HISTORY OF THE U. S. FOOD AND DRUG ADMINISTRATION

Interview between:
William Horwitz, Ph.D.
Director, Scientific Policy Staff
Center for Food Safety and
Applied Nutrition
and
Fred L. Lofsvold
U.S. Food & Drug Administration
Washington, D. C.
July 25, 1983

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 NUMBER(S) 1,2,&3

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

DATE: July 25, 1983 PLACE: Washington, D.C. LENGTH: 105 minutes

INTERVIEWEE	INTERVIEWER
NAME: William Horwitz, Ph.D.	NAME: Fred L. Lofsvold
ADDRESS: U.S. Food & Drug Admin.	ADDRESS: U. S. Food & Drug Admin.
Washington, D.C.	Denver, Colorado

FDA SERVICE DATES: FROM 1939 TO: Present RETIRED? No

TITLE: Director, Scientific Policy Staff, Center for Food Safety and Applied Nutrition
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
Because of a faulty tape this portion was not recorded.			1	Dr. Horwitz's education.
			2	How he came to FDA.
1	A	0	3	Lloyd Mitchell and staff at Minneapolis.
		2	4	Analytical work at Minneapolis.
		3	5	C. W. Harrison
		9	7	Filth analysis
		19	8	Training for new analysts.
		17	10	Horwitz's early AOAC work.
		23	15	Dr. Horwitz as Chief Chemist at Minneapolis.
		24	15	Lloyd Mitchell's early chromatographic work.
		25	17	Whitefish work at Minneapolis.
		26	18	Heinie Lepper
		28	19	Horwitz's experience as court witness.
		29	20	Transfer to Washington to understudy Lepper.
1	B	0	20	Research on decomposed eggs.
		2	21	Training frozen egg examiners.
		5	23	Decomposed fish and cream work.
		9	24	Taste testing of coffee.
		11	25	Taste testing by the "Liars Club."
		13	26	Lepper as section editor for chemical abstracts.
		22	30	J. Kenneth Kirk
		25	31	Training of field Chief Chemists.

1	B	27	32	Present work on sensitivity of analytical methods.
		29	33	Early FDA efforts to develop computerized FDA information system (1961).
2	A	0	35	Goddard reorganization.
		2	36	Opinion on reorganization in FDA.
		5	37	Horwitz as Secretary of AOAC.
		11	40	History of AOAC (centennial publication).
		13	41	FDA-AOAC relations.
		15	42	Changes in analytical chemistry 1939-1984.
		18	43	Importance of the AOAC analytical methods.
		26	51	FDA and Codex Alimentarius.
2	B	0	53	FDA and Codex Alimentarius (continued).
		4	55	Commissioner Paul B. Dunbar.
		7	56	Commissioner Charles W. Crawford.
		10	57	Opinions about other top managers in FDA.

Attachments:

Henry A. Lepper obituary
Horwitz resume
The Great Collaboration, Kenneth Helfrich, 1984

This oral history recording is one of a series on the history of the Food and Drug Administration. Today we are interviewing Dr. William Horwitz of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration in his office at 200 C Street S.W., Washington, DC, July 25, 1984. The Interviewer is Fred Lofsvold.

FL: Would you please give me an oral curriculum vitae: When and where you were born, educated, and how you came to the Food and Drug Administration.

WH: I was born in Gilbert, Minnesota, a small town on the iron range and educated in the Duluth Public Schools. I attended the Duluth Junior College for 2 years, obtained a scholarship to the University of Chicago, and completed my work for a Bachelor of Science Degree in Chemistry in the subsequent 4 quarters, graduating in the summer of 1937. That time period was the basis for a rumor which circulated in the Food and Drug Administration that I obtained my Bachelor of Science Degree at the University of Chicago in only 1 year. That was technically true, but misleading.

FL: You and Harvey Wiley.

WH: When I was ready to graduate I went to the head of the Chemistry Department at the University of Chicago, Dr. Schlesinger, and indicated that I would like to look for a

job and did he know of any. He reviewed my courses which, at that time (in the Hutchins era), only required physical and organic chemistry past analytical chemistry for graduation. He handed me back my transcript with the exclamation, "You're not a chemist yet!" As a result of that traumatic interview, I enrolled in the graduate school of the University of Minnesota for further training. I received a Master of Science Degree in physical chemistry in 1938, with a minor in agricultural biochemistry, and I continued my studies toward a Ph.D. Concurrently, I took the junior chemist Civil Service examination. In those days it was a very long exam covering inorganic chemistry, analytical chemistry, organic chemistry, and physical chemistry. In the summer of 1939 I was called in for an interview at the Minneapolis Station of the Food and Drug Administration. FDA at that time was expanding its activities as a result of the passage of the 1938 Act. The only thing I remember about that interview was the question which J. O. Clarke (Chief of Central District) asked, knowing that I was applying for a chemist job. "Why do you want to be an FDA Inspector? I don't know whether I answered it to the effect that I would make a good or a bad inspector, but the answer apparently was sufficiently impressive to be hired as a chemist and to report for duty on September 11, 1939. As I recall, Dan Banes and quite a few other Food and Drug people, who have subsequently retired, were in the same class. At

Minneapolis, Ralph Weber reported at approximately the same time, but as an Inspector. When I was hired, I had completed all of the course requirements for the Ph.D. Degree, with only a thesis left to do.

One of the most fortunate things that occurred to me was having the opportunity of working under Lloyd Mitchell. He was a superb laboratory operator. His technique was absolutely flawless in weighing, transferring, pipeting, filtering, and all the other fundamental operations of analytical chemistry. Lloyd Mitchell was also a devout Catholic and he would get up very early every morning, as early as 5:00 a.m., and walk to the Minneapolis Cathedral in time to attend mass and then walk down to the laboratory in time to open it up. He only drank distilled water and he had his own beaker next to the distilled water bottle and made periodic trips to supply himself with this beverage. Shortly after I reported for duty, Sam Perlmutter and George Keppel were transferred to Minneapolis. I believe both of them came from New Orleans. At the end of 1939 the entire laboratory crew of the Minneapolis station consisted of Lloyd Mitchell as the Chief Chemist, Al Hansen as a veteran drug chemist, a Mr. Snyder, later who went to GSA as an experienced chemist, then Keppel, Perlutter, and I, with me being the junior chemist. George Keppel died in March, 1984.

The station had a very efficient system for keeping the laboratory supplied with work. One of the freight yards was directly across the street from the federal office building, and whenever the inspectors didn't have anything else to do, or Mitchell indicated that the laboratory could use a little more work, an inspector was sent over to the freight yard to look for some cars of butter which came through Minneapolis. Usually, there were any number of cars to select from. The laboratory became very proficient in butter analysis for composition, and later for filth. We had some very large sinks which were partially filled with warm water and the butter samples in Mason jars were placed in the sinks to liquify. The next step, usually performed by a laboratory helper, was to shake them to homogeneity and keep them homogeneous until the two gram portion was weighed out for moisture, salt and curd determinations. We developed a very efficient operation with each of us having our own set of weighed and numbered moisture dishes, whose weight remained constant, and a set of weighed and numbered gooch crucibles, which were retained and rewashed after every use. We only ran salt and curd when the moisture was more than a certain amount, so the moisture value did a substantial amount of screening. Having the weight of our equipment available moved the analysis along very rapidly, particularly when you had to use a two-pan balance, although we did use a single swing method for weighing. Usually you

could analyze about 30 samples a day, but if necessary we did as many as 50 a day. We had the analyses down so pat that we could interpret the results ourselves, in that whenever we found a sample that contained less than a certain amount of fat, as I recall, 79.65, we always turned it over to another analyst automatically for a check analyses, without even consulting the Chief Chemist.

One of the few things I remember about C. W. Harrison, the Chief of the station, was that he immediately let you know that he was a descendant of President Harrison. He gave me my first important lesson in interpretation of analyses. I had made a rather lengthy analysis of sugared and salted yolks for adulteration, where you have to run the protein, solids, fat, salt, and sugar, and then calculate your eggs to a sugar-free salt-free basis. One day early in my career, Mr. Harrison, who came up the ranks as a chemist, called me in and complimented me for having done such an analysis so early in my training, but he said, "Did you ever stop to add up what you found?" I said, "No, this wasn't called for in the method." He said that summing an analysis was always a good idea. He added it all up for me and came up with 110%, so he suggested that I better go back and see where the analytical error was. That was my first lesson in consistency of analysis -- that you should always look for an external basis for checking your results. I also learned that analytical results are never infallible.

Every year Mitchell would take off December as annual leave, and come to the laboratory to do research work in the laboratory on methods. He left instructions to tell everybody that "he was not here." He was the Food and Drug expert on eggs. He established the constants used to check the adulteration of eggs. He and Sam Alfend in St Louis had worked on it and all that work is published in the A.O.A.C. Journal. We don't need that information anymore because we have egg inspection under USDA, so chemical analysis is no longer needed. Now you know the authenticity of your material by actual visual inspection.

Shortly thereafter Harrison retired, and Chester Hubble came in. Then the war began and we couldn't get any more chemists. We hired medical technologists from the University of Minnesota. One of the first was Gloria Getchell, who was with us for a few years. Then she went off to the Veterans Hospital in Los Angeles. There was Joyce Merting and Donna Simpson. Donna later married a doctor and lived in Minneapolis. The medical techs and made excellent analysts, particularly for filth work.

FL: Yes.

WH: Our primary filth work was on dairy and bakery products. Hubble, Lennington, who succeeded Moberg as Chief Inspector, and Ralph Spink, George Vinz, and James Anderson (later Director, Dallas District) made careers of filth inspections.

Later came Jim Herring and Sooy. We had quite a reputation for cleaning up the dairy industry in the states of Iowa, Wisconsin, and Minnesota, as a result of these inspections.

The one thing I didn't like was filth analysis, so I sort of resisted doing filth; I never did become a good bug catcher or filth analyst. After all, I was studying for a PhD in physical chemistry, and what I going to do looking at bug parts? Perlmutter, Keppel, and the girls were excellent at that sort of thing. I did a lot of chemical work, particularly in veterinary drugs; we had quite a bit of that. My number one story, it must have been very early, within a year or so of beginning work was how I found out that I was a pretty good analyst. They didn't worry about giving you a progression of more and more difficult analysis; they just assumed you were a chemist, that you knew how to follow directions, and did it. One of my first drug samples was an alkaloid in a natural product, one of these Belladonna or Stramonium ointments. I found a deficiency. It didn't have as much alkaloid as was declared. I did it again and found that it was still low. Since I was the new analyst, they couldn't believe my results. So they sent the sample to Chicago where they had the experts. Chris Glycart was the drug expert. I still remember how I was on pins and needles for about 3 or 4 weeks until his analysis came back. It was right on the head! Once I was checked by an expert like that,

I had a lot of confidence in my work. I didn't have to worry about having my results checked after that.

FL: Bill, when you first reported in Minneapolis, what kind of training did they give you in addition to laboratory training?

WH: They didn't give much laboratory training, either; it was just a question of on the job training. You worked with a more senior analyst, like Mitchell, or George Keppel and Sam Perlmutter, who had been in about 3 or 4 years. I think all of us at that time learned about the new 1938 law, and we did have some sessions. It's very fuzzy now, because at that time I wasn't too interested in the legal aspect. I was only interested in analysis.

FL: Were the new inspectors also involved in the same courses?

WH: Yes. The inspectors and chemists would go through the new law line by line and say what they thought this meant. Some of them had come down to Washington to the conferences on what the new law was. They would tell us what the people down in Washington thought the new law meant. From my point of view in the laboratory, it was a matter of running an analysis and was your figure above or below what it was supposed to be. At that time we were doing a lot of standards work. We were establishing the composition of basic foods. A program would come out of Washington and the inspectors were supposed to

collect, say, 40 macaroni samples, or 100 egg samples, or something like that. We would set up a sort of an assembly line to analyze all of these samples efficiently.

FL: The reason I asked that question was because I reported in the old Western District, and they assembled all of us for a couple of months in San Francisco for training. In the Eastern District, I have had people tell me how they did it, and I was curious. No one has described the basic training for the class of '39 in the Central District.

WH: There may have been basic training for inspectors, but for the chemists, we just had some semi-formal discussions of what the law was, by local people.

I'll get into some of the court cases at that time. We had a large veterinary drug industry, and some of the landmark cases in drug labeling were established from samples collected and analyzed in our laboratories. The Salisbury case was one of them. I don't remember too much about it because I was just testifying as a fact witness: breaking the seal, analyzing it, and finding certain values. The chemical facts weren't questioned, since the case was mostly a question of labeling.

I began getting interested in statistics very early in my training. Lila Knudsen, who was the first statistician that Food and Drug had, came from Minnesota. She would often stop by the laboratory. I expect that's where my interest originated. The first time I took an airplane ride was with Lila,

because at that time I was working on cheese sampling. It was a big problem (how to take a sample of cheese); here you have a 50 pound wheel of cheddar cheese. Where do you put your trier in, in order to get a decent sample? Dr. Price, the expert on cheese sampling, was at the University of Wisconsin. One summer when Lila came up to Minneapolis on her vacation, we made an appointment to see Dr. Price, to discuss cheese sampling with him. That's when I had my first airplane ride in one of these little "puddle jumpers". We went to Rochester, La Crosse, Eau Claire...we made three or four stops before arriving at Madison. I hung onto my seat all the way.

Lila married Inspector Josh Randolph. She died after they were married only a few years.

One of the good things in Minneapolis was that both Mitchell and J.O. Clarke, Chief of the Central District, were heavily involved in A.O.A.C. work. They got me interested in that sort of thing. Mitchell was Associate Referee on a number of topics, and introduced all of us in the laboratory to it. Whenever there was any slack period in the lab we could work on analytical research. I was given a specific research project on phosphatase in cottage cheese, because they were afraid that if the milk was not properly pasteurized, and cottage cheese was such a big seller, we could really have a major health problem. Food and Drug was putting the

phosphatase test for pasteurization in the Standards for the hard cheeses: Cheddar, Swiss, etc. FDA wanted to know if that test could be modified to apply to soft cheeses like cottage cheese. I started working on it and became a phosphatase expert. In around 1945 or 1946, they sent me to Washington to work with Sanders of USDA for a whole month, and that was really an eye-opener. I became acquainted with all the people that worked in the Washington labs. I knew them on a first-name basis. I set up a daily program where I would go over to the Department of Agriculture, work with George Sanders and Oscar Sager, who later came to work with Food and Drug, until about 2:30-3:00 on the problem of applying their phosphatase test to cottage cheese, and then I'd come over to FDA. The Bureau of Dairy Industry in Agriculture was over in the sixth wing of the South Building at that time, and FDA was in the first wing. So, every afternoon about 2:30, I'd come back to FDA and stop in somebody's lab, talk to them, and see what they were doing. In that way, I met practically everybody, Doc Elliott, Kirk, Larrick, all of the administrative people, and Heinie Lepper and Dr. White. I didn't confine it to foods, either. Drugs: Dr. Wiley, Jonas Carol, Dan Banes, Lew Welsh, etc. Then I could recognize all the names of the people who wrote and signed the memos. A. G. Murray, who always read his Bible. He had a Bible right on his desk.

As a result of this phosphatase work, I became a semi-expert on the analysis of dairy products. Guy Frary from North Dakota was the A.O.A.C. Referee on dairy products, and when he retired, they gave the job of Referee on dairy products to me. I had worked on sampling, moisture, and fat in cheese, and Sam Perlmutter was working on moisture and fat in cottage cheese. The time-consuming problem was sampling. I developed a plan in which I was going to get some midget cheeses which weighed about 5-6 pounds. One of the firms, Kraft or Borden, did make them up for me. One time we had a lull between Thanksgiving and Christmas, and we had about six or eight analysts at the time. We were able to put all the analysts on this one project. We divided the cheeses into five layers, 16 wedges, and 5 concentric rings. We cut the cheese into these little pieces and then had to grind up each one of them. We ran moisture on every one of the 400 pieces in order to find the distribution of moisture in the cheese. Since we also wanted to know how it varied as the cheese aged, we analyzed other cheeses one week, a second week, a month, three months, and six months later. We put the data on 16 pieces of cardboard, representing the wedges, tied them together at a center point with string, fanned them out in a

circle, and we had a model of the moisture distribution in the cheese. I turned these models over to Lila Knudsen and the statisticians. There was so much data they just couldn't handle it. They had to wait for computers, but once they got the computers they couldn't find my data. They don't make cheese this way any more...draining the curd, putting it into hoops, pressing, and storage on shelves. Now they make it in barrels, but they still have the sampling problem. Vince Zehren from Schreiber in Green Bay, was in a couple months ago and said, "The problem we have now is sampling this barrel cheese. We put it in 55 gallon drums and the only access is through the bung hole. How do we put our trier into the bung hole in order to sample the cheese?"

When I was working on it, the National Cheese Institute had hired Price as their expert on cheese sampling, and they came to the conclusion: Put your triers in the center. At least that is a well-defined point. If you tried to put it any other place, you'd have the double problem of where do you put it and what's the moisture distribution? We know it should be near the edge to give you an average value, but the moisture varies around the cheese, as well as down into the cheese, because it's drying out from the surface. I don't think we'll ever solve the problem of sampling cheese. Just take a sample and hope for the best.

FL: Make it an arbitrary method, so long as everybody does it the same way.

WH: That's right. Then if you do find a violation, you go back, get the whole cheese, grind it, and perform many analyses. Cheese comes out of big vats these days, so you can get many samples.

One very significant thing has occurred in going from those days to these days. Back in those days, the viewpoint we got was that the manufacturers really were out to cheat the consumers. At least that was the viewpoint we got. It was our job, as policemen, to find them, and it wasn't too difficult to find. We could find violations in 10% to 15% of all the butter samples we analyzed. These violations were very easy to find. Now, the problem is no longer handled by laboratory control, but rather by auditing control. Something I've begun to realize in the past 20 years is that laboratory work is very expensive, and it should be avoided whenever possible. Inspectors are much more efficient in detecting violations than the laboratory, and auditors are even more efficient than inspectors. What has solved the adulteration problem for the dairy industry is the milk marketing orders where the plants have got to account for all their milk. They buy a certain amount of milk and sell a certain amount of dairy products and they must match. The auditors make sure they do match. If they do not, the auditors go back and find out why. It's a much more efficient way of controlling adulteration than sending samples to the laboratory, because lab analyses have

terrific variability compared with the auditing variability, which is negligible. Although the dairy industry has been cleaned up, both from adulteration and from a sanitary point of view, I don't think we chemists can take too much credit for it. It has really been constant vigilence on the part of the inspectors, and even more vigilence on the part of the auditors.

In 1947, after I received my PhD, I was made Chief Chemist. That was probably the most embarrassing situation I was ever in, because Lloyd Mitchell, whom I was replacing, was still there. He had been the Chief Chemist for perhaps 15 years, and they apparently did not have too much confidence in Mitchell anymore. He evidently did not keep up with new things. Having a PhD in a laboratory was quite impressive so I was made the Chief Chemist. Lloyd Mitchell was very happy to work with me because I let him do research work. Paper chromatography was coming in then, and one of our problems was decomposition. Lloyd had a lot of ideas about looking for amino acids, which was one of the first things paper chromatography was applied to. He would let cream, eggs, and fish decompose and make an extract, put it on this paper, let it travel up, and see if he could see how the amino acids pattern would change with decomposition. He became a real expert in paper chromatography. He began applying it to some of the pesticides and was able to move the pesticides up in paper chromatography. (I'm getting ahead of my story a little bit.)

I was transferred to Washington in 1951, and one of the first things I was able to do was to get Lloyd Mitchell from Minneapolis to Washington, to become our expert in paper chromatography. Lloyd Mitchell is recognized as the father of the multi-residue pesticide methodology, which we use today, but with the technique of gas chromatography.

I have an article from England which acknowledges that Lloyd Mitchell's paper on a chromatograpic separation of pesticides is the basic work showing that pesticides could be separated by chromatography.

FL: Does that stem from that article I remember from the AOAC Journal, which I thought was the most marvelous title for a scientific paper...I think he called it, Ascending Paper Chromatography - A Way To Do It.

WH: Yes. That's where he summarized all his experience with paper chromatography. He was the first one, I think, to demonstrate that you could separate the common pesticides of those days: DDT, BHC, methoxychlor, etc.

Well, then he applied it to a lot of other things, but he never got past paper chromatography. When thin layer chromatography came in, he stuck with paper, although paper was even then obsolete. Thin layer chromatography permitted us to control the aflatoxin situation. But Mitchell was the pioneer in pointing the way to Food and Drug's policy. Everybody else was working on specific methods. They would get methods for

DDT, lindane, chlordane, heptachlor, etc., but Bill Cook and Henry Fischbach, who directed the program saw that what FDA needed was a multi-residue method. We didn't necessarily know what pesticides were going to be used; therefore, we needed a method that would separate all the pesticides.

I would like to mention the fish business. Another of the big things we did in Minneapolis was to examine Canadian fish: whitefish and tullibees for parasites. One of the first things you learned to do was how to fillet a fish. The fish would come in from Canada along those northern border ports such as Pembina, North Dakota. The Customs inspectors would take a sample, seal it, and send it down with the shipment to Minneapolis, where American Express would deliver it, about 11:30 a.m. It was a messy package--smelly fish packed in melting ice, in wooden crates. We expected this every day, so we had our lunch first. I got into the habit of eating lunch about 11:00 every morning. Mitchell and the lab helpers taught us how to cut fish. We weren't cutting fish for efficiency, to get the maximum amount of meat on. You were cutting to expose the maximum amount of flesh which contained the parasites. If you had parasites in there, they were very obvious! I still remember the name, Triaenophorus tricuspidatus.

The work load would vary all the way from one lot that we could knock off in 5-10 minutes, to a huge influx on some days of 10-20 lots. We would look at them for decomposition, too. If they were decomposed, we would send an inspector out to take a look at the lot to see if they were really bad. They would never let me smell fish for decomposition because I was too sensitive to it. I'd say it was rotten when it was just a "fishy" odor. Nevertheless, I did become pretty good at egg smelling. (I will later talk about the Egg Smelling Schools).

I was Chief Chemist at Minneapolis until 1951, when I was transferred to Washington. This was one of the rare cases where Food and Drug did a little advanced planning, because they brought me there specifically to understudy Heinie Lepper. Heinie was our Chief Food Chemist. He had participated in a lot of the fundamental adulteration work of the Food and Drug Administration, building up our authentic data, particularly in decomposition. He was a marvelous story teller. He had been associated with some of the pioneers of FDA. I don't think he had too much to do with Wiley, because he came in about 1909 or 1910 and Wiley was just on his way out then. But he did work with Dunbar, Crawford, Larrick, Kirk, and Elliott. These people had a terrific amount of respect for Heinie Lepper and relied upon him to a very great extent, not only because he had a lot of knowledge, but he had

a personality which gave you a lot of confidence in what he said. He had one of these gravelly voices, which once you heard, you never forgot.

I don't recall too much about the Chief Chemist job in Minneapolis except that it was the nicest job I had.

FL: Did you participate in any court trials in Minneapolis?

WH: Yes. I participated in some of them as a fact witness, where you just recite your analysis. I had to go to Jackson, Mississippi on a cheese trial, as an expert. I met the people from New Orleans at that time. It was a fat or moisture case. I don't remember the outcome; whether we won or lost. In one case, a really bad one in the sense that it was extensive and required a terrific amount of investigation and analysis testimony, was Powder-X, where a fellow was selling pumice to control all of your ills. I did a rock analysis at that time, in order to establish the composition of this material, and now I am amazed of having had the audacity to do a rock analysis, because now I realize how difficult that was. It should have been sent to the Geological Survey, rather than give it to an FDA chemist. A chemist was expected to know how to analyze anything in those days. Analytical chemists do become specialized. They become food chemists, food additive chemists, pesticide residue chemists, etc. They have to, in order to do good work these days. FDA doesn't have the all-around chemists that we were expected to be in those days, where you

could analyze foods, drugs, cosmetics, dyes, filth, and occasionally we'd even get a toxicological sample, such as a box of candy somebody got sick on, and we were supposed to find the poison.

FL: Now let's go to Washington.

WH: I'll probably think of a few more things as we go along, but the Egg Schools are important. Fred Hillig worked with Heinie Lepper on his adulteration and decompostion project. Fred died a couple of years ago at the age of 90 plus. Did you manage to interview him?

FL: No, I didn't get started in time for that.

WH: I see. Fred, Heinie, and Bartram are involved in decomposition. Have you interviewed Bartram?

FL: Not yet. I have him on the list.

WH: They developed a program to detect decomposition in eggs in a practical manner. Heinie used to say, "A good egg has no odor." A fresh egg has absolutely no odor. They would let eggs stand around and develop rotten odors. Fred was the chemist, Bartram was the microbiologist, and later Dunnigan. They would take the mess and see what they could find that might be an index of decomposition. They also developed the concept of egg schools, in which they would go out to a big egg plant in St. Louis, Kansas City, or Chicago, where they would get the cooperation of the manufacturer. They would get about 20 inspectors who had been nominated by the Districts as

being pretty good "egg smellers" and everybody would break out eggs. You would smell the fresh eggs; Heinie would impress upon them that a fresh egg has no odor; then along the way there would be some naturally rotten eggs. Those with embryos, mold, blood spots and rots. All those went into special cans, for moldies, musties, acids, putrids, etc. Then we would take, say, 1% of a putrid and mix it with good eggs and everybody would smell that. The rotten eggs,--putrids, moldies, and musties--all these would be checked with various amounts of good eggs mixed in with them. You would "calibrate" your nose on these authentic mixtures. Then we would let some good eggs spoil at room temperature for various times. After a day, they are still good, but the second day they begin getting the putrid odors. In this way you would know first hand that when you encountered a bad egg out in the field, you could associate it with your training: That this one must have stood for a long period of time at room temperature to have developed an odor like this. Then those cans were put in the freezer. They are all marked originally, 1% musties, 5% putrids, etc. They were brought out the next day, after being hard-frozen, and you drilled them with a drill, as knowns. Everybody put their nose into it. This is a good egg; this one stood for 24 hours; this one stood for 48 hours, and this one had 10% musties in it, etc. The next day you did them as unknowns. You drilled them in groups of 3 or

4, put your nose in it right after it was drilled, and marked down pass or reject. The scores were then tabulated. There were quite a few who were perfect. We had some really good people who could distinguish good from bad eggs very well. We passed them even if they let a rotten egg go by occasionally, but we would never give a diploma to anyone who called a good egg bad. If you ever called a good egg bad, you could not be a Certified Egg Smeller.

Some inspectors were very acute. Harold Southworth of Minneapolis was one who could even distinguish duck eggs from hen eggs. He died very young.

FL: Yes, I remember him.

WH: He could tell duck eggs. We used duck eggs because there was a little bit of an off odor in duck eggs which we wanted the inspectors to know about.

FL: Fresh duck eggs.

WH: Yes, fresh duck eggs. He was the only one who could consistently finger duck eggs. Pete Dunnigan, the microbiologist, was good on musties. We would put a 10th of a percent musties into a can of eggs and he would find it as an unknown when no one else could. It was important to be able to do that, because once you put a musty egg into a cake, it ruins the cake. So, the egg people were very careful to be sure not to put any musty eggs into the frozen eggs.

I got pretty good at smelling eggs so that I became one of the reference points along with Heinie Lepper, Bartram,

Dunnigan, and George Vinz. George Vinz was very good at egg smelling. Of course, being in Kansas City, we had several schools there and George set those up. We would also take chemical and bacteriological samples out of them. There is a whole series of papers in the A.O.A.C. Journal on the progression of volatile acids and microbial counts with age, as we let the eggs decompose.

As a result of this work we won a court case which said that so many milligrams of acetic acid per 100 grams and a bacteria count of 5 million per gram constitutes rotten eggs. Fred also developed the lactic acid method for eggs.

Those were the days when the qualities of foods weren't very high. They didn't pay attention to refrigeration, didn't have a good concept of sanitation, or how to keep things clean and cold. These days we don't have to worry about that type of adulteration very much because the manufacturers just cannot sell low quality food. The American public is very quality conscious and you can't sell rotten eggs, or rotten cream or rotten fish.

The fish industry is remarkable for the change in the quality of fish. We wouldn't even eat commercial fish back in the 1940's because it tasted so bad. We were allowed to take some of that whitefish home with us. I understand they aren't allowed to do that anymore.

FL: Were you involved on the work on sour cream and rotten cream?

WH: Not too much. We didn't have too much of it up in the Minnesota, Wisconsin area. They had a lot more of it down in the Ohio Valley, Cincinnati and St. Louis, where it was warmer. I never did get to be much of a cream taster until I got to Washington. Then they would hold some cream tasting sessions there and I got into the tasting. I had to get innoculated for typhoid and a few other things.

FL: Were you involved in the chemical work then?

WH: Yes, I think, I am on one or two of the papers with Fred Hillig at that time.

One good story is how I didn't become the Chief Coffee Taster of the United States Government. Heinie Lepper was the Chief Coffee Taster. All the coffee that was bought for the prisons was checked by him. They couldn't afford to have bad coffee, or they would have riots in the prisons. That was his story at least. The way the coffee was bought was that manufacturers would submit bid samples. They stated: "We are going to furnish you with 10,000 pounds of coffee which corresponds to this sample which I am submitting." We had a lab helper who had been with Heinie for a long time, named Webb. We had a laboratory coffee roaster and Webb would roast each one of these samples, and then grind and brew it. Then they would put it in cups, so many grams per cup, pour hot water in it, stir it up, let it settle, and he would swirl it around in his mouth, then spit it out. He always did two portions of

each sample. He didn't want to know what they were. Webb would mix them up and then he would try to match the samples. The bid samples were checked to see whether they matched Santos # 1 or Santos # 3, or whatever it was. He always made sure that he could match the samples himself before he would say that it had such and such a grade. He was very good at that.

He put out some samples for me right after I arrived at Washington and he said, "Arrange these samples in order of what you think--good, bad, etc. So, I tried to imitate him and take a spoon of the coffee, swirl it around and spit it out. I arranged them and he said, "You won't make a coffee taster." I had arranged them exactly backwards.

Later the volume of coffee became too much to handle, so USDA quality grading people took over the grading of coffee. In any case, after Heinie retired, there wasn't anybody in FDA to take over that job.

Along the way he had accumulated a lot of coffee, because they would send in coffee for testing and you didn't use it all for testing. So we had the Liar's Club. This was an institution that goes way back to the beginning of coffee tasting. They would brew up 2, 3, or 4 liters of coffee for lunch. Everybody brought their lunch in those days, including the Deputy Commissioner, and Kirk, Elliott and Murray. The Liar's club met in the cutting room. It had a couple of

stainless steel tables on which cans were opened, fish was examined, or anything that had to be looked at in large quantities. The Liar's Club was the best means of communication the Food and Drug Administration ever had. When something happened, everybody knew it.

FL: All ranks were present.

WH: Right, from the laboratory helpers all the way up. Every once in a while we wanted to check something for edibility, whether it was fit for food or not. It was put out on trays, people would taste it, and give their judgement as to whether it was good enough to eat. You could tell by how much of it disappeared. If it all went, it was fit for food. If most of it was left, it wasn't fit for food. A lot of decisions were made that way.

I remember once in the monosodium glutamate business, where we were trying to figure out what effect monosodium glutamate had on cooked chicken. Everybody claimed it had flavor-enhancing properties. We had a fellow whose name was Walter (I forgot what his last name was). He used to be a Navy cook. We had ovens then, so we had him roast some chickens with and without monosodium glutamate. We put them out and asked the "Liars" if they noticed any difference between them. We even called the attorney, who was submitting all of the petitions. We had him come and taste these chickens with and without monosodium glutamate to see whether he could tell

any difference. He said, "I can't tell any difference between these things," but he still claimed that monosodium glutamate does have a flavor-enhancing effect and apparently some people can tell the difference, but our Liar's Club couldn't.

Do you have a copy of Heinie Lepper's obituary?

FL: No, I don't. I've heard of it but I have never seen it.

WH: OK. I'll give you one, I think I have a reprint at home that I'll send to you.

FL: Good.

WH: At that time I gathered together a lot of these stories about Heinie and put them in that obituary. He was really a character.

FL: A very colorful man and a very able one.

WH: Oh, yes.

FL: Was W. B. White head of the Food Division then?

WH: W. B. White was the Director who got me transferred from Minneapolis to Washington to understudy Heinie Lepper. However, Dr. White died just before I came to Washington at the end of March 1951. When I got here in early April, Dr. White had died.

FL: That was very sudden and very tragic.

WH: Yes, very sudden.

FL: So, Frank Vorhes was...

WH: Frank Vorhes then became the head of Food Division.

At that time Heinie Lepper was the Secretary of the A.O.A.C. That was one of the jobs they had brought me in for; to take over the job as secretary of A.O.A.C. They put Milstead in there for one year. I didn't want to jump right in, not knowing what to do in Washington, and who was who. Then in 1952, I became the Secretary and held that position until A.O.A.C. was separated from FDA in 1979.

FL: What year did Heinie retire?

WH: I don't remember exactly; it would be in the obituary. It was in the 1950s.

FL: You had several years with him.

WH: Yes, I had 5 or 6 years with Heinie. I inherited all of his files. He had a very extensive file on food composition. I also inherited another job from him. He was the Section Editor for foods for Chemical Abstracts. The Food and Drug Administration, Food Division, since almost the start of Chemical Abstracts has had the responsibility for the section on foods. Even before Heinie, I believe Balcom had this job. Balcom initiated Heinie Lepper into abstracting for Chemical Abstracts, and Heinie became the Section Editor. After he initiated me into abstracting, I used to abstract the A.O.A.C. Journal for Chemical Abstracts, and then I became the Section Editor. One of the reasons they had this job was because they had the resources of the Department of Agriculture Library right there. Every time Heinie Lepper would get a galley

proof, he would go through this religiously and raise a lot of questions. He'd send Webb down to the library to pick up those journals on which he had questions. He would fix up the abstracts and send them back. He enjoyed doing that. That took a lot of time, and it delayed the publication of the abstracts. Chemical Abstracts didn't like it. It wasn't just the food sections, but all of them. They decided they had to get the abstracts out quicker, so first they stopped sending manuscripts and then galley proofs to the Section Editor. As soon as that stopped, Heinie lost interest in it, because his great joy was to find mistakes. He'd say, "Just look at that dummy who abstracted this thing; it just can't be. Let's get the article and see what it really said." When he lost interest in Chemical Abstracts, I took it over. I am still on the masthead as Section Editor, but section editors have very little work to do now.

That reminds me of a story that Heinie used to tell on himself. He had an excellent secretary, and when he would dictate, he would dictate in his German style with a verb at the end, etc. She would translate it into ordinary English. When she was on leave, he borrowed another secretary. I think it was Dr. Slocum's secretary, Gladys, who later became Gladys Slocum. He dictated to her. She, a good secretary, took notes exactly the way he talked. Heinie was used to not even bothering to read over his letters, because he knew his

secretary would fix it up, so he sent it on to Dunbar for signature. Dunbar read every last word and returned a note, "Heinie, don't you read your letters?" Heinie had to go and apologize to Dunbar and set things straight that it was an accident and an oversight. You had to be very careful in those days how you handled things.

Heinie was really a wonderful character. I'll be sure to find that obituary, because I gathered together a lot of stories from Lowrie Beacham for it. Have you interviewed him?

FL: No, but I have him on the list.

WH: Beacham goes back further than I do. He goes back to about 1934. I think that was when he was hired. He was assistant to Dr. White at the time he died. Beacham had a desk right in the next room to Dr. White when I came in 1946 and did that research work on phosphatase, when I first met Lowrie Beacham. They had a lot of canned food experts like Lovejoy, Bonney, Ben Gutterman, and Sam Oglesby. I didn't know Sam very well. I met him after he retired and left FDA. Ben went to GSA, too. Lovejoy went to GSA from the Canned Food Section.

When I first came into Washington I knew I was going to understudy Heinie Lepper. They did something very smart. They first sent me over to the administrative office where they put me at a desk across from Ken Kirk. Kirk was an amazing man. He had a vast memory and knew everything that

had happened in regard to food decisions. He could put his finger on practically anything. Any case that came in, that he had handled before, he could associate "these facts" with "those facts". Any letters he had written before, or that anyone else had written that he had signed or reviewed, he knew about, too. He was smooth. I sat in on interviews with the trade. When they came in and wanted something, he would listen and tell the group why it could or could not be done.

Kirk always relied upon his experts. He would constantly send things over to Bartram, Lepper or any of the other experts like Beacham. When I started sending comments over to him, he had a habit of calling you up and saying: "Look, I appreciate your advice. It is excellent and that's fine, but I can't follow it; here is why..." Then he would tell you that there are other factors involved; didn't have factory inspection; this doesn't support it; we are just not ready, or, the case just isn't very strong, etc. He would go out of his way to tell you exactly what the situation was. FDA really lost a lot when Ken retired.

FL: He was really forced out by the new Administration.

WH: Yes. He would have made a wonderful Commissioner.

I think every Chief Chemist in the field ought to have that type of administrative training with someone like Kirk. When you come up from being an ordinary chemist and then become Chief Chemist in the lab, you focus from the bottom up,

not from the top down. Unless you've had experience with the top, you don't know what the top wants. You might think you know. You've been told; you read memos and everything else, but you really do not have an insight into exactly what is needed to support a case until you have reviewed the cases and tried to spot the weaknesses. Every Chief Chemist who has to make a recommendation based on analytical findings, should have some training in Washington regarding the type of evidence needed. Just writing and telling it just isn't good enough. You have to handle it. We don't do that sort of thing now.

I haven't been out in the field for a long time, but I understand it has changed quite a bit. The kind of cases we take are altogether different. The analytical work is different and the number of court cases we have these days has changed entirely. The lawyers are probably as bad as our ordinary chemists too, in not knowing what is needed, so now the situation must be altogher different now. The type of analytical work we do has also changed. We don't do much food composition work to speak of. It is all trace residue analysis, etc. That's what I'm working on right now; the uncertainty of analytical work down in the trace area. It is really fascinating.

FL: Is that the sensitivity of methods?

WH: Sensitivity of methods, yes. Dr. Miller has been letting me do lot on my own with this, and I have come up with a couple of new concepts about it. I've been getting into the literature and I have a curve named after me: the Horwitz Curve, which people are beginning to understand.

After I was in the Food Division, until about 1961, the Food and Drug computers were beginning to come in. After the thalidomide incident, they determined they had to have a scientific information system in the Food and Drug Administration, and needed somebody to establish such a system. They put it in Dr. Kline's shop. He was the Associate Commissioner for Science. He asked me to take over the Science Information job as his Assistant. We got a contractor, Arthur D. Little, who spent an entire year going through the Food and Drug Administration from top to bottom. They came up with the recommendation to establish an agency-wide information system. They started implementing it with a second year contract, but it just never got off the ground. None of the FDA units wanted to cooperate with the other units. The field was an entity to itself, and the Bureau of Medicine was developing their own system at the time. They had some people who thought they knew how to do it better and they didn't want to have anything to do with the Field or with Foods. Foods did not have much of a data base and they weren't interested in it.

Then when Goddard came in 1966, Dr. Kline left and his organization disintegrated and I guess we have never had a really good information system. FDA still is trying to develop one.

FL: What would that have covered?

WH: Everything. They were going to put in the new drug applications, the pesticide petitions, the food additive petitions, and correspondence files. Arthur D. Little identified about 20 different categories of basic information. Of course, it couldn't be implemented very cheaply in those days, either, so it was a very expensive proposition.

FL: Would it have included precedents too?

WH: Yes . They wanted to put in precedent files. I don't know where Heinie Lepper's precedent files are now, but he kept a copy of every letter that established policy. I suppose the file is down at Food Technology, if they haven't thrown it away. When Steve's unit (Malcom Stephens) was established, Steve, Milstead and Walt Moses were going to codify the precedent material. I think I actually did one letter on butter, as an example. Then I got off on something else and don't think anyone ever went through them letter by letter to establish a codified precedent manual.

FL: Is the Arthur D. Little report still around?

WH: Yes. I have a copy someplace that really should be in the archives. They did a good job and if we had followed it,

we probably would now have a very good information system. I think it was a bit ahead of its time, because terminals were not in common use at that time. These days, with a terminal at everyone's desk, it could really be implemented.

FL: Computers were still big and complicated.

WH: Very big and complicated, yes. When I first started, Mrs. Kelsey's husband was involved in computers from the department's point of view.

FL: What year was that?

WH: It was in the early 60s. Senator Humphrey was having hearings on the Hill on how to handle medical information.

Well, after Goddard came in, everything was reorganized. At that time, I began working with Dr. Summerson, the Director of the Bureau of Science, Dr. Summerson retired and there was further reorganization. I just continued working along.

FL: Who succeeded Dr. Summerson?

WH: Well, then they reorganized. I remember Summerson was the Bureau Director of the Bureau of Science.

FL: Yes, that's right.

WH: They reorganized along commodity lines. Keith Lewis was Director for a while in Foods. Then Wodicka came in Foods and the Bureau of Medicine was established as a separate entity.

WH: One of these days we will reorganize back into the functional areas with another Bureau of Science, and Bureau of Regulatory Affairs.

FL: I've always maintained there are only two ways to organize the agency, and that is, one is functional and one is subject matter, unless you do some of both.

WH: Let me mention something about the planning business. The new Commissioner was here yesterday and he was very much impressed by all the planning that we do. We have 3 or 4 people in this bureau whose job it is to plan. It seems to me that we don't look at it right. We never go back and see how well previous plans worked out. If we did, we'll find we've been wasting our time. We've got to realize you cannot plan for the next emergency. What you have to plan for is how to handle unplanned emergencies. That's our job. One of these days maybe we will save ourselves a lot of time and money by planning for that type of thing--not for planning what we are going to do routinely, but plan for what we are not going to do with various kinds of emergencies.

FL: Plan for what changes we are going to make in an emergency.

WH: Yes. Our primary job is to handle safety emergencies. It is just like fire fighting, you've got to sit around for a while and learn to be available; but oh no, this isn't done. You've got to be efficient, you cannot sit around

waiting for the next emergency. You've got to be doing something and that means that you are probably not prepared for the next emergency. Fortunately our emergencies have not been too bad. Some people would say that if you kill one or two people with botulism that's bad, but when you consider there are potentialy 200 million people who could be exposed to something in the food and water supply, we are doing marvelously well. Someone should plan for unplanned things, and not plan for the things they are going to do, and then discover that they can't do them.

FL: Bill, over the years you've been identified with the A.O.A.C. (Association of Official Analytical Chemists) in many different ways. Would you talk a little bit about how you got started with it and what you have done.

WH: I got started with A.O.A.C. because Heinie Lepper was the Secretary and I took over the job from him. It was almost a one-man operation when he started. He and Rosie Pierce, the business manager, handled everything on the A.O.A.C. Dr. White was the Editor of the Journal. As a matter of fact I think Heinie was the Editor of the Journal until Doc White came to Washington from New York State. Doc was a literary man. He loved to write, he loved words, and he could write beautifully. So handling the editorship of the Journal was just a natural thing for him.

FL: Whenever I read any of Dr. White's stuff, I always thought he probably wrote with a thesaurus in one hand and Barlett's quotations in the other.

WH: Right. It was wonderful to read anything of Doc White's. We published a Food Control Statement at that time and Doc White contributed to that too. He would have a little piece in there now and then, and it was just a pleasure to read his stuff.

Everything at that time was built around the A.O.A.C. meeting. There was one meeting a year, always in Washington the last part of October or early November. Heinie used to say the time was set when the State Chemists were very important in the A.O.A.C. They were political appointees, and this was just before the election. This was their last opportunity to get a trip to Washington before they were replaced by someone else.

The A.O.A.C. was pretty small in those days. Heinie could handle it in a couple hours a day. Mrs. Pierce kept the journal subscriptions and she was just a couple of doors down. FDA handled everything--space, supplies, telephone, etc. FDA needed the methods of analysis for foods and drugs, which A.O.A.C. approved. We also had a little bit of fertilizer and feed work which the states handled, but FDA was sort of a grandmother to the states too. Conducting A.O.A.C. scientific affairs was considered part of our official duties.

FL: I think details like that, as to dates when we had paid editors, etc., is very well covered in this book by Kenneth Helrich, The Great Collaboration, that commemorates the first 100 years of A.O.A.C., the book you so kindly gave me the other day.

WH: Yes, I think we'll have to send one down to the Food and Drug Library. We should put it in the Medical Library as well, and in the Food and Drug Archives.

FL: If you have an extra one, we could annex it to your transcript and put it in as an appendix.

WH: Yes, we can do that. It does have all the details of Helrich's research in regard to the transition. As part of this great openness in government, the Food and Drug Administration decided that it didn't look so good having its employees run the A.O.A.C. As a result of the Ritts Committee review of the situation, A.O.A.C. was made an independent organization. I often say this was the only recommendation out of 100 or so which the Ritts Committee came up with which the FDA ever implemented. At the time our attorneys would not let me go with the A.O.A.C., so I stayed with FDA. All of that is gone into in great detail in the book because that was a very important change.

FL: We did furnish some financial support in the way of contracts and things of that sort, didn't we?

WH: What Food and Drug now does is to have a five year cooperative agreement with A.O.A.C. wherein they give them a

days they have digital balances, and how do you know that something didn't slip in the condensers and resistances in the black box. We just take a terrific amount of things on faith these days. That requires a little change in our methodology.

Before, when everything depended upon stoichiometric reactions and complete extractions, etc., you knew what the fundamental principles were of the reactions that you were dealing with. These days you don't. As a matter of fact, our Technicon autoanalyzer is based upon non-equilibrium conditions, in which they diffuse out 4-5% of your analyte, and depend on diffusing out the same fraction every time. If something goes wrong, you don't know it. We just don't build in enough skepticism on the part of our chemists to constantly be questioning: "Is this result right? Is it consistent with what I know? Is the response I get consistent with what I think it should be?" We have a terrific problem of quality control. It is not the type of personal quality control that we used to have. Instrument quality control is an entirely different story. We have to build into our methods these days, an element of self-checking, so if you put in a microgram of DDT into your gas chromatograph, you should get a peak height of say 3" or 75 millimeters, or something like that. If you don't get it, you'd better stop and check out why.

One of our big problems is the adulteration of honey with invert syrup. They have some fantastic mass spec methods now for detecting whether or not the bee or the plant put in the sugar, but you have to have some reference standards.

FL: You know, that is finally solving a problem that has plagued us as long as I can remember, the adulteration of honey and demonstrating that the sugar was put in by somebody, rather than a bee.

WH: That's right, as in Sorghum syrup. I guess the people from the South know about that, I don't know.

I remember Heinie tell me about a fellow in New York Station, when he was trying to identify decomposed eggs. He ran about 50 different tests. Acids, bases, volatiles, etc., and then put them into a great big equation. Well, that is exactly what these pattern recognition people are doing today. They are analyzing for a lot of things and now they can do it easily, as in the inductively coupled plasma spectrometer. You put in a tenth of a milliliter of the sample and you get the concentration of 30 elements displayed for you right there.

We have a big problem with orange juice right now. They are trying to apply computer pattern recognition here, too. Well, now they can put them in three dimensional space in the computer, add it all up into something and say, "This

is the oranges from California; this is from Florida, and this one has never seen an orange!"

I remember after the war, when drug smuggling was just beginning, the Army came over to us in the Food Division and wanted to know whether we had any ways of telling whether this drug came from China, Indochina, or South America. At that time, we said, "Gee, we wouldn't have any idea how to go about doing that." In these days of pattern recognition, you can do it because you get a plant grown in a certain type of soil and it will reflect, to a certain extent, the elements in the soil.

This reminds me of another project. One of the first projects I was on in Minneapolis was selenium. They had high selenium soils in the Dakotas, and some of the wheat contained high selenium. It would be eaten by the chickens and cows. Some of the milk and eggs were also high selenium. So we were playing around with parts per million of selenium, which was my first introduction to microchemistry, except we did it with buret, we titrated in the parts per million range. You only got a 1 or 2 ml titration so it was not very reliable, but we could tell the difference between low selenium and high selenium foods.

FL: Selenium, of course, was an element that was toxic.

WH: In high quantities it was toxic. That is how they came on to this, because animals were getting sick. They finally traced it to high selenium soils.

During the period in A.O.A.C., I was doing almost everything for the A.O.A.C. As the Secretary, I arranged meetings, went over and prepared changes in methods, practically everything except the Journal, which Helen Reynolds handled. It has become a big organization now, they have about 15 people in Arlington on the A.O.A.C. staff. They have to rely more upon their private sustaining members that give them $500.00 a year, and big food and drug firms and FDA and the other government agencies give them tens of thousands and hundred thousands of dollars, because it is absolutely essential. I think it was Larrick, he probably got it from Heinie Lepper or somebody before him, that said if there wasn't an A.O.A.C. we'd have to invent one. You just cannot have people using any old method to enforce laws. It was under Wodicka when we put Section 2.19 in the Code of Federal Regulations which said, in effect: "The Food and Drug Administration, unless otherwise specified, will use the methods of the A.O.A.C." This was rather amazing. FDA, for all these years, relied upon the A.O.A.C. methods, but they never said so. Heinie Lepper used to say that because all of the administrators of the Food and Drug Adminstration were inspectors, they didn't know what the chemists were doing at all. When you wanted to put something like that into the law, they would say it wasn't necessary; everybody knows you use the A.O.A.C. methods, so

you don't have to say that. Once we had to expose all of our operating procedures, we suddenly realized that we never said that we used A.O.A.C. methods, so that is how that section got in the Code of Federal Regulations.

FL: I guess the only time we said it was when we were in Court, and the Court always took notice that this was the accepted method.

WH: Right, they took judicial notice of it. You see, the A.O.A.C. was not put into the law like the USP. I could never understand why. Heinie claimed in was jealousy on the part of the inspectors. They didn't want to recognize A.O.A.C. because the inspectors didn't have an organization that corresponded to what the chemists had.

FL: I don't know why it couldn't have been, as we did with the Pharmacopeia. Even the 1906 Act was recognized it.

WH: Yes. AOAC indirectly got into an Appropriation Act, in the 1940s, where it permitted the Food and Drug Administration to cooperate with organizations devoted to methods of analysis. They wouldn't come right out and say A.O.A.C.

FL: Various methods were specifically named in regulations setting food standards.

WH: In food standards we did specify A.O.A.C. methods because the Division of Food would first perform the collaborative study to be sure that the method worked properly. Then they would send it out to the field, and say go out and

gather samples and analyze them by this method which will be the method that is going to be used in enforcement.

Now, we have all of nutritional labeling and this section applies, but what we have discovered is that the nutritionists have little conception of analytical accuracy. That's why you just can't let them go to the books and put a number from the books onto a label.

Nutritionists came out of the biochemical area, and those people don't have the concept of validation of methods. They just try any old thing. They get a number and think it is correct automatically. Or they analyze foods by some method and get numbers all over the map and ascribe it to biological variability, and it is not. It's just plain incompetence. If you start comparing some of the values that are in the literature for some of these food components with actual values, they just don't match at all because the literature is just replete with inaccuracies and incorrect application of methods. That is why nutrition is not a very good science.

Iodine is a very good example. We know our diet is high in iodine, and that's about all we can say. Every nutritionist gives a different answer for his iodine values. Mary Heckman from Ralston Purina did a beautiful study. She was the Associate Referee on iodine. The first thing she did was to send out some samples of foods and said, "Analyze

these foods by your method." It varied over a hundred-fold on the same samples. It didn't faze the nutritionists one bit. They just said, "Gee, look how variable the iodine content of foods is."

FL: It was a split sample?

WH: Yes. The problem was in the methodology. She sent out identical samples and got results varying a hundred-fold.

FL: It sounds very much like the account in that volume about the history of A.O.A.C., as to the early results on fertilizer samples for phosphorus and nitrogen.

WH: That is an interesting anecdote. In all my days of A.O.A.C., we only had two floor fights; one was on phosphorus in fertilizers, the problem which established the A.O.A.C. in the first place.

FL: It started the whole organization back in the 1880s.

WH: Phosphorus is one of the expensive elements in fertilizer. In the 1950s they discovered that there was a systematic error in the method of analysis that they were using. They were getting results which were too high. The manufacturers didn't like us to go to a method which gave them a lower result because that meant that they would get a smaller return.

FL: They would have to put in more phosphorus.

WH: Right, put in more phosphorus and the product became more expensive to them. The old volumetric or gravimetric methods were inaccurate. They gave you 0.2-0.3% high

values. It wasn't very much, but from a commerical point of view on a million dollars of fertilizer, it made a lot of difference. When they finally wanted to go over to the colorimetric method, which was faster and more accurate, we had a floor fight and it was the first time I had ever seen a vote taken. In the A.O.A.C. you vote by states. Each state has one vote. Each federal agency has a vote over commodities which it regulates. FDA didn't have a vote in the determination of phosphorus in fertilizer, only the states did. It was passed over Dr. Etheredge's almost dead body, you might say; he was holding out for that old method. His position was that with a volumetric or gravimetric method, you know that the answer is right. They actually had to take a roll call vote on it.

FL: Could you tell me something about your activities with Codex Alimentarius?

WH: This was one of Mr. Harvey's dreams that became a reality.

FL: That is Jack Harvey?

WH: Jack Harvey, Deputy Commissioner. He made a lot of the preliminary arrangements with FAO to develop a program on International Food Standards, which eventually became our Codex Alimentarius. The first committee established was on milk and milk products and it had the very elaborate name of "Committee of Experts on the Code of Principles for Milk and

Milk Products." The first meeting was about 1958. I was selected to attend that meeting as a member of the United States Delegation. It was headed by one of the people over in USDA's Dairy grading and marketing area. This was one of the few times people from FDA had gone abroad. Our clerical staff had absolutely no conception how to go about handling the red tape and paperwork involved in an international trip.

FL: About what year was this?

WH: 1958. I think Harvey had gone abroad previously on some trip involving dates.

FL: Yes, he went to what is now Iran and Iraq when they had wormy dates.

WH: A few Food and Druggers had gone abroad, but no one from the Division of Food had gone so I had a lot of problems with getting approval, despite the fact the Deputy Commissioner had indicated I was to go, and the fact that they wanted somebody from FDA on the delegation. As a result of attending that meeting, I made a large number of contacts abroad, and have been preaching the requirements for validation of methods of analysis used in International Standards. Finally, after about 20 years of these types of agitations, other international organizations, particularly the Codex Alimentarius, have gotten around to requiring the use of validated collaboratively studied methods of analysis.

This committee first started on milk, and it went along for 4-5 sessions, until finally the Codex group itself in Rome expanded it into other commodity areas, like fats and oil, sugar, processed fruits and vegetables, until now the Codex has over 20 specific committees. In 1966 I stopped going to the Codex Committee on milk and milk products. Dr. Wiek then took it over. I began going to the Codex Committee on Methods of Analysis and Sampling, where all of the methods of analysis from most of the other commodity-oriented committees come to Methods of Analysis for approval. I'll be going to the fourteenth session of the Codex Committee on the Methods of Analysis and Sampling in Budapest in November, 1984. I attended all except the first meeting on Methods of Analysis, so I will have gone to thirteen of those meetings. I've lost track of how many international trips I've gone on now, at least two dozen or more. I always try to stop at the Laboratory of the Government Chemist in London on my European travels, because they are always in the forefront of some of the food and drug problems or they are working on the same type of problems that we are.

FL: Has the Codex adopted a collaboration system like our A.O.A.C.?

WH: They don't do it themselves, but they accept methods from other organizations. What they say is that they are

going to accept only collaboratively studied methods for use with their Standards. For political purposes they do have another category of methods called Candidate methods, where anyone can throw their methods into the pot, but it doesn't get into the higher categories of reference or alternative methods unless it was established with a collaborative study.

The next step will be in October, 1984 in conjunction with the A.O.A.C.'s Centennial Meeting, we are having a symposium entitled Harmonization of Collaborative Analytical Studies, in which there will be representatives from all the important international organizations that engage in collaborative studies. It is going to be held at the Academy of Sciences, and we are going to see if we can come up with a protocol, which we can all accept as a minimum requirement. If you require more in the way of validation, more laboratories, more samples, more analysis, etc., you put it on top of that.

FL: Bill, one of the things we like to do in these interviews is to ask the person being interviewed for anything that he would like to say about people who were Commissioners, or otherwise helped run the agency; what they were like such as personality, their management style, some of the problems and how they dealt with them at the time, anecdotes about them, just anything you want to say. You

were appointed, like me, when Walter Campbell was still the Commissioner.

WH: I didn't have too much to do with any of the Commissioners. I just saw Walter Campbell once when he came through Minneapolis, and just shook his hand. I remember he was a very impressive man.

When I transferred to Washington, I was on the Commissioner's staff. In fact, Dr. Dunbar retired just a couple of months after I came to Washington. As a member of the Commissioner's staff (I wasn't really a member of his staff, but I was sitting across the desk from Kirk), I was invited to his retirement party at his home in Chevy Chase. The only thing I remember about Dunbar was that I came in one day with my shoes very muddy, and apparently I had made some tracks on the rug. Dunbar came in, looked at those marks, and said, "Who came in with those dirty shoes?" That's the only thing I remember about Dunbar. I really didn't have to have anything to do with any of the Commissioners.

FL: Did Dunbar and any of the other Commissioners ever show up at the Liars Club?

WH: When the whole staff was in the South Agriculture Building, Dunbar and Crawford were there. Heinie told one episode about Crawford. He had been an Associate Commissioner for a long time, and one day he was bragging about his powers as a chemist. This was after he had been out of

the laboratory for 20 years. Somebody, (I forget who was the practical joker here) took him up on it and said, "I bet you can't titrate any more." He said, "I'll bet I can; how about getting me something and I'll show you how to titrate." So they set up a buret and they got some vinegar and gave him some sodium hydroxide, and an indicator. He filled up the burette and he put his hand to the tip of the buret and tasted it. He said, "Yes that's caustic alright." He put his finger on the sample and said, "Yes, that's vinegar. You boys aren't tricking me." Then he put in some of the indicator and started titrating and emptied out the whole buret. "Boy, this must be strong vinegar you guys got!" He filled up the buret again and continued. He never could get an end point. Then he suddenly tried the hydroxide on the indicator and said, "You guys just gave me alcohol!"

FL: It wasn't phenolphthalein or whatever he thought it was.

WH: That's right, they had just given him plain alcohol instead of phenolphthalein as the indicator. They were always playing little practical jokes like that.

You knew about the Yellow Dogs? Did you get initiated in the Yellow Dogs?

FL: No, I never did. I wasn't around Washington in those days.

WH: They always had a ceremony for visiting dignitaries, in which you got initiated into the Yellow Dogs. They gave you the impression that it was a unique organization, but I understand it is in all the land grant colleges, so it probably started in USDA.

FL: I see.

WH: They had a little ceremony. No women were admitted to the initiation ceremony. The Yellow Dogs died out with Heinie Lepper, who was the Chief Cur.

I don't recall very much about the other commissioners. Crawford wasn't there very long, but Heinie Lepper spoke very highly of both Dunbar and Crawford. He thought quite a bit of Larrick, but since Larrick was an inspector, rather than a chemist, he couldn't think so highly of him.

Once Goddard came in, the organization just didn't have the homogeneity that it had before. When you rose up through the ranks and got a Commissioner who knew all of your problems, it was quite a bit different than a brand new one. All the Commissioners that we had were very intelligent people. You didn't have to explain the problem to them in much detail before the grasped all sides of the problem. After all, that was what we paid these guys for. In many cases, there is no really right decision. You put somebody in at the top and say: "You're going to make the decisions and you are going to take the responsibility for it. I

don't care what the decision is, but someone has got to make it, so you do it." On a lot of these things, it doesn't matter too much whether you go on one side or the other side. Clear-cut decisions are made at very low levels. It is only the major ones that get up there, and those are really close calls.

I think we probably have made a lot of mistakes in the safety area, in leaning way over backwards. We say that we are relying upon scientific data, in the studies on cyclamates, and saccharin and all these sort of things, but we really aren't. I remember Dr. Lehman said one very significant thing about chemicals and toxic materials in general. He said, "Why do you think we have a such a big liver?" He pointed out a great big area here, in front of the body of humans and animals. "That liver is there to take care of toxic chemicals; that's natures' way of getting rid of natural toxins because you cannot escape being exposed to them. The liver is supposed to be the detoxifying agent." I always remembered that.

Now, as I am studying the variability of chemical analysis, and I see that as we go down to lower and lower levels, to the trace analysis area, our variability is getting bigger and bigger, merging with biological variability. Biological variability is the sum of an awful lot of little chemical variabilities. When it gets too big, it is no

longer a question of plus or minus so many percent. It is a question of false positives and false negatives. That is what the toxicologists are beginning to see. That is why you get all these various carcinogenic studies, some of which say, "Yes, the stuff is carcinogenic" and others say, "No, it is not carcinogenic." Some studies turn out positive and some turn out negative, because of the huge variability you've got in these studies. If animals live long enough, they are going to get something and that's natures' way of turning life off. Lloyd Mitchell used to say, "When you get old nature just has a way of turning things off since it has no more use for you." That's why he drank distilled water, in order to forestall exposure to a lot of these toxic materials.

The other Commissioners are just a blur. Goddard was a real flamboyant fellow. I was Deputy to Dr. Summerson, who was ill a good deal of the time. He had part of his stomach removed because of ulcers. He was really a remarkable gentleman. He was privately wealthy because he had invented the Klett-Summerson Colorimeter, which was one of the first colorimeters on the market for clinical work. He was also the co-author of a text book: Hawke, Oser, and Summerson, which was a very famous biochemical book in medical schools. He was also Chief Scientist up at Edgewood Arsenal. He was a remarkable gentlemen.

FL: Yes, I remember he came to us from Edgewood.

WH: He really established an excellent scientific organization in FDA. Dan Banes was his original Deputy and Dan became Associate Commissioner of Science when Lee Kline left. So I stepped into Dan's place as Deputy to Summerson. It was when Summerson retired that Ley called me up and said, "We are going to appoint Keith Lewis as the head of this bureau, but we are going to be reorganizing and it is going to be a bit different." I guess that was the forerunner of going into the commodity-oriented bureaus. That was the only contact I had with Ley. After Ley, we had Edwards, then Schmidt, who was followed by Kennedy and then Hayes.

WH: I guess we haven't had too many Commissioners, but we have had more in the last ten years than we had in the 40 previous.

FL: Yes, they only stayed 2 or 3 years.

WH: We just had Dr. Young here yesterday. These people who are heads of agencies have terrific capabilities. They've got to or they wouldn't be where they are. He understands the problems and from the way he was speaking, he knows something about organization and management as well. He said, "Novitch is going to handle the day-to-day work. He is my Deputy and I am the Chief Executive Officer. You take your problems to Novitch and then if necessary come to me, but I am going to be the long-range planner type for the Food and Drug Administration."

FL: And the outside man on the Hill.

WH: We have a crazy system here, where tomorrow he can be called up to the Hill and be held accountable for everything that has gone on in the Food and Drug Administration, and is supposed to be knowledgeable about all of our problems.

I really haven't had to have much contact with the Commissioners. In fact I've purposely not had to; I've preferred to worry about our scientific work.

FL: Thank you, Bill, for your contribution to this project. I'm sure that your recollections, reminiscences, opinions and anecdotes will add a great deal to this record of what the Food and Drug Admnistration has been. I appreciate your taking the time.

Attachment: The Great Collaboration

OBITUARY

OBITUARY

No one who ever met Henry Albert "Heinie" Lepper ever forgot him. His rasping voice and his positive personality always left a lasting impression on even his casual contacts. He retired on December 31, 1956, as Assistant Chief of the Division of Food of the Food and Drug Administration after 43 years of government service and as Secretary-Treasurer Emeritus of the AOAC after an equal period of volunteer service. He died on January 1, 1973, at the age of 83.

Heinie was a native Washingtonian, born on March 27, 1889. His parents operated a store in the old Center Market of Washington, where Heinie obtained first-hand knowledge of food handling at the retail level. After attendance at McKinley High School in the District, he enrolled at George Washington University, receiving a BS degree in Chemistry in 1913. One summer during this period he worked for the Geological Survey. In high school and college he was a runner, and he turned down a track scholarship in favor of remaining in Washington. His family was musically inclined and Heinie mastered the violin.

On December 15, 1913, he was appointed from the Civil Service roster as Assistant Chemist in the Bureau of Chemistry of the Department of Agriculture. He remained with the regulatory wing of this organization through all of its subsequent reorganizations for his entire career. His first published work was on fruit products with Dr. Paul B. Dunbar, who later became Commissioner of Food and Drugs. His next publications were on coffee, and he became one of the acknowledged experts on this subject in the United States. His keen sense of smell and taste gave him the ability to grade and classify coffee. Because of his experience in this area during World War I, other organizations requested his services to judge bid and delivery samples for the Army, Veterans Administration, and Federal prisons. During the last few years preceding his retirement, he could truly be called the chief coffee taster for the United States Government, although the volume of work had begun to decrease considerably when these other organizations found it necessary to set up their own mechanisms to handle their huge purchases. His skill in matching bid samples with deliveries was respected by the trade and resulted in laying down principles for accepting bids and deliveries of coffee by governmental institutions.

A by-product of this activity was the accumulation in his laboratory of large supplies of reference green coffee which were stable indefinitely. To dispose of the surplus, every day enough beans were roasted to brew by beaker and Büchner funnel, what expanded ultimately to six liters. The coffee was consumed by the "Liars' Club," a famous Food and Drug Administration institution whose members gathered daily to eat lunch and swap tall tales.

It was a very efficient means of communication, since it was visited routinely by the major administrators of the agency, the technical Division and Branch Chiefs, and most of the senior professional staff. Many decisions were made here as to whether or not a product was "fit for food," depending on what fraction was left uneaten after an invitation to partake of the displayed material.

The members of the Liars' Club became connoisseurs of coffee, and many a wife told Mr. Lepper how he had undermined her coffee-making ability. On occasion, when he had an unusual sample or when he needed to verify a difference, he would substitute the new material for a portion of the standard Santos-Colombian (1+1) blend. The Liars would almost invariably detect a difference in quality. Visitors found the brew too dark and heavy for their unsophisticated tastes until, through practice, they too could not tolerate any lesser quality.

HENRY A. LEPPER
1889–1973

Another famous by-product of the availability of the lunchtime coffee was Kennel No. 1 of the Independent and Effervescent Order of Yellow Dogs. The Chief Cur of Kennel No. 1 of the Yellow Dogs was, of course, Heinie Lepper. There is some dispute as to whether the Yellow Dogs was founded in Washington and spread to the field or vice versa, but the fact remains that many land grant colleges and agricultural experiment stations also have Yellow Dog Kennels with similar initiation ceremonies.

Practically all visitors who spent more than a week in the FDA offices or laboratories in the South Agriculture building, or who happened to be present on the day an initiation was scheduled, were invited to become members of this exclusive organization. Word quickly spread that an initiation was to be performed and the room was crowded for the secret rites. Subsequently, members have always proudly displayed their membership card, performed the secret handshake, and uttered the sacred password whenever they met another little Yellow Dog. After his retirement, Heinie returned to perform a few more initiations, but the retirement of other key members of the kennel, the expansion of the Food and Drug Administration, the loss of access to the high quality coffee, and the relentless overcrowding of FDA space, led to the eventual dissolution of the Liars' Club and the Yellow Dogs.

After becoming an expert in coffee, Heinie became proficient in other areas requiring a keen sense of taste and smell—cacao products, vinegars, spices, and condiments. This culminated in his becoming the unquestioned expert on eggs and dairy products, particularly the application of chemical methods to detect their adulteration and misbranding. He became responsible for the direction and execution of studies designed to provide objective scientific evidence to detect decomposition in those food products most easily subjected to bacteriological and chemical changes through careless handling or deliberate cheating. During this period Heinie also became the star government witness in a number of important cases which established the definition of the section deeming food to be adulterated if it consists "of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." Practically the only research on decomposition of food had been done by the government and largely under Mr. Lepper's direction. He could, therefore, testify with authority and vividness regarding the production of smelly acids and bases by bacteria operating in the food under conditions which, at best, could only be described as careless. He developed a system of training inspectors in "egg schools" which were conducted like a laboratory exercise. Good eggs were broken and smelled by the inspectors to demonstrate the basic regulatory fact that a good egg has no odor. (Similarly, good fish and good cream have practically no odor.) Then various types of rotten eggs were broken: moldy, musty, sours, putrid, stuck yolks, and other categories. Those with the most pronounced odors, such as putrids and sours, were usually diluted with substantial quantities of good eggs. Good eggs were also permitted to stand at room or refrigerator temperatures for various periods of time and were smelled at intervals to learn when they passed from good to bad. The eggs were then frozen and drilled as knowns and later as unknowns. Only those inspectors who never called a good egg bad and who only occasionally permitted a bad egg to slip by as good were awarded diplomas as "certified egg smellers." These cans of eggs were then later sent to the laboratory for analysis for fatty acids and other chemical indices and for bacteria counts. The results of a number of such training sessions formed the basis for his testimony and assurance that when qualified egg examiners pronounced a can of eggs bad, they knew what they were talking about. Such evidence as well as the manner in which he presented it was usually very impressive and persuasive to a judge and jury.

Since he knew all the deficiencies of the 1906 Pure Food and Drug Act and was present during the gestation of the 1938 Act, he played an important role in developing informal interpretations of the final Food, Drug, and Cosmetic Act passed by Congress in 1938. He often supplied interpretive material and the basis for briefs by the government attorneys involved in adulteration and decomposition cases. The attorneys invariably consulted him on matters of law as well as matters of science. Many laudatory letters were written by pleased District Attorneys after successful conclusion of cases in which he participated. However, he often enjoyed telling about the case when he was a leading witness at a public hearing to establish a food standard. His testimony supported a proposed provision that ultimately was not incorporated in the final standard. The standard was challenged and went to the circuit court for review. In upholding the standard the court took the opportunity to observe that "witness Lepper had testified in favor of the desired provision, but the Administrator [of the Federal Security Agency] didn't have to believe him and said Administrator didn't believe him."

Another of Heinie Lepper's impressive qualifications was that of Section Editor for Foods for *Chemical Abstracts*. He started abstracting for *Chemical Abstracts* shortly after joining the Bureau of Chemistry. This was a common activity of the chemists in the Bureau of that day. In 1926 he and Dr. Blanck took over the Editorship of the Section and Heinie retained it until 1965. E. J. Crane, the long-time editor of *Chemical Abstracts*, had occasion to comment on Mr. Lepper's work as follows: "None of the many chemists who have volunteered to help in the

useful work of *Chemical Abstracts* can excel Mr. Lepper in his devotion to the service and in the effectiveness of the work done. Mr. Lepper has long been one of our best section editors and his abstracts have always been excellent. No matter how great the effort necessary may be, Mr. Lepper never hesitates to tackle whatever task may be necessary to make an abstract for his section of *Chemical Abstracts* clear, accurate, and effectively useful." Heinie used to delight in finding the mistakes that abstracters made and with the vast resources of the National Agricultural Library at his disposal in the South Agriculture Building, he usually obtained the original article and made the corrections himself. One of his great disappointments occurred when *Chemical Abstracts*, to speed up publication, no longer sent the raw abstract copy to the Section Editors. When he only had the galley proof of the abstract to work on, he lost much of his zest for abstracting. In common with all copy readers, he had a great reluctance to make changes in print, but a great relish for making them at manuscript stage.

Heinie worked for the AOAC in practically every capacity from Referee, beginning in 1916, to the Presidency in 1952. After that, he remained on the Executive Committee in the capacity of Secretary-Treasurer Emeritus, constantly reminding the members of the importance of the AOAC to regulatory agencies and its mission of public service. Another of his favorite stories was about the time when he and the other senior members of the AOAC had to go to the Riggs Bank during the depths of the depression and sign personal notes to borrow sufficient funds to produce an edition of the AOAC Book of Methods. After that experience he steadfastly maintained the wisdom of a sound financial basis for the AOAC, avoidance of "luxuries," and keeping its products at the lowest possible prices as a public service.

Many people, including George P. Larrick, former Commissioner of Food and Drugs, considered Mr. Lepper's contribution to the AOAC as important as his other duties in the Food and Drug Administration. Mr. Larrick, in recommending him for a Superior Service Award of the Department of Health, Education, and Welfare, wrote in 1952, "The AOAC and the Food and Drug Administration are virtually interdependent. Without support of the Administration it is doubtful that the Association would be sustained and perpetuated. On the other hand, the Association is a logical development of the need of the Administration for a mechanism through which the analytical methods it employs may be developed, improved, established and recognized. Effort devoted to management of the Association affairs is equally devoted to a prime necessity of the Administration."

Mr. Larrick further commented, "These methods are used many times daily in the civil and military laboratories of the Federal Government. If there had been no AOAC the Federal Government would have had to develop such methods itself at great expense. Even if that had been done, the methods would not have had the ready acceptance of the local authorities and industry which is accorded the AOAC methods. Defendants in court would feel that the government had dictatorially imposed methods of analysis upon their chemists and much time would be consumed in establishing the validity of the methods that are now accepted as standard." Mr. Lepper's contributions to the AOAC were considered by the Department as a "great contribution to public welfare, government, science, and industry outside his official duties but within their scope," and he was awarded the Superior Service Award in 1953.

On the occasion of his fortieth anniversary of service to the AOAC, Mr. Lepper was presented with a sterling silver coffee and tea service engraved as follows:

"Presented to Mr. Henry A. Lepper, Secretary-Treasurer Emeritus, in token of Appreciation of Many Years of Devoted Service to the Association of Official Agricultural Chemists, October 11, 1954."

In his acknowledgment, speaking for his wife and himself, he said, "It came as a complete surprise to both of us, so much so, that I was practically speechless and unable at the time to express our appreciation. It will be among our special treasures in the years to come." Those who knew Heinie were aware that the event must have been important and made quite an impression on him to render him speechless. At the seventy-first meeting of the AOAC, during the first year of his retirement, the Association made Mr. Lepper an honorary member and presented him with a certificate reading as follows:

"The Association of Official Agricultural Chemists
presents
Henry A. Lepper

This honorary membership in recognition of his forty-four years of service to the Association in numerous capacities, including those of President, Secretary-Treasurer, Editor, and Referee, and of his steadfast interest and devotion to its aims and purposes.

Presented during the Association's seventy-first meeting

October 14, 1957
M. P. Etheredge President
William Horwitz Secretary"

Honorary membership in the AOAC previously had only been accorded to two other members, Harvey W. Wiley and H. A. Huston. Subsequently, largely at Mr. Lepper's urging, Paul B. Dunbar was accorded this honor after his retirement as Commissioner of Food and Drugs because of his long-

time support of the AOAC through the Food and Drug Administration.

Heinie's active life resulted in many interesting experiences and these afforded him a rich fund of anecdotes which he enjoyed relating—even though he was the "fall guy" in them. Among some of his favorites were the following:

Once when he was visiting the New York FDA office he had a sudden change of plans that required him to leave hurriedly for Chicago. He asked the clerk in New York to wire Chicago and arrange for an inspector and necessary equipment to be available to work with him the next day. This she did, but somewhere a misspelling occurred in the message and a few minutes later an irate but primly respectable secretary in Chicago stormed into the Chief's office and inquired acidly what kind of a man "this Mr. Lepper is who wires us to have an inspector, with a car and a 'girlie' available for him tomorrow." When the Chief could control his laughter he explained to her that the "girlie" really referred to a Gurley balance needed for close weighing in preparing experimental packs.

In a hotly contested trial involving a seizure of vinegar alleged to have been made from dried apples instead of fresh apple cider, Heinie was the government's expert analytical witness. He had a blackboard set up in the court room and presented first his analyses and then the calculations used to prove the use of sulfured dried apples. The defense challenged some of his figures, which led him into further calculations in which the judge became quite interested and began to participate with suggestions. However, the answer Heinie was seeking seemed to elude him until he stopped, considered the array of figures on the board a moment, and recognized the cause of the difficulty. Whereupon he blurted out, to the dismay of the protocol-conscious laywers and other court officials, "You're wrong, your Honor—we're both wrong. Now I see the trouble — "

He enjoyed telling of a prolonged court case that was held in Memphis in the middle of the summer. The court room was not air-conditioned in those days and the heat was oppressive. Nevertheless the judge required everyone to wear coat and tie. Heinie was on the witness stand when there came a brief recess in the proceedings and protocol was relaxed. He used the opportunity to comment to the judge, who was standing behind the bench a few feet away, how hot and uncomfortable it was. The judge agreed, but added that he had tried to have the case scheduled earlier in the spring but the opposing attorneys would not cooperate. Now they could just sweat for their obstinacy. But he, the judge, had an advantage and he opened his robe slightly to reveal to Heinie that under it he wore only his underclothing!

Heinie's childhood language had been German and this influenced his English grammar and syntax in later years. Having a very competent secretary, he came to rely heavily on her to edit and revise his dictation and put it into the slightly stilted and impersonal style required of "governmentese" in those days, and even now. Once when the secretary was absent and he was using a substitute he forgot and placed the same reliance on her ability to polish his dictation. Instead she wrote it just as she heard it and in an ill fated moment he signed it without realizing the import of what he was doing. It was directed to Dr. Dunbar, then Assistant Chief of FDA, who was a perfectionist and something of a martinet as well. Almost immediately it came back with a buck slip which read—to Heinie's chagrin and dismay—"Lepper, don't you read what you write? P B D." Poor Heinie had to eat crow to restore peace.

Heinie always backed up his chemists even in awkward situations. One of his good analysts had reported finding a relatively toxic preservative in a food product produced by one of the largest food firms in the country. The vice president of the firm came in to see Heinie on another matter and the finding was mentioned to the representative. The vice president said that such a finding was impossible. The company would not be using such a material without his knowledge, since it was his responsibility to approve the use of all such materials. Heinie was firm and suggested that he investigate the situation on his return. A few days later, Heinie received a profuse apology with great respect for the chemist. The firm indeed had started using the preservative without the vice president's knowledge and it was stopped forthwith.

Heinie loved his home and his family. He married Georgie Hummer, whom he had known from childhood, soon after joining the Bureau of Chemistry. They have two sons, Henry A. Lepper, Jr., of Silver Spring, and Mark H. Lepper, of Hinsdale, Illinois; two grandchildren, and one great-grandchild. For over 30 years he lived in a large two-family house that he and his parents built on a large plot in Silver Spring which they called Seven Oaks. He had an extensive garden and he offered the leaves from the large oaks to all comers every fall.

Heinie represents the last of the AOAC members who had any contact with Harvey W. Wiley, the Father of the Pure Food and Drug Act and a founder of the AOAC. He served the AOAC without remuneration "as a labor of love" for almost five decades. He truly deserved the title, "Mr. AOAC."

WILLIAM HORWITZ

William Horwitz, PhD
[redacted]
(Office) (202) 245-1057

Present position: Acting Director, Science Policy Staff
Bureau of Foods, HFF-7
Food and Drug Administration
Washington, DC 20204

Birthplace: Gilbert, Minnesota February 4, 1918

Education:

	Duluth Junior College, Duluth, MN	1934-1936
BS	University of Chicago, Chicago, IL	1936-1937
PhD	University of Minnesota, Minneapolis, MN (Professor Bryce L. Crawford, Jr.)	1937-1947

Employment:

1980 - Present (GS-16) -- Acting Director, Science Policy Staff: Under immediate direction of the Bureau Director, investigate, with the assistance of detailed staff, fundamental, long range problems in the application of science to regulatory issues.

1967 - 1980 (GS-16) -- Deputy Director (various titles and organizational units due to reorganizations) of unit consisting of 400-1,000 professional and support personnel responsible for the research and scientific aspects of the enforcement of the Food, Drug, and Cosmetic Act.

1963 - 1967 (GS-15/16) -- Assistant to Assistant Commissioner for Science: Initiate, develop, and coordinate FDA-wide system for exchange, storage, and retrieval of scientific and medical information. Implement, review, and evaluate scientific program and its administrative support.

1951 - 1963 (GS-12/15) -- Chief, Food Research Branch: Direction of laboratory research to develop methods of analysis required for the enforcement of the food provisions of the Food, Drug, and Cosmetic Act. Assist in agency-wide planning, review, and interpreting results of analysis of foods in terms of regulatory activities.

1949 - 1951 -- (GS-12) Chief Chemist, Minneapolis District, Food and Drug Administration. Supervising laboratory operations of 10 chemists in the analysis of foods, drugs, and cosmetics and interpreting the results in terms of proposed regulatory action.

1939 - 1951 -- (GS-5/11) Chemist, Minneapolis District, Food and Drug Administration. Analysis of foods, drugs, and cosmetics.

1938 - 1939 -- Research Assistant, University of Minnesota: Conducting laboratory work in physical chemistry under Professors George Glockler and R. Livingston

Collateral Activities:

Association of Official Analytical Chemists

Associate Referee
Referee on Dairy Products
Secretary-Treasurer, Executive Director 1952-1978
Editor: Official Methods of Analysis of the Association of Official Analytical Chemists
1955, 1960, 1965, 1970, 1975, 1980 editions

Chemical Abstracts Service, American Chemical Society

Abstractor 1952-1980
Section editor for Foods 1955-
Member, Editorial Advisory Board 1975-1980

Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Food Standards Program; Codex Alimentarius Commission

Advisor to US Delegation to Committee on Government Experts on Milk and Milk Products: Rome Italy, 1958, 1960, 1961, 1962, 1963, 1973. Alternate Delegate: 1964, 1965, 1966

US Representative to the Codex Committee on Methods of Analysis and Sampling; Berlin, Germany, 1966, 1967, 1968; Cologne, Germany, 1969; Bonn-Bad Godesberg, Germany, 1971; Budapest, Hungary, 1972, 1973, 1975, 1977, 1979, 1981

FAO/WHO

Chairman FAO/WHO Expert Consultation on Methods of Sampling and Analysis of Contaminants in Foods, Rome, Italy, 1976

Advisor Second FAO/WHO Expert Consultation on Methods of Sampling and Analysis of Contaminants in Foods, Rome, Italy, 1977

US Department of Agriculture Graduate School

Instructor, 1951-1962

Awards:

US Department of Health, Education and Welfare

Superior Service Award	1956
Superior Service (Unit Citation)	1961
Distinguished Service Award	1965

Association of Official Analytical Chemists

Harvey W. Wiley Award ($750)	1975

Invitational Lectures

Health and Welfare Canada, Toronto and Ottawa. 1980. Regulatory Analytical Chemistry

Royal Australian Chemical Society, Governments of Australia and New Zealand. March-April 1981. Regulatory Analytical Chemistry; The Zero of Analytical Chemistry.

Nordic Analytical Committee, Oslo, Norway, Collaborative Analytical Studies. 1981.

International Union of Pure and Applied Chemistry. Helsinki, Finland. Harmonization of Collaborative Analytical Studies. 1981.

Memberships:

Association of Official Analytical Chemists
American Chemical Society
American Oil Chemists' Society
American Association for the Advancement of Science
Institute of Food Technologists
Sigma Xi

PUBLICATIONS OF WILLIAM HORWITZ

1. A Simple Calorimeter for Student Use. J. Chem. Ed. 16, 287-90 (1939) (with R. S. Livingston).

2. Sulfur Bands and an Attempt to Obtain HS Bands. J. Chem. Physics 7, 857 (1939) (with G. Glockler).

3. Rapid Measurement of Glass-Capillary Diameters. Rev. Sci. Instruments 9, 271 (1939) (with G. Glockler).

4. The Theory of Electrokinetic Phenomena. J. Chem. Ed. 16, 519-535 (1939).

5. Detection of Decomposition in Eggs. J. Assoc. Offic. Agr. Chemists 24, 319-26 (1941) (with L. C. Mitchell).

6. Determination of Salt in Egg Products. J. Assoc. Offic. Agr. Chemists 26, 352-4 (1943) (with L. C. Mitchell).

7. Modified Scharer Phosphatase Test for Milk and Soft Cheeses. J. Assoc. Offic. Agr. Chemists 29, 129-165 (1946).

8. Sampling, Fat and Moisture in Cheese. J. Assoc. Offic. Agr. Chemists 30, 421-422 (1947).

9. Pasteurization Test for Soft Cheeses. J. Assoc. Offic. Agr. Chemists 30, 430-436 (1947).

10. A Raman Apparatus for Quantitative Polarization Measurements. J. of Chemical Physics 15, 268-274 (1947) (with B. L. Crawford, Jr.)

11. The Raman Spectrum and Structure of Nickel Carbonyl. J. of Chemical Physics 16, 147-150 (1948) (with B. L. Crawford, Jr.)

12. Use of the Sodium-Chlorine Relationship for the Detection of Sodium Neutralized Non-Fat Dry Milk Solids. J. Assoc. Offic. Agr. Chemists 31, 121-124 (1948).

13. Sampling, Fat and Moisture in Cheese. J. Assoc. Offic. Agr. Chemists 31, 300-306 (1948) (with Lila Knudsen).

14. Sampling, Fat and Moisture in Cheese. J. Assoc. Offic. Agr. Chemists 32, 303-309 (1949) (with Lila Knudsen).

15. Phosphatase Test in Dairy Products. J. Assoc. Offic. Agr. Chemists 33, 529-544 (1950) (with Lila Knudsen and W. Weiss).

16. Sampling, and Preparation of Sample of Soft Cheeses. J. Assoc. Offic. Agr. Chemists 35, 204-212 (1952) (with S. H. Perlmutter).

17. The Role of the AOAC in the Passage of the Federal Food and Drugs Act of 1906. Food Drug Cosmetic Law Journal 11, 77-85 (1956).

18. A Chemical Method for the Determination of Histamine in Canned Tuna Fish. J. Assoc. Offic. Agr. Chemists 40, 892-904 (1957) (with O. S. Sager).

19. Studies of the Chick Edema Disease Factor. J. Assoc. Offic. Agr. Chemists 42, 129-140 (1958) (with L. Friedman, D. Firestone, D. Banes, M. Anstead, and G. Shue).

20. Authentic Packs of Edible and Inedible Frozen Eggs and their Organoleptic Bacteriological, and Chemical Examinations. J. Assoc. Offic. Agr. Chemists 43, 108-113 (1960) (with F. Hillig, A. P. Dunnigan, and L. L. Warden).

21. Heated Fats II. The Nutritive Properties of Heated Cottonseed Oil and of Heated Cottonseed Oil Fractions, Obtained by Distillation and Urea Adduct Formation. J. Nutrition 73, 85-93 (1961) (with L. Friedman, G. M. Shue, and D. Firestone).

22. Studies of the Chick Edema Factor II. Isolation of a Toxic Substance. J. Am Oil Chemists's Soc. 38, 60-62 (1961) (with A. Yartzoff, D. Firestone, D. Banes, L. Friedman, and S. Nesheim).

23. Heated Fats. I. Studies of the Effect of Heating on the Chemical Nature of Cottonseed Oil. J. Am Oil Chemists' Soc. 38, 253-257 (May 1961) (with D. Firestone, L. Friedman and G. M. Shue).

24. The Examination of Fats and Fatty Acids for Toxic Substances. J. Am Oil Chemists' Soc. 38, 418-422 (August 1961) (with D. Firestone, L. Friedman, and G. M. Shue).

25. Heated Fats III. Determination of Urea Filtrates. J. AOAC 44, 465-474 (1961) (with D. Firestone, S. Nesheim).

26. The Composition of Roasted Peanuts and Peanut Butter. J. AOAC 45, 734-739 (1962) (with H. Smith, W. Weiss).

27. Chick Edema Factor III. Application of Microcoulometric Gas Chromatography to Detection of Chick Edema Factor in Fats or Fatty Acids. J. AOAC 46, 384-396 (June 1963) (with D. Firestone, W. Ibrahim).

28. Quantitative Determination of Formic, Acetic, Propionic, and Butyric Acids by Gas Chromatography. J. AOAC 46, 486-493 (June 1963) (with R. N. Shelley and Harold Salwin).

29. Fatty Acid Composition of Oil from Roasted and Unroasted Peanuts by Gas-Liquid Chromatography. J. AOAC 46, 718-725 (August 1963) (with J. L. Iverson and D. Firestone).

30. Collaborative Studies of the Rapid Detergent Method for Butter Fat in Raw Milk. J. AOAC 46, 737-743 (August 1963) (with D. J. Mitchell).

31. Collaborative Studies of Methods for Butter Fat in Homogenized and Chocolate Milk. J. AOAC 47, 573-576 (June 1964) (with D. J. Mitchell).

32. The Association of Official Agricultural Chemists. In Residue Reviews, Vol. 7, edited by F. A. Gunther, 1964, pp. 37-60.

33. Collaborative Studies of Methods for Butter Fat in Homogenized and Chocolate Milk. J. AOAC 48, 806-10 (August 1965) (with D. J. Mitchell).

34. Comparison of the FAO Schmid-Bondzynski-Ratzloff and Official AOAC Methods for Determining the Fat Content of Cheese. J. AOAC 49, 515-7 (June 1966) (with R. W. Weik).

35. Developments in Adulteration of Food and Its Detection. J. AOAC 50, 1024-1032 (October 1967) (with H. Reynolds).

36. Association of Official Analytical Chemists; Its History, Present Activities, and Future Goals; Procedures for Standardization of Laboratory Methods. 44th Annual Report. New York State Association of Milk and Food Sanitarians. September 23-25, 1970. Syracuse, New York.

37. The AOAC Style Manual--Analytical Methods for "Official Methods of Analysis" and "Changes in Methods" 1972, 51 pp. (with H. Reynolds).

38. Reliability Requirements of AOAC and Food Codex Methods of Analysis. FDA By-Lines 3 (5), 249-260 (March 1973).

39. Obituary. Henry A. Lepper. J. Assoc. Offic. Anal. Chemists 56, 235-8 (March 1973).

40. Surveys of Mercury Levels in Fish and Other Foods. Pesticides Monitoring Journal 7, 127-138 (March 1974). (with Robert E. Simpson and Caesar A. Roy).

41. *Wiley Award Address. The Inevitability of Variability. J. Assoc. Off. Anal. Chemists 59, 238-242 (1976).

---

*Also published in Hungarian: Husipar 29 (May - Sept.) 115-119 (1980).

42. Methods of Analysis Approved by the Codex Alimentarius Commission. I. Acid Value. J. Assoc. Off. Anal. Chemists 59, 658-661 (May 1976).

43. Problems of Sampling and Analytical Methods. J. Assoc. Off. Anal. Chemists 59, 1197-1203 (Nov 1976).

44. A Review of Sampling Plans and Collaboratively Studied Methods of Analysis for Aflatoxins. J. Assoc. Anal. Chemists 59, 1315-1343 (Nov 1976) (with Pieter L. Schuller and Leonard Stoloff).

45. Food Additives and Contaminants. Chapter 10 of Section 9 Reactions to Environmental Agents in Handbook of Physiology. American Physiological Society (1977)k Bethesda, MD 20014 pp. 167-180. (With A. D. Campbell, J. A. Burke, C. F. Jelinek, J. V. Rodricks, and S. I. Shibko).

46. The Establishment of Official Methodology. J. Chemical Information & Computer Sciences 17, 97-102 (1977).

47. The Variability of AOAC Methods of Analysis as Used in Analytical Pharmaceutical Chemistry. J. Assoc. Off. Anal. Chem. 60, 1355-1363 (Nov 1977).

48. Analytical Food Chemistry. Chapter 11 in Quality Assurance Practices for Health Laboratories. (1978) Stanley L. Inhorn, Editor, American Public Health Association, Washington, DC 20036. pp. 545-646 (with S. Cohen, L. Hankins, J. Krett, C. H. Perrin, and W. Thornburg).

49. Collaborative Study Procedures of the Association of Official Analytical Chemists. Anal. Chem. 52, 203A-206A (Feb. 1978) (With E. D. Schall, C. W. Gehrke, A. J. Malanoski, J. P. Minyard, Jr., F. W. Quackenbush, and F. S. Windham).

50. Good Laboratory Practices in Analytical Chemistry. Anal. Chem. 50(6), 521A-524A (May 1978).

51. Methods of Analysis Approved by the Codex Alimentarius Commission. II. Determination of the Loss on Drying of Lactose. Collaborative Study. JAOAC 61(3), 558-560 (May 1978) (With Charles T. Bourland, Robert W. Weik, and Randall L. Anderson).

52. Sampling Methods for Trace Organic Analysis in Foods. National Bureau of Standards Special Publication 519, Trace Organic Analysis: A New Frontier in Analytical Chemistry, Proceedings of the 9th Materials Research Symposium, April 10-13, 1978, held at NBS, Gaithersburg, MD. (Issued April 1979), pp. 231-242 (with John W. Howard).

53. The Inevitability of Variability in Pesticide Residue Analysis. Advances in Pesticide Science. Part 3. H. Geissbuhler, ed. Pergamon Press, Oxford and New York 1979, pp. 649-655.

54. Practicability in Regulatory Analytical Chemistry. Anal. Chem. 51, 741A-745A (June 1979).

55. IUPAC Gas Chromatographic Method for Determination of Fatty Acid Composition: Collaborative Study. JAOAC 62, 709-721 (1979) (with David Firestone).

56. Commonly Used Methods of Analysis for Tin in Foods. JAOAC 62, 1251-1264 (1979).

57. Arsenic and Tin in Foods. FAO Food and Nutrition Paper 9. Food and Agriculture Organization of the United Nations, Rome (1979), 108 pp.

58. Quality assurance in the analysis of foods for trace constituents, JAOAC 63, 1344-1354 (1980) (with L. R. Kamps and K. W. Boyer).

59. Analytical Methods for Sulfonamides in Foods and Feeds. I. Review of Methodology. JAOAC 64, 104-130 (1981).

60. Analytical Methods for Sulfonamides in Foods and Feeds. II. Performance Characteristics of Sulfonamide Methods. JAOAC 64, 814-824 (1981).

61. Analytical Aspects: An Introduction. Chapter 20 of The Pesticide Chemist and Modern Toxicology. S. Kris Bandal, Gino J. Marco, Leon Golberg, and Marguerite L. Leng editors. American Chemical Society Symposium Series 160. 1981, pp. 331-333.

62. Analytical Measurements: How Do You Know Your Results are Right? Chapter 24 in Item 61. Pp 411-438.

63. Analytical Aspects: A Summary. Chapter 26 in Item 26. Pp 461-463.

BOOKS

Editor: Official Methods of analysis of the Association of Official Agricultural Chemists:

8th Edition, 1955, 1008 pp.

9th Edition, 1960, 832 pp.

10th Edition, 1965, 957 pp.

PUBLICATIONS OF WILLIAM HORWITZ (Continued)

11th Edition, 1970, 1015 pp.

12th Edition, 1975, 1094 pp.

13th Edition, 1980, 1018 pp.