History

of the

U. S. Food and Drug Administration

Interviewee: Fred J. Kingma

Interviewer: Robert G. Porter

Date: February 28, 1990

Place: San Diego, California

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Fred J. Kingma

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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 & 2

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

DATE: Feb. 28, 1990 PLACE: San Diego, CA LENGTH: 80 Min.

INTERVIEWEE	INTERVIEWER
NAME: Fred J. Kingma	NAME: Robert G. Porter
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Admin.
[redacted]	

FDA SERVICE DATES: FROM 1957 TO: 1980 RETIRED? Yes

TITLE: Deputy Director, Bureau of Veterinary Medicine
(If retired, title of last FDA position)

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BP: This is another in our oral history interviews with former employees of the Food and Drug Administration. Today we're interviewing Fred Kingma. Fred retired from the Food and Drug Administration in 1980. His FDA career began in 1957. What was your title when you retired, Fred?

FK: I was Deputy Director of the then Bureau of Veterinary Medicine. I guess that's now been changed to Center for Veterinary Medicine.

BP: Good. The date is February 28, 1990, and the interview is being held at Fred's winter home in San Diego, California. My name is Bob Porter.

Fred, why don't we start this interview by your giving us a thumbnail sketch of your education and career so that the people who listen to this recording will know who you are?

FK: I'll be happy to, Bob. I graduated, got my Doctor of Veterinary Medicine degree in 1938 and an advanced degree in 1939 from The Ohio State University. I stayed on there as a faculty member and went through various promotions. When I resigned in 1955 I was a full professor and chairman of the Department of Veterinary Physiology and Pharmacology. I also had the opportunity to practice what I preached in that I worked in the clinic and actually had hands-on experiences with animals which were brought there for hospitalization. Following that I had two years of experience as director of Clinical Evaluations, conducting drug evaluations for Abbott Laboratories in North Chicago, Illinois.

While I was at Ohio State I became quite well acquainted with Henry Moskey, who was running the veterinary program of the Federal Food and Drug Administration; also John H. "Jack" Collins, who succeeded him. We talked frequently about the possibility of appearing as an expert witness and so forth so that I became reasonably familiar with the Food and Drug Administration and its activities. I recall at one point, Jack Collins asked me why I didn't spend a little time in Washington getting hands-on experience there and so I did. I promised to stay for a couple of years. Well, as any of you who are familiar with government might imagine, that two years soon became twenty-three years. I had a very, I thought, interesting and enjoyable career with the Food and Drug Administration.

I saw it grow from, I think there were six of us: Dr. Paul C. Underwood, who worked at Beltsville doing drug research out there; Dr. Charles G. Durbin, who spent part time out there and part time in the city; Jack Collins, who was director of the group at that point; Roland Gessert, who subsequently left us to go with a drug firm; and LaVerne Harold and I. Laverne Harold and I retired at the same time in 1980.

At this point, Bob, do you want me to . . .

BP: I'll tell you what I would like. If you'd get into your early contacts with FDA when you were a professor at the university and tell us what you know of the veterinary drug branch at that time, and then move right on in to how it changed in the years you were there.

FK: Well, as I mentioned earlier, Bob, I was somewhat familiar with the workings of the Food and Drug Administration. I remember Dr. Moskey telling me of one instance where there was a court case out in Nebraska. It involved something called

Corn Husker, one of those remedies for everything. But it particularly took care of intestinal abnormalities. Dr. Moskey needed some extra help on that. One of our faculty members did go out and testify in that particular case. But the type of cases that were confronting them are a far cry from what they have at the present time. Fifty years later looking back, you wonder who would ever have bought that so-called Corn Husker, the cure-all for any intestinal abnormality in cattle.

In 1957, I did come to Washington to work with the Food and Drug Administration. Jack Collins was the director of what was then a veterinary branch in the Division of Medicine. The veterinary group remained a part of the Division of Medicine for several changes after that, but when the human medicine group achieved bureau status, we were not too far behind. It was some few years later that the veterinary group also moved up from division to bureau status.

BP: Fred, when you came in, who was the director of the Division of Medicine?

FK: Good, I'm glad you asked that, because he was one of the finest men I've ever worked with. Dr. A. H. Holland. Dr. Holland is the one, by the way, who had the responsibility of putting the final okay on the birth control pills, a tremendous decision that had to be made and one that was frought with much controversy. As I mentioned Dr. Holland was one of the finest administrators, the finest scientist, and one of the finest gentlemen that I've ever encountered anywhere. It was fun to be working for a man like that. I might mention something, an aside, which kind of tickled me. Coming to Washington, never having been a bureaucrat before . . . I came in July I think it was. The group had just moved to what was previously a nurses rooming quarters at 501 First Street Southeast.

BP: I remember.

FK: The big conversation point at the coffee break at my first day of work was about where to hold the Christmas party. It was suggested that the library would be a great place (and subsequently was a great place) to hold the Christmas party. I had never heard such advance planning for an event such as that. This seemed to be a prime concern on the minds of all those involved with the medical group at that time: to plan your Christmas party six months in advance. As it turned out, I could see why. It was a most enjoyable affair. Later on, the Christmas parties moved into a hotel, and that was Dr. Holland's gift to the group: he paid for the suite at one of the big hotels in town. Everybody contributed toward food and beverages. It was a great get-together and was typical of the camaraderie that was so much in evidence at that time. The veterinary medical group was a very, very closely knit group. It was a fine place to work.

It was a real, real small group, as I say, at that point. The numbers currently--I can't tell you with accuracy--but I know those six people have now expanded to something like 275-300 people. It's a little difficult for me to fathom that there have been that many changes in the law since 1957 that would account for that many people, but I guess that's not being a member of the club when you question an expansion such as that. Being a taxpayer now, I look at it, I guess, a little differently. (Laughter)

In the early stages, too, I can remember getting involved quite early with gadgets, devices. I did have the fun of being involved in a device which was originally something to grow hair in humans, and the Food and Drug got it off the

market for that. A barber up in St. Paul/Minneapolis area who had invented this instrument put a magic wand on the end of it and stroked it into the drinking water of a cow. When drunk it was then supposed to cure mastitis in the cow. It was kind of fun to work on a case such as that. And needless to say, that item is no longer available on the market.

BP: Now this was before medicated feeds?

FK: Oh, yes. I think, Bob, you're right in asking about medicated feeds, because a few years after I got here, it became apparent that the big future in animal drugs was not going to be individual animal treatment but rather herd treatment. And herd treatment of course immediately brings to mind the fact that there had to be a way to administer this and, of course, the logical way was in the feed. Well, that brought a group heretofore remote from federal regulations into the purview of the Food and Drug Administration. No longer was a feed manufacturer just making feed free from federal control. Now they were suddenly drug manufacturers because of the introduction of drugs into the feed.

To further complicate it though, and this is what has really added to the difficult part in introducing drugs, are those which are to be used continuously in the feed of animals. Immediately that brings up the question of not only the safety of that item to the animal involved but the safety of edible products derived from that animal when consumed by human beings. We must know if there is or isn't any residue in the edible products. Well, of course, that entails some tremendous research and a very costly type of research.

But even more complicated was the requirement to develop a sensitive method of assay which was also a very easily performed method so that these tissues could be policed and found to be safe, thus assuring the public that such edible products were safe. So the cost of marketing something such as that has risen unbelievably. It costs millions of dollars now to develop a product because of the cost of developing this sensitive method of assay so that the edible tissues from these food-producing animals can be tested efficiently, easily, and accurately.

And then, of course, the same has to do with the feed itself. The feed has to be checked constantly and made certain that the levels that it purports to contain actually are there. So it made for an entirely new ball game as far as veterinary medicine was concerned. Here we had in one case the product administered en masse to animals whether it be for growth promoting purposes or for treatment purposes. These are really treated the same insofar as the cost of coming up with the data which had to be presented to Food and Drug Administration. Over the years, the individual treatment of animal drugs, of course, in small animals has also continued to be a very sizeable part of the new drug administrative process. In large animals there has been less and less individual treatment just because of the impracticality of administering to individual animals.

There was great concern raised by some because of the continuous low-level feeding of antibiotics to animals. The concern was based on the fact that, with such low levels in the feed, the bacteria which may be present in those animals receiving the feed could develop a resistance to treatment with those same antibiotics and a difficulty could arise when humans infected with those then resistant organisms failed to respond to treatment. This really was the concern which was the basis for the so-called Swann Report out of England, which had to do with the development

of resistance and led, as I recall, to the abolishment of the use of low-level antibiotics in animal feeds in the European community.

BP: Did that Swann investigation and report come about because of clinical experience with people who were sick and maybe died?

FK: There was an incident in England which they linked to some deaths, human deaths. It was not a 100 percent certain that that was the cause, because in actuality, as I recall--and this isn't awfully easy for an old fellow like myself--but as I recall, there were veal calves involved who were infected with a coliform organism. They were treated, I believe by injection, with tremendously high levels of antibiotics. The resistant organisms then did infect people and there were deaths recorded. But it was difficult then, and it still is for me, to correlate that with what happens when low levels are fed over a continuous period of time. It didn't deal with that issue. Nothing has ever really been done to prove that, although enough evidence apparently appeared so that the low-level feeding is no longer frequently used.

BP: You mean it's not allowed?

FK: I'm not sure what it is. Some of them have been disallowed. Certain ones have been disallowed.

BP: Now, the low level dosage, was that for growth or was that for the prevention of . . . ?

FK: That was mainly for growth promotion.

BP: A thought comes to me and maybe you want to talk about it later and maybe this is the time, but you said that the Division of Veterinary Medicine took over these medicated feed problems to the degree that they were interested in the carry over into food. Now this must have caused you to work together with and maybe bump heads a little bit with the Bureau of Foods. Is that right? Was that a problem or was that an easily solved situation?

FK: Actually, that wasn't too difficult at all, because it was under the same umbrella, namely Food and Drug Administration. We worked with them. They had to approve of the method of feed assay. They had the expertise to do that. But that actually prolonged, in some cases for unbelievably long times, the time interval from the submission to the approval of a new drug application. It was just another layer, just like later on the attorneys got involved, and that, too, stretched it out to unbelievably long periods of time. I guess maybe I thought back to the cozy little group back in the late fifties and early sixties. There were not these outside interests, or in some cases maybe interferences, and we could get the job done in a reasonable period of time.

BP: When this came up then, you didn't establish within your division analytical laboratories to take care of this methodology; that was done by the Bureau of Foods?

FK: Yes, the expertise was already over there in the Bureau of Foods, and the co-operation actually was great. It was excellent.

BP: Good.

FK: But what it did do is get us very, very intimately involved with USDA because of the meat inspection. This, I shouldn't say, posed problems, but it did definitely add another layer to the review process, because they had to be satisfied that their field people could use the method of assay of edible tissues submitted with the New Drug Application. Each person in Washington seems to have an inherent desire to protect his little bailiwick and resents intrusion by someone else. It's bad enough if they're brothers in the Food and Drug Administration, but when they're those "other guys from USDA," that sometimes gets to be demanding of great diplomacy, all of which we had in great amounts, of course.

BP: If they let you take over too much, they'd come to the office in the morning and find their desk out in the hall.

FK: (Laughter) In regards to medicated feeds, a symposium was held in the mid- to late-fifties, a medicated feed symposium in Washington, at which various concerns were voiced. It was a three-day symposium, published fortunately, and that publication has become pretty much of a classic as to the state of the art at that particular time. Ten years later a group of us got the idea that it was time for another similar symposium. Instead of taking on the job ourselves to get the speakers and all, we contracted with a group in Washington, the National Academy of Sciences. They arranged the symposium. I was pleased that they chose as the man to supervise the job for them, to get the speakers together, was the man who succeeded me at Ohio State. So I knew they had a good man.

A few years later, an additional requirement for new drug approval was added; that was the requirement that efficacy data was required. Up to this point new drugs, in order to be marketed, had only to prove safety.

BP: That was in the 1962 Drug Amendment?

FK: Correct, right. So that meant there were a lot of drugs apparently on the market which had not been approved for efficacy but just for safety. We then contracted again with the National Academy of Sciences/National Research Council (NAS/NRC) to gather blue-ribbon panels in various specialties to review all the drugs currently the subject of New Drug Applications. The panels decided whether or not they were efficacious or partially effective. I forgot what were the five categories that they designated on each one of those. This meant of course in some instances we were pretty much obliged to take the drugs off the market or at least challenge the people because of a lack of efficacy data. This meant, of course, a whole new area in which we had to have pretty astute people going over the report from the NAS/NRC and contacting various firms to try to get their status established.

There were still some drug firms who claimed that we were not within our legal rights to require that--because they had been given approval under the previous law and we couldn't go back on them. Eventually it worked out, however, to the satisfaction, I think, of all concerned.

An interesting aspect of my FDA experience is the fact that I had offices in most every area of Washington D.C. One of them was a temporary building in an area that is currently a parking lot for the RFK Stadium. I remember I stole away from work one morning and went over the hill to the ceremonies at which they turned over the first spade full of dirt for RFK Stadium.

BP: Is that right?

FK: I obtained a program of the ceremony. What a neat thing if I had been able to save that. I think it's in my belongings there at Food and Drug somewhere. I hope whoever finds it will appreciate what a nice memento that is. But it was kind of interesting; at that point they were featuring the fact that you could get to RFK by rail, because the train ran close by; you could get there of course by bus; you could get there by water, because it's right along the Anacostia River. Currently we find it's inadequate to accommodate the crowds wishing to see Redskin football games.

Of course, from there we went over to Crystal City. We were in the first building there at what is now a tremendous complex. Our office was in the first building put up there. I think it was number six. We watched that whole thing go up--a really interesting development. From there, we moved to Rockville, the current location, which of course posed a tremendous problem for many people moving from the District, particularly the clerical help. The move to Rockville, Maryland, resulted in the loss of many clerical employees. It also was a costly move. If your move entailed more than a certain number of miles, the government paid for it. Some of those bills were five and six thousand dollars.

BP: They paid for my move on that.

FK: Did they?

BP: Yes, it fit the formula.

FK: Which was great, and certainly fair, but as I say, it made it a costly venture. I envied the European M.D.s who had the foresight to buy that land and then come back to the government and get money to buy the building on the strength of the fact that they had obtained a government lease, a rent lease, which would pay that building off in seven years.

BP: It's an atrocious building, as far as I'm concerned. Those narrow corridors and so on.

FK: Yes, but my office was the best I ever had.

BP: Well, let's see, Fred, let's turn it off a minute and go over some of our subjects.

(Interruption)

BP: Okay, we're back on, Fred. There are a few subjects here that have come to mind that I'd like to talk about if there is something to say about them, and the first one is the problems with sulfonamides in feeds.

FK: This is particularly significant in swine because of the fact that a few years ago, swine tissues on the market, a relatively high percentage, certainly not an acceptable percentage, showed detectable levels of sulfonamides. There are those, of course, who think sulfonamides are cancer-causing drugs, which puts them in a very, very suspect and very sensitive area. For some reason or other, it seemed impossible to get these long-lasting sulfonamides out of the feed or environment of swine. Even after you discontinued the drug, apparently it was in the environment enough, maybe the bedding, so that it recycled. And it was serious enough so that, if I am correct now, they have taken at least one of these long-lasting sulfonamides off the market and made it illegal for use in swine.

BP: In any way.

FK: Yes. Right. Nitrofurans were also the subject of much debate. They were the subject of much study over what seemed like an endless period of time. I think they've just about reached the point where they're not used to any extent anyway, but they're now in the forbidden category.

BP: Somebody has suggested that we talk about chloramphenicol.

FK: Chloramphenicol is an entirely different item. Chloramphenicol is an extremely effective antibiotic, but because of the fact that it had never been proved that it could be safely used in food animals, it was never approved for such use. The fact that it has a suspicious history of side effects in humans, the drug was never approved for use in any food producing animal. In spite of this it was misused in great amounts in food producing animals. It showed up in edible tissues and in milk, I think, also. It has been the subject of regulatory action, if I'm not mistaken.

BP: I was just about to ask you that. Were regulatory actions taken in regard to sulfonamides and chloramphenicol?

FK: Sulfamethazine is currently under discussion. Chloramphenicol, definitely, because chloramphenicol was being smuggled into this county for use in food animals.

BP: If there are any cases or any more details about that that might be interesting, why I'd be glad to have you talk about it.

FK: Well, I'm not sure I could recall the facts with sufficient accuracy so that it would be of any value.

BP: Okay. All right, I've also been asked to get into the story, the use of molasses as a carrier for medicated feeds and the carryover then into unmedicated feeds.

FK: This was an area which was, of course, entirely new to the feed companies: the fact that they were now adding drugs to their feed, put them into a whole new ball game and one in which they were not real comfortable. The fact that the Food and Drug Administration was looking over their shoulders and also the USDA for possible contamination of edible products from food producing animals. They

found it difficult to produce feeds which were nonmedicated, totally devoid of these drugs. These drugs were contaminants and got there apparently in a variety of ways, some of which I'm sure they have not even determined at the present time. Molasses apparently was one of the things that they had difficulty in cleaning out when they switched from a medicated feed to a nonmedicated feed.

BP: Did they use molasses as a medium to carry the medication into the feed? Was it first mixed with the molasses?

FK: It was a constituent of the feed, and during the cleaning out of the equipment it was almost impossible to get it entirely out of there.

BP: I see.

FK: And again, once they brought drugs into their plant, their environment was a source of contamination. Some of these drugs, a lot of them, are potent drugs, and it's unbelievable what minute quantities are capable of being detected. Frankly, it's been hard for me at times to think there was a great deal of danger in the minute amounts which the sensitive, exquisite assay methods could detect. There are many folks who have said, and I think rightly so, that our ability to detect has gone way beyond our ability to know the significance of those minute amounts to human health.

BP: And that's true in a lot of areas, isn't it?

FK: Surely. The methods . . . Well it's just mind-boggling what a small quantity can be detected. And it's also difficult for the average person to attach real health significance to those minute amounts. But to prove the opposite, that that minute amount is not harmful, is an impossible assignment.

BP: Well, AVMA, is that the American Veterinary Medical Association?

FK: Right.

BP: And the BVM, what was the relationship you had with them?

FK: Well, the AVMA, of course, is the umbrella organization in the veterinary profession. In addition to that there are now many splinter groups such as the American Animal Hospital Association and then every specialty, the surgeons, the internal medicine people, the pharmacologists, the physiologists. Each of these has a splinter group. But it's the AVMA which still speaks for the veterinary profession. The Food and Drug Administration has always tried to maintain a very good close relationship with them.

The headquarters of the AVMA has always been in Chicago or the Chicago area. They have their own building in Schaumburg, Illinois. They also have maintained an office in Washington. The representative of the AVMA in Washington has always maintained very close contact with the Food and Drug Administration. It makes it a lot easier for Food and Drug to get the message to the practicing veterinarian if we can convince the higher-ups in the AVMA that the action contem-

plated or taken is a logical one and is worthy of the cooperation of the veterinarian out in the field.

BP: Does this mean, I presume they have a journal, and through their journal you could get the word out? Or am I wrong about that?

FK: You've asked a real excellent question and I'm so glad you have, because in every issue, and I have a copy in front of me right now, there is a little box on some page of that journal which says, "If you have experienced an untoward reaction to a drug, call this toll free number and report it and discuss it with a Food and Drug representative."

BP: And was there feedback from the organization itself to FDA or was it more a way of FDA communicating with individuals?

FK: Definitely a two-way street. Definitely. If one of their councils is considering a current problem in FDA and the council takes an action, that action is reported immediately to the Food and Drug Administration. It's an excellent arrangement. And fortunately, we've had FDA personnel who have been very active in the AVMA organization itself. I had the good fortune of being a delegate representing the District of Columbia Veterinary Medical Association in the House of Delegates of the AVMA. FDA veterinarians have also been an integral part of the AVMA Council on Biologic and Therapeutic Agents.

BP: I see.

FK: I might say that we also provided the AVMA with an Executive Secretary. The first BVM director left Food and Drug to assume the position of Executive Secretary. That was Dr. M. R. Clarkson.

I might mention this as an aside since we mentioned director. Dr. Moskey was the original head of the group that was in agriculture and later moved to HEW. Dr. Collins succeeded him. I guess there was a period then, after Dr. Collins died, where the group was kind of in limbo between the time when we were a division in the Bureau of Medicine and when we became a Bureau of Veterinary Medicine. Dr. C. G. Durbin was the director of the DVM at this time.

When the group attained bureau status, Dr. Clarkson, who had retired after a long and illustrious career in USDA, came back and was with us for a couple of years. I had the fun of being his deputy, and between him and Dr. Holland I had two of the greatest people to work for that anyone could ever imagine. When Dr. Clarkson left to assume the position with the American Veterinary Medical Association in Chicago, a new man came in, a Dr. C. D. Van Houweling. Dr. Clarkson had worked closely with Dr. Van Houweling over many years in the Department of Agriculture.

Dr. Van Houweling, I think, came in at a time when there were many problems facing the bureau. All of a sudden for some reason or another, congressional interest was at a peak insofar as veterinary medicine was concerned, some of it brought on by people working in the bureau taking actions which were questionable to some of us. But anyway, it was a source of embarrassment in that Dr. Van Houweling was called up and faced some pretty serious grilling by Congress on some accusations which were never really proved. That is to say it was a source of

embarrassment to Dr. Van Houweling. Dr. Van Houweling was moved into the office of the commissioner and worked with the commissioner, Dr. Edwards, quite closely for a few years before his retirement.

At that point, Dr. Crawford, who was on the faculty at the University of Georgia, College of Veterinary Medicine came in as the bureau director. He has left the agency now to move over to agriculture and is the director of Food Safety and Inspection Service, FSIS.

And Dr. Gerald Guest, who has worked up the ladder in the Food and Drug Administration, is now the director of the Center for Veterinary Medicine and is doing an excellent job. Gerry is a fine administrator.

BP: Why don't we go back and cover those just a little bit. For instance Moskey, we've mentioned that he was the director and before your time and then Collins. Could you go back and talk about them as managers and cite us just a little bit, rather than just for us to have their name in the record? What kind of people were they?

FK: Of course, I just knew Moskey as a result of a couple of visits that he made to Ohio State when I was on their faculty. But from everyone I know, Dr. Moskey, who graduated from veterinary school at the University of Pennsylvania, was a very kind and gentle man, a good scientist who surely saw the Food and Drug's veterinary medical group come from a small group to the point where it is one of the respected Centers in the organization. His era was certainly a lot easier than now in that the drug industry was just not very large, not very significant at that point.

BP: I suppose the problems were mostly with quackery.

FK: Quackery involving both drugs and devices. That's right. And the fact that these people didn't have to really prove much other than safety. Actually only lack of harm had to be proved to clear the NDA approval process. I look back at some of those early new drug applications; it wouldn't take very much of a morning to review and get that whole thing taken care of. The fact is there are some historians who claim that some of these came in and received approval the same day.

BP: I suppose that's at least possible.

FK: Sure. I would think so from what I saw. By the way, these are the same new drug applications which the National Academy of Sciences recently reviewed and of course were appalled at, but that was the state of the art and the requirements back in those early days.

Dr. Collins was the one who was the branch chief at a significant time in that he was in that office at the advent of the sulfonamides and the antibiotics, which of course were just tremendously important insofar as veterinary medicine is concerned. A whole new world was opening and it was a fast, fast moving era. Therefore, the applications of course became much more complex at that point and got into this area of human food safety, which again, made it an entirely different ball game. Dr. Collins was a good administrator. People liked him. He wasn't afraid to assign you a responsibility, but with it he gave you authority, and it made for a very, very fine working arrangement.

BP: Now what years would that be, Fred, about?

FK: Oh, I'd say probably from the late thirties to late forties or early fifties.

BP: Wasn't he still there when you went in in '57, or have I missed the boat somewhere along here?

FK: Oh, yes. Yes, he was here when I came here in '57. In fact he was the gentleman to whom I promised I would come and stay for two years. That two years became a career, and twenty-three years later I retired. He was a fine man. I don't think I can tell you the exact year of his death.

BP: But we're talking about the forties and . . .

FK: Dr. Collins lost his wife in the late fifties. She was at NIH with some strange malady, and it wasn't more than six months later that he suffered a heart attack and died.

BP: And he was followed by . . . You say there was a break in there?

FK: Yes, there were acting directors. Dr. Charles G. Durbin was acting director, I believe, for a while there. But then it became a bureau and that's when Dr. Clarkson was brought in.

BP: Now, how about Clarkson? What kind of a man was he?

FK: Clarkson was a great administrator. People still talk about him on the basis of what a great guy he was to work for and how he could talk you into doing things that you know you never could accomplish but you could for him. He could help you, steer you in the right direction and let you go. He had a great rapport with the people who worked not *under* him but *with* him and *for* him.

BP: And what were the major problems would you say that he had to cope with?

FK: Well, he saw immediately that it was time to get the experts together to see what was happening in this medicated feed situation, the use of low-level feeding and so forth, and bring it up to the state of the art. He was responsible for contracting with the National Academy of Sciences.

BP: For the symposium?

FK: For the symposium. He did that within a year after he came with us. It was typical of his listening to the story, seeing that it was a legitimate story that we needed this kind of thing. Ten years had elapsed since the previous symposium. We hated to lose him, but certainly realized at that point the AVMA was in dire need of a strong man, because they had had some difficulties up on topside and needed a man such as he to assume the position of running the American Veterinary Medical Association.

BP: Okay, are we now at Van Houweling?

FK: Right. When he left he recommended Dr. C. D. Van Houweling. He had worked with him; he had seen his ability to assume a leadership role and thought that he could do the job here. I had known Dr. Van Houweling for many, many years. He's a good Dutchman, just like I am. The fact is there were some who, not very nicely referred to us--he as director, I as deputy--as the Dutch Mafia. This was the drug industry and not the people working with us.

BP: You talked some about Van Houweling. How, for instance did he differ in his administrative methods from Clarkson?

FK: I don't think he had the patience of a Clarkson. Of course, you're comparing a man to a saint in my book, and that's tough. I couldn't think of a harder act to follow than to follow Clarkson. He is such an outstanding gentleman. Dr. Van Houweling is a very well qualified person. Of course, his career in government was really from a different angle. I may be wrong but I've always pictured USDA as favoring the producer, and I look at Food and Drug as favoring the consumer. And when you stop and analyze it, those are two completely divergent philosophies. One, you're helping the guy producing the product. We in FDA are regulating the drug company. We're making sure the drug company, what he produces is what ~~he~~ says it is and that it's not going to hurt anybody and also do some good. So it's a different philosophy, and I think at times maybe that got in the way.

(Interruption)

BP: Now we're back on tape two, Fred, and we were talking about the different philosophies of the Food and Drug Administration and the Department of Agriculture. When did Food and Drug come out of USDA, in about '38 or some such time? And I suppose the thing you were just talking about is the main reason Food and Drug was taken out of USDA.

FK: I think that's a real great possibility. I was thinking of it and trying to explain the fact that there were some folks in the Bureau of Veterinary Medicine who felt that Dr. Van Houweling at times used undo stress to try and get them off their duffs and get something done, and that was interpreted as being favorable to industry. It wasn't that; it was a man trying to get the job that he's supposed to get done in a reasonable period of time. It's pretty frustrating for somebody topside to see some employees who are apparently just sitting and unwilling to take an action one way or the other. And when you step in, it's interpreted as interference and trying to coerce someone. This is I'm afraid what happened in a couple of instances with Dr. Van Houweling. I don't agree with it at all. I think Dr. Van Houweling did an excellent job. I think he certainly did what he thought was right. He's a pretty straightforward man, a religious man who lives that type of life. So to hear him being maligned as he was is a pretty hard thing to take. I certainly have complete empathy for the man.

BP: Do you think that these problems--that kind of thing wasn't isolated to that bureau--the Bureau of Medicine has had maybe different but still sort of similar kinds of things . . .

FK: Right. Well, I shouldn't say this, but professional people are kind of a difficult lot in that they feel that their territory is their territory and you better not step into that circle. And if you're questioning something that they're doing, the prima donna in the people comes out real, real loud and clear. I can think of many instances where that occurred in the Bureau of Medicine. But, it's not easy. And I would say by and large the camaraderie which was there at Food and Drug when I first came and for many years was lost when the agency grew in size to where it's a different environment completely. The fun was pretty much over with.

BP: I came into FDA in 1942, and while I think the field has kept that old feeling a whole lot more than the Washington bureaus, I've seen similar changes in my time, too.

FK: I sure agree with you about the field. I enjoyed visiting field offices because of that feeling that here's a really closely knit group. Of course, I think, and I'm sure you would agree with me, Bob, that each district director involved certainly was largely responsible for that. Didn't you think the type of people they had as directors and the individual directors really wanted to establish and maintain that type of camaraderie?

BP: I think so. I don't know why, the distance from headquarters seems to allow the field directors maybe to, their personality, to more greatly affect what's going on. I don't know. I don't really know.

FK: I looked forward to the meetings, the annual meetings where all the district directors came in, and it seems to me after dinner there was always a poker game. I've always felt that if you play poker with somebody or you play golf with somebody, you know that man and know him quite well. That's where I got to know these district directors extremely well.

BP: How about your relationship with the field over the years? Are there any stories or incidents of any kind that you might find, might think about and tell us about?

FK: Yes, there are several stories, but before I get to that I might mention, and this is a little different. When I came to FDA in '57, there were some M.D.s out in the field. I think they were down to maybe two at that point: one in San Francisco and one I don't know where that was.

BP: Chicago.

FK: But anyway, contrary to that, about ten years after I got here, somewhere in there, we sent either six or eight veterinarians out into the field. It seemed like a good idea at the time. I've forgotten what the real rationale behind it was, but it was kind of a nice working arrangement. Frankly, at the end, it seemed to me these people became P.R. men as much as anything.

BP: Don't you think the medicated feed problems in the field had reached the point where they needed a professional of that kind right on the spot?

FK: I think you're 100 percent right. This was a new field for everybody, and I am sure that the folks out in the field benefited by having a veterinarian that they could go to and see what the significance of some of these things were in regard to public health. I'm not sure whether there are any of those still out in the field or whether they've all retired.

BP: No. Ed in Denver, Ed . . .

FK: Sterner. A student of mine at Ohio State.

BP: Oh, is that right? Ed just retired, I would say in October, something like that--September or October--and he was the last one of those field veterinarians, I believe.

FK: Would you believe I recently saw Ed? I went to a football game last September at Ohio State in Columbus, and Ed Sterner was there. We had a nice visit.

BP: Had he retired?

FK: Yes, I think so.

BP: Just retired.

FK: Yes. Well, we were talking about my relationship with field personnel. I remember one real nice experience I had. I wanted to make a field inspection, a drug inspection. I thought I needed that experience, so I was sent for a few days to the St. Louis district, and Bill Southworth was director. Southworth had moved from Washington out there. I had known him quite well in Washington. He had a son who was the same age as one of my boys, and they played against each other, baseball, Little League. Southworth's son was an outstanding athlete even as a youngster. At fourteen he was big and he was good. So I was real happy to visit with the boy. He was now in high school, about ready to go to college. I thought I had him pretty well convinced that he ought to go to Ohio State, because he had become a great football as well as a baseball player. Well, unfortunately, Billy Southworth died shortly thereafter, before I think the boy was even ready for college. He went into professional baseball to try to bring in a few dollars for his mother.

Mr. Kerr, out in San Francisco? Prior to that it was McKay McKinnon, Jr., wasn't it out there?

BP: McKinnon was out there most of the time during your career I think. Bud Kerr was actually not director in San Francisco; he was chief inspector. Then he went to Minneapolis as director, if I recall.

FK: That's where I spent time with him, because I had some work going on a device there at the University of Minnesota, and that's where I spent time with Bud Kerr.

BP: Well, Fred, we haven't talked too much about regulatory actions that you were involved in. I'm aware that they're begun and later carried on by the field, but you

must have played a pretty important part in decisions as to whether the cases should go forward and adequacy of them and so on. Are there any tales that you can tell us about regulatory actions?

FK: Yes, I think there's one that comes to mind immediately. Dr. Underwood out in Beltsville is a veterinarian that's been there--he's retired now, of course--but he had been there. He had done some work on an anthelmintic for chickens. This anthelmintic in question was being put out by a firm in Iowa, and there was a regulatory action against the firm. Well, first we went out to Dubuque, Iowa, as I recall, and did some depositions or something, but I think the trial was up in Sioux City, Iowa. Would that be the district in which it would have to be done?

BP: Where was the company?

FK: The company was in Iowa.

BP: Well, if in Western Iowa it might have been Sioux City.

FK: It might have been Sioux City. Well, the firm was in Charles City, Iowa. As I recall, I didn't think much of our chances in that case when I saw the people on the jury. There were several middle-aged to older ladies. And when I saw the attorney that the drug company had, a really good looking, suave, very eloquent guy who could get his point across to those ladies--I don't think they were listening much, but they sure enjoyed his presentations--and we were assigned a one-eyed banjo player on a Mississippi river boat as the attorney presenting the government's case.

BP: What were the charges?

FK: That the drug was ineffective, and as such the chickens would die, so it was unsafe because there was a better drug on the market. But I think the best we did there was a hung jury. It was not a really great experience.

BP: Did you testify?

FK: I didn't have to, but Dr. Underwood did. He tried hard to testify. He tried hard to show what good testing he had done, but this suave attorney indicated, "Well, really, we're not interested in that." It made Dr. Underwood very unhappy taking time off from his busy workshop to come out to Iowa to show his wares and didn't get much for it.

I'm trying to think of a device case in Minnesota also, but I'm not sure that they didn't throw in the towel before it ever came to a prosecution.

I've been interested and a little upset at something I see in my American Veterinary Medical Association journal about some veterinarians who have been importing bulk drugs and using them contrary to the FDA law. Apparently they're found guilty and they're being penalized. I would have to admit that I have mixed emotions about a veterinarian being prosecuted, but knowing the story in these cases, this is not the type of veterinarian I'm real proud of. And it's the human health factor which has to be uppermost in the minds of anyone working with Food and Drug Administration.

BP: Let's go back and talk about your reaction to and experiences with the commissioners that you worked under, Fred. When you came in, I guess George Larrick, was he already commissioner at that time?

FK: Yes, George Larrick was commissioner, and George Larrick was obviously the man who had come up through the ranks, and he knew everything there was to know about the Food and Drug Administration. I think he had done it somewhere along the way. The fact that he was an Ohioan certainly didn't hurt him, as far as I was concerned. (Laughter)

BP: You seem to favor them. (Laughter)

FK: It meant we had something in common. I thought that the great standing that George Larrick had with his own people, but even more so with people on the Hill, was amazing to me as a novice in Washington. I realized after a few years that you better have some friends up on the Hill or you're not going to get a heck of a lot done in your agency. George Larrick was extremely adept at that. His deputy, John L. Harvey was certainly a favorite of mine, because he did like to play poker, and we even had a few neighborhood poker games where he was involved. And Tilly Checchi . . .

BP: He hired me.

FK: Did he? Well, he knows a good man. I hadn't been with Food and Drug for a long period of time, and somehow or other I got wind of the fact that a Pillsbury bakeoff award luncheon was going to take place at the old Statler Hotel on Sixteenth and K. I went there and observed George Larrick just as I came in. Maybe I shouldn't report this--but there was a little uneasiness because there was a free bar right close by. Well, after a suitable length of time he finally said, "Come on, Fred, let's go. Let's go have a cocktail before we sit down for this lunch." This was typical of George Larrick's behavior as far as I was concerned.

I had an experience with John Harvey, "the Judge," that might be of interest. I was involved in an automobile accident resulting in a law suit. Mr. McGuire, a chemist with our veterinary group, was the driver of the vehicle, and he had retained Mr. Harvey as his attorney. So we had several sessions together over this particular happening that again gave me, I think, an excellent opportunity to get to know the man. I thought he was a great one.

Of course, with the retirement of Mr. Larrick--I hate to say this; maybe I shouldn't say it--but there went the neighborhood. The commissioners from here on in were not folks who had an intimate knowledge of Food and Drug. Subsequent commissioners were political appointees. I think the whole environment changed with that. Maybe some would say for the better; I don't go along with that. I think when someone came in there like Larrick, this was his life. Somebody coming in for a limited period of time I don't think can have that same attitude about the organization. The people who have spent twenty or more years there feel that Food and Drug is partly theirs, and they don't like to see an outsider mess with it. I think this was, of course, why some of the subsequent commissioners didn't have the greatest time while they were in there.

Dr. Goddard I think was as smart a man probably as ever held the post of commissioner. A learned man, a really good scientist. He made a blunder when he

said, "Marijuana's no worse than alcohol." That did not go over big and he never lived it down. I think it cost him the job as commissioner in the end.

Dr. Edwards certainly was a capable administrator, a good administrator I thought. And I've had the good fortune of staying in touch with him. He currently is the director of the Scripps Clinic here in San Diego, or La Jolla--it's a little nicer address when you do call it La Jolla. I was at the clinic for a back problem last year and got to spend a bit of time with him. I had several chances to visit with him. He enjoys his work out here immensely. He loves San Diego as does anybody who's been here for more than a week or ten days. It's a great spot.

BP: We haven't interviewed him yet, and we're going to have to try to work something out with him.

FK: He's a busy man. He does an excellent job in this position. A lot of it is, of course, fund raising, and he's a past master at that. Nobody can hold a candle to him from what I've observed. And he looks not a day older than when he was with the Food and Drug Administration. I don't know whether that's because he plays a lot of tennis and stays in good shape or it's this San Diego environment.

BP: It might be just his genes.

FK: His genes are good to start with, right. I thought Dr. Schmidt was one of the nicest gentlemen I've encountered. I didn't have a great deal of contact with him insofar as the functioning of the organization. He was good to us. He did have a good understanding of veterinary medicine, and that helps. That helps immeasurably. It's difficult when you start out by trying to establish what a veterinarian is. The first thing you have to do is dispel the thought that we don't eat meat. That's something else entirely. (Laughter) Well, anything else?

BP: Well, why don't we turn it off and talk a little bit. Maybe then something will come up that we want to get in.

(Interruption)

BP: Well, Fred, if that kind of runs you dry, at least for this morning, do you have anything else that you'd like to add before we close this tape?

FK: Well, I think, this is real personal on my part, but I've been real pleased with my career in that I had three different ones, but all of them revolving around the same subject: teaching drugs, how they should be used at Ohio State; developing them at Abbott Laboratories; and then becoming the policeman in Washington to make sure these drug companies make them the way they should be made and with directions so that my colleagues, the practicing veterinarian, can use them properly.

The experience in Washington has been a great one. My family has been exposed to so much. Fortunately we took advantage of most of the things that are available in the Washington area. I always say most of the interesting things in Washington are free, and 'tis so. The chance to grow up in this environment I'm sure has been a great one for our kids. I would hate to live any closer to Washington than we do. Washington as a place to live makes me shudder right now, frankly. It's too bad, because it has to be one of the world's most beautiful

cities. I get there now frequently--that is, every couple of weeks or so--I act like a tourist, mostly because I am a tourist now. I recently visited the Lincoln Memorial for the first time. I told a lot of people about it and that they should go. This time I did it. But we're doing things like that now and appreciating immensely the many things that are available in the Washington area.

The Food and Drug Administration, I'm sure that their problems are greater than ever. It has to be: with increased responsibility comes increased problems. But I'm sure that in the fashion in which it was established many years ago that a good job will be done.

BP: Thank you, Fred. This ends the tape.