By 1945, bacterial and yeast growth methods for thiamin had been developed. In 1947 Dr. Leo Friedman and I reviewed the several reported procedures, and pointed out the shortcomings and advantages. These were much less time consuming than animal methods and in some cases more specific than the chemical method. We stated that "for a method suitable in regulatory and control laboratories the highest degree of precision and specificity should be required." The degree of precision with the yeast-fermentation method was in a range comparable with that expected of the best animal assays.

During this period (1936-44) improved methods for riboflavin, vitamin C, and vitamin B_6 were also being put to use. Our laboratory gradually changed from an animal lab exclusively to one including biological and chemical methods.

Riboflavin determination is a case in point. We found the accepted microbiological method, measuring the growth of Lactobacillus casei, although reasonably accurate with high potency products, was unreliable with lower levels of the vitamin. We learned that careful removal of the protein and fat fractions of the test solution eliminated the non-specific growth effect.[3] This encouraged the modification of the U.S.P. method of riboflavin.

In 1947 we dealt with the frequently raised question of availability from the human intestinal tract of the vitamin content of some food products, since we were aware that some water-soluble factors are absorbed with relative ease, and eluted quantitatively only under narrowly specific conditions. We approached this problem with human subjects, measuring the urinary excretion of the water-soluble vitamin, following a precodure proposed by the Food Research Laboratories. We used five members of our staff, providing complete food intake for each for three days, collecting the urine of each and determining the vitamin content. The first day vitamin excretion served as a basal, the second day the product test, and the third day a second product test.[4]

Our diet squad was standarized and maintained, with assays conducted weekly. The reproducibility of subjects

was excellent. We worked particularly on two vitamins, thiamin and riboflavin, because of their ready adsorption on many adsorbing agents, without ready elution. Our limited experience with vitamin C and Niacin was favorable. This study was of importance in evaluating the accuracy of the biological methods then in use.

The recognition of vitamin B_{12} came somewhat later in the vitamin B group, and was not available until the late '40's. In 1951 we published a method for B_{12}[5] the result of two years study, that was adopted by the U.S.P., and later was accepted by the AOAC. It was well known that B_{12} prevented and cured pernicious anemia, and its early clinical use greatly reduced the number of pernicious anemia cases in this country.

By 1939 vitamin B_6 had been fully identified and named. There were reports in the literature describing the effects of its deficiency. In 1939 Dr. Jukes reported the occurrence of spasmodic convulsions in chicks receiving a B_6 deficient diet. Fouts and co-workers reported a similar condition in dogs, cured by the addition of B_6 to their diet. Dr. Daniel, Dr. Tolle and I reported in 1942 the results of our study of diets deficient in B_6.[6] In rats, on diets devoid of vitamin B_6, mothers had no difficulty in producing young, but failure of normal growth

in the young was observed during the lactation period, and characteristic symptoms were noted between the fifteenth and eighteenth days of age. The young were emaciated, showed tremor, uttered sharp cries, and exhibited a series of running fits, accompanied by convulsions, and in most cases, by death within a day or two. We were unaware of any previous report of characteristic symptoms of this deficiency in young rats. We further demonstrated that the condition is readily reproducible, and that pyridoxine is specific in its cure and prevention.[7]

Vitamin B_6, renamed pyridoxine, exists in three forms: Pyrodoxine, Pyridoxal, and Pyridoxamine. Our studies demonstrated that the pyridoxal form is readily destroyed by moist heat, such as that used for sterilization treatment of milk, while the other two forms are stable.

Late in 1953 FDA inspectors became aware of an outbreak of convulsions in infants 2 to 3 months old in several parts of the country.

Further investigations indicated that no remedy had been found; that there were cases of brain operations which proved futile, and that a number of deaths had been reported. The reports were sent to Washington, to the Division of Pharmacology. After a thorough study, the

cause of the infant convulsions remained unidentified. The file was sent to the Nutrition Division for review, a not uncommon procedure, and came to my desk. In reading the report I was struck by the similarity of the convulsions described with the "screaming fits" and convulsions we had seen occuring in our experiments with rats on a B_6 deficient diet. Further study of the similarities of the two conditions suggested to me that the infant convulsions were the result of a lack of vitamin B_6 in the diet of the children. The Inspectors information indicted that the milk product used in the formula fed to the convulsive infants was liquid SMA, a Wyeth product, which had sterilized at a high temperature. In our studies B_6, Pyridoxal had been destroyed at high temperatures.

I took my evaluation to Dr. Nelson who, after his usual thorough probing, discussed the matter promptly with the FDA Medical Division. Three days later Dr. Irving Kerlan of that division attended a medical meeting in Chicago, which was also attended by Dr. Charles D. May, of the University of Iowa. At the meeting, infant convulsions were widely discussed, and soon after Dr. May's return to Iowa, a case of this type was admitted to the University Hospital. Dr. May's story is best told by himself in the following excerpt from his paper in the Proceedings of the

Institute of Medicine of Chicago; Vol. 20, No. 4, April 15, 1954.

VITAMIN B_6 IN HUMAN NUTRITION: A CRITIQUE AND AN OBJECT LESSON

CHARLES D. MAY*

The Twenty-ninth Ludvic Hektoen Lecture of the Frank Billings Foundation of the Institute of Medicine. Delivered before a Joint Meeting of the Institute of Medicine of Chicago and the Chicago Pediatric Society, March 16, 1954.

Within the past year a dramatic outbreak of a singular type of convulsive seizures in babies has provided convincing evidence of an essential role for Vitamin B_6 in human nutrition under natural circumstances.[1, 2]

But it is more important that this episode be considered as a reminder of the complex interrelationships which permeate studies of nutritional factors and as a warning against hasty conclusions. It also serves as an illustration of the hazard in premature or uncontrolled application to human nutrition of isolated fragments of knowledge concerning nutritional factors.

The existence of Vitamin B_6 was discovered in 1934 by experiments with rats.[3] Symptoms of deficiency of this vitamin were soon described in several species of animals but not in man. Within a few years the chemistry of the vitamin was determined and the synthesis achieved. Considerable information as to the metabolic reactions affected by a deficiency of Vitamin B_6 was rapidly accumulated.[4] Only recently, 16 years after the discovery of Vitamin B_6, the *Council on Pharmacy and Chemistry of the American Medical Association* reviewing the status of our knowledge of the role of Vitamin B_6 in human nutrition reached only a cautious acceptance of an essential dietary requirement for Vitamin B_6 in the human.[5]

The original observations which called attention to the problem of unusual convulsions in infants and pointed the way to its solution were made by a doctor in practice,[6] just as were similar observations** which led a few years ago to an appreciation of the circumstances producing a deficiency of folic acid in infancy.[7] This should encourage practitioners to realize that close observation of their patients still permits fundamental contributions to be made without the paraphernalia of a hospital research center. It should also remind professors that conspicuous phenomena are still passing before them unseen.

The critical observations referred to were that an unusual number of infants of about 2 months of age were being brought to this doctor with a type of convulsive seizure which struck him as odd; that all were being fed the same commercially prepared modification of cow's milk; and that as soon as such an infant was given some other cow's milk formula the convulsions ceased with amazing abruptness. These observations were promptly confirmed by numerous reports which came to official agencies and to the manufacturer involved. It became apparent that some property of this one product was responsible for convulsive seizures in an alarming number of babies.

*Chairman, Department of Pediatrics, College of Medicine, State University of Iowa.

**By Dr. E. N. Nelson, Minneapolis, Minnesota.

The manufacturer disclosed that a change in the product had been made just prior to the widespread appearance of convulsions in babies fed the product. There was a natural flurry of suspicion of some toxic or infectious contaminant but none was found. Furthermore, the convulsions followed ingestion of only the liquid form of the product; a dried form of identical composition had caused no difficulties. Careful examination and study of the infants failed to reveal a cause for the seizures.

The changes in the incriminated product which had preceded this widespread appearance of convulsions was the substitution of palm oil for coconut oil in the formula, and, according to one report,[1] the liquid product was also sterilized under more vigorous conditions to assure freedom from harmful organisms.

The characteristics of the convulsions under consideration were universally recognized to be unusual. In most instances the seizures began between 6 weeks and 4 months of age and were unaccompanied by signs of infection. Neither neonatal nor rachitic forms of tetany would be expected in this age period. Quite regularly the babies were described as "nervous," "jumpy," easily "startled" by noise, or colicy and irritable. Seizures appeared abruptly with marked opisthotonus and the convulsive movements were stiff and jerky. Consciousness seemed to be lost, the seizures were brief, 2 to 3 minutes, and consciousness usually quickly recovered. Attacks varied in frequency from occasional, more often 1 to 3 daily and sometimes much more numerous. Between attacks the baby would remain "jumpy," and by the time seizures appeared, became anorexic and gained poorly. In the milder cases the change to some other formula brought an end to the symptoms either immediately or within a few days, the baby began to thrive again, and no sequelae were evident. A slight elevation of spinal fluid protein was frequent. Only a few of many such babies examined were found to have anemia. Numerous other studies customarily done in seeking a cause for seizures in this age period were regularly normal. Electroencephalographic tracings were sometimes abnormal but were not recognized as specific.

The infants had all been fed liquid SMA* from birth or shortly thereafter with little or no supplementation from solid foods or vitamin preparations (All the vitamins known to be essential were incorporated into the product during manufacture). It was finally estimated that seizures developed in about 3 per thousand babies fed exclusively on this product. No convulsions of this type were reported on similar products or other modifications of cow's milk, perhaps due to faulty observation, but certainly such seizures must have been rare.

As the magnitude of the problem became clear the manufacturers returned to the formula for SMA in use before the palm oil was substituted for coconut oil. To everyone's dismay the incidence of convulsions amongst babies fed liquid SMA continued unabated.

If one could recapture the grave concern and bewilderment which must have seized those giving thought to the problem one might more fully appre-

*Liquid-Synthetic Milk Adapted (Wyeth Co.)

ciate the astuteness of Dr. O. L. Kline of the Division of Nutrition of the U.S. Food and Drug Administration, who must receive credit for pointing out the likely cause for the development of convulsions in these infants. After a few hours scrutiny of the massive reports he concluded these infants were suffering from a deficiency of Vitamin B_6.

How could Dr. Kline arrive at this opinion with such apparent ease when for 16 years numerous attempts had failed to find unequivocal evidence that deficiency of Vitamin B_6 develops in humans under natural circumstances? Here we have another confirmation of Pasteur's maxim, "In the field of observation chance favors only the prepared minds." In 1940, Daniel, Kline, and Tolle had conducted some neat experiments to explain a deficiency of Vitamin B_6 which had been observed as an incidental finding in previous animal experiments actually arranged for another purpose.[8] With this experience as a background Dr. Kline quickly noticed the close resemblance between occurrences in young rats deficient in Vitamin B_6 and the sequence of events surrounding the advent and cure of the convulsive seizures in infants. The idea that a deficiency of Vitamin B_6 might be responsible for the seizures in infants fed liquid SMA was given substantial support from the timely report of a similar syndrome in an infant fed a synthetic diet deficient in Vitamin B_6 and shown to be cured by pyridoxine.[9]

The obvious next step was to try the effect of pyridoxine on infants with seizures from feeding liquid SMA. Just as this idea was broadcast a suitable candidate on liquid SMA, having frequent seizures daily, was admitted to the University Hospital of the State University of Iowa. No further convulsions occurred after the injection of 10 mg. of pyridoxine though the same batch of offending product was continued unchanged for several days before discharging the baby. The subsequent course on a fresh cow's milk formula was uneventful.

*Acknowledgement is gratefully given to Dr. John C. MacQueen and Dr. J. A. McArthur for compilation of this information.

In addition to laboratory testing, our division became involved in FDA Public Hearings on food standards and regulations for labeling of foods for special dietary use. The Food, Drug and Cosmetic Act of 1938 had an important effect upon food supplementation through its provisions for establishing food standards and regulations for labeling of

foods for special dietary use. The food industry moved rapidly to market a variety of foods purported to be of value, containing vitamins and minerals widely publicized as of great value for any number of human conditions.

An FDA Public Hearing, to establish a standard for white flour was held in the spring of 1940. Among other issues, testimony was offered by industry, requesting the addition of certain minerals and vitamins to flour. There was a wide discrepancy in views as to which vitamins, and the amount of each, were to be included in the standard, and the hearing recessed for several months for further study.

This was a tense period in the European phase of the war, and nutritionists were much concerned in improving the nutrition of this country. An interdepartmental committee, under Dr. M. L. Wilson, who had served as Assistant Secretary of the U. S. Department of Agriculture, was assigned the task of developing an effective program, to present to the National Nutrition Conference for Defense, held in May 1941. Of major concern to this committee was the proposed additions to flour. The National Research Council of the National Academy of Sciences called together those nutritionists most involved, to form an advisory group, which met first on November 25, 1940, to form the Committee on

Food and Nutrition. Members of this committee testified at the reconvened Flour Hearing in support of a position that Dr. E. M. Nelson, testifying for FDA, outlined at the hearing. Thus the Food and Nutrition Board of the National Academy of Sciences was born, in and of the throes of food enrichment.

Dr. Nelson was a man of courage, with a clear and forceful presentation of principles considered essential in meeting the requirement of the law that a standard "shall promote honesty and fair dealing in the interest of consumers." In developing his theory, presented to and supported by the Food and Nutrition Board, and in testifying at the Flour Hearings, he pointed out that (1) proposals to add vitamins or minerals to flour should be supported by evidence of deficiency of proposed nutrients in a substantial segment of the population; (2) addition of vitamins not established as needed should not be considered; (3) any vitamin not stable in flour during storage or in the baking process should not be added; and (4) the added quantity of nutrient should be sufficient to make an important contribution, but not exceeding the established minimum daily requirement.

On the basis of Dr. Nelson's evidence, supported by others, additions to flour of thiamin, riboflavin, niacin

and iron were justified; calcium and vitamin D were made optional. The name accepted for the product was "enriched flour". This accomplishment was of importance, as it provided the pattern of evidence needed in establishing a standard for other enriched foods.

The Board issued a statement of policy in 1941, which was reaffirmed and restated in 1953 jointly by the Board and the American Medical Association's Council on Foods and Nutrition which reads as follows:

> "(1) With carefully defined limitations, the principle of the addition of specific nutrients to certain staple foods is endorsed for the purpose of maintaining good nutrition as well as for correcting deficiencies in the diets of the general population or of significant segments of the population. The requirements for endorsement of the addition of a particular nutrient to a particular food include (a) clear indications of probable advantage from increased intake of the nutrient, (b) assurance that the food item concerned would be an effective vehicle of distribution for the nutrient to be added, and (c) evidence that such addition would not be prejudicial to the achievement of a diet good in other respects. These requirements have been met in the specific cases indicated in paragraph (6).
>
> (2) The desirability of meeting the nutritional needs of the people by the use of natural foods as far as practicable is emphasized, and to that end education in the proper choice and preparation of foods and the betterment of food production, processing, storage, and distribution as to provide more fully the essential nutrients native thereto are to be encouraged.
>
> (3) In order to avoid undue artificiality of food supply, foods chosen as vehicles for the distribution of additional nutrients should be, whenever practical, those foods which have suffered loss in refining or other processing, and the nutrients added to such foods should preferably be the kinds and quantities native to the class of foods involved.

(4) The addition of other than natural levels of nutrients to foods which are suitable vehicles of distribution may be favored when properly qualified judgment indicates that the addition will be advantageous to the public health and when other methods for effecting the desired purpose appear to be less feasible.

(5) Whenever technologic and economic developments lead to extensive reduction in the consumption of a staple food, with a consequent nutritionally significant reduction in the intake of an essential nutrient or nutrients, consideration by qualified bodies should be given to the desirability of restoring such nutrient or nutrients to the dietary.

(6) The endorsement of the following is reaffirmed: the enrichment of flour, bread, degerminated corn meal, and corn grits; the nutritive improvement of whole grain corn meal and of white rice; the retention of restoration of thiamin, niacin, and iron in processed food cereals; and the additon of viamin D to milk, of vitamin A to vegetable fats, and of iodine to table salt."

As Dr. Nelson's successor I continued to work with the Food and Nutrition Board from 1959 until my retirement from FDA. A close association of FDA with the Food and Nutrition Board has continued to the present. This committee has been most effective in resolving many issues. It established formulas for Standardized Enriched Foods that were accepted by FDA as official, and through the years has made additions and modifications where needed.

The accompanying list of publications will indicate that I have attempted to describe only the highlights of our work together. I would like to express my gratitude

to my colleagues working in the laboratory to accomplish the research that I have outlined, many of whom I have been unable to mention by name in this brief resume. It was gratifying to all of us that our Research Staff, in 1969, was given a Superior Service Award by the Department of Health, Education and Welfare.

My thirty years with FDA was a very satisfying experience.

FOOTNOTES

1. See Kline Publication List: Item 21
2. See Kline Publication List: Item 23
3. See Kline Publication List: Item 35
4. See Kline Publication List: Item 36
5. See Kline Publication List: Item 50
6. See Kline Publicaiton List: Item 31
7. B_6, first named B_4 in our Wisconsin Studies. See Publications 12-17.

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15. Further Studies on Vitamin B_4. (Abstract). Kline, O. L., Elvehjem, C. A., and Hart, E. B. Proc. Am. Chem. Soc. Meetings (Biol. Div.), Cleveland, Sept. (1934).

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BIOGRAPHICAL SKETCH

Dr. Glenn G. Slocum

Dr. Glenn G. Slocum was born in Indianola, Iowa, on February 26, 1906. He was graduated from Indianola High School and attended Simpson College in Indianola, receiving his B.A. degree in 1928 with a major in Biology. He took graduate study in Sanitary Bacteriology at Iowa State College (now University) and received his M.S. degree in 1930.

After reporting to the Food and Drug Administration as a Junior Bacteriologist in July, 1930, he pursued graduate study at George Washington University, and later at the University of Maryland, from which he received a Ph.D. degree with a major in Bacteriology and minors in Zoology and Biochemistry.

Dr. Slocum advanced through the ranks in Food and Drug Administration as a bacteriologist, specializing in work on food poisoning, food sanitation and decomposition, drug sterility, and antiseptics. He was appointed Chief of the Bacteriological Branch and Acting Chief of the Division of Microbiology in 1946, Chief of the Division in 1952, and Director of the Division in 1959.

Dr. Slocum is a member of the American Society for Microbiology, a Fellow in the American Public Health Association, the Washington Academy of Sciences, the Association of Official Agricultural Chemists, and the Institute of Food Technologists. He is a member of Sigma Xi, Beta Beta Beta and Sigma Alpha Omicron, all honorary scientific societies.

He served on AFDOUS Committee on Canned, Frozen and Prepared Foods, International Commission on Microbiological Specifications for Foods of the International Association of Microbiological Societies, Chairman U.S. Delegation to Expert Committee on Food Hygiene, Codex Alimentarius 1964 and 1965, and Sterile Products Committee of the U.S. Pharmacopoeia.

He retired from the Food and Drug Administration in 1965. Since then, he has served as a consultant to the food and drug industries, as Professional Coordinator for the International Committee on Microbiological Specifications for Foods, as a member of the Study Section on Environmental Biology and Chemistry, National Center for Urban and Industrial Health, Public Health Service, and on two Subcommittees on Food Microbiology, Food Protection Committee, Food and Nutrition Section, National Academy of Sciences.

BERT J. VOS, Ph.D., M.D.
CONSULTANT PHARMACOLOGIST
P.O. Box 569
McLean, Virginia 22101
(703) 356-7765

Biographical Sketch

Born - Sept. 18, 1908, Bloomington, Indiana

A.B. (Chemistry), Indiana University, 1930
Ph.D. (Physiological Chemistry & Pharmacology), University of Chicago, 1934
M.D., Rush Medical College, University of Chicago, 1937

Intern, University of Chicago Clinics, 1938
Instructor in Pharmacology, University of Chicago, 1939
Pharmacologist and later Deputy Director, Division of Pharmacology, U.S. Food and Drug Administration, 1939 to 1964
Director, Division of Toxicological Evaluation, U.S. Food and Drug Administration, 1964 to 1968
Deputy Director, Division of Pharmacology and Toxicology, U.S. Food and Drug Administration, 1968 to 1969
Deputy Director, Division of Toxicology, U.S. Food and Drug Administration, 1969 until retirement in July 1970
Acting Director, Division of Pathology, U.S. Food and Drug Administration, May 1970 until retirement in July 1970
Consultant Pharmacologist, 1970 to present

Fields of Interest: Toxicity Evaluation, Statistics, Biological Assay

Publications: 20 articles in the fields of pharmacology and biochemistry
Licensure: Licensed to practice medicine in Virginia

Membership in Scientific Societies:
American Society for Pharmacology and Experimental Therapeutics
Society for Experimental Biology and Medicine
Sigma Xi
American Association for the Advancement of Science

Membership in Honor Societies:
Phi Beta Kappa
Phi Lambda Upsilon

Awards: Superior Service Award (1959) and Distinguished Service Award (1963) from the Department of Health, Education, and Welfare

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41. Chapter on Vitamins. Kline, O. L. Remington's "Practice of Pharmacy". IX ed., Mack Publishing Co., Phila., (1948). Later education included, see #70.

42. Report on Thiamine. Kline, O. L. J. A.O.A.C., 31, 455 (1948).

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65. A Rapid Determination of the Relative Purity of Vitamin B_{12}. (Cyanocobalamin) in Pharmaceutical Products. Bruening, C. F., Hall, W. L., and Kline, O.L. J. Am. Pharm. Ass., Sci. Ed., XLVII, 15 (1958).

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72. A Folic Acid Method Involving Permanganate Oxidation. Schiaffino, S. S., Webb, J. M., Loy, H. W., and Kline, O. L. J. of the Am. Pharm. Assn., Scientific Ed., Vol. XLVIII, No. 4, April, 1959.

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78. Nutrition is a Problem of Ecology, edited by Paul Gyorgy and O. L. Kline. Publ. by S. Karger, Basel; 224 pp. (See separate book).

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80. White House Conference on Food, Nutrition and Health, Follow-Up Meeting (at Williamsburg) by O. L. Kline.

O. L. KLINE

Curriculum Vitae

1905:	Born in Reynolds, Indiana -- September 12
1925:	Entered the University of Wisconsin
	B.S. 1929, M.S. 1931, Ph.D. 1934
	Staff member at UW in Biochemistry 1934-36
1936:	Elected to membership in American Institute of Nutrition
	Joined staff of FDA's Vitamin Division in Washington
1947-58:	Director of Research for Vitamin Division, FDA.
1949:	Chr. of Society for Experimental Biology and Medicine
1952:	Chr. Animal Nutrition Research Council
1955:	Elected Treasurer of AIN - twice re-elected
1950-58:	Referee for AOAC on Nutritional Adjuncts
1956:	Recipient of Distinguished Service Award, HEW
1958:	Editorial Board of Journal of Nutrition
1958:	Director of Food Division, FDA
1959-62:	Director of FDA's Nutrition Division (formerly Vitamin)
1960:	Member of Organizing Committee for 5th International Congress on Nutrition, held in Washington, D.C.
1962:	Spent month of May in Amman, as Consultant to the Jordan government in re the organization of food and drug control
1962-66:	Appointed Assistant Commissioner for Science in FDA
1962:	Listed in Who's Who in America
1965:	President of AIN
1965-66:	Visiting Professor in Nutrition at Michigan State U.

(continued)

1966-71: Organized the Office of Science Services for AIN, with an office at Beaumont House at FASEB headquarters

1968: Member of IUNS Working Commission II, which met at Rockefeller Center in Bellagio, Italy

1968-69: Consultant to Dr. Jean Mayer, in setting up the organization for THE WHITE HOUSE CONFERENCE ON FOOD, NUTRITION, AND HEALTH

1969: Chairman of IUNS meeting in Belgrade, Yugoslavia, prior to the International Congress on Nutrition in Prague

1969: As member of Institute of Food Technology, served on committee for organizing their International Congress in Washington, D.C.

1971: The Conrad Elvehjem Award for Public Service in Nutrition was awarded to him by AIN

1971: Member of IUNS working commission meeting in Tunis

1971-76: Executive Officer for AIN at FASEB Headquarters in Washington

1972: Member of IUNS Working Commission in Washington, D.C. prior to International Congress on Nutrition in Mexico City

1976-78: Executive Officer for National Nutrition Consortium

1978: AIN elected him a Fellow -- an honor reserved for older members

1978: (con) Member of Committee for arranging the McCollum Centennial Celebration in Washington, D.C. at the National Academy of Science, and arranging for a series of Memorial Lectures in his name

(continued)

Additionally, he was a member of the National Research Committee Advisory on Nutrition to the Quartermaster.

For a long period of years, he was invited by the American Academy of Pediatrics to attend its meetings as a consultant.

He was on an advisory Committee for:

National Academy Science, National Research Council & U.S. Pharmacopeia and the National Formulary

Further organizations in which he had membership:

ACS

AAAS

American Public Health Association

Society for Nutrition Education

Cosmos Club of Washington

CURRICULUM VITAE:

EDWIN P. LAUG, Pharmacologist

Background: Ph.D., Biochemistry, University of Pennsylvania, 1930.

Tenure with FDA: 1935 - 1965

At the organization of a new Division of Pharmacology in 1935, I was appointed Assistant Pharmacologist to do research on the toxicology of lead: Such studies to give scientific support for setting tolerances for lead (and also arsenic) in fruits sprayed with lead arsenate.

At time of retirement, I was Chief Special Investigations Branch, Division of Pharmacology. I published 64 papers in technical Journals on methodology and basic research to give support for the setting of tolerances for toxic substances in foods and drugs. Broadly, these studies concentrated on three general areas of toxicology.

(1) The heavy metals, such as lead, mercury, arsenic, etc.

(2) The organic insecticides, such as DDT, Lindane, Aldrine, Dieldrin, etc.

(3) Impact of radioactive contamination of foods, following the atmospheric release of radioactive substance in connection with the testing of atomic bombs.

RESUMÉ

ROBERT S. ROE

Date of Birth: March 7, 1902

Place of Birth: Denver, Colorado

Education: Denver Public Schools
University of Denver - A.B. 1924
Major - Chemistry
Minors - Math, Philosophy
University of Chicago - part time, 1926-1929
19 Semester Hours Graduate Credit in Chemistry and Bacteriology

Professional Experience:

1923-1925 - McPhee & McGinnity Company, Denver, Colorado
Plant Control Chemist (Paint Factory)

September 15, 1925 - July 15, 1967, Food and Drug Administration as Chemist and Administrative Officer:

9/15/25 - 6/30/30, Chicago Station
Analytical Chemist - 2 years food
2 years drug
1 year Acting Bacteriologist

7/ 1/30 - 3/15/34, Washington, D.C.
Assistant to Chief, Import Supervision

March 1934 - May 1937, Assistant Chief, San Francisco Station

May 1937 - June 1943, Chief, Seattle Station

July 1943 - August 1952, Chief, Los Angeles District

August 1952 - October 1954, Washington D.C.
Director, Division of Program Research

October 1954 - June 1956, Washington, D.C.
Associate Commissioner of Food and Drugs

June 1956 - January 1965, Washington, D.C.
Director, Bureau of Biological and Physical Sciences

January 1965 - November 1966, Washington, D.C.
Director, Bureau of Scientific Standards and Evaluation

November 1966 - July 1967, Washington, D.C.
Associate Director, Bureau of Science