History

of the

U. S. Food and Drug Administration

Interviewee: F. Edward Sterner DVM

Interviewer: Robert G. Porter

Date: May 7, 1990

Place: Denver, Colorado

DEED OF GIFT

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F. Edward Sterner

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INTRODUCTION

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1 and 2

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

DATE: May 7, 1990 PLACE: Denver, Colorado LENGTH: 78 Min.

INTERVIEWEE	INTERVIEWER
NAME: F. Edward Sterner, DVM	NAME: Robert G. Porter
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Administration
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1965 TO: 1989 RETIRED? Yes

TITLE: Regional Veterinarian
(If retired, title of last FDA position)

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BP: This is another in a series of oral history interviews with retired Food and Drug Administration employees. Today the interview is with Dr. Edward Sterner, retired Regional Veterinary Medical Officer. The recording is being made at the Denver district office. The date is May 7, 1990. My name is Robert Porter. Ed, so that persons who read the transcripts of this recording will know who you are, would you please begin with sketch of your background, education, and FDA career?

ES: Okay, Bob, I'll try to give you the information that you want. I was born and reared on a little farm in the south-eastern part of Pennsylvania. I went to a country elementary school, the ones you see now in a history book. Just a one room school-house with one teacher with all eight grades in one room. I got ahead when I got to the fifth grade because I was the only one in the fifth grade, so they just skipped fifth grade and I went to sixth grade. I've been wrestling with that now the rest of my life. I went to a little country high school. I knew I didn't want to farm. I was trying to figure out what in the world I was going to do, and I talked with my mother one time, she mentioned the fact of what I thought about being a veterinarian. The more I thought about it the more I liked the idea, because I knew the veterinarians that came to our farm there in the country.

I went to veterinary school at Ohio State, graduated in 1949, and then I went back home, but instead of Pennsylvania I went south a little bit, eleven miles into Maryland. I had a mixed practice there from 1949 to 1964. I started getting a little tired of practice because it just seemed to be a routine monotonous type of activity. So I left practice on the encouragement of Dr. Max Crandall who also ended up being a field veterinarian with FDA.

BP: I know him.

ES: At the time he was a station veterinarian with USDA's Research Division down in Beltsville. I went down to see him one day for an interview, and I liked what I saw down there. The two of us were veterinarians for the entire research facility there in Beltsville, which had quite a good size dairy herd, a beef herd, hogs, and sheep. So we really were just veterinarians taking care of the animals that were used for their research projects. And that was interesting. But FDA had a little

research facility, a veterinary research facility right on the same grounds, and we'd go over there and do biopsies or different things for them.

After I was there--I started there December 7, 1964--and the following Fall, in '65, I understood there was an opening for a research veterinarian right out there at Beltsville with FDA, and the potential for increase in grade was a lot better than it was there with USDA which was rather stuck. So it happened that the deputy director for then the newly established Bureau of Veterinary Medicine had been my former pharmacology instructor out at Ohio State: Dr. Fred Kingma. So I went in to interview with him. I filled out a civil service application for transfer over there, and that's how I ended up November 20, 1965, with FDA as a research veterinarian in Beltsville. That was a nice place to work but it was isolated, you really didn't know what was going on in the rest of the agency or what was going on in the rest of the country, really, from morning till you got home again and listened to the radio.

So when FDA announced that they were going to staff field offices with veterinarians, I applied for that. Luckily enough I was one of four of us that were selected that went on a year's training program before we went out to the field. On the selection basis there when we finished, one veterinarian wanted to go to Denver and they weren't going to fill Denver, so he dropped out and stayed with the agency there in Rockville. The other three of us were assigned: one went to Baltimore, one went to Detroit, and I was assigned to Minneapolis. So then, the summer of 1968 I became the district veterinarian in the Minneapolis district office. Then when the Nixon administration came in and FDA went to regional offices, someone in headquarters, I'm not sure who, I think Paul Hile in the EDRO had quite a bit to do with the feeling that the veterinarian should be in a regional office and not in a district office. So I was really rather lucky: I was given a choice of three regional offices Boston, Chicago, or Denver. So I selected Denver and came out here in October of 1972. I spent the rest of my years with FDA here in Denver, which I enjoyed.

BP: When did you retire?

ES: September 1, 1989.

BP: Good.

ES: That's what I thought too, good.

BP: Retirement isn't all bad, is it?

ES: No, it isn't. It's quite a bit of an adjustment to make though, but I enjoy it. I haven't done too much exciting, but it's the first time really in all my life that I've been able to goof off this long and I'm taking advantage of that.

BP: Great. Tell me something about the management of the Bureau of Veterinary Medicine when you went in to do your one year training, I guess you call it, your indoctrination. Who was the director of the bureau at that time?

ES: I went into training in about 1967 and the Bureau of Veterinary Medicine then had it's second director who was Dr. Van Houweling. The first director was Dr. Clarkson.

I do think it was a mistake when the Bureau of Veterinary Medicine was established to bring in directors from USDA. Their philosophy as a regulatory agency was strictly service. And their understanding of Food and Drug law, their understanding or interpretation as a regulatory agency I think always hurt the bureau a little bit in its relationship with the other bureaus within FDA. I may be wrong, but over the years when I became more and more aware of district field regulatory actions of FDA and food and drug law courses that I've taken over the years, I could see that they were not in sync with the feelings and attitudes of Van Houweling in those days.

BP: Would you have been better off, for instance, if you'd maybe gone to the field first for a year or something and then gone back to the headquarters to get filled in with how things worked there?

ES: Absolutely, yes. I think there were a lot of new people in the Bureau of Veterinary Medicine that I think would have really benefited the entire agency if they had had some field experience as to how things operate.

BP: Early on.

ES: Yes. I think they had this one viewpoint of veterinary medicine and veterinary drugs and tissue residues and I don't think they applied it in a real good, practical sense, really. Just something seemed to be missing as far as an understanding was concerned.

BP: Back in those days, FDA was more policeman-minded than it is now.

ES: That's true. A lot of USDA people came over to BVM, FDA. And the political atmosphere has changed; that's right, it has.

BP: What kind of manager was Van Houweling?

ES: I would never have rated him very well. Another mistake, he brought in two of his cohorts. They were under him; they were in USDA. He brought several people and had them head divisions within the Bureau of Veterinarian Medicine. There again they were former USDA people. Nothing against them personally--but especially K. M. Johnson, he was a real nice guy--but still they had USDA's philosophy. They did not have FDA's philosophy.

BP: Which meant they were no help to Van Houweling in that regard.

ES: No, no they were just backing him up on his philosophy as a service organization and really not injecting Food and Drug's interpretation on a lot of the classifications of different violations that happened.

BP: Ken started in the field as a Food and Drug Inspector.

ES: That's right. In fact here in Denver, I understand.

BP: Yes.

ES: But there again, even if he had some of these feelings he would have been overridden by Van Houweling.

BP: Well, there were many years in between, too.

ES: Yes, this is true. He was in USDA quite a few years in the interim.

BP: What were the kind of things you did when you went to Minneapolis? You were establishing a new position there?

ES: Right. And it was kind of unusual because at that time all of the field veterinarians--eight of us--were under the administrative guidance of headquarters from the Bureau of Veterinary Medicine. So we were actually independent as far as operations were concerned in the field office.

BP: You didn't report to the district director, regional director?

ES: No. We reported to headquarters. In fact, we sent in weekly reports.

BP: You reported to BVM?

ES: Right. In fact, they had a position there that was a supervisor of field veterinarians. The idea of establishing these positions was good. The Bureau of Veterinary Medicine was new--they just became established November 7, 1965, and I went to Minneapolis in 1968. Whenever a new bureau is established, by the time activities really get in force, it takes a couple of years. The purpose for us going out to the field was that this was a new activity, veterinary drugs; especially a thing that was new were medicated feeds and the terminologies that went along with feeds, pre-mixes, concentrates, supplements, finished feeds, plus the drugs that could or

could not be used in medicated feeds and who approved what could be used and at what levels with what directions.

To cut down a lot of communications between the field and headquarters, they thought it would work a lot faster and a lot better if we went right off to the field and worked with the investigators and the supervisors and the district directors as to what is the philosophy as we understood it of headquarters and the Bureau of Veterinary Medicine. We could do this right on the spot; you wouldn't have to send a letter in or you wouldn't have to make telephone calls and talk and talk and talk. And I think that part worked out real well. I think the new Bureau of Veterinary Medicine was accepted in the field offices, especially where we were, a lot faster and a lot better with better understanding, since we were there on the spot.

BP: I think that's true. Did you go on inspections?

ES: Yes. I went on inspections in the field with inspectors; now they're investigators, but at that time in '68 they were inspectors. I went on inspections to feed mills. I remember the first one I went on was one of the Cargill plants there in Minneapolis. It's interesting how something like that happens. Boy, word gets to headquarters, business headquarters, industry's headquarters real fast. The next morning I got a telephone call from the supervisor of Cargill Mills there in the state of Minnesota; he wanted to know what I thought of the mill that I went in to see. I didn't tell him that was the first one I'd ever been in, I couldn't tell whether it was good or bad. I had to take it on the word of the inspector. And then I did a lot of going out with the inspectors when we had tissue residue reports.

BP: Tell me something about that.

ES: This was new as far as USDA checking for illegal residues, drug residues in animal tissues. At that time, if I remember right, there were only seven drugs that USDA was testing for, and whenever they'd find an illegal level they'd let us know--it was kind of cumbersome in those days to what it is now--and then we'd go out to the farm and find out why that residue occurred. Being in Minnesota and Wisconsin, our biggest problem were residues of antibiotics and sulfa drugs in veal calves, because both of those states raise quite a few veal calves. For some reason, they established hearing officers in the district offices and when a tissue residue was

reported, we'd communicate with the farm, and they'd have to send some representative or lawyer into our office and we'd have a hearing there in the office. I became hearing officer for tissue residues in the Minneapolis office. Did that for several years.

I think one of the big things that the field veterinarians did, too, was to make contacts. We all contacted veterinary associations, local, individual veterinarians, universities, the veterinary colleges, agricultural colleges, producer groups, and being new we got a lot invitations to talk at their annual meetings or whatever. In fact, I used to give a monthly talk at the veterinary school there at the University of Minnesota to the veterinary students all on the philosophy of the proper use of veterinary drugs and the big importance that it was as far as causing an illegal residue in animal tissue: meat, milk, or eggs.

Especially with the veterinarians, so many of them expressed appreciation that there was somebody out in the field that if they had a problem or a question they could call in and talk to someone. Sometimes if it was much of a problem, I'd go out and see them. It brought FDA so much closer home to the veterinarians by having someone right out in the field that they could talk to than to try to communicate with someone they didn't know in Washington. If they wrote a letter, it was maybe half a year till they got an answer back. All of us know that when you try to call headquarters and talk to people, they're all in a meeting. They don't know who to talk to, and then if they do know they have a hard time contacting them, so they really appreciated that there was somebody out in the field that they could call up and talk to if they had a problem.

BP: Would I be right in saying that these were people who had very little reason to be in contact with FDA until the medicated feed problems began?

ES: I'd say that's absolutely right, yes.

BP: Because I don't think the FDA did a whole lot with veterinary drugs in those earlier days.

ES: No, you're right.

BP: They did get involved in quack veterinary remedies.

ES: There was a division of veterinary medicine within the Bureau of Drugs originally, and I think there were only three or four veterinarians in that group, and they didn't do very much--didn't have too much to do really. It was when the Food Additives Amendments went into effect or passed in 1958--takes years for them to become effective--that everyone started really to become aware of the tissue residue problem in edible tissue from animals. I don't think anyone ever gave it too much of a thought before. In fact, some of the stories I heard, I mean, really kind of make you sick where these chemical companies would feed a pesticide or something like that or dip them or whatever--animals with pesticides one day and those that were alive the next day they'd send into slaughter. You can imagine how loaded they must have been with pesticides. I'm sure they did the same thing with drugs and everything else, and no one really ever gave it too much of a thought.

Then when USDA did start finally checking in the sixties, like I say, they were only checking for about seven drugs; three of those I think were pesticides, DDT, the chlorohydrocarbons were definitely one, stilbesterol, sulfa drugs, and arsenical drugs. And now I understand they're testing somewhere between forty-five to maybe sixty different drug/pesticide entities nowadays. And on a rapid scale too to what they did . . .

BP: Probably wasn't the methodology in those days.

ES: I'm sure there wasn't. No, because since then, you know, the drug firms now are required that when they apply for approval of an animal drug, that's one of their requirements that they have a testing procedure that's practical for a residue in the edible tissue. It may not be the apparent drug that was given to the animal but a metabolite it had broken down to while it was going through the animal's body. So that's all developed really since the sixties, now up into the nineties.

BP: Did you have drug manufacturers in your territory in Minneapolis and later in Denver that were submitting veterinary drug applications?

ES: Not per se. In both locations, Minneapolis and Denver, there are several small veterinary drug manufacturers, but they are really small. None of them have the resources to go ahead from scratch and develop a new drug. Your big veterinary drug areas were in Chicago and Detroit and especially Kansas City--this was the largest.

BP: You were dealing with user problems, in a way. Well, that isn't quite true, is it?

ES: Well, yes, more so than the drug producer. I really have never gone to veterinary drug manufacturers per se, because there just weren't the establishments in Minnesota or here in Denver.

BP: The people with jobs similar to yours in those areas, I presume, did a lot of that.

ES: Not too much, I understand.

BP: Is that right?

ES: Right.

BP: They left that to the investigator.

ES: Yes. We'd go back whether it was large or small when we'd get adverse drug reactions to a product that was out on the market. We'd follow up on that. Then another thing that we got involved in was the bio-research program. Originally all the investigational veterinary drugs that were followed up on and monitored were done by the field veterinarians until FDA had an official program established. The investigators are doing that now. We got a list of all investigational drug trials that were being conducted within our areas and we were required to do at least 10 percent of them as far as following up and monitoring them as far as the amount of

drug they received, records on distribution of the drugs, records on results of their trials and this type of thing.

BP: Those were on-site, you went out?

ES: Those were on-site, right. And that was an interesting way to contact people. Some of them were being done by veterinarians; most of them were being done in universities. That was a good way to get in to talk to research people at a university. Once they became aware of you, then they always asked whether we would come back and talk to their class, which worked out good as a way of getting introduced.

BP: The educational aspects of the whole thing were very important then in those early days?

ES: It really was. Because before that there really wasn't that much regulation of veterinary drugs or the investigational work that was being done with veterinary drugs. The universities and other researchers were more or less given a free hand as to what they wanted to do or what they did with the animals after the investigation.

BP: How they set up their tests? It was all up to them.

ES: All up to them, prior to 1958.

BP: I'm trying to think now. At the time you went to Minneapolis, you said four of you went out at that time?

ES: In '68. Three of us went out: one fellow declined to go out.

BP: In subsequent years did all of the districts get a veterinarian?

ES: No, only eight.

BP: Only eight.

ES: Right. And that shifted from time to time. They tried to put them always in agricultural areas, like Kansas City, Dallas, San Francisco handled California and the west coast, here in Denver. There was one in Detroit, and then it was moved from Detroit to Chicago when they went to regions. There was one in Atlanta, one in Philadelphia, and they had one in Boston for a short while, then even in Cincinnati for a while.

BP: During the years you were in Minneapolis, did your relationship change from reporting to somebody in headquarters to becoming a member of the district staff? Or did that remain pretty much the same?

ES: That remained the same in Minneapolis and, when you mentioned that, Bob, I forget what year that was, but there was a transfer, and I think that happened when we went to the regional staff. In fact, I think that was incorporated at the same time, on or about the same time. Instead of being under administrative jurisdiction from headquarters anymore, it was strictly at the field level.

BP: See, I was at the other end, kind of. I was in headquarters in EDRO working for Paul Hile and I know it was our philosophy that we wanted to get people who went from headquarters with special expertise to become members of the field staff and to report through the field administrative staff rather than to report to somebody in headquarters. That was just our general feeling. Because we were a bunch of old field guys, you know, and we thought that was rather important.

ES: I don't know, I get the feeling that this changing from headquarters to field supervision happened a year or two before I came here to Denver. In fact, I'd almost bet it did.

BP: In my recollection, you and I came here to Denver almost at the same time, and it seemed to me that you reported to the regional director at that time.

ES: Yes, that's the way it was administratively set up from EDRO, that we would report to the regional director. And what's really strange, every field veterinarian did except me.

BP: Is that right?

ES: Yes, after a short while I went from reporting to the regional director to the district director.

BP: Oh, I see.

(Interruption)

BP: By the time you came to Denver this change had been made and you were reporting to the Regional Director or at least to the local management. Is that right?

ES: That's right.

BP: How did that go?

ES: It went fine. I guess I was here about two months, and then the regional director said we were going to have a meeting and wanted to know if I could attend it about 10:00 or something like that. I said, "Certainly." So at the meeting there were the regional director and the district director and myself, and I was told by the regional director that it seemed like more of my activity was associated with district interest than with regional. I couldn't exactly agree with that, but they decided that I should report to the district director and not the regional director. Then some years after that there was a change of district directors here in Denver, and the new district director said that he thought I was more involved with compliance than I was with district activity, so I ended up in the Compliance Branch and had been then for the rest of the time I was here in Denver. So that was ten or twelve years, I guess, that I was in the Compliance Branch in Denver.

BP: It wasn't true of the other field veterinarians?

ES: No, all the other field veterinarians still continued to report to the regional director.

BP: Don't you think that was mostly because Denver was a one district region?

ES: Yes, that could be. And again, I think it was just more or less personal philosophies of the administration here in Denver, and again they have that prerogative. And really to me as far as my activities were concerned, I didn't have any problem with it, except in the latter years in Denver being in the Compliance Branch, my activity as a veterinarian became almost nil. I would say the time spent anymore in veterinary activity was no more than maybe 5, 10 percent at the very most.

BP: You were doing other Compliance Branch work?

ES: Yes, it was more or less work the compliance officer would do, although for one I was given the job of being a Small Business assistant, whatever they call that, Small Business, what, Bob?

BP: Well, let's see, Small Business Representative or something like that?

ES: Yes, that's what they called it, it never sounded like the title was correct for what you did, which was primarily at first to answer and assist small business in the medical device industry, but it ended up that every call that came in whether it was human drugs, most of them human foods or medical device questions, I got them. Which actually in a way I found stimulating and interesting. After a while, you became aware of the kinds of things that these people were inquiring about. When I didn't know, it was interesting to run down the answer. Then I also was doing the import officer's job here in Denver for the last four or five years. I tried to get that transferred back again to a compliance officer, but I didn't succeed so I ended up

doing that up till the last day. There were a lot of general inquiries that come into the office; I would get those to answer. And like I say, out of all the inquiries I really didn't get many inquiries as far as veterinary drugs were concerned.

BP: Just as you kind of got weaned away from the veterinary business, what happened to all the other district or other regional veterinarians?

ES: About four years ago when the regional directors had their annual meeting up in Boston, this question came up about the field veterinarians, and they decided that really the time has passed when the field really needs veterinarians anymore. They decided as the veterinarians transfer or retire or whatever, they were not going to refill that position. Most of the veterinarians actually were not transferred, but they all retired. Well, one did transfer: Max Crandall transferred back to EDRO, went down to Puerto Rico as district director and then came back to headquarters in the now Center for Veterinary Medicine. But all the others retired and they vacated the position, and I was the last one of the field veterinarians to finally retire.

BP: So when you retired, the field veterinary program was over.

ES: That's right. In fact, in a sense, according to my activities, the job here kind of died, too. It was always kind of a slap in the face, and I can't blame the district for doing it, but every time we got cut back on monies, I was always the first one that was told I was cut. And like I say, as far as priorities are concerned, I can see an inspector, an investigator going out and doing their job is probably more important than me traveling around just for P.R. for whatever bureau I'd be traveling on. But it kind of got to me over the years that that always happened.

When the Reagan Administration came in we got a budget cut or a freeze--I don't think we got cut, but we got frozen--I was the first one cut, and at the end of that fiscal year we got money, and then I was told, "Well, you can travel again, if you want to." I told them, "I don't want to, ever again." And I really have never traveled since then, where before I used to go out, like I say, to the veterinary schools, Ag. schools, producer groups and veterinary association meetings. But I really didn't do

much traveling in the latter years. But they were really interesting, those earlier years, to talk to these groups, very interesting.

BP: Ed, over the years I'm sure you must have been involved in some interesting investigations, either doing them personally or being involved deeply in them. I was just wondering, can you think of any stories of investigations that you can tell us?

ES: I guess the most interesting ones were the accidental poisoning episodes that have occurred during the years. Originally they were pesticides, and they occurred because the chlorohydrocarbons--which is the family of Lindane and DDT--were being phased out because of their long residual residues that they carry year after year after year. It's the half life on those pesticides. And that industry was switching over to the organo-phosphates, because organo-phosphates did not stay that long in animal tissue after they were used. But you can give an overdose or accidentally feed DDT to cattle and it wouldn't hurt them, but you give an accidental dose of organo-phosphates to cattle and it's going to kill them.

It's a suggestion I think everyone has made for years that pesticide products should be color coded which would indicate this is a pesticide; it is not an animal feed. And that was never carried through; it was never done. But you go out into an old feed shed and that's so often where pesticides were kept. These old bags of pesticides or organo-phosphates next to a bag of a mineral, and you opened them up and looked at them and they almost looked identical. And what happens so often, they'd be cleaning out the shed, they'd find this old bag of pesticide and they'd think it was mineral, dump it into the cattle feed one day, and the next day over fifty percent of their cattle were dead.

I know in Minneapolis there was an episode, I think this farm lost something like about fifty-five head out of, they only had seventy or something like that. I mean, you didn't find them sick or anything like that--they were dead. So I think it was two investigators and I went out to this farm to see if we could find out what accidentally happened. We took samples of feed, samples of this, that and everything else. It was just dumb luck, but I happened to take my sample out of an old bucket that was sitting in the corner of this cattle barn. I couldn't get more than maybe three or four tablespoons of it left in the bottom, but that was the pesticide.

I think it was diazanide or something like that. It was an organo-phosphate poisoning which the farmer accidentally fed. And he admitted that he'd emptied out the storage barn the day before; he thought it was a bag of mineral and put into the cattle feed.

BP: Did he try to dispose of those dead cattle for food?

ES: You know, I don't know what happened to those cattle at that time, Bob. I'm pretty sure they went to a rendering plant and were rendered. No one thought with a small amount of meat scrap, which is what comes out of a rendering plant, and after the heat treatment they go through in a rendering plant, that there'd be any amount of organo-phosphate that would be present that would be of any importance.

BP: It decomposes rapidly.

ES: Yes, it does. I know since I was here in Denver, in South Dakota we had well over a hundred head of cattle accidentally were poisoned. Well, accidentally on purpose, really. This ended up that it was a neighbor with a fight with his other neighbor; to get even with him, he went ahead and dumped some organo-phosphate pesticide in his animal feed and it killed over a hundred head of cattle. We became aware of this through the diagnostic laboratory in Brooking, South Dakota, which there again I think is one of the advantages of visiting these places and they let us know about it. By the time we got up there to check it out they had identified the pesticide--it was an organo-phosphate. We tracked down where the dead animals went, made sure that they were heat treated in a rendering plant. It went to a deboning company in Nebraska, and then from there it was shipped to Wisconsin and canned as dog food. So we were kind of suspicious of this. We did go to Wisconsin. We went to the dog food plant. We put the entire lot under hold while we ran some analysis on the finished product, and it came up negative that there wasn't any organo-phosphate present in the dog food, so we released it.

BP: There had been enough processing and time and heat, whatever those factors were . . .

ES: Right. Yes, of course your canned dog food is heat treated, and between the factor of time and the heat treatment for canning, it turned out to be all right.

I guess one of the more interesting cases we've had here in Denver--and there again we got word of this from the diagnostic laboratory of the veterinary school up in Fort Collins--they had a report of eighty-some head of cattle that accidentally died, on a purebred Red Angus farm down in southwest Colorado. Didn't have any idea what in the world caused it. They were going to fly down and they wanted to know if we were interested. I said, "Absolutely." Did they have any idea? The little bit of history that they had it seemed like it was definitely in the feed and it probably was medication, which really kind of sparked our interest. So Jim Garnet and I drove out to Grand Junction, stayed there overnight, and then went out to the ranch near the Utah border the next day. By that time the people from the diagnostic laboratory from Fort Collins were also there.

We met in the kitchen of this farmhouse. I explained to them that Jim and I were there only to assist as far as determining whether there was anything in the feed or in the medication that these cattle were receiving and that they had the primary responsibility to rule out a disease or anything like this, and we'd just dovetail all of our reports and see what we came up with. Well, we found out that they were feeding a medicated liquid feed with the drug Monensin in it. Monensin is not approved for use in liquid feed. It is approved for use in a dry medicated feed for cattle.

We have a feed company here north of Denver in Johnstown that mixed up the liquid medicated feed, put it one of these big tanker trucks, drove it from Johnstown here all the way over to southwest Colorado and put it in their big storage tank, an upright storage tank. I forget how many gallons that thing held. Three thousand or thirty thousand; it was big. And he dumped it in there, and the owner was saying that when they were emptying the tanker truck, there was so much of this medicated feed that went into kind of a slush that came out of the tanker at the very end. Liquid feed really should all be in kind of a suspension type of a . . .

BP: To be uniform.

ES: Right. We knew that if you overdose or when you suddenly start feeding Monensin to cattle, especially if they get too much Monensin, that it will kill cattle. And the way the cattle were fed from this storage tank after the arrival of the medication and everything else, it just seemed like it probably was the Monensin had settled out and they were getting a concentrated dose of Monensin in their feed.

So Jim Gamet went up to the top of that tank and took a little metal can with weight in with a wire on, and he sampled top and bottom and left and right of this storage tank, identified all the samples, brought them back here to the laboratory and we just got all types of variation on the concentration of the drug in that storage tank. In fact, they had a circulator in that tank. We'd run that thing for a half an hour and then sampled again. It didn't do an awful lot to change the crazy concentrations that were in there. So by analyzing the contents of some of these dead cattle and the history and everything else, we definitely concluded that it was the unauthorized use of Monensin in a liquid supplement that caused the cattle deaths. I think there were 115 head that died all together.

BP: What was the Monensin in there for? What was the reason for it? Is it a feed supplement or is it a drug? You maybe said, but I . . .

ES: No, I didn't say, Bob. It's a drug that increases feed efficiency. They will gain more pounds per pound of feed consumed when they're on Monensin. They said they'd been--and I can't understand this--that they had been feeding Monensin in a liquid supplement before and didn't have any problem. But maybe this had been concentrating in that tank more and more over time that it might not have been just this one shipment per se.

But there again, after Jim and I got back, it was just a day or two, one of the big shots from the Elanco (Products) Company, which is a feed company that makes Monensin, from California stopped in to see us. I was, I don't know what you call it, subpoenaed to give a deposition to a group of lawyers for insurance companies about a half a year afterwards. So it was an interesting case. The company finally did improve suspension agents with Monensin and it now is used as a liquid sup-

plement, but, like I say, the suspension agent's been approved and added to it, and there's no problem when it works that way. So these poisoning cases, which were unfortunate to the owners, were interesting.

One case, since there wasn't a regional veterinarian in Kansas City anymore--(Laughter) one that I think is still funny--a state official from Nebraska called because there was a lead poisoning incident of cattle in the western end of Nebraska. And what they wanted to know is can these cattle be salvaged through a rendering plant and used as animal feed? They had done some analysis of some of the animals that had been rendered and the material was put into a silo, and I forget what the levels were anymore. They were not too high. And I checked with a toxicologist at Texas A & M University who had worked for BVM, Bureau of Veterinary Medicine, for a year, and I got to know him pretty well talking to him there. I told him what levels were being found and so forth and so on, and he said, "Well, at that level," he said, "there would be no danger going ahead and using that tankage for their animal feed."

But the local veterinarian who first saw these animals that died from lead poisoning said, "You know, these animals have to be incinerated; you can't use them for animal feed, period." So the veterinarian told the rendering plant "Don't take these animals, they have to be incinerated." And the farmer lost two more cows, I think, over one night. The rendering plant wouldn't take these two dead cows, so what's he do? He drops them off in the front yard of the veterinarian. Now what he did with them I don't know.

So we've had lead poisoning; we've had pesticide poisoning. On medicated feeds the one with Monensin as a liquid supplement was the worst one that we ran into in that category.

BP: Have you had to testify in court? You had just mentioned you gave a deposition, I just wondered have you also testified in court in connection with the drug work?

ES: No. I guess maybe only one time, which was the first year I was in the FDA out at Beltsville. We did some feeding of an unapproved food additive which had been used in poultry feed. The food additive had gentian violet in it. We hadn't

approved it and were skeptical of it based on the food additive unapproval. Why I had to go to the court case I don't know; it's just the fact that I observed the measuring out of the gentian violet, the feeding to the chickens, the slaughtering of the chickens, the packaging of the chickens that were sent into the laboratory in Kansas City. I had to fly all the way from Washington, D.C., to Tyler, Texas to testify--I don't know why they couldn't have done it on deposition--that this is what I observed and so forth and so on. That's funny. That gentian violet case, that happened way back in '67, I think. Yes, '67.

We won the case but the judge died; shortly afterwards the company appealled--Remco in Missouri I think was the name of the company--and that thing was in litigation back and forth for almost fifteen years. Now it's approved, it can be used, I think, in low parts per million just for mold control in animal feed. That was my only time in court, which really was no more than what a chemist would talk about. I didn't think it was really necessary. Over the years, other than this deposition on the Monensin poisoning, I really didn't become involved in court-cases. I've become involved a lot of times in the district offices as far as hearings were concerned with producer groups and some drug firms.

BP: I thought when you were talking about the gentian violet in chicken feed, if it had gotten into animal feed, would it produce a purple cow?

ES: Well, you know, it's used in wound dressings from way back, day one I think, and it certainly turns those blue. No, this company was advertising that they use it in poultry feed to cut down on intestinal fungal infections that chickens do get. But then there again everyone was concerned about the residue factor that was undetermined. Also, no toxicity work had been done on gentian violet as to whether it was suspect as possibly being a carcinogen or not. But that lingered along for years and years. In fact, every case which is difficult to understand in a way just lingers on forever and ever. The issue of diethyl stilbesterol in cattle feed or in implants, that thing was argued back and forth for ten to twelve years. Low level antibiotics was argued back and forth for a half a dozen years and finally decided that there is no public health hazard to the low level feeding of antibiotics to cattle or food producing animals.

BP: You know, there's one other thing we might well talk about, Ed. Were you involved in FDA federal-state cooperative efforts along during your career?

ES: Yes, I certainly was and I think every field veterinarian was, too, although this may not have been one of the reasons that they established a position of a field veterinarian. But over a very short period of time, it became obvious that because of the Harris-Kefauver Amendment, all medicated feed establishments and all drug manufacturing establishments had to be inspected at least once every two years. That meant that these feed mills, medicated feed mills, also had to be inspected once every two years. There were about 11,000 feed mills in the country and FDA did not have enough inspectors to inspect all these medicated feed mill facilities.

All states, usually under their Department of Agriculture, have state field people going to these feed mills, picking up feed samples primarily to check on the composition. For instance, to see if they declared twelve percent protein that there is twelve percent protein present in their rations. Since they're already out there, they know the feed mill operators--why not train the state people so that when they're out there they can also do a medicated feed mill inspection for us?

The other veterinarians and I participated in what we called medicated feed workshops for state people, and we had our inspectors, our compliance people, and the veterinarian talk to state people in these training sessions time and time again as to how to do a medicated feed mill inspection. We set up a program so that after the state people had so many hours of this type of training we would commission them so that they would, in a sense, have the same authority as an FDA inspector in these feed mills as far as writing up the report and also using his material, his information if there was any kind of a regulatory follow-up to be made.

And really over the years this has worked out very well for FDA. They can do a medicated feed mill inspection at a lesser cost then what it cost us to do it. And we, over the years, have had contracts with these states and we've paid them to go ahead and do the inspection. We get the report. We've been doing some of the sample analysis ourselves; they've been running some of the samples. We paid a per diem; we paid the car expenses; but doing all of that I think FDA has ended up with a good deal. It's increased so much, it's been so successful that now 85 to 90

percent of feed mills that are inspected are being inspected by state employees and not federal, and they've been doing good work.

If they have any problems, and there again, as being the veterinarian here, especially those earlier years, they'd be out at the feed mill and run into a situation they'd call in here to the office and I'd talk to them, and that worked out real well. They've become so proficient over the years. These latter years we get very few calls anymore.

BP: It's still going on?

ES: It's still going on, yes. So that's another thing that began, grew, did real well and is still in progress. It does not need that much support anymore.

(Interruption)

BP: Now, we were talking about the feed mills. I don't know just where we ended up on that last . . .

ES: Well, I guess I was trying to amplify how successful training of state people to do the medicated feed inspectional work has been. They're doing so many of these inspections now themselves, 85 to 90 percent of the inspections are done by them, and if they hire a new state person, they go ahead with their older people training their new people, so we really don't even have to train the state people anymore; they do that themselves. So it really has been a successful program. In fact, I think we've dropped out of it maybe so much that the states are probably better informed and can probably do better medicated feed work anymore than what the Food and Drug does.

BP: It seems to me there was quite a bit of controversy around the Bureau of Veterinary Medicine for a while, in the last two years that Van Houweling was Director of the Bureau. What do you know about that? Was there anything to it?

ES: I'm sure there was something to it. I think basically at the bottom of it all was that USDA philosophy that Van Houweling brought with him of being of service to industry and service to their producer's groups out there in agriculture. Evidently, there were groups in the compliance section of FDA and groups in the toxicology section of FDA who submitted their review on various subjects especially regarding toxicology, the evaluation of a toxicology trial or test results. When they would recommend an action, Van Houweling wouldn't think that it was indicated or it was necessary.

Evidently this occurred often enough that it agitated enough people and the word got out to congressional committees that this was occurring within the agency and they had their own hearing on this subject. I don't think anyone was specifically indicted or pointed to that they were intentionally doing anything wrong. In this regard, most of the agitation seemed to have been toward Dr. Van Houweling. I think the committee ruled that he was doing what he felt was the right thing to do, but yet it seemed like he was really not doing what the agency, what the Food and Drug Administration intended for him to do. When this all cooled down I think Van Houweling retired. Even some people within BVM transferred in headquarters, and now we seem to be back as one happy family again. I haven't heard of any internal bickering going on.

BP: There was a philosophical difference?

ES: I think so. I do not think that there was anything there intentional at all. There was nothing undercover or underhanded about any of this. I think it was philosophical. There may have been a few guys in toxicology and compliance that were over-eager and probably Van Houweling was not quite eager enough, and it just hit the fan.

BP: I'm sure that there are things that happened during your career in FDA that were interesting and anybody reading this transcript would be interested in and yet I've run out of questions. Can you kind of think for a moment of any aspect of your work that we haven't covered and that you think might be interesting and might

help some historian sometime who's talking about this period in FDA and help him to know the kinds of things that happened?

ES: Well, over the years it was certainly a wonderful learning experience. I am so appreciative that I had never, other than these latter years, ever got caught in a daily routine, that before I came into the office I knew exactly what I was going to do from 8:00 to 9:00, 9:00 to 10:00, 10:00 to 11:00. Every day was different. There would always be new problems. There would be new situations arise. Like I mentioned earlier, I think the Bureau of Veterinary Medicine would have gotten off to a better start if we would have had more FDA-oriented type of people in administrative positions in the bureau. Who was our executive officer that we had from the commissioner's office in the agency? He was district director for years in Detroit; he's now back in the compliance office and headquarters?

BP: Al Hoeting.

ES: Yes, Al Hoeting. Al Hoeting was the executive officer from the commissioner's office that was in the agency at the beginning, I guess, kind of to run shotgun, but the agency wasn't really an FDA agency sometimes going out there in left field all by themselves.

BP: You're talking about the bureau now?

ES: I'm talking about the Bureau of Veterinary Medicine, right, when it was first established back in '65.

BP: I'd forgotten that. I remember now that Al did that.

ES: I don't know what the extent of his authority was. I think maybe he could have been stronger. I always got along with Al real well though; I always liked Al. But it just seems like maybe if that would have been played out a little bit stronger we would not have gotten, kind of a weak bureau as far as compliance was concerned. I realize there'd probably be a lot of political pressure, and no one in fact was really

dying because of it, but I always felt bad and apologetic for the FDA that we did not take more actions against producers who sent animals into market that had a violative residue, and they knew it. They knew what they were doing and they always figured, you know, "God, I'm one of how many million out here; they're never going to catch me." And when we did catch them we'd say, "Ah, ha, we caught you." And he'd say, "Well, so what?" We said, "Well, don't do it again." And we never did take, really, regulatory actions that should have been taken against producers that intentionally violated drug use.

I realize there were a lot of accidental cases out there where one guy treated an animal; the other guy sold it. He wasn't aware the other guy treated it because he didn't have good records on these animals on how they were medicated. But there are a lot of cases where they intentionally were sent to market with the idea that they figured there were so many cattle going in there they were never going catch him. And when we did catch these kind of guys--and there were a lot of them like that--we really didn't do anything about it. It just seemed that USDA actions, when they would put them on restricted marketing and test them for two or three shipments before they could freely go ahead and send cattle to market, got their attention more than anything that FDA did to these producers.

BP: If we had set a few examples maybe . . .

ES: That's right.

BP: It would have been salutary for the whole industry.

ES: Right. You know, there were a few cases where we've taken action. Maybe the biggest one was the diethyl stilbesterol in veal calves in New York state here the other year. Of course that was really a biggie, bringing in DES illegally into the country and illegally mixing it in with penicillin suspensions and illegally injecting these veal calves with it at a time when DES had been banned for use in any food producing animal.

Of course it never received much publicity, but there was the case of the feed lot in Ohio that had accidentally fed treated seed grain that had been treated with

mercury. We put a hold or an injunction on this feed lot and wouldn't permit them to send these animals to market. There's only a few real significant cases like that, and maybe that was all right, but it just seemed like there were too many producers just laughing at us that, you know, "So I get caught, what are they going to do about it? Nothing." I mean even a small fine, $500 or $1,000, would get their attention, but we did nothing really as far as compliance actions.

BP: Just warn them.

ES: Right.

BP: Is our veterinary drug program in the Food and Drug Administration a strong one today, would you say?

ES: Yes. I would say it's stronger than it has been ever since the Bureau of Veterinary Medicine was established. Over the years I think they've been fortunate. They've always seemed to have received good support by the commissioner of Food and Drug. In regard to distribution of money and personnel, I think they've been on an equal basis with the other bureaus. Whenever anything comes to national attention it seems like the commissioners have always been supportive. I think over the years, with the hiring practice in the Bureau of Veterinary Medicine, we do have a lot of personnel in there that have never been to a field office. You hear this talk not only in veterinary medicine, but in the other bureaus. I think it would be important if there was more exchange of personnel between the field and headquarters. Especially veterinarians now in veterinary medicine, they're hiring recent graduates out of veterinary school. They really don't have any practical experience. Certainly don't have any experience as far as the field operation of FDA is concerned.

I think it would be good if a lot of these people could come out to an office at least sixty days--no less than sixty days--to get their feet wet and get a feeling of print-out meetings in the office, regulatory activities that are going on in the field. And there again, they need not necessarily come to Denver, but rather to areas where drug firms and food producers are more or less concentrated. Kansas City, Chicago, Cincinnati would be better than Minneapolis or Denver if they wanted

some experience. We don't have that many actions in the veterinary medical side of our activities out here anymore. So if they are going to go out, they probably should go to more of an active regional office or a district office. It wouldn't have to be necessarily a regional office.

BP: Well, do we have anymore to say? If we're beginning to run out, why don't we quit for now. Maybe if something comes to mind after lunch or during lunch period, we can come back and add some to it.

ES: All right.

BP: OK? In case we don't say anymore, I want to thank you for coming in for this interview.

ES: Well, you're certainly welcome. Do you want to know where you can send your check to? You have my address? No, I enjoyed it, Bob.

BP: Well, thanks, Ed.

ES: You're welcome.