AN INTERVIEW WITH WINTON B. RANKIN

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This document is a transcript of an interview with Winton Blair Rankin conducted by Adelynne Hiller Whitaker concerning regulation, under the Food, Drug, and Cosmetic Act, of insecticide residues on food products. The interview was held in Mr. Rankin's home at [redacted], on July 31, 1973.

Mr. Rankin joined the Food and Drug Administration as an inspector in 1939. In 1948 he became Assistant Director of the Division of Field Operations of FDA. He became Assistant to the Commissioner for pesticide operations in 1954, and in 1956 became Assistant Commissioner for general purposes. In 1964 he moved to Assistant Commissioner for Legislation and Planning. Later he became Deputy Commissioner. He retired in 1969 from his post as Special Assistant to the Assistant Secretary for Health and Scientific Affairs.

Mrs. Whitaker is a doctoral candidate at Emory University, writing a dissertation on "Pesticides and Regulation."

Mrs. Whitaker:

Mr. Rankin, would you start by telling me something about your career, when you went with the Service and what you did down through the years?

Mr. Rankin:

Yes, Mrs. Whitaker, I started with the Government Service in 1939 as a seafood inspector in the Food and Drug Administration, which at that time was with the Department of Agriculture. In 1940 the Federal Security Agency was formed and the Food and Drug Administration was one of the federal agencies transferred to that new unit. Shortly I became a full food and drug inspector and worked in the Atlanta, Baltimore, New York, and Boston offices. From Boston I was transferred to the Washington offices for administrative staff work in the drug field. That was in 1946. In 1948 I became Assistant Director of the Division of Field Operations which had supervision of the field staff of FDA.

Mrs. Whitaker:

That included the scientific staff in the field as well as the inspectors?

Mr. Rankin:

That included scientific, inspection, clerical, and administrative staffs. In 1954 I became Assistant to the Commissio

for pesticide operations and was responsible for two years for establishing pesticide tolerances under a new law, the Miller Pesticide Chemicals Amendment. In 1956 I became Assistant to the Commissioner for general purposes and turned over the pesticide operations to others.

Mrs. Whitaker:
That put you, then, working with the entire range of products.

Mr. Rankin:
Yes, it did. Later I became Assistant Commissioner, and I don't recall the date. You may have it.

Mrs. Whitaker:
I think I have 1964?

Mr. Rankin:
I think that's right, yes. I was Assistant Commissioner for Legislation, Assistant Commissioner for Planning, and later became Deputy Commissioner. In late 1969, I was transferred to the Department as Special Assistant to the Assistant Secretary for Health and Scientific Affairs, and worked in that post for two years.

Mrs. Whitaker:
And retired then?

Mr. Rankin:

And retired at that time.

Mrs. Whitaker:

Going back to the early period in your seafood inspection days, was that on the West Coast?

Mr. Rankin:

No, that was on the East Coast. I was stationed in Southern Georgia and Florida.

Mrs. Whitaker:

I am trying to recall the seafood inspector on the West Coast, whose name I have encountered so frequently. Would that have been Mr. Larrick?

Mr. Rankin:

Well, now, Mr. Larrick was our Commissioner for a while. I don't recall that he was stationed on the West Coast.

Mrs. Whitaker:

Perhaps not.

Mr. Rankin:

Mr. Harvey was transferred to Washington from the West Coast. That was in 1948 when he came to Washington.

Mrs. Whitaker:

He had done a great deal of work with the pesticide residues.

Mr. Rankin:

Yes, he had, in the states of Washington and Oregon.

Mrs. Whitaker:

When you first came with the Service, had the 1938 law already become operative?

Mr. Rankin:

Yes, the 1938 law had been enacted and was in the process of becoming operative. I was one of the new group of recruits hired to put the greater push behind the new law that was necessary.

Mrs. Whitaker:

Was there any particular change in the inspection procedure that you know of at that time, under the new law as compared to the old 1906 law? Did you have a more authoritative position as an inspector, do you think, under the new law?

Mr. Rankin:

There was a definite change under the new law. Firms manufacturing foods and drugs for shipment across state lines were required to allow inspection of their manufacturi

operations. Under the prior law there had been no requirement for a firm to permit inspections. Most manufacturers did allow it voluntarily, but as you can imagine the ones who did not were very likely the ones who had something to hide.

Mrs. Whitaker:
And you had no recourse?

Mr. Rankin:
We had no recourse unless we could prove a violation was occurring, in which case you could get a court order directing the firm to let you in. But that was a difficult and time-consuming operation. We seldom resorted to it. The inspection operation after 1938 became more refined than it had been before, there were more inspectors, in general they were more highly trained than a number of those who had been on the staff before. And I don't mean to downgrade the earlier inspectors. They were highly competent individuals. There was a gradual improvement in the inspection operations from about 1938 on to the present day. I think the improvement was still going forward when I last knew the details of FDA operations.

Mrs. Whitaker:
Were they recruiting more carefully, or were they training them more adequately before they put them into the field?

Mr. Rankin:

I would not say that they were recruiting more carefully, because in my observation FDA had been unusually careful in recruiting its people over a period of years. In fact during the depression years in the early thirties when jobs were very scarce, there was perhaps a higher degree of selectivity than there was later during World War II when jobs were plentiful and people were scarce. There was a great emphasis on increased training. There was a great emphasis on better reporting by the inspection staff, so that a supervisor in reading a more detailed report could more readily determine whether the inspector had done a good job or just fair.

Mrs. Whitaker:

Between 1930 and 1940 you were responsible also for taking samples of all insecticides and disinfectants too during that period when the Insecticide Division was still with Food and Drug.

Mr. Rankin:

That is correct, yes.

Mrs. Whitaker:

Actually the men who were in the field then were sampling the entire range.

Mr. Rankin:

Yes, we had insecticide operations and also administered the old Naval Stores Act. We even picked up samples of turpentine once in a while.

Mrs. Whitaker:

How about the Tea Act. Did they have their own inspectors, or did you do that?

Mr. Rankin:

FDA administered the Tea Act. I did not sample tea. There were specially trained tea examiners located in New York, Boston, and I believe San Francisco, the ports where tea entered predominantly, and the actual collection of the tea generally was performed by import examiners stationed at these points, and the examination by the experts in the laboratory.

Mrs. Whitaker:

The caustic poisons remained with Food and Drug, even after insecticides went to the Department of Agriculture?

Mr. Rankin:

Yes. We picked up samples of caustic poisons. The Caustic Poison Act was rather limited in scope. It only covered ten groups of chemicals, and it was not until the early sixties that a broader, more effective law was enacted.

I believe that is still administered by FDA.

Mrs. Whitaker:

I think it is. Products frequently came under the surveillance of all three acts, the Insecticide Act, the Caustic Poison Act, and the Food and Drug Act, I noticed from scanning the Notices of Judgments. I wondered how it was determined from an administrative standpoint which of the three acts would be brought to bear on a particular product.

Mr. Rankin:

In general the principal use to which a product would be put determined the act that would be brought to bear. For example, if a substance were offered primarily as a drug but also had insecticidal properties or happened to be a caustic poison, the drug chapter of the act would be used. On the other hand if it were offered primarily as an insecticide, ordinarily that act would apply. There were occasions in which an act other than the one which governed the primary use could more effectively regulate an abuse, and in that case the other act would be employed.

Mrs. Whitaker:

I noticed in reading through these Notices of Judgment a few cases where a product might have been prosecuted

under one act and then several years later it might have been prosecuted under another act, and I wondered perhaps if that had to do with what you have just mentioned, that it might be easier under certain circumstances to get a judgment under a different act, especially in the area of the antiseptics and disinfectants.

Mr. Rankin:
I think that would be correct. Sometimes manufacturers were very reluctant to remove wild claims from their labels, and they would figure out how to skirt around one law and forget that there was another one which still applied, and so we could catch them the second time under the second law.

Mrs. Whitaker:
For example, on disinfectants, between 1938 and 1947 if the Insecticide Act alone applied to them, they would not have to put directions for use on them, but they did have to have directions for use under the Food and Drug Act. Is that correct?

Mr. Rankin:
Yes, if they had drug claims. And many insecticides do have drug claims.

Mrs. Whitaker:
In the early period when you were still an inspector,

I had noticed with considerable interest that Campbell was put in a rather difficult spot as far as seizures, multiple seizures, because of the provision in the 1938 Act which allowed a manufacturer to consolidate his cases and have the trial in the area most convenient to his location. Do you recall that circumstance?

Mr. Rankin:
Yes, I do.

Mrs. Whitaker:
That created a great many problems for you, did it not? In that it put the litigation in the manufacturer's home territory.

Mr. Rankin:
Well, it depends on the kind of litigation you are referring to. In a criminal or injunction case, it is in the manufacturer's home territory anyway.

Mrs. Whitaker:
But in the seizure cases?

Mr. Rankin:
Seizure cases are not tried in the judicial district where the factory is located. Certainly if we made multiple seizures, the manufacturer could be expected to seek to

consolidate the cases for trial in a jurisdiction where he thought he would get the best reception.

Mrs. Whitaker:

Yes.

Mr. Rankin:

And infrequently, I would say, that did cause trouble, but not very often.

Mrs. Whitaker:

Not as often as I might have assumed?

Mr. Rankin:

I might amplify that. If we could anticipate a consolidation of seizure actions in a jurisdiction that was known to be unfavorable to FDA cases, we just didn't make any seizures in that jurisdiction. So we still had some control over it before we brought the action.

Mrs. Whitaker:

Then that would explain what I found in the correspondence in Campbell's letters to his inspectors in which he cautioned them to refrain from making seizures as you described in the different territories so that he could select the seizure area and get the case outside the unfavorable climate. I am speaking only about the spray residues.

Mr. Rankin:

There were judicial districts that did not look with favor on seizures of fruits and vegetables because of excessive spray residue, and there is no use bringing a case in one of those jurisdictions--Oregon was one. In the center of the apple growing district, there is no point in trying to seize apples in the state of Washington and the state of Oregon, because you are going to lose the case. So if it became necessary to deal with Washington apples, they were dealt with in some other judicial district.

Mrs. Whitaker:

Because of the difficulties of sustaining administrative tolerances, before legal tolerances were established, even under the new law, somewhere in my reading I noticed that Campbell also said that there really was not much point in seizing products that had only a slight residue above the administrative tolerance, because it was too difficult to sustain this in the courts, and suggested that the inspectors limit themselves to products that bore at least twice the administrative tolerance. Would that have been also because of the attitude of the courts?

Mr. Rankin:

Yes. The attitude of the courts, and the attitude of people in general. If the speed limit on a given street is 25 miles an hour, and you are going 26 miles an hour,

and the policeman arrests you, you can be expected to protest that he is shaving a little too close to the announced speed level. So it's routine practice in the case of speed limits and also in the case of pesticide tolerances to allow a sufficient level above the announced speed limit or tolerance so that there is little question in anyone's mind that the person violating the law was engaged in a serious violation and not just a careless or chance infraction.

Mrs. Whitaker:
It is quite expensive to bring these cases to trial, is it not?

Mr. Rankin:
Yes, it is expensive, and it is time-consuming.

Mrs. Whitaker:
And if you seize a product, in a perishable item especially, what was the procedure there if you couldn't get a speedy court hearing, for instance on pears or something that might spoil. Did the shipper ever hold Food and Drug liable for the costs?

Mr. Rankin:
Some shippers tried to, yes. I do not recall that such efforts were successful, except with respect to some

seizures that we made of a leafy vegetable, spinach I believe. This must have been in the fifties. We made some seizures because of high residues. The court did not sustain our position, and the shipper and the producer sued, seeking redress. The district court granted the redress. I lost track of the case. I don't recall whether the government ever paid or not. I believe it did, through congressional enactment.

Mrs. Whitaker:
You had more than one handicap then to overcome in getting these cases through the courts.

Mr. Rankin:
We were supposed to be very sure the case was right before we brought it, yes.

Mrs. Whitaker:
During the 1938 period--I realize this is before your time--but I wonder if you might recall stories circulating after you came with the force concerning particularly the congressional appropriations which took scientific investigation of toxicity of spray residues out of the hands of Food and Drug and placed it with Public Health Service.

Mr. Rankin:
Yes, I recall a lot of stories.

Mrs. Whitaker:

I would love to hear those, and anything you can recall from that period, of how this came about and the people involved.

Mr. Rankin:

The insecticides that were used in those times primarily contained arsenic. Later fluoride-containing insecticides came into use. In the very intensive apple growing areas in the Pacific Northwest, the insects began to cause trouble. When a crop is intensively cultivated over many, many acres, harmful insects may develop such huge populations that they become serious economic problems. That occurred in the apple growing areas, not only in the Pacific Northwest, but it occurs everywhere that you have intensive cultivation of apples or of other fruits. So to combat the increasing pests, the growers applied more and more insecticides, and they found that they had to apply them more often. What happens is that broad spectrum insecticides like arsenic or fluorides kill off not only the harmful insects, but they kill off predators, insect predators that normally would take care of large segments of the population of the destructive insects. So you have a vicious cycle. You apply more insecticides, you kill more helpful insects as you kill the harmful ones, and the next year you have a more difficult problem, and you spray more often. The result was that the apples

out of the major growing regions were coming to market with extremely high levels of arsenic. FDA began an intensive program to cut down on those spray residue levels. The apple producers found that it was possible to reduce the residues by passing the apples before shipment through an acid bath and under brushes that scrubbed the fruit. Those who went to the added expense of washing in acid and brushing and then washing with clear water were able to ship fruit that met the government's informal tolerances, or administrative tolerances. In order to save money, periodically the shippers would slip in a carload of apples that hadn't gone through this rather time-consuming cleaning process; when that happened and when the government found such a shipment across state lines, it brought seizure action. It is quite a loss to a shipper to have a carload of apples seized. There is a lot of money involved there. The apple growers didn't like these activities on the part of the government. They were angry, angry to the point that on one or two occasions when our principal representative on the West Coast, John Harvey, went around to address meetings of apple growers, he found it wise to leave the meeting by the back door, and get out of town before he was mobbed. The Public Health Service at about this time was making studies on man to determine whether the levels of arsenic that we were being exposed to were causing any detectable change. These are very proper studies, they need to be made

industrially and otherwise; but man is not the best test subject for the effect of poisons, because you can't treat him quite like you can a laboratory animal. You can't put him to sleep at will, and cut him up and inspect his organs under the microscope to see whether there has been some effect that doesn't show up grossly. So while these studies were and are very proper, they were and are not an adequate substitute for more detailed, long-term studies conducted on laboratory animals.

Mrs. Whitaker:
Food and Drug was at this time also, in the Pharmacological Division, doing laboratory experiments?

Mr. Rankin:
FDA at that time, yes, was performing pharmacological studies on the effect of arsenic on laboratory animals. The FDA studies indicated that the administrative tolerances for arsenic should be lowered. The Public Health studies on man indicated that there was no detectable effect on man from the higher tolerances that had been in effect earlier. You can imagine that the apple growers, the apple shippers, the congressmen and senators from the apple-producing states found it much more desirable to rely upon the Public Health Service studies than to rely upon the FDA studies; and the net result was that FDA was directed in one of the appropriations bills--you

would know the date better than I--'38

Mrs. Whitaker:
I believe it was '38, or 1937.

Mr. Rankin:
FDA was directed not to use any of the appropriated monies to conduct spray residue studies, and Public Health Service was directed to conduct studies on toxicity of spray residues for the federal government.

Mrs. Whitaker:
What was Secretary Henry A. Wallace's position on this? What was his attitude?

Mr. Rankin:
I can't give you specifically Mr. Wallace's position. I can state in general that the Food and Drug Administration was not well located in the Department of Agriculture. That Department has as its primary objective aid to the farmer in the production of more food, and aid to the farmer in increasing his income. Many of the actions taken by Food and Drug Administration such as seizures of apples that have a high spray residue result in economic loss to the farmer. So there was a built-in conflict of interest between this regulatory agency, FDA, and its parent body, the Department of Agriculture. And over the years from

the very time that FDA was established to exercise regulatory functions, it had come into repeated conflict with its supervisors in the Department of Agriculture. So while I do not know specifically what Secretary Wallace's actions were at the time, I can say that in all likelihood he simply reflected the traditional view of the Department of Agriculture that FDA was a bump on the log of progress.

Mrs. Whitaker:
Tugwell at this time, in the early period, when this dispute, if we could call it that, existed between Public Health Service and FDA, was more more aggressive in consumer protection.

Mr. Rankin:
Yes, he was. Tugwell was very much more aggressive. Tugwell was the man who, when many of the deficiencies of the existing food and drug law were explained to him, about 1932 or 1933 said, "Well, we'll simply get you a new law. Mr. Campbell, you draft the kind of law you would like to have and bring it over to me." And those efforts which started in Congress in 1933 resulted finally in the enactment of the 1938 law. It was not at the urging of Secretary Wallace.

Mrs. Whitaker:
Wallace's position was probably greatly relieved after

Public Health Service recommendations were followed, and this would have taken some of the pressure off of the Department from agriculturalists.

Mr. Rankin:
Yes. I feel sure he was relieved.

Mrs. Whitaker:
Yes, the circumstances would at least lead us to think that he probably was. I had not found much in the correspondence on that. He seemed not particularly anxious to have Dr. A. J. Carlson work on this problem, because Carlson's opinions were more in line with Food and Drug. Did you know Dr. Carlson?

Mr. Rankin:
Yes, I did. Not at that time, but I knew him later.

Mrs. Whitaker:
I would really be interested in any recollection that you might have about him. He is a most unusual and interesting personality.

Mr. Rankin:
Well, A. J. Carlson in his prime was one of the world leaders in toxicology and pharmacology. I recall a story told by one of our men who was scheduled to meet Dr. Carlson

in preparation for a court trial, a contest of one of our seizures. Dr. Carlson had agreed to testify as to the pharmacological properties of the insecticidal residue that we had found on a crop. Our inspector went to the hotel in the city where the trial was to be conducted and he began looking for Dr. Carlson. The clerk at the desk said, "The last time I saw him, the doctor was sitting out on the front porch." So the inspector went out on the porch, and the only fellow there was a seedy looking gentleman with one of his trouser cuffs rolled half-way up his leg. His pants were not pressed. He just wasn't the kind of man that you would associate with a world-famous pharmacologist. But he was the only one there, so our man went over and said, "Do you by any chance happen to be Dr. Carlson?" "Why, hell yes," he said, "I am." He was indeed a remarkable character, a very brilliant man.

Mrs. Whitaker:
He seemed never to hesitate speaking his convictions.

Mr. Rankin:
He had no hesitation about speaking his convictions, and while he testified for the government on several occasions, he also testified against the government in one of the cases we brought on a product called filled milk. There was a law that forbade the addition of any fat other than butterfat to milk, vegetable oil, for

example. This was designed at the behest of the dairy industry to put out of business a competing product called Milnot, made out of skimmed milk and vegetable oil, which could be sold much cheaper than evaporated milk. Nutritionally there is no reason why you shouldn't have the competing product, and Dr. Carlson so testified. The government prevailed in that case, however, and Milnot was for many years illegal in interstate commerce.

Mrs. Whitaker:
I did not know that. It is not now, is it?

Mr. Rankin:
At the present time with appropriate label safeguards, I believe it can be sold.

Mrs. Whitaker:
Dr. Carlson, of course, is not living any longer.

Mr. Rankin:
I believe not.

Mrs. Whitaker:
In 1940 when Public Health Service finally presented its preliminary findings to Campbell, Campbell was considerably disturbed about the difference that you mentioned a moment ago on recommendations. Carlson was the man that Campbell relied upon, saying something to the effect

that if Carlson approved Public Health Service recommendations, then Campbell would be willing to accept them. Carlson did not approve, if I remember . . .

Mr. Rankin:

I believe he did not.

Mrs. Whitaker:

And there seemed to be some contest between Neal's opinion, who was the surgeon with Public Health Service, and Carlson. Do you recall any of the details of that confrontation?

Mr. Rankin:

No, I do not recall the details. Now the man that might be able to give you the most information on that is Dr. A. J. Lehman.

Mrs. Whitaker:

I didn't know that Dr. Lehman was still living.

Mr. Rankin:

He is still living, yes. He lives over here in Arlington, not very far from here.

Mrs. Whitaker:

Very good.

Mr. Rankin:

Either Arlington, or Fairfax County, right near the line.

Mrs. Whitaker:

Did he replace Dr. Calvary?

Mr. Rankin:

Yes. Now while Dr. Lehman was not intimately involved in this earlier period, I would assume that he has heard more of the discussion concerning it than I have.

Mrs. Whitaker:

What do you recall about Dr. Calvary?

Mr. Rankin:

He was a very personable gentleman. He certainly gave the impression of being an extremely competent scientist. That is about all I recall of him.

Mrs. Whitaker:

About the time that fluoride came into widespread use, it was hoped, was it not, that that could replace arsenic and be less toxic to humans?

Mr. Rankin:

Yes.

Mrs. Whitaker:

And it proved not to be?

Mr. Rankin:

Well, fluorides are toxic in a different manner. Initially when fluorides were first employed it seemed that they permitted control of the insects with less frequent spraying schedules, perhaps less intensive dosage of poison. But pretty soon the insects began to develop resistance to it, their populations expanded, and just as with arsenic sprays you had to have a heavier and heavier application of fluoride in order to achieve control, so that the net result was in a few years that you had just as big a problem with fluorides as we had earlier with arsenic.

Mrs. Whitaker:

The agitation seemed to come from a very small group of growers in the Pacific Northwest, the ones who viciously opposed Food and Drug. Does the name Ira D. Cardiff ring a bell with you?

Mr. Rankin:

I have heard the name, but I can't give you any of the interesting details about Cardiff. It does ring a bell.

Mrs. Whitaker:

Food and Drug lost a case against Cardiff. This would

have been in the period before your service. His name undoubtedly stayed with Food and Drug for quite some time, because he really upset the whole procedure.

Mr. Rankin:
Right.

Mrs. Whitaker:
I am jumping around a bit, but while we are on the matter of fluorides, Campbell, after 1938, began almost immediately pushing rather aggressively for hearings to establish a legal tolerance. I think he stated at one point that he would rather have a legal tolerance that was higher, but something that he could enforce, than operate on the administrative tolerances. He didn't accomplish hearings until 1944 on fluoride, and most of the records indicate that the growers opposed hearings. They undoubtedly then were more satisfied with Public Health recommendations than they would possibly have been with what you could have established as legal tolerances?

Mr. Rankin:
Well, they didn't trust Campbell. They did trust the Surgeon General of the Public Health Service. As you say, they were more satisfied with his recommendations. I am satisfied that they regarded Mr. Campbell and his associates as evil men out to destroy the apple growing industry.

Mrs. Whitaker:

I think they said "a gang of hoodlums" at one point.

Mr. Rankin:

Some such term was used, yes. So given an administrative tolerance which I believe was twice as high as the one Food and Drug Administration had intended to impose, and given the fact that they could not control Mr. Campbell once he got into the hearing procedure and didn't know whether he would set the firm legal tolerance at the then more liberal administrative tolerance or at a stricter lower level, they were scared of the prospective hearings, and they did resist hearings.

Mrs. Whitaker:

How did Campbell manage to get the hearings in 1944 on fluoride?

Mr. Rankin:

Well, he was in a position to call a hearing if he wanted it. Now the time lag was not entirely due to the efforts of the apple growers. The provision of law under which the hearings had to be held said that FDA could establish tolerances for any poisonous or deleterious substance which was added to food, where such addition was required, and so FDA had first the problem of establishing that the fluorides were in fact poisonous or deleterious.

Now the tests that were generally performed in this early period of the 1930's on pesticides were acute toxicity tests on animals, to see how much was required to kill half your animals. The long-term or chronic toxicity tests as we know them today were only beginning to become accepted as necessary, so in the absence of the longer tests to establish whether or not this material was in fact toxic in a small dosage over a long period of time, FDA had to do quite a bit of research work and develop background support for the position, first, that fluorides are harmful, or deleterious.

Mrs. Whitaker:
And he called these hearings in spite of the objections of the apple growers at that time?

Mr. Rankin:
My recollection is that, yes, the hearings were scheduled over the objections of the apple growers.

Mrs. Whitaker:
While we were on arsenic--why was not lead arsenate included in those hearings? Do you have any recollections of why . .

Mr. Rankin:
I don't know the answer to that. My guess is that the job of developing background material was so extensive

that the agency decided to zero in for the first hearing on the most recently adopted pesticide which was then most widely used. It is a guess on my part.

Mrs. Whitaker:
By 1944, then, you would estimate that fluoride was more actively used than the lead arsenate.

Mr. Rankin:
I believe it was on many crops.

Mrs. Whitaker:
That hearing turned out to be a disaster for Food and Drug, in that a circuit court of appeals set the tolerances aside because of a technicality. Was it called fluoride rather than . . .

Mr. Rankin:
No, the order which issued from the hearing referred to a tolerance for fluorine, which of course is a gas. It is part of the fluoride compound that was in use, and the circuit court ruled that since fluorine is a gas, and since fluorine is not what is applied to the crop, the tolerance for fluorine had no application to the residue on the crop, and the regulation was without effect.

Mrs. Whitaker:
How did that unfortunate terminology get in there, do

you know the circumstances?

Mr. Rankin:

No, I don't remember the circumstances. Oh, someone without imagining that it might turn out to be poor legal drafting simply adopted the rather common practice among chemists of referring to fluorides as fluorine. It was admittedly a poor use of language, but it is understandable.

Mrs. Whitaker:

And then there were no further hearings after the findings of that hearing were set aside until the hearings in 1950?

Mr. Rankin:

That's right.

Mrs. Whitaker:

Before we get into that period I want to ask a little bit more about the early period and vegetables. The inspectors' reports would indicate that spray residues on vegetables were sometimes even more serious than the ones on fruits and vegetables and yet there was never public clamor concerning that as there was about the apples. Do you have any explanation for that?

Mr. Rankin:

The vegetables that hold the highest spray residues in general are the leafy crops. Spinach and cabbage, kale,

and the like. They have a large surface area for the pesticide to settle on. In the case of cabbage, the leaves soon fold over and they enclose residues within the head, the rain and winds will not erode that residue off very much. But you do not have a concentrated produc[illegible] industry of these leafy vegetables in the same way that you have a concentrated producing industry for apples. While you do have sizable apple producing areas in other parts of the country, the Pacific Northwest is for commer[illegible] purposes the apple-producing part of the United States. You don't have such concentration in the case of the vege[illegible] tables, so we did not have the very intensive and sustai[illegible] effort on the part of the vegetable growers to block the FDA's efforts to control residues on those vegetables.

Mrs. Whitaker:

I had assumed that that might be it, because I had found no record of any kind of organized opposition to Food and Drug. One other point on that that I was curious about--the records indicate that Food and Drug under Campbell's direction spent considerable thought and time in educational programs directed toward apple growers in the hope that through education they might see the benefi[illegible] of producing a safer product for commerce. But I did not find any record of the same kind of intensive progra[illegible] applying to vegetable growers. Would that be tied in with this same factor--that vegetables were dispersed and grown over a wider area?

Mr. Rankin:

While there may be no record of such an intensive program with respect to vegetable growers, I know that the educational programs were directed at all fruit and vegetable producers. The record is built up in the case of the apple growers because that is where most of the howls were coming from. But Mr. Campbell for many years, well from before the enactment of the 1938 law, was a strong advocate of educational efforts first, with prosecution or other legal measures being reserved for those cases where people just wouldn't pay attention, and failed to heed the educational efforts. So that there were many examples of educational work by FDA in addition to the spray residue educational programs. There were programs with regard to shell fish sanitation, with regard to dried fruit sanitation, with regard to good drug production--throughout the range of FDA's area of interest there were educational programs of one type or another.

Mrs. Whitaker:

And so it would not be limited to the apples. They got more publicity than any others?

In the insecticide records there is one particular case that the government lost, which established a rather serious precedent in that having lost the case it could not then again under constitutional guarantees prosecute this same product. Do you recall any cases relating to

spray residue where this kind of thing might have occurred other than the one I have already mentioned of the case that FDA lost to Cardiff that might have made Campbell skittish about bringing cases?

Mr. Rankin:
I believe the situations would be different in the insecticide label cases brought under the insecticide law and the spray residue cases brought under the pure food and drugs law. I don't recall the exact case you refer to, but my judgment would be that that was a case that charged a label violation.

Mrs. Whitaker:
Yes, it was.

Mr. Rankin:
The label of this particular insecticide either did not have adequate directions for use or did not have adequate warnings. Once having lost that case, the government then would be barred from bringing another case based on the same label, unless it developed new scientific evidence not earlier available to support its action. But the pesticide cases brought against apples did not charge label violations; they charged that a food contained an added poisonous or deleterious substance. So having lost one pesticide case, you would not necessarily be barred from bringing action against a different

shipment which ordinarily would have some different level of pesticide residue. I don't believe that that influenced Mr. Campbell, no.

Mrs. Whitaker:
So he would not have been faced with the same situation.

Mr. Rankin:
No.

Mrs. Whitaker:
Both the insecticide act and Food and Drug, I believe I am correct in this, I think I read the appropriations in 1943 were cut, I know they were cut for insecticides act enforcement, and I think that they were cut also for Food and Drug enforcement in 1943. Do you recall what prompted that? The appropriations hearings do not specifically state. Was this a political factor, or was it involved with the War and finances in general?

Mr. Rankin:
I'm aware that there was a reduction in our appropriation about that time. I have no clear recollection of the reason for the reduction. My guess would be that it was as part of the economy effort to preserve funds to pursue the war. This particular cut in appropriations was not, as I recall, the result of a crusade by some

offended member of Congress against the agency.

Mrs. Whitaker:

Back again to the earlier period, there is one more product that I have some interest in and that is the selenium sprays that were at one time used on the citrus. Do you have any recollections about that particular chemical?

Mr. Rankin:

Selenium is an extremely toxic chemical. I would say that its order of toxicity is considerably greater than the toxicity of the chemicals that had been used, such as arsenic, fluorides, and later DDT. In fact we now know that selenium is capable of producing cancers in test animals when administered to them in relatively small dosage. So the Food and Drug position over the years has been that selenium has no place in agriculture. I believe that it enjoyed at one time some use where it could be applied to the crop, say a citrus crop, before the fruit had formed on the tree, to control a pest at that time; but so far as I am aware selenium has never been allowed to be applied to a crop after the edible portion had started to form.

Mrs. Whitaker:

Campbell then certainly was justified as far back as 1933 in viewing selenium with a great deal of alarm even though perhaps the toxicity studies were not completed

at that time. He certainly was alarmed about it.

Mr. Rankin:
The evidence that has developed since indicates that he was well advised to proceed with caution in 1933.

Mrs. Whitaker:
I have one more question about the early period, and then we will perhaps get off of that. Lead arsenate and fluorides remained in rather active use in the 1940's, after DDT had made its appearance. Am I correct in that assumption?

Mr. Rankin:
Yes, that is correct. When DDT came into widespread production, the U. S. Department of Agriculture, agricultural departments of the states, and county agents began to recommend its use for control of many, many pests, and the larger growers, those who consult agricultural experts and abide by their recommendations on an annual basis of course shifted over to DDT promptly. But there are many thousands of farmers who do not consult an agricultural agent on an annual basis and may not follow his recommendations even when they do. So there was a period of some several years during which the use of arsenates and fluorides was gradually decreasing, and use of DDT was increasing dramatically. We were still finding some excessive arsenate and fluoride residues even in the fifties

Mrs. Whitaker:

Then they figured--those two products--in the hearings in 1950, did they not? Tolerances were discussed for lead arsenate and fluoride.

Mr. Rankin:

Yes, they were. And were established for them.

Mrs. Whitaker:

I wonder how much influence came from the very word "arsenic" as compared to DDT in the wild abandon with which DDT was used right along. Most people knew that arsenic was poison and were cautious to some extent, but DDT sounds so harmless compared to arsenic. Was this a factor in the excessive use, do you think?

Mr. Rankin:

It might have been. Oh, unquestionably it was a factor, yes. Arsenic over the centuries has been known as a poison and has been used as a poison, and I can well recall that when we were having our difficulties with arsenic and fluorides as spray residues, we would say: If there were only some non-metallic substance, some organic substance that would do the job, wouldn't that solve all of our problems? And then chemists came along and developed this organic material, DDT, which does not have the acute toxic properties of the arsenic and

fluorides, and in truth it seemed like the dreamed of period had arrived, that we had now reached the point where spray residues would never be a problem again. DDT was effective in small amounts. It was effective against a tremendous variety of insects, so the age when man had finally achieved success over insects seemed to be at hand. Another thing that contributed to the very widespread use of DDT was the fact that we had for the first time a substance that could be used to essentially eliminate the malaria-carrying mosquito. So in addition to the recommendations of agricultural experts, we had Public Health experts throughout the world urging widespread use of DDT. There was just a peculiar combination of circumstances that led to a more rapid introduction of this new compound and a more widespread use of it than perhaps had ever occurred before with any new chemical compound.

Mrs. Whitaker:
I was interested in Dr. Wayland J. Hayes' comments about the hazards of arsenicals even as late as 1953. In his correspondence it was also brought out that you were still plagued with arsenical residues that late, especially in the household insecticides.

Mr. Rankin:
Yes, that was one place that they were still being employed rather widely.

Mrs. Whitaker:

Back again to a question that I had overlooked earlier about the Public Health Service and Food and Drug recommendations. It was interesting to me, and perhaps you could elaborate on this, the fact that Food and Drug was primarily a regulatory agency and Public Health Service was not, and would this have contributed some to the fact that they were more willing to get out on the limb as far as their recommendations, because they did not have to enforce it and did not have to take the full brunt of any criticism that came.

Mr. Rankin:

I should introduce my remarks at this point by saying that I have a very high regard for the Public Health Service, and for the sincerity and integrity of the individuals who have made up that Service over the years. It has truly been a major factor in better health in the United States. I do think you put your finger on a problem that the Public Health Service itself did not recognize, and that is the fact that the individual who is not engaged in regulation and is not acquainted with the problems that occur in a regulatory operation may not stop to consider the regulatory implications of his scientific pronouncements. On the other hand, the individual who is engaged in a regulatory operation must necessarily consider not only the science that is involved but also the process by which this science can be translated

into a practical control mechanism where control is necessary. As a result, there is no doubt in my mind that the Public Health Service made recommendations which it believed were scientifically accurate that were poor recommendations from the standpoint of regulation of pure foods and drugs. They did it honestly; they didn't do it with any intent to harm the nation. But the net result was a definite harm to the regulatory programs of the Food and Drug Administration.

Mrs. Whitaker:
It made no allowance for the fact that the speed limit you were talking about earlier, that there would be always those violations, or at least those producers who would, by just a slight margin, extend themselves beyond the legal tolerance to begin with.

Mr. Rankin:
That is part of it. Also the recommendations of the Public Health Service upon occasion were based almost entirely on human experience with a compound, DDT for example, and did not recognize the fact that in our society we can't test the effects of a poison to its ultimate extent on man. And you have to take into account the results of testing on laboratory animals. So while the Public Health Service found that DDT was essentially a safe substance for man, the Food and Drug Administration tests indicated that there were definite problems that required

strict limitation, much more strict than Public Health Service wanted.

Mrs. Whitaker:

I wonder if you might give me some information about the cooperation or the feeling between Food and Drug and the Insecticide Division in formulating the 1947 Act?

Mr. Rankin:

I can't help you on that point.

Mrs. Whitaker:

Let me be a little more specific, perhaps bring up something. Was there a point at which Food and Drug recognized that control of insecticides through some kind of registration process such as the 1947 Act provided could eventually lead to tolerance control? Was this considered by Food and Drug in that period?

Mr. Rankin:

I don't know. I can give you the sum and substance of my knowledge about this period very briefly. Administering the old insecticide act was regarded by many Food and Drug employees as a burden that interfered with the primary obligation of insuring pure food and drugs. So while we in the field, to give you the inspector's viewpoint, did the assigned insecticide work, we did it with no great

enthusiasm. There was a general feeling of relief when the insecticide work was left with the Department of Agriculture as we went to the Federal Security Agency. Some people who previously had been employed by FDA remained behind to handle the insecticide work. There were very cordial relations continuing between these old friends who had been in the same agency, and I would judge that FDA without offering any great assistance applauded the efforts of the Department of Agriculture in getting an improved law in 1947. It was only after that law became operative and was being implemented that some problems developed between the two groups.

Mrs. Whitaker:
I am aware of some of those problems in a vague sort of way. I will just say what impressions I have gotten from the manuscript material, and that is that Agriculture or the insecticide people sometimes thought Food and Drug was a little too exacting.

Mr. Rankin:
There's no doubt about that. This continued the view that the Agriculture people had had when we were with the Department of Agriculture, yes.

Mrs. Whitaker:
It became something of a problem out in the open when

the registration thing came in, did it not?

Mr. Rankin:

Yes. Now, the Food and Drug scientists on the other hand felt that as Agriculture registered labels for insecticides to be used around the home or to be used around food producing establishments, they sometimes were lax in the requirements that were imposed, or in the precautions that were imposed in the label directions.

Mrs. Whitaker:

Do you think that reflected yet the old difference also of the economic interests on the one hand and the public health interest that Food and Drug would have had?

Mr. Rankin:

As the Department of Agriculture administered the federal Insecticide, Fungicide and Rodenticide Act of 1947, it sometimes ignored the recommendations of the FDA scientists, the formal recommendations. There was initially a very close informal working relationship between the scientists. They were located in the same building, the South Building of Agriculture, they knew each other well and did confer. But as labels were offered to the Department of Agriculture for registration for uses that would allow a pesticide around a home or around food-producing establishments, directions for use or cautions against misuse crept in

that seemed to the Food and Drug Administration to be unwise. Informal representations were made by FDA personnel to the Agriculture personnel in an effort to achieve some tightening of their control. At a later date this was pursued to the point that Agriculture was required by the key personnel over there to consult FDA on labels having to do with food and drug uses. And they were required to receive FDA comments formally.

Mrs. Whitaker:
This was before the 1954 act now that you are talking about? This was in that period before the Miller Amendment?

Mr. Rankin:
It was right around the early- or mid-fifties that it started yes. I believe before, but then the records would need to be checked on that. Unfortunately the people in authority in Agriculture did not impose the requirement upon the FIFRA administrators that they abide by the FDA recommendations, so there were occasions in which FDA recommendations for more stringent control on pesticides for use around the home or food were ignored and repeated and ignored and repeated and ignored. This obviously led to some strained relations between the two agencies.

Mrs. Whitaker:
Was that a factor in getting the Miller Amendment into

motion that would require a cooperative effort between the two?

Mr. Rankin:

No, I believe that was not a factor there. The factor that required that cooperative effort as stated in the Miller Amendment was this -- Let me give you a little background first: In the mid-forties, about the time that DDT exploded into widespread use, there were many other new chemicals that were finding their way into foodstuffs or were being considered for food uses for just scores of different purposes--as emulsifiers, humidifiers, or anti-caking agents, as agents to make bakery mixes foolproof for the inexperienced cook, and so forth. The law with regard to the chemicals in foods--not just pesticides, but any chemicals--at that time did not require the manufacturer to test a substance for safety before it was marketed. It prohibited the addition of a poisonous or deleterious substance to food, but the tests to determine whether a new substance was in fact poisonous or deleterious did not have to be performed by the manufacturer.

Mrs. Whitaker:

It was incumbent upon Food and Drug . . .

Mr. Rankin:

And thus it became incumbent upon the federal government, or a state government, or a private institution to make

tests if no one else did. It takes more than two years to test a new substance for chronic toxicity, three or more. The animal tests alone require two years just to administer the chemical in the diet, and thereafter you have to sacrifice the test animals and examine their various organs and systems. So three years for total testing is short time. With hundreds of new products coming on the market, it was impossible for FDA to test all of the new materials being offered for food use. Some of the proposed uses would have led to the addition of millions of pounds of inadequately tested chemicals to the human diet per year; additives to bread, for example, to make it stay soft longer. Then Commissioner Paul Dunbar, who succeeded Mr. Campbell, became concerned about the public health problem that he saw developing, and he went up to Capitol Hill to discuss the matter with Congressman Frank Keefe, an influential member of the House Appropriations Committee who had shown great interest in safeguarding the food supply of the country. Mr. Keefe listened with a great deal of interest to Commissioner Dunbar's statement of problems that were developing The Congressman said he needed to think about the matter, and talk with some of his associates about it. He did get in touch with Dr. Dunbar shortly and said that the facts the Commissioner had related were not generally known on the Hill, nor were they generally known throughout the United States. Mr. Keefe believed there was no way to secure adequate remedial action until there was a wider

appreciation of the problem. So he decided to sponsor an effort to get a broad study made of the addition of chemicals to food by a special committee of the Congress; he introduced a Resolution in the House to establish a select committee to investigate the use of chemicals in food and pesticides on food. The Resolution passed. The Select Committee was chaired by Congressman John J. Delaney, and came to be known as the Delaney Committee. Over a period of three or four years, it developed details concerning the facts Dr. Dunbar had related to Mr. Keefe. It developed the views of informed scientists that there was indeed a public health problem of significant magnitude confronting the American people. And the Committee recommended that very strong legislation be enacted to require a new substance to be tested for safety and approved by the government before it is introduced into the food supply. This recommendation led to prompt action by the pesticide manufacturers. The National Agricultural Chemicals Association, the national association of the major pesticide manufacturers, believed that if legislation were enacted to control under the same language pesticides and other food additives that their compounds would be at a serious disadvantage because of their greater relative toxicity. So they pursued actively and almost immediately the recommendations of the Delaney Committee with respect to pesticide alone. The Food and Drug Administration was glad to support improved control measures for pesticides and offered

some strengthening language to the bill suggested by industry. With combined Government-industry support the Pesticides Chemicals Amendment was enacted in 1954. (It was not until four years later that the Food Additives Amendment was enacted to control chemicals that reach food through other means, by direct addition, for example, or by indirect incorporation during manufacture.) Now let's see, your question was what prompted the requirement that we consult the Department of Agriculture in setting pesticide residue levels. The pesticide manufacturers maintained, and properly so, when the pesticide law was under consideration, that Food and Drug employees are not agricultural experts; they are experts in their field, but that is not agriculture. The manufacturers and agricultural experts said agriculture must have something to control insects for our nation to produce an adequate food supply. So while they did not ask that the Department of Agriculture set the level of safe pesticide residues, they did ask that when FDA set the level of safe residues it keep in mind the requirements of agriculture, whether a substance is required and whether the recommendations of the manufacturer or the person who seeks a tolerance would in fact yield control of the insect to be attacked. That was a reasonable proposition, and we agreed that there should be a provision in the law that before setting a pesticide tolerance FDA should take into account recommendations of the Secretary of Agriculture, although those would not be controlling.

Mrs. Whitaker:

I was amazed in reading the records of the Miller Amendment how quickly it did become accepted, and the cooperation of Mr. Lee Hitchner of the National Agricultural Chemicals Association.

Mr. Rankin:

It shows what can happen when the government and industry work together as a team rather than as adversaries in seeking new legislation.

Mrs. Whitaker:

It must have been quite costly for an insecticide manufacturer, for instance, to perform the studies required for his product before it would be accepted for registration.

Mr. Rankin:

It was extremely costly, yes. I have seen various estimates. I don't believe anyone estimates much less than a million dollars as the cost of putting a new pesticide on the market, and others estimate considerably higher than that. It requires up to five years, sometimes longer.

Mrs. Whitaker:

The question I had was why did the manufacturers of these pesticides so willingly agree to support the Miller Amendment, when it was going to be so costly for them.

Mr. Rankin:

They thought that was much to be preferred over getting thrown into the same control mechanism that regulates less toxic food additives. I think they were quite perceptive in that regard.

Mrs. Whitaker:

So that that was a well-organized industrial group of manufacturers?

Mr. Rankin:

Very well organized, yes.

Mrs. Whitaker:

You knew Mr. Hitchner of course. I know nothing about him. I have not been able to find any of his papers. Could you tell me something about him just as a person, any dealings you might have had with him?

Mr. Rankin:

Well, Lee Hitchner was a very likeable individual, as you would expect. Most of these Washington lobbyists are. I believe they called him Executive Director of the National Agricultural Chemicals Association. He was head of the Washington office. He was not a scientist. He had been in the pesticide manufacturing business. Now just why he decided to leave that and come to Washington as a trade representative, I don't know. He did, and he made

a very effective one. I dealt with him for a number of years. I don't think Lee Hitchner ever lied to me. He was honest. He certainly represented his Association well and vigorously. He didn't hesitate to use any proper method of bringing his Association's views to the forefront. But he did not want to create a situation in which the government and the pesticide chemical manufacturers were fighting each other. He said, "Look we are all responsible people. We have the same goals. We don't want to poison people any more than you folks in government want us to. Let's sit down and work it out together." So we did over a period of years operate on a very frank, friendly, straightforward basis. And I think we accomplished in a short period of time much more than could have been accomplished had each side adopted an adversary position and had we started fighting everything out in the courts.

Mrs. Whitaker:
When you actually began establishing tolerances for products after the Miller Amendment . . .

Mr. Rankin:
Excuse me, but could I say one more thing about Hitchner at this point. While Hitchner said the things that I have just related, "Let's not fight; let's sit down together" to the government, he was saying them in much

stronger tones and much more forcefully to the pesticide industry. There were some manufacturers who wanted to start out in an adversary relationship as we administered this new 1954 law. And Lee Hitchner, through his own persuasiveness and by enlisting the aid of other manufacturers who had sounder thoughts, was able to swing the entire industry into a position of cooperation rather than opposition to the administration of this new law. I think the man deserves a lot of credit.

Mrs. Whitaker:
I wanted to know more about him, because I think he played the same role in passage of FIFRA in 1947.

Mr. Rankin:
I believe he had a strong role in that, yes.

Mrs. Whitaker:
They had very little opposition from industry over particular points. They may have disputed and compromised some, but the idea that the law be necessarily revised was held by Hitchner as well as inspectors. I don't know if Hitchner is still living.

Mr. Rankin:
I don't know either. He retired some years ago, and I would be surprised if he is still living.

Mrs. Whitaker:

Did you know Hamilton who represented the Chemical Specialties Association?

Mr. Rankin:

I did not work with him. I have met him but can't say that I know him.

Mrs. Whitaker:

One of the things that puzzled me somewhat and that I observed in the correspondence files was that Food and Drug officials displayed a great deal more confidence and assurance concerning safety of products in their correspondence with consumers than they did to one another. The concern over DDT, for instance, was not as obvious in public utterances as it was in private ones. Do you have a comment on that?

Mr. Rankin:

Yes. First, I have observed the same thing that you have, and I have observed it first hand, that once a rule was established, or a tolerance was established, the Food and Drug Administration adopted the philosophy that there could be nothing wrong with it, it was just exactly that way. There was a general feeling unwritten, unstated, but I am sure it was there for many years in Food and Drug that if you ever admitted to any doubts publicly, your whole program would be wrecked. You would destroy

the confidence of the American people in the Food and Drug protection mechanism of the country. Now that was a mistake, and I think that the continued operation under that philosophy over a period of years hurt the Food and Drug Administration. In later years, I'll say within the last ten years, the agency has turned more to the philosophy that it is perfectly obvious that no one is perfect, and you will get more effective regulation of foods and drugs if you take the public completely into your confidence and let them share your doubts with you, and let them support you when it's necessary to press a recalcitrant industry or a recalcitrant Congress into taking steps that they prefer not to take. So I would confirm your observations and say that I think it is unfortunate we operated that way for so many years.

Mrs. Whitaker:
I have heard individual consumers make the comment that Food and Drug perhaps went a little overboard on things, and as a result of that, sometimes viewed with skepticism the activity of FDA.

Mr. Rankin:
Well, that is a slightly different twist on the same thing, but certainly I would agree that Food and Drug was overly defensive, overly protective of the agency for many years.

Mrs. Whitaker:

There is another factor in this that perhaps you would comment on, that is the lag that necessarily, I suppose, occurred between industrial development and then the scientific findings. For instance, you mentioned that it took up to five years in some cases to prove the safety of a product. And so you were handicapped in that five year period by not being able to adequately control products that were available to consumers, that is before the Miller Amendment, for instance. The agency must certainly have had some frustrating periods in knowing that there was something on the market over which you had no control.

Mr. Rankin:

Indeed we did. And we had some hair-raising escapes. With limited laboratory facilities and with scores of new products coming on the market at all times, the best that we could do was to make a well-informed guess as to the substances that deserved first attention. A couple of examples occur to me: one was monochloracetic acid, a chemical that has wonderful preservative properties and was being offered quite widely for use as a preservative in various food products, pickles, wines, to mention two. Our pharmacologists believed that that material probably had some unusual toxic properties, so they started an investigation very promptly after it appeared in food.

First we recommended against the use of the substance; but a number of firms used it anyway. We found that it was a nerve poison, an extremely potent one, and as soon as that discovery was made, we took steps to remove from the market all the products containing monochloracetic acid. Another example is a chemical called thiourea which has excellent anti-oxidant properties. You know when you peel peaches and let them stand out for a short time they turn brown. If you pour a solution with a little bit of thiourea over those peaches, they will stay fresh looking for a longer time. Thiourea turned out to be a cancer-producing substance in test animals, and that one also had to be removed from the market rather rapidly. Fortunately, both of those chemicals were selected for early intensive study.

Mrs. Whitaker:
What determined products that you selected for intensive study?

Mr. Rankin:
The chemists tried to keep abreast of what was coming on the market. They consulted on a daily basis or a weekly basis with the pharmacologists who, based on their knowledge of the physiological impact of other compounds that had been tested, made informed judgments as to which of the new compounds most deserved attention. And fortunately

in most cases their judgment was right. They picked the right compounds. Now if they had failed to pick those compounds and had selected some innocuous substances instead we could have had more difficult problems--some real harm could have been caused.

Mrs. Whitaker:
What you said brought to mind the question of lindane, and were you in any way involved in efforts to keep the lindane vaporizers off the market?

Mr. Rankin:
I was not personally involved. But, yet, the Food and Drug Administration was involved. First, the lindane vaporizer is simply a piece of equipment with a heating element in it, so designed that when you put some of the pesticide containing lindane in the cup, the lindane is vaporized and goes into the atmosphere throughout the room where the unit is located. The advertising under which this was offered indicated that it was perfectly safe, that people could live in the room, you could use it in a bedroom, use it anywhere in the house. We didn't think that was right. Lindane is one of the chlorinated hydrocarbons that is in the same general family as DDT, and it didn't make sense that man could over a long period of time inhale this substance without suffering adverse effects. So we were strongly opposed to registration of lindane vaporizers by the Department of Agriculture,

and so stated both informally and by formal letter. Unfortunately our recommendations were not accepted. The vaporizers were registered and were rather widely used until at some later date the Department under considerable pressure, I believe, decided that they had made a mistake and withdrew the registration.

Mrs. Whitaker:
And they could do that under the provisions in the law? In the light of new scientific developments they could withdraw registration for a product and it was a fairly simple operation?

Mr. Rankin:
Yes, I thought it was a simple operation. They didn't think so. They regarded the prospect of withdrawing registration with absolute horror. But it was rather simple though. Any time an administrator makes a move and finds that it is an error, it is obvious that he can reverse that. That is a well-established principle of law.

Mrs. Whitaker:
With what frequency did products stay on the market that should have come off earlier than they did?

Mr. Rankin:
The Department of Agriculture did not, so far as I know,

withdraw any registrations for pesticide chemicals until in the mid or late sixties Congressman Fountain and his Intergovernment Operations Subcommittee of the House Committee on Government Operations began investigating the administration of the insecticide law and brought tremendous pressure upon the Department of Agriculture to mend its ways.

Mrs. Whitaker:

This is going back even further, and certainly before your time, but I wondered if you might have heard something on this. Dr. J. K. Haywood, who had been Chairman of the old Insecticides and Fungicides Board was quite an aggressive, active man, and by 1927 when Food and Drug took om the administration of the Insecticide Act and the old Board was abolished Haywood, through his efforts in Congress, had gotten the appropriation for enforcing that act up to about $200,000 a year, and he had five inspectors. It seems strange to me that by 1944 when the number of products must have been at least 10 times over what Haywood was handling, appropriations for enforcing the Insecticide Act had dropped down to $168,000 and they had only seven inspectors. Was there any kind of feeling that it had been Dr. Haywood personally and his aggressiveness that had built insecticide enforcement up to the point it reached in 1927, compared to where it was in 1942 and 1943?

Mr. Rankin:

I don't have any knowledge on that specific question or on Dr. Haywood, but I would comment that this fact of no increase in inspection capability, in fact a slight decrease, at the same time that the problems to be dealt with were multiplying manyfold is a reflection of a lack of public support, public understanding first and public support for the agency's goal. I think it goes back to what we were discussing a moment ago. So long as the Food and Drug Administration insisted eloquently that everything is just fine as long as we are looking after you, Mrs. Consumer, you don't have any demand by consumers for an increase in enforcement staff. And the Congressmen are not going to pay much attention to your pleas for more money to do a better job. You've got to take the consumer into your confidence, let him and let her know that you've got some real problems here you can't deal with, let them bring pressure on the Congress, before you are going to get any real increase and support for your programs.

Mrs. Whitaker:

And then the insecticide people themselves, those in the Department after 1940 who were handling it, were not met with much consideration or concern prior to the DDT thing, was that perhaps because of the nature of their law, since it was only a labeling law, so that consumers

were simply not much concerned with what kinds of insecticides they were using?

Mr. Rankin:

Well, the insecticide people were in somewhat the same fix in the Department of Agriculture that Food and Drug had been prior to its transfer out of the Department. They were a regulatory agency in a Department dedicated to improving the lot of the farmer, improving his capabilities to market crops and make money. So any actions that they took which appeared to the farmers to impede that primary goal were met with resistance both from without the Department and from within. There is a built-in conflict of interest which was virtually impossible to overcome.

Mrs. Whitaker:

You had mentioned earlier that while Food and Drug was more or less saddled with the task of enforcing the insecticide act, it was not their desire to have done so. I wonder if the Insecticide Division slipped into--well of course it did--a secondary position that it was not immediately able to recover from when it did go back to, or when it did remain in the Department of Agriculture? There was no unit really concerned with enforcement of the insecticide law other than this small staff of three or four people perhaps who ran it?

Mr. Rankin:

Now you have just reminded me that I failed to make one point earlier that I should have made. The primary reason for control of insecticides initially under the insecticide labeling law was not to safeguard the public health; it was to safeguard the farmers. The Department of Agriculture did not wish the farmers gypped by insecticides that promised to control boll weevil, for example, when they would not in fact control boll weevil. Or by insecticides that would control boll weevil but at the expense of damage to the cotton crop. So that you have first that primary thrust of the law and of the administration of the law. So long as there were sufficient personnel to look at the claims for a pesticide to determine if they were accurate as regards to crops, Agriculture was satisfied. This is a harsh thing to say, maybe too harsh, but they really didn't give much attention to the public health aspects of it. Let somebody else take care of that. I think that was the major reason that the operation rocked along at a low level for so long. There were enough people employed to do a fair job of evaluating the claims for effectiveness against insects and for safety as regards crops.

Mrs. Whitaker:

And that was really the extent . . .

Mr. Rankin:

And that was their real interest in it.

Mrs. Whitaker:

And was the purpose of the entomologist in the very beginning, in the 1907-08 period, when that act was formulated, the old 1910 act, primarily economic protection for farmers?

Mr. Rankin:

And still is. In the 1947 act, the primary thrust was protection for the farmer and insofar as health was concerned, agriculture looked after the safety of the man that applied the pesticide, not the man that ate the crop.

Mrs. Whitaker:

It is almost ironic that the farmer eats the crop too.

Mr. Rankin:

But he doesn't have to eat one that has been sprayed. He knows which one he didn't spray.

Mrs. Whitaker:

He knows which one to select. Some of the arguments that appeared in the 1930's and early 1940's too during the height of the spray residue thing made me wonder about the agriculturalist, whether he selected a tree or two for his own family that he didn't spray or whether he just went ahead and ate the same fruit that he shipped.

Mr. Rankin:

I think you found both situations. There have been examples

in which farmers have poisoned their families by unwise use of pesticide-treated grain, for example. I suspect there are farmers that pick and choose what they eat on their own table.

Mrs. Whitaker:
There is another question about the spray residue that has been largely overlooked, and that would be the residues from fumigant sprays on grain crops, one that really got very little publicity. But was this much of a problem for Food and Drug?

Mr. Rankin:
You're talking about before 1954?

Mrs. Whitaker:
Yes.

Mr. Rankin:
No, it was not a problem before 1954, for the reason that we didn't think that there was any residue from the fumigants; they were so volatile that everyone said to himself, "Oh, there couldn't be any residue from that stuff. Ventilate it until you can't smell the fumigant, and you are all right." After 1954 when the manufacturers had to make some tests to determine whether there was a residue, we found to our amazement that residues did remain, and they became not a problem but another control

operation that had to be put into effect.

Mrs. Whitaker:

There were other instances also concerning residues that I have encountered that did not get any publicity at all and related to arsenicals.

Mr. Rankin:

Excuse me one minute. Back on the fumigants.

Mrs. Whitaker:

Oh, yes.

Mr. Rankin:

There was I recall a glaring example of a problem from a fumigant which we regarded as so extraordinary that it didn't change the usual situation I just described. We thought there were no residues. There was a dock strike in Baltimore and many of the foodstuffs that came in by ship just were stuck. They couldn't be unloaded, they couldn't be shipped. There was a boatload of raisins that was sitting on the dock for some weeks. To keep the bugs from walking away with the raisins, they were treated very heavily with hydrogen cyanide. The raisins absorbed so much cyanide that they poisoned a little girl that ate them later. But that was an unusually heavy application of the fumigant, and a repeat application. And we didn't wake up even then to the fact

that ordinary applications of fumigants might leave significant residues.

Mrs. Whitaker:
And present more danger?

Mr. Rankin:
And present dangers, yes.

Mrs. Whitaker:
It was, though perhaps not in the same degree of intensity, a rather common practice to fumigate dried fruits and things as they came in, and before they went into warehouses?

Mr. Rankin:
Yes. Hydrogen cyanide was probably the most effective fumigant. It is extremely toxic, and some people turned to methyl bromide or some other bromide that is more expensive but it is not quite so dangerous to the operators of the pesticide fumigating facility.

Mrs. Whitaker:
But certainly that was one aspect of spray residues that received so little publicity that very few people realized, and, as you say, FDA did not realize the problem. I wonder if all the furor that did arise over the arsenical residues did not contribute somewhat to blotting out the significance

perhaps of problems of equal significance?

Mr. Rankin:

I don't know about that. With regard to the fumigants I believe the answer would be that it just did not seem reasonable in the early days to the chemists who looked at the volatility of these compounds that there could be any significant residue at all from their application.

Mrs. Whitaker:

Still in the early period, consumer organizations were considerably disturbed by the amount of arsenic that was applied on tobacco plants. And there was no way, of course, under the old Food and Drug Act to control that use. Is this still a problem for Food and Drug?

Mr. Rankin:

It is not a problem for Food and Drug; because FDA has no authority to control tobacco unless it makes drug claims, which most tobacco products do not. Yes, the presence of pesticides on tobacco, not only arsenic, but also the newer organic pesticides such as toxophene or benzene hexachloride in my view are a significant public health problem. While part of the pesticide may be destroyed or otherwise filtered out of the smoke so that it doesn't reach the body, a good part of it is vaporized with the smoke which is taken into the mouth or even

inhaled. And so far as I am aware, there still is no mechanism for controlling the pesticide residue on tobacco. Of course there are other elements of tobacco that are extremely harmful also, but if people are going to smoke, perhaps they should be safeguarded against toxic pesticide residues.

Mrs. Whitaker:
This was the feeling as far back as the 1930's that it was almost incumbent upon government to in some way protect consumers, and, depending on your viewpoint, whether it would be from one of their vices or one of their pleasures. But even under the registration of products from the labeling standpoint if it is recommended for use on tobacco plants, there still is no way that its use can be prevented under the old insecticide law. I don't know about the new one.

Mr. Rankin:
Under the old and under the new, at least following the interpretation that Agriculture used up to the time I left the Food and Drug Administration. Now there was a theory at one time that Agriculture if it wished to could regulate health hazards to consumers under the Insecticide Registration Act. I believe that theory was never accepted by the General Counsel's Office in the Department of Agriculture up to about 1969. I don't know whether there has been a change since then.

Mrs. Whitaker:

I did want to ask you if there is anything else particular about Mr. Campbell's retirement, what the circumstances were, and about . . .

Mr. Rankin:

He finally just had it up to here one day, and he walked out of the office and said, "I'm through." Is that the kind of thing you wanted?

Mrs. Whitaker:

Yes, it is. Was he at retirement age? I could check that out. I don't remember.

Mr. Rankin:

Yes, he was at retirement age. Well, Mr. Campbell for years had been taking abuse from some of the Congressmen and Senators because of the regulatory actions that were being pursued by the Food and Drug Administration. He had a personal problem in that Mrs. Campbell had arthritis and needed more care than he had been able to give her. But he liked the work so much that he stayed on until something just turned his stomach, so to speak, and he decided it was time for him to quit so that he could give more attention to Mrs. Campbell, and hopefully the Food and Drug Administration would be better off without him. So one day, according to the reports that I have heard, Mr. Campbell stood up at his desk and said, "I've

had enough now; I'm quitting." He got his hat and started out the door and his secretary said, "But, Mr. Campbell, what shall I do with these files on your desk?" And he said, "I don't care what you do with the files on the desk. Goodbye." It may not have been quite that abrupt, you know. Stories tend to grow with age. As to exactly why Mr. Campbell finally got fed up, there have been two or three rumors. One that I give the most credence to is the fact that shortly before this time a Food and Drug inspector in California had made an inspection of a firm producing both drugs and biologicals. Now biologicals, those drugs derived from animals or from animal glands, were subject primarily to control under the Biologics Act, administered by Public Health Service. They also were subject to control under the Food and Drugs Act. But we simply, as a general rule, kept hands off. This inspector walked in and found a biological product prepared from blood being manufactured from some rotten raw material. It wasn't just a little bit spoiled; it was rotten. He reported the facts and the Food and Drug Administration was prepared to take legal action against that manufacturer; but the manufacturer got in touch with the Public Health Service and the Surgeon General made representations to the administrator of the Federal Security Agency requesting that FDA be ordered to keep its hands off biologics. The net result, after considerable negotiation, was that FDA was ordered to leave biologics alone, and only come into the picture on biologics on those

occasions when the Surgeon General or the Public Health Service requested, specifically requested, FDA assistance. It is my belief that that is one incident that hastened Mr. Campbell's retirement, though, as I say, there were other factors involved.

Mrs. Whitaker:
I am sure that he had had years and years of harrassment from producers.

Mr. Rankin:
He had indeed, and from Congress, from some elements in the Congress.

Mrs. Whitaker:
Let me ask you about DDT. I want to ask also about Albert Deutsch and his relation to DDT. Does that name ring a bell with you? He was a New York journalist who was really the first of the crusaders to get on the DDT hazards with spectacular publicity. The New York Post ran three-inch headlines about "DDT will kill you."

Mr. Rankin:
Oh, sure, I didn't place that name, but I recall those stories.

Mrs. Whitaker:
A series of articles, yes. It of course aroused a great

deal of interest in the DDT hazards, and I wondered what the feeling in the Department and at FDA was at that time, other than the published responses to his articles.

Mr. Rankin:

Well, I can tell you what my feeling was, and I believe that it was not too different from the feeling throughout the agency. I thought the New York Post was engaged in yellow journalism, that it was overemphasizing the DDT hazard. I still think so to some degree, perhaps not so strongly after these several years have passed. I think based on the available evidence that the Post articles went further than science would warrant, but as I am going to relate to you later there were problems with DDT that we recognized within FDA that we were unable to handle.

Mrs. Whitaker:

Would you elaborate?

Mr. Rankin:

Just go right ahead on those? These related to the establishment of the informal tolerance of seven parts per million for DDT residues on fruits and vegetables, specifically, I believe, on apples and pears. After the fluorine tolerance disaster when the courts threw out our first formally established spray residue tolerance, it became apparent that under the procedures of the existing law

and with the limited scientific abilities available to the FDA, we could never keep abreast of the flood of new pesticide chemicals coming on the market through the very cumbersome public hearing process established in that old law, the '38 law. So in order to establish some degree of control FDA decided to continue the informal tolerances that had been in existence for several years. This meant simply that FDA would study all of the evidence without holding a public hearing and would announce to the public that in its best judgment residues not exceeding a given value for a certain pesticide would not warrant legal action. If a manufacturer or a shipper wished to put out products with a higher residue he could still do so, and FDA would have to take him to court and prove that these higher residues constituted a poisonous or deleterious substance. But at least most shippers and manufacturers would try to observe the informal tolerance, and some degree of control would exist. Based on the evidence that had been developed primarily in the FDA laboratories, the agency decided that it ought to establish a tolerance for DDT at a level of five parts per million. The Public Health Service was interested in promoting the use of DDT worldwide as a public health measure, and properly so.

Mrs. Whitaker:

That would be a disease control.

Mr. Rankin:

This was for disease control, particularly in the control of malaria, although a number of other insect-borne diseases were involved. Malaria is, has been, one of man's scourges over the centuries. It has been one of the greatest killers of man historically. DDT for the first time seemed to give some very effective and widespread relief from malaria-bearing mosquitoes, so the physicians, the public health physicians and PHS were anxious to stimulate widespread use of DDT. They didn't want Food and Drug Administration to take any action in what they regarded as a narrow area, control of residues on foods, that would place the slightest barrier to the widespread use of DDT as a malaria control agent. They sincerely believed on the basis of studies made on human beings in DDT factories and in agricultural areas where DDT was used as a dust or spray that the product had relatively little hazard, so they pressed for a tolerance level of ten parts per million, just twice what FDA wanted. The FDA figure, proposed figure, of five parts per million was based, among other things, on some studies made on rats by one of the FDA pharmacologists which showed that at a feeding level of five parts per million over the lifespan of the rat, a two year period, a very slight change detectable microscopically occurred in the liver cells of the rat. Whether it was a deleterious change, no one knows. But the pharmacologist must be cautious. He must assume that a change from the normal is potentially deleterious. So FDA proposed to set the tolerance at the

level that produced this minimal change in the belief that other studies showed this was not especially harmful. The two agencies couldn't reconcile their differences. I believe the matter went to the Federal Security Agency, but I don't know to exactly what office in that agency. And essentially by direction there was a compromise which allowed FDA to set the tolerance level at seven parts per million for DDT. This was too high, we now know, much too high. Five parts per million would have been too high also, so we were essentially in the same ball park with the other folks. Incidentally you cannot today detect these minimal changes at a feeding level of five per million of DDT, because there is so much DDT throughout the world that all laboratory animals, the "normal" ones, have livers that represent the abnormal ones that we found in the mid-forties. So we can never again detect that change, because we'll never again get what was then known as a normal rat liver.

Mrs. Whitaker:

That's alarming. Did you have the same kind of resistance from the entomologists, for instance, in setting that tolerance as you did from Public Health Service, for the similar reason that they too were promoting widespread use of DDT for agricultural purposes?

Mr. Rankin:

I'm not aware of widespread pressure from the entomologists.

Now I was not intimately associated with the activity at that time. I believe, however, that the burden of negotiating with FDA was left to the Public Health people and not to the agricultural entomologists.

Mrs. Whitaker:

I have in my reading come across some statements of caution from entomologists, federal entomologists in those years, that I found very conservative in light of statements that were coming from private researchers. That I found interesting because it did represent such a potential cure-all from the agricultural standpoint, I thought there would be more enthusiasm than what I find in some of the printed material which was extremely cauticus from time to time about the potential dangers of DDT.

Mr. Rankin:

I expect you are referring to the research entomologists. The research entomologists have much the same problem as the Food and Drug control official. They take the broad view. They are looking not just at next year or ten years from now, but a hundred years from now or more. And over the years they have seen a new compound come into vogue, and they have seen it applied almost with abandon in agriculture, frequently with near-disastrous results. Some of the research entomologists in the Department of Agriculture were just about as concerned about the widespread use of DDT as were the scientists in FDA,

but for different reasons. They feared what would happen to the insect population when it became resistant to DDT, and their fears were borne out.

Mrs. Whitaker:

They most certainly were. How much difficulty did state officials create, that would be state entomologists, the ones who dealt directly with the farmer, through the Extension Service or the agricultural colleges?

Mr. Rankin:

The state entomologists or their equivalent in general were either unsympathetic with or hostile to the FDA control efforts. They believed that FDA was going way overboard in establishing tolerances and trying to cut down on the use of sprays. I'm talking about the mid-forties and early fifties now. They would not in general--there were exceptions--they would not cooperate with FDA to the extent of letting us know exactly what they were telling the farmers, or letting us know where there were abuses, grossly excessive use of pesticides in other cases. It was not a happy relationship, and it was only after the enactment of the Miller Pesticide Amendment in 1954, the establishment of binding tolerances under that law, and the bringing of quite a few legal actions by FDA to seize crops with excessive residues that the state officials recognized that, like it or not, they were going to have to live with the FDA tolerances and they had better start

making appropriate recommendations. Now lest I might be misunderstood, there were some states that were truly exceptions. New York, California, Florida, and I believe very shortly thereafter Texas, the very heavy truck farming areas, and New Jersey. If they ever had this hostile attitude that I mentioned, certainly they lost it years before most of the other states. And they put in their own pesticide control programs. They were in the vanguard of enlightened control of spraying practices years before most of them.

Mrs. Whitaker:
Would that be even before the Miller Amendment, or would it have followed the Miller Amendment in most cases?

Mr. Rankin:
I'll have to think a minute. California had a pretty good program operating before the Miller Amendment came into effect. New York had done a lot of work on the research end. I don't know whether they had much of a control program, but the recommendations of the state department of agriculture were enlightened before the Miller Amendment. I think Texas and Florida came on board probably just after the Miller Amendment.

Mrs. Whitaker:
From an administrative standpoint, concerning the Miller Amendment, how did this increase the inspection force,

for instance? Did it make provisions, or did you have funds available for expanding and enlarging your inspection forces?

Mr. Rankin:

We didn't expand the inspection force very much. There was a slow expansion. Let's see, the Miller Amendment came in '54. Fifty-five marked a beginning of a gradual expansion of FDA's total staff, inspection and scientific. This was not primarily to take care of pesticide residues in those early years, but I would say about 1960 or shortly thereafter it became quite apparent that the total federal effort toward controlling pesticide residues was too small. As I recall, we had worked up to the point then that we were sampling and testing perhaps one-third of one per cent of the shipments of crops that went across state lines, and our Commissioner was advised that as a very minimum we ought to triple that rate, to sample and test at least for a period of time one per cent of shipments. I don't remember the exact year that we hit that one per cent level, but we did set that as a goal and we reached it. At present, testing probably is at a slightly lower level, because with the experience that was gained over the several years that we reached the one per cent level we were able to identify the crops that almost never had excessive residues, and thus did not need that much attention, and on the other hand the crops that were very susceptible

to retaining high residues and did need more attention.

Mrs. Whitaker:
Under the Miller Amendment, did this narrow down the number of products that were on the market because of the cost of getting . . .

Mr. Rankin:
The number of pesticides?

Mrs. Whitaker:
Yes.

Mr. Rankin:
I think it did not. I don't believe it had much effect one way or another on the number of products. You see the expensive research is conducted by the big firms that manufacture basic chemicals. Shell Oil Company, for example, had a pesticide unit, I don't know what they called it. Esso had one. Dow Chemical had one. Now these firms are going to develop new products, they are going to run the necessary tests on them, and thereafter the smaller firms, the fabricators, can rely upon the safety data developed by the large firms, so I believe that the Miller Amendment had little effect upon the total number of products.

Mrs. Whitaker:

The smaller manufacturers, then, could market these raw materials under their own trademark.

Mr. Rankin:

They would buy the basic pesticide chemical from the basic manufacturer and rely on his safety data, and then formulate and market under their own brand name.

Mrs. Whitaker:

And they did not have to come back to you for registrations, I mean to Insecticide for registration . . .

Mr. Rankin:

They did have to. Every product that is marketed has to come to Agriculture for label registration, but instead of developing the very expensive safety data on their own initiative, they simply secured permission from their supplier to rely on his data which had been supplied to Agriculture. The records of the Department of Agriculture would show what change there had been in the number of formulations registered. As I recall, all during the period slightly before the enactment of the Miller Amendment and continuing for some years afterward, it was somewhere in the neighborhood of 55,000 individual formulations, up or down a small percentage.

Mrs. Whitaker:

I have read the figure somewhere, and I think they registered in that first year after the law became operative something like 50,000.

Mr. Rankin:

It later crept up to a somewhat higher figure.

Mrs. Whitaker:

A problem that bothers me is why there were no legal tolerances--of course after the 1944 disaster with the fluoride--but why were there no tolerances coming out of the 1950 hearings? Because in 1954 you apparently were still operating under administrative tolerances.

Mr. Rankin:

Well, that was . . . The tolerances resulting from the 1950 hearings were established in 1954, or 1955. It was just about the time that the Miller Pesticide Amendment went into effect. The reason that tolerances had not been established earlier as a result of those 1950 hearings was that we didn't have a particularly good hearing record. Our General Counsel's office believed that in the case of court challenge tolerances based on the 1950 hearings were subject to overthrow in the courts.

Mrs. Whitaker:

This would be even the legal, the ones established under the provisions of the law?

Mr. Rankin:

Under the provisions of the old law, the one enacted in 1938. It was our belief that if we established formal tolerances in advance of enactment of the Miller Pesticide Chemicals Amendment we would invite court challenge, we would lose again on some technicality perhaps as we had lost in the fluorine episode, and we would lose the many man-years of effort that had gone into that 1950 operation and those hearings. So we very deliberately withheld the issuance of any tolerances under the old law until the new law became operative, in the knowledge that if we were overthrown then we could promptly re-establish the tolerance under the new law, and we had every expectation of prevailing in the courts then. Whether our fears were justified, I can't say at this time. We were not challenged on the basis of the 1950 tolerances that eventually went into effect, and thus we did salvage that extensive effort in 1950. That's the story in a nutshell.

Mrs. Whitaker:

That follows the same tactic that Campbell used a number of times in the almost calculated risk as far as consumer criticism by sometimes holding off until he was more sure of his ground.

Mr. Rankin:

He was an expert at that, yes.

Mrs. Whitaker:

Perhaps that is one of the things I really admire out of his record, that he seemed to have a very fine balance between what he could realistically accomplish and what would serve consumers' best interests. But he was severely criticized for his judgment by many sources, prominent sources . .

Mr. Rankin:

Yes, he was. The regulations, the proposed regulations following that 1950 hearing had been drafted and were ready to be published 18 months after the hearing ended, but it just didn't seem to be good business to publish them at that time.

Mrs. Whitaker:

Well, the Delaney hearings were going on at the same time that the tolerance hearings were going on, were they not?

Mr. Rankin:

I believe they overlapped in part, yes.

Mrs. Whitaker:

It became fairly obvious even while those hearings were going on that there would be legislative results from the Delaney hearings.

Mr. Rankin:

There was every reason to believe, yes, that there would be legislation.

Mrs. Whitaker:

You felt then even in 1951, shortly after these tolerances were established, though not published, out of the 1950 hearings that you would have a more effective means of supporting your tolerances in the courts. This lag of four years between '50 and '54 was fairly well covered by the feeling that you would certainly get a better legal control?

Mr. Rankin:

Well, it isn't quite that simple. I would say that in 1951 we were still engaged in the laborious process of going through the record and preparing a proposed order to establish tolerances. Meanwhile we were beginning to develop reservations about our ability to sustain the order in case of court challenge. I believe that about 1952 the proposed order was pretty well drafted. I'm not sure that it was apparent yet that we would get legislation, but it was apparent to our legal advisers that we were quite vulnerable in case of court contest, so we just sat tight for a little while and wondered what to do, and then before too long--perhaps about 1953--it began to look like we would get a pesticides chemicals amendment, and it appeared most desirable to wait until that became law.

Mrs. Whitaker:

Well, that answers the question that loomed rather large in my speculation as to why after so many years you had the hearings and then did not publish legal tolerances.

Mr. Rankin:

We received a lot of criticism for that four-year delay.

Mrs. Whitaker:

I was aware of that from reading newspaper reports, and from consumer people.

Mr. Rankin:

You don't explain to the public as I've just explained what you are doing at the time. Even today, despite my earlier plea for taking consumers into your confidence, I believe that a regulatory agency upon occasion is not free to go into a detailed explanation.

Mrs. Whitaker:

A parallel to that would be the situation that the insecticide people found themselves in after they lost a serious court case and then could not go back and prosecute that same manufacturer without establishing new scientific material. They were criticized also, but . . .

Mr. Rankin:

I recall that, yes.

Mrs. Whitaker:

And they could not at that time, I felt from reading the records, explain to the public what had happened for fear that the manufacturers would take advantage of that very situation, at least those who were not particularly concerned with abiding by the law. It seemed that it would have announced a loophole to manufacturers.

Mr. Rankin:

Possibly. I would think that any manufacturer with a good legal adviser would immediately know that he had a loophole there. At least in the Food and Drug area we found that the firms were abreast of developments about as fast as we were.

Mrs. Whitaker:

Were the Notices of Judgment--I know that those now come out in the FDA Papers--but were they a significant factor, the Notices of Judgment, in a deterrent way as far as discouraging violations.

Mr. Rankin:

I think they were not because they were too slow in coming out. And they may be more helpful now that they are coming out earlier. But we had tremendous time lags. Oh, one time we got to within 18 months of being current and thought we were doing pretty good. It was shameful.

Mrs. Whitaker:

What accounted for that?

Mr. Rankin:

Our General Counsel's office was understaffed; we were understaffed. When a rush job came along, the Notices of Judgment, preparing Notices of Judgment for publication got pushed over to the side of the desk. When you got that emergency handled, your man got back to the Notices of Judgment, and if another emergency intervened he was called off to take care of that. That was largely the problem.

Mrs. Whitaker:

Did you find that kind of thing, especially before Food and Drug became as much in the public eye as it is now, that the Attorney General's office was sometimes guilty of the same thing, in that they put your cases aside for things that they felt were more urgent? What were your relations with the Attorney General's office in actually carrying out the litigation of the cases that your General Counsel prepared?

Mr. Rankin:

You would get better information from someone who was in the General Counsel's office. I am under the impression, however, that Food and Drug cases were taken up by the

Attorney General's office as received, subject only to having truly emergency matters supersede them, and that they were not deliberately pushed aside over in the Department of Justice. I think we received the same consideration there that other agencies did.

Mrs. Whitaker:

I have a notation that I think you probably have covered, but in one of the inspector's reports in 1944 concerning the DDT residues, he said that he hadn't the remotest idea of what a tolerance should have been on DDT, and that would have reflected the fact that conclusive studies had not yet taken place in 1944? Do you recall when Food and Drug actually began the scientific research on DDT?

Mr. Rankin:

I think we had started it before that. I think we started in 1943. I doubt if our tests had proceeded by that time to the point that we were ready to announce a tolerance. I believe it was about 1945 before we were prepared to make an announcement.

Mrs. Whitaker:

I have a note also to ask you about this factory inspection decision in the 1950's--I believe it was in the 1950's when Ira D. Cardiff brought suit against Food and Drug and then you were not able to make factory inspections until certain adjustments were made in the law. Was that a truly serious

blow to Food and Drug?

Mr. Rankin:

Not so much as you would imagine. It would have been a most serious blow if Congress had not corrected the defect in the law promptly, but the agency almost immediately started moving to get the law amended and corrected. The industry knew we were moving in that direction, and in most cases inspections were permitted voluntarily during this interim period. Now if Congress had turned us down, I think that over a period of time there would have been a very serious regression, a development of a situation in which responsible industries as well as fly-by-nighters would say, "Well, we would just as soon not be bothered with you, so will you stay out?"

Mrs. Whitaker:

What was your personal reaction to Rachel Carson's Silent Spring, and also what was the FDA's reaction to that publication in the 1950's?

Mr. Rankin:

It was my personal feeling, and also the view of Food and Drug Administration, I believe, that while Miss Carson's book Silent Spring seemed to emphasize, perhaps overemphasize, some aspects of the danger of pesticides, she had on balance rendered a distinct public service by outlining for public view facts that had not been known

to the general public before. Prior to Silent Spring the business of trying to regulate pesticide residues was extremely difficult. We had little public support. It was hard to convince people that the actions we were taking against fruits and vegetables were required. There was beginning a barrage of criticisms sponsored, I believe, by the pesticide chemical manufacturers designed to require FDA to relax some of the requirements. We were beginning to see articles about the prohibitive costs of testing pesticides to meet the FDA requirements. Almost overnight with the publication of Miss Carson's book the atmosphere changed. There was much more public support for the control measures that we had been finding necessary. There was much more support for the basic research that is required if you are going to do an enlightened job of administering a law like the Pesticide Chemicals Amendment, and on the long haul Miss Carson's book stimulated a rethinking within the Food and Drug Administration of the testing requirements that we had been imposing upon the pesticide manufacturers. FDA today is requiring a type of testing that would be impossible without the public support generated by a book like Silent Spring. I think Miss Carson did a public service.

Mrs. Whitaker:

It certainly had an impact.

Mr. Rankin:

It certainly did.

Mrs. Whitaker:'

Was there any time that you can recall from the time that you went with the Department in 1938 when the Department itself shifted its emphasis perhaps from the public health aspect of pesticide residues to that of a broader ecological, environmental thinking that went beyond just the human factor?

Mr. Rankin:

In your question did you say Food and Drug or the Department?

Mrs. Whitaker:

Well, let's separate them, maybe deal with one first and then the other, with Food and Drug for instance.

Mr. Rankin:

The Food and Drug Administration was beginning to look at the broader environmental impact of its pesticide regulatory activities toward the end of the sixties, but I would say it was only a beginning. I don't think that at any time the agency truly considered all of the environmental problems. I can't speak for the Department. The Department had individuals that I know were concerned about the situation, but whether that reflected itself

in a true departmental attitude, I can't say.

Mrs. Whitaker:

I would welcome any further comments that you have.

Mr. Rankin:

My comment would be that you have been thorough in your research and your questioning.

Mrs. Whitaker:

Well, I appreciate your candid response, and if I think of something more I will probably write to you.

Mr. Rankin:

I wish you would feel free to do so. It has been a pleasure.

Mrs. Whitaker:

Thank you.