

# History

of the

## U. S. Food and Drug Administration

Interviewee: George A. Mitchell

Interviewer: Robert A. Tucker  
Ronald T. Ottes

Date: June 26, 2001

Place: Rockville, MD

## INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

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Food and Drug Administration  
Rockville MD 20857

CASSETTE NUMBERS: 1,2

GENERAL TOPIC OF INTERVIEW: History of The Food & Drug Adm.

DATE: June 26, 2001 PLACE: Rockville, MD LENGTH: 75 minutes

INTERVIEWEE:

INTERVIEWER(S):

NAME: George A. Mitchell

NAME: Robert A. Tucker

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Food & Drug Adm.

FDA SERVICE DATES: FROM: 1988

TO: 2001

TITLE: Associate Director for Policy & Regulations, CVM

(Last FDA Position)

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RT: This is another in a series of FDA oral history interviews. Today, June 26, 2001, we're interviewing George A. Mitchell, Doctor, Veterinary Medicine, currently serving as Associate Director for the Center of Veterinary Medicine and as Associate Director for Policy and Regulations in the Center. The interview is being conducted by Ronald Ottes and Robert Tucker.

Dr. Mitchell, we like to begin the interviews with a brief history of where you were born, educated, and any relevant employment you had prior to your joining the Food and Drug Administration.

GM: It's good to be here to have this interview. I guess the first thing I want to do is to emphasize that my nickname is Bert, and that I'm known that way mostly, except in the organizations that have employed me over the years where it seems that none of their human resources systems were capable of separating George Albert from Bert. [Laughter]

RT: Well, we'll address you as Bert if you prefer.

GM: So please, yes.

Well, education. I was educated in the University of Toronto system. That university had three colleges in Guelph, Ontario; I attended two of them. One was the Ontario Agricultural College, and the other the Ontario Veterinary College. Incidentally, I think I got a good education from both. I will comment that John Kenneth Galbraith also graduated from the Ontario Agricultural College about thirty years before me, and he is widely reported as declaring the Ontario Agricultural College to be possibly the worst undergraduate education anyone could possibly have.

Anyway, after graduating from the Ontario Agricultural College, I went on to the Ontario Veterinary College and graduated in '64, with a doctor of veterinary medicine degree, DVM.

RT: In the College of Agriculture, did you complete a degree there as well?

GM: Yes, BSA, bachelor of science in agriculture. I did some practice in veterinary medicine, but not a great deal, mostly at clinics in college. But it wasn't very long in my veterinary education that I felt I wanted to do research.

I was hired before I graduated, to go to St. Louis, Missouri, to work for the Ralston Purina Company, which at that time was a very significant market force in supplying animal feeds in the United States and Canada, and at one time they operated businesses in five continents. There's been quite a decline in that organization in these last years, but at that time it was clearly the largest feed manufacturer in the United States, and I was director of one of their research organizations. Research in health products, that's all the drugs that were used in animals, such as anthelmintics like deworming compounds and insecticides. I had a staff of about thirty people evaluating these compounds, all of which were approved by EPA [Environmental Protection Agency] or FDA. Based on the results of our research, we advised the Purina dealer organizations which of these currently available products were the most effective. I was there for eighteen years in St. Louis, Missouri. It's where I got my U.S. citizenship, and I have a great many friends still in St. Louis.

RT: You have dual citizenship?

GM: I do.

RT: When you were in private practice, was this general animal practice?

GM: Yes, food animal practice, although we had a few dogs and cats come in, but mostly just food animals, dairy, largely. Some pigs.

I had been approached a couple of times, actually three times in total, to return to Canada and to compete to be the Director of Bureau of Veterinary Drugs in Ottawa. While I turned them down twice, the third time I went and won that competition. I directed that organization for six years.

RT: Is that in the Food and Drug program?

GM: Yes. The department is now known as Health Canada. I accomplished a few important public health actions there. I had a model in this case from the U.S., because BVM, as it was known at that time, Bureau of Veterinary Medicine of the FDA, had taken action against the intermammary infusion products, and that work had not been done in Canada. So I undertook to negotiate an end to the use of unapproved intermammary infusion products in dairy cattle in Canada. There were thirty-some of these products that had been on the market since the late forties and early fifties and had never been formally approved. There also were a number of approved products that had been introduced in later years.

I was really quite pleased with the way I was able to successfully negotiate this change with the representatives of the Dairy Farmers of Canada, the Canadian Animal Health Institute, and the regulatory people in the Health Protection Branch so that those products, thirty-some intermammary infusion products, were no longer used.

Once that manufacturing had stopped, then we took formal action to withdraw the drug identification number. Once the DIN number was withdrawn, the products could not go back on

the market. In summary, that health protection regulatory action went through without a political ripple. I'm really pleased with the way that was done.

The second one I'll mention is chloramphenicol.

RO: Let's back up to the intermammary. What was your main objection to those?

GM: Residues in milk. It was a public health concern. The analytical methods were getting better, and we were finding residues in milk and also complaints that the cheese manufacturing process wasn't working in some cases. So it was motivated by public health, and the dairy farmers recognized that they couldn't have these residues in milk with consumers becoming more concerned about the health effects of residues.

RT: Would you say that the Canadian process for approval and regulation of veterinary drug preparations is somewhat similar to that of the United States?

GM: Very much so. U.S. and Canadian food and drug laws have been quite similar since the sixties. The advent of the new drug regulations in '62 here was followed a year later with very similar regulations in Canada. Over the years, there were amendments to both acts that make them not quite so harmonized now, but at that time they were both motivated by the thalidomide issue. That issue stimulated the changes in both countries.

RO: Chloramphenicol, you were probably about at the same time that the FDA was getting into chloramphenicol.

GM: Yes. The difference with respect to chloramphenicol between Canada and the U.S. is that



my colleagues here in the U.S. at that time were dealing with a drug that had never been approved for use in food-producing animals, whereas in Canada it had been formally approved. So we had to go through the whole due-process withdrawal approach. It was hard fought.

There were thirty-two companies selling chloramphenicol products in over 130 formulations. The chloramphenicol formulations dominated sales of everything else that was there. So there were large economics factors against what I was trying to accomplish.

There was a lot of opposition to the proposal to stop the use of chloramphenicol in food-producing animals. What assured the withdrawal was there were some trade arguments going on about live hogs between Iowa and Manitoba. Hog farmers in Iowa were saying, "We can't use chloramphenicol." The CVM [Center for Veterinary Medicine], by that time, had removed it so it could not be used. Iowa hog farmers said, "If we can't use it in our pigs, then we don't want any pigs coming in here that have had the advantage of having off-label or extra-label product use." So it was that export market risk, really, that swung the politics enough in Canada that we could get those chloramphenicol products permanently withdrawn for use in food-producing animals.

RO: Is the procedure for withdrawal up there similar to the way it is in the States here, that is, publish in the *Federal Register* or something similar?

GM: Yes, publish it in the *Canada Gazette*. Now, in the parliamentary system, it is much easier to take something away. Unlike under the U.S. Constitution where a taking is a very serious matter for the executive branch to do.

Well, in Canada, with a prime minister having so much power, more powerful than any figure in the U.S. government, the liberal caucus or the conservative caucus decide the sense of the country is, in this case chloramphenicol, that we don't want chloramphenicol anymore, then it's easy. So once you get to that point in Canada, then it was easier following the due process there

than it would have been here.

From an operational standpoint, I've done this sort of thing wherever I've been, and that is, introduce standardized procedures, standard operating procedures. Like I did that in St. Louis in the research organization, developed standard operating procedures for writing research protocols, that sort of thing. I introduced standard operating procedures into the Bureau of Veterinary Drugs in Ottawa and had fifty or so written, mostly on the administrative side. I really wanted to do more on the review side, but that was too hard to get done. It's actually very hard to get done here, too, get the reviewers into a regulatory mode of evaluating these submissions. And I introduced computers, got some little computers into the Bureau of Veterinary Drugs in Ottawa. Believe me, it was a big deal then.

RT: Were those computers used primarily in laboratories, and perhaps also by field personnel?

GM: No, we weren't near that since laboratories and the field organization were separate from us. Actually, AT&T had a computer at that time, manufactured by Olivetti. We bought a few of those, half a dozen. It had a keyboard and a little screen. The drug-manufacturing people took them on the quickest and created a database of their products and a list of manufacturers, and began to organize their information.

RT: Were you involved in what would be the approval of new animal drugs, and were these computers used then in that process?

GM: A little bit. Not very much. Mostly we were, as we said, using stubby pencils. People write their own notes. Work files, they were all in lead pencil. Reviewers, scientists writing notes. They didn't even use typewriters at the reviewer level.

RT: As you know, with FDA, at least in the area of human drugs, one of the criticisms has always been is a lack of prompt approval. Did you have that similar problem for animal drugs in Canada?

GM: Yes, we were criticized for slow evaluations and slow approvals.

RT: Did you have any statutory directive regarding time for that process?

GM: Same, 180 days. But we violated it lots.

RO: The Food Protection Branch had a field force. Did you have a portion of that for your work?

GM: Yes.

RO: Making inspection for you?

GM: Yes, drug manufacturers, primarily animal drug manufacturers. We did some inspections of feed mills as well, but mostly drug manufacturing. Yes, that was the field operations director. Elliot, did you remember Elliot?

RO: Ross Elliot.

GM: Ross Elliot, yes.

RT: Of course, here we have a biennial drug inspection mandate, or targeted at least. Was there any similar provision on frequency of inspection in Canada?

GM: Yes, I believe so. I don't recall that specifically, but we did try to get back to each drug manufacturer regularly.

RT: Did the Canadian Government have seizure or embargo powers?

GM: Yes, yes, they could do that. One other thing I'll comment on the Canadian experience is that I was a principal architect in the writing of the U.S.-Canada Free Trade Agreement having to do with veterinary products, that annex I wrote. It is incorporated to a very large extent in the succeeding North American Free Trade Agreement.

Related to that, I opened up lines of communication between the Bureau of Veterinary Drugs in Ottawa and the Center for Veterinary Medicine here. We had exchanges, people going back and forth. That continues today. We've been able to keep that going pretty well.

RO: In animal feed in this country, they've had problems for years in trying to use recycled animal waste in animal feed. Did you have a similar problem there?

GM: Well, I don't recall that, but I wouldn't be surprised but what it happens. But I didn't face it as an issue.

RT: The term "ruminant-to-ruminant" feed, is that aligned at all with Ron's question about recycled animal waste?

GM: No, recycled animal waste is manure, actually, from avian species being mixed into the diet of ruminant animals. From a biochemistry standpoint, cattle make protein out of the uric acid that's excreted by chickens, chickens and turkeys. So while it is a disgusting practice and we still seek to end it, there's probably still some of that going on.

In '88, Gerry Guest suggested that I compete for a position here, and I was successful in becoming Director of the Office of Surveillance and Compliance in the Center for Veterinary Medicine. I was there for about ten years, '88 to '98.

RO: Who did you follow as director?

GM: Dr. Bill Bixler.

RO: When you first came, who was your deputy?

GM: Gary Dykstra. He later became deputy to Ron Chesemore, and acting ACRA for a while.

RO: What were some of the main issues that you confronted when you came in as Surveillance and Compliance Director here?

GM: Well, certainly the biggest, I think, as far as this record is concerned, is the ramifications of the discovery of Mad Cow Disease in the U.K. [United Kingdom]. You mentioned, Bob, the ruminant feed ban. That process, beginning in March of '96 with the publication in the U.K. of the association of deaths of ten people with a human form of Bovine Spongiform Encephalopathy, BSE, Mad Cow Disease. We'd been monitoring this for ten years or more and were worried

about scrapie in sheep and what that might be doing here in the U.S. Once there was a credible connection between human health and BSE in cows, we decided immediately as an agency to prevent the possibility of amplification of BSE in the U.S. We would do so with regulations to prevent the carcass of an animal that died of BSE from entering the rendering system, because that's the theory how the disease spread in the U.K.

So in a matter of fifteen months, beginning March of '96, we went through four *Federal Register* publications: Advanced Notice Proposed Rulemaking, Proposed Rule, Draft Codified Section of the Final Rule, and the Final Rule, in fifteen months. I understand that's about as good as it's ever been done in time, but we had the whole resources of the FDA behind that effort. We would have twenty-five people working on it at a time in these meetings. It was amazing to see what the FDA brought to bear on that regulatory process in terms of talented people, dedicated people, and the success we had in getting those regulations through, written and put in place.

We also had guidance documents after that and a lot of education and lot of other things we can talk about. I'm proud to say that my name is on that regulation and that I'm a key architect of getting that through, and I'm very pleased with that accomplishment.

RO: Briefly, what does that require?

GM: The regulations prohibit the feeding of most mammalian proteins to cattle and other ruminants. Doesn't include milk. Doesn't include meat and bonemeal derived from purely horses or pigs, but everything else. Mammalian protein is prohibited from being fed to "cattle and other ruminants."

RT: Apparently, there's really been no occurrence of Mad Cow Disease except maybe in an isolated instance or two in this country, is that correct today?

GM: None. And USDA is looking. Now, we have related diseases that might be confusing it. We've got Chronic Wasting Disease in deer and elk in Montana and Wyoming and a part of Colorado. We've got scrapie in sheep. We also have a disease called mink encephalopathy. The last time that was diagnosed was 1984. We haven't seen it since. But those are the three diseases that are prion diseases that occur in the U.S. No BSE has been seen in the U.S.

RT: What was the term you said before?

GM: Prion, a term that was coined by Stanley Prusiner at Berkeley, California. He got the Nobel Prize for medicine in 1997.

RO: There's got to be some mechanism for controlling what goes into some of these animal feeds by inspection, and FDA is doing that.

GM: Yes, we are.

RO: But you know, the rendering industry was always a bad industry.

GM: Yes, we have a lot of inspectors spending time and contracts with state officials, too. That's probably the biggest thing I've accomplished in S&C.

But I want to talk about the milk program, too, because CVM contributed, I think, quite a bit to the milk program when I was there. Going back to like '90 and '91, when the *Wall Street Journal* and others were collecting milk samples and assaying them with commercially available drug tests, and they found inhibitor substances and antibiotics in the milk. FDA was called to hearings, Shays had hearing, and Weiss had hearing before that. It was a mess that needed regulatory attention.

Well, one of the first things we did on this at CVM was propose the formation of an Intercenter Coordinating Committee [CFSAN and CVM]. I think Bob Tucker was involved in some of that for several years. We had half a dozen people from CFSAN [Center for Food Safety and Nutrition], about the same from CVM. We would meet every month. It took some time for us to be able to actually accomplish things and to fully trust in each other, but in the end, you know, I think we had a very effective working group. It continues today.

One of the things we accomplished was to write and implement the National Drug Residue Milk Monitoring Program. The program had enforcement, analytical, research, and background sections.

RT: We've had some nuclear accidents like Three Mile Island. Was that the program related to that or to something else?

GM: No, that's the Market Basket Survey that gives information on the radionucleotides.

CVM now has a research program that determines the specificity and validity of commercially available methods for the assay of drug residues in milk, and we make recommendations to states on which ones are the better methods. So that's an important outcome of that program. Overall now we find that producers, processors, veterinarians, and regulators appear to be doing a good job in keeping drug residues out of milk. Millions of milk samples are assayed each year and very few are violative for drug residues.

RO: Do you know, Bert, how many drugs or--

[Begin Tape 1, Side B]



RO: ...how many residues. First I said drugs, but I'm changing this to residues, because there's dioxins and things that can be in milk. I was wondering how many residues you've monitored for.

GM: How many we have assays for would be a guess. But regular assays for antibiotics in milk would be about twelve or fourteen antibiotics or families of drugs. In terms of medicinal ingredients, drugs for which we could have assays are considerably more than that, but those are the antibiotics that are chiefly used in lactating dairy cows.

RO: I was wondering, we were getting back to when Dr. Van Houweling was director of CVM and the methodology problem that Dr. Ken Johnson raised about what we had methodology for. So I was just curious, which I'm sure you remember.

GM: No, I don't, actually. Like penicillin in milk at that time?

RO: Well, we had problems with penicillin in milk, but there was also drug residues. We had the whole problem of sensitivity of methods and things of that type.

In the Office of Surveillance and Compliance, you, of course, were pretty much responsible for the recommendations coming in from the field for seizures or prosecutions and so forth. What were some of the big ones that you can recall?

GM: The biggest advance in those years had to do with us developing and implementing with ORA and Office of Chief Counsel a process for stopping the marketing of animals with drug residues. We simply used the injunction process. We had tried a number of ways of dealing with this, but finally we got the injunction process honed and working well enough that we could put

an injunction in place for dairy farmers, principally dairy farmers, who repeatedly sold animals with violative drug residues for slaughter. This is on the meat rather than milk side.

Related to that was, you recall way back, DES [diethylstilbestrol] residues and that sort of thing, that we had the authority for inspection of live animals on farms. That's in the history of the Food, Drug and Cosmetic Act, going all the way back to its inception.

This history is written up now in a case report of a trial when I was director of the office. It is Tuente Livestock in Ohio. They were selling pigs with violative sulfamethazine residues, and doing so day after day. We enjoined them, stopped them from doing that, and they took it ultimately to an appellate court. I'm not sure about that. They took our section to court, and the judge wrote up the entire history of the Food, Drug and Cosmetic Act, all the legislative research, all the legislative history, going back to early 1900s, what Congress intended for the Food, Drug and Cosmetic Act, and came out with one short, very meaningful sentence, and that is, "Hogs are food." In this case, it had to do with pigs. What it meant in the context of this whole ruling was that live animals are unprocessed food and they're subject to regulation under the Food, Drug and Cosmetic Act. It was a pivotal case, very, very important to us. So that was a very important enforcement action.

RO: I recall at one time there was a question whether the Food and Drug had authority over live animals. I remember some cases involving veal calves, for instance.

GM: We use the authority sparingly, but it's a very important authority to have if you need it to protect public health.

RO: Do we have any problem with DES anymore?

GM: I think not. This fairly recent experience. I'm not sure this should go in the written part of the history because it has to do with the Swiss. We exported some of our very best beef from feedlots in Kansas to the European Union, and the Swiss, about two years ago, took some samples of it and said, "There's DES in it." We at FDA have done a lot of research, investigations, and collection of samples, and can find no evidence of it in U.S. meat.

On challenge from us, the Swiss sent some of their samples to Holland, which is the reference laboratory in the EU for assay of hormone residues, and the Dutch said they couldn't find it. DES is a difficult analyte to deal with in the labs because it contaminates glassware, and it's hard to keep things clean. So I say, no, I don't think there's DES in U.S. meat.

RO: What about extra-label use with veterinary products? Is that still a problem?

GM: Let's talk about the legislation that took place while I was in S&C. The regulatory initiative really started out with selenium. We had approved selenium for use in animal feeds at 0.1 part per million, and it wasn't enough to prevent selenium deficiency diseases. So it was proposed by a number of people that the level be increased in some species to 0.3 parts per million.

Between the time selenium was first approved at 0.1 and the time that these 0.3 part-per-million submissions came in, Congress passed the National Environmental Policy Act. Our chief counsels have said that we needed to take the National Environmental Policy Act into account when you regulate under the Food, Drug and Cosmetic Act.

The National Research Defense Fund alleged that selenium residue from the waste of animals fed 0.1 part per million was draining into lakes and killing ducks in California. This issue, I think, polarized a group of animal health coalition organizations, the American Veterinary Medicine Association, cattle, dairy, chickens, turkeys, and they were able to, through Congress, get us to, I guess, avoid somehow the implications of the Environmental Policy Act and have us

As a result of that political activity, that coalition of animal producers, chicken farmers, and animal health people, veterinarians, and cattle producers who had never been able to talk to each other politically found that they had some common interests after selenium. The first thing they did after selenium, two years later, was achieve passage of the Animal Medicinal Drug Use Clarification Act, AMDUCA. We abbreviated that to AMDUCA.

AMDUCA gave veterinarians the right to use approved animal drugs in an extra-label way. It gave veterinarians the same professional latitude that physicians have had. So that really changed things, as far as we were concerned, and we wrote the regulations when I was office director there, the AMDUCA regulations. We have a section in there on compounding and issued a guideline on compounding. That was a big deal, too.

Two years later, the next statute to come along that affected our area was the Animal Drug Availability Act, the same coalition, and regulations of that and a new definition of substantial evidence, adequate and well controlled. A number of provisions with wide ramifications for us.

Did you want to follow up on extra-label drug use?

RO: Sure. I was curious because it used to be a major problem where these almost retail outlets were selling to anybody that came in. They didn't have to be a veterinarian to buy.

RT: Also, some of the hucksters traveled to farm country, dispensing drugs out of trucks.

GM: Yes, some of this was going on before I came. It was in the early eighties when these bulk drug cases were being brought to the fore, where veterinarians and producers were buying unformulated drugs and using them. That's not really extra-label; that's just plain illegal. But the court cases on them didn't end until after I came. So '88, '89, we were winding up the court cases

where the judiciary agreed that the use of these bulk drug compounds was illegal.

AMDUCA didn't reverse that. In fact, we made it real clear in the regulations that this extra-label authority for veterinarians applied only to the use of approved drugs. That's a big change in twenty years, a big, big change in the Midwest in the drugs that were used in pigs and cattle. Tremendous change.

RT: Another area, the irradiation of meats for pathogen control, is that something that came to the fore during your tenure?

GM: Yes, but the issue didn't reside with us to any extent. It's a CFSAN issue, and the only thing we dealt with was a food additive petition to allow the irradiation of laboratory animal feeds, so that there were no bacteria going into the laboratory animals. It's been expanded into some other species groups now so that we permit irradiating more animal feeds than just that, but the big issue, the controversy, is a CFSAN issue.

RO: You mentioned milk a while back, and there were two things I thought you might touch on. One was BST [Bovine Somatotropin], and the other was the raw milk issue that came up about whether FDA should allow the sale of raw milk, unpasteurized milk.

GM: The raw milk is also a CFSAN issue, more than ours. I'll let it go at that, I think.

But BST, I was right in the middle of that. I did not approve it. I wasn't the one who signed the approval, but I supported and agreed with the decision. We in the post-approval office were responsible for collecting reports of adverse reactions. So we were bumping along with a few thousand adverse reactions per year, and then we had BST approved, and suddenly we had 4,000 more a year.

4,000 more a year.

RT: Was that related to mastitis, the BST?

GM: That was part of the controversy, yes. The adverse reports we wanted. We encouraged dairy farmers to submit anything that they thought was an adverse report, and then we would decide whether it's related to the drug treatment or not. We did find some of these reports related to drug treatment having to do with reproduction, and a label change was made as a result of that. But mostly these reports of adverse reactions from BST were not drug-related. We couldn't tell for others if they were drug-related or not. But it was very, very controversial drug approval, and we had to deal with briefing the commissioner and briefing the department. It was a drug derived of biotechnology and administered to cows to increase milk production.

RO: That was more of an economic situation, wasn't it, and really didn't it end up to be that rather than a health problem?

GM: Yes. Several groups opposed the use of BST because they felt it would help get small farmers out of the business. So there were groups that were trying to keep the small rural landscape farm in place. There was also the fact that the food was milk. And people like to think of it as pure and natural in all respects.

RT: Over the past number of years, one of the items that has elicited congressional interest and, I think, four hearings and perhaps two statements for the record from the agency, was anthrax vaccine. Is that something that you have any comment about?

GM: I have been involved in that a little bit because I've been participating in the counterterrorism working group, and anthrax is one of the things that we think might be an agent of bioterrorism. But our concern is primarily the pulmonary form that would be spread into a crowd of people and result in human illness. As veterinarians, we deal with anthrax in animals all the time.

RT: I remember years ago, and this has been a long time, there were some anthrax concerns about Belgian bonemeal. As that was years ago, and I don't know whether this problem has that's continued in products like bonemeal for animal feed.

GM: Yes, well, it could. I expect that the spores are killed in heat processing.

RO: What about some of these biotech products? I'm thinking of Star Link corn and things like that, if they would end up in animal feed, is there any possibility of problems? I think FDA felt there wasn't any problems with the Star Link corn used in taco shells.

GM: Well, it had been approved. Star Link, specifically, had been approved for use in animal feed. It was not approved for use in human food. So we in the Center for Veterinary Medicine regarded it as acceptable for use in animal feeds. There was no evidence of any adverse effect. We have approved about forty or forty-three, genetically modified feed ingredient types like cottonseed meal and others--a large number like that.

There is another aspect to modern biotechnology that the center's engaged in, and that is the transgenic animal, the Atlantic salmon is the big one, and the concern about it being released into the wild if the fish are in a net pen and the net pen is torn. Then the Atlantic salmon would get out in the ocean and they grow so much faster than the wild salmon because they grow in cold

the native salmon are sort of in hibernation, just swimming around. So the concern is that these larger fish would use the food supply of the native salmon and crowd the native salmon out of the native fish environment.

We are saying that these animals will be regulated as new animal drugs, because the changes fit into the definition of a drug under the Food, Drug and Cosmetics Act. Ultimately, Congress might have something to say about that, but that's where we're going with it. None are approved at the moment.

RO: You have served under a number of different commissioners, and I wonder if you've noticed any difference in their enforcement philosophy and their whole management style. I think you started under Dr. [Frank E.] Young.

GM: I did. Well, I didn't report directly to any one of them. Commissioner Young was very interested to hear about voice mail. Of course, it's a common thing now, but it's interesting that he put so much emphasis on that technology. It's like my interest in computers in Ottawa, you know, you're involved in introducing the technology and trying your best to get a buy-in by the organization.

The next commissioner did have a much more strident approach to enforcement. He wanted a major enforcement action virtually every month.

RT: Are you speaking of Dr. [David A.] Kessler now?

GM: That is right. Orange juice and things like that. I can't remember. [Laughter] And, oh, breast implants. Goodness, just one after the other.

So that or something else that was successful in getting us back on track after the generic



drug problem. That commissioner wanted us to take some action against animal drugs of some sort to help our case, too, but we just never got our priority high enough to compete with the other enforcement issues that he was after.

The last commissioner, Dr. [Jane E.] Henney, she was a fine person to work for. I really didn't report to those people, so I don't know as there's anything I can say very much there.

RT: Do you have sort of a vision as to where either the center and/or agency is going perhaps in regard to the common market or some of these trade agreements? Is that going to impact on the industries that your center is concerned with?

GM: Well, it could. The U.S.-Canada Free Trade Agreement has been in place now since the mid-eighties, and it hasn't had a big impact in our side of the animal drug regulatory business. The regulation of animal drugs, yes, there are discussions going on regarding harmonization, and Canada is going to publish some more tolerances that will be identical or very similar to ours, and that's good. But fifteen years later, no, harmonization is not moving at the speed of light.

Now, those trade agreements are affecting trade and tariffs are going down, and so you've got steel and softwood lumber and issues like that, and a lot of trucks going across the northern border and the southern border. We're exporting nearly as much as we import. There is a trade deficit in the U.S., but there is just tremendous volumes of exports going out, too.

RO: Is there much of a population of veterinary pharmaceutical producers in other countries from which those products come to our nation as imports?

GM: The German firms are still pretty strong. The animal drug industry is not economically healthy. Their market is going down. Producers are using less drugs, fewer drug treatments.

healthy. Their market is going down. Producers are using less drugs, fewer drug treatments. There's a lot of consolidation going on in the animal drug industry, and this consolidation is not doing much to increase profitability. The Swiss, for instance, have gotten out of the feed additive market in the U.S. altogether. Hoffman LaRoche is gone. They sold it.

The old I.G. Farben organization that's Hoechst and BASF. Anyway, the German pharmaceutical industry is--Bayer. Bayer is another one under I.G. Farben organization. They're a little closer. They're waffling a bit right now. Hoechst is completely out of it in the last year. They've gotten out of the animal drug business. Bayer threatens to get out, but they're staying in at the moment. BASF doesn't have much. So, yes, there are European companies. There's a little firm in Canada, Vetropharm. Some of the U.K. companies have U.S. subsidiaries as well.

RT: With regard to foreign-produced animal drugs, does FDA conduct any inspections of those as we do human drugs?

GM: Yes. Preapproval inspections for new chemical entities and regular GMP inspections.

RO: What do you think of the health of FDA, political and otherwise?

GM: Well, I think the consumer perception of the agency is strong, continues to be strong, and that's good. That's to our advantage. We need to look after that. We don't want to do anything that's going to cause us to lose the public trust.

We probably could do better by accelerating the rate at which we change. We are changing all the time. But I think it would be better for us if we got a little better at that while serving our customers, consumers, and stakeholders. I think that would help us ensure our future if we could be a little more inclined to change.

[Begin Tape 2, Side A]

GM: Well, I was talking about what I thought was most important for the agency. That, in my view, is not necessarily reviewing submissions or evaluating submissions. What is most important is that we retain the decision to approve or disapprove, no matter who does the reviewing, for instance. We might need to think along those lines at some point.

There are some examples of third-party inspections going on that I think have the potential to increase protection of public health. We must not give up our oversight of those, our ability to decide whether they're actually inspecting to good manufacturing practices or not.

RT: What's your thought about user fees as it applies to CVM responsibilities?

GM: Well, we would like to have them. Our industry has been opposed up until now, but I think with our backlog of reviews that maybe in this next round of budgeting, CVM will have user fees as well. I think that's fine, as long as we retain decisions and oversight and don't give up the act in order to get user fees. But if it can fund resources that we need to be able to make decisions, then, that's fine.

RO: Is there any other thing you'd like to say? Since you think we're running out of tape, we'll let you decide.

GM: Well, I have greatly enjoyed my career at FDA. I'll tell you a little anecdote. When I was out in St. Louis, there, Cliff Harden was a former Secretary of Agriculture, former Dean of Agriculture at Nebraska, until Nixon coaxed him down to the old USDA Building. He was here for a couple years as Secretary of Agriculture, one election cycle, and off he went, out to industry.

So he got to be in a senior position on the fifteenth floor, that's the top floor, of Ralston Purina in St. Louis. Anyway, he fancied himself in research and had done some research in his time, Ph.D. in research, and so he sort of took some of us science people in Ralston Purina under his mentoring arm.

He'd inquire a couple times a year what we were thinking of as far as our career was concerned and where were we going and how were we keeping our education up and our continuing education and things like that. One time I said, "I don't know about this business here at Ralston really. As far as I'm concerned, I might not be able to be here my whole life. If I was going someplace, I'd like to go to the FDA."

He says, "Well, you'll never get there from here." [Laughter] So I kept that in mind, and so I actually went to Ottawa and ended up here.

RO: Interesting.

GM: I had to go somewhere from industry before I could be eligible to be hired by FDA.

RT: We have covered quite an area, and we really appreciate having the opportunity to interview you, and wish you well as you leave the agency in whatever pursuit you follow.

RT: Including whale-watching.

GM: Thank you.

[End of interview]