

History
of the
U.S. Food and Drug Administration

Interviewee: William M. Rados

Interviewer: John P. Swann, Ph.D.
Robert A. Tucker

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INDEX

<u>Tape</u>	<u>Page</u>	<u>Subject</u>
1 – A	1	Personal, education & military background information
	3	FDA employment – FDA Bureau of Veterinary Medicine – Industry Information Specialist
	5	Duties – Information Specialist
	6	Field work with consumer safety officer Blanche Erkel “Feedstuffs” Magazine (antibiotics use in animal feeds education)
	7	“FDA Veterinarian,” Fact Sheets, et. al. – FDA publications re: safe use of animal feeds
	8	Off-label veterinary drug use
	9	DDT ban
	10	Intergovernmental cooperation
	12	Press Office assignment – medical devices & radiological health issues + writer for “FDA Consumer” magazine
	13	Press officer duties & responsibilities
1 – B	18	Salient consumer-associated issues for agency, 60’s & 70’s
	20	Press release corrections/retractions
	21	Medical Device Amendments of 1976 – consumer education initiatives
	22	Intraocular lens issues Advisory committee – actor Robert Young’s appearance (TV’s Dr. Marcus Welby)
	23	Three Mile Island radiation-related emergency John Villforth’s designation, Department radiation emergency coordinator
	25	Technical Information Division, Center for Radiological Health
	26	Editorial Director, <i>FDA Consumer Magazine</i> – Publication functions

INDEX

Tape	Page	Subject
	28	Responsible persons – development of quality agency publications
2 – A	32	“Jake Walk Blues” published article
	33	Communications/publicity impact of Commissioner David Kessler
	35	“Read the New Food Label” + “Fresh Orange Juice” labeling issues
	36	FDA’s website + agency Home Page development
	38	World-wide agency website
	40	Dockets posting on website
	41	End of Interview

Interview with William M. Rados

June 13, 2006

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, the interview is being held with William M. Rados, who retired May 4, 2006, as Program Manager of the FDA public website in the Office of Public Affairs. The interview is taking place in the Parklawn Building on June 13, 2006. Dr. John P. Swann and Robert Tucker of the FDA History Office are conducting the interview.

Bill, as we begin the interview, we would like a brief personal history of where you were born, educated, your professional work prior to coming to the FDA, and then move on to your FDA career. So we'll ask you to begin, Bill, in that manner.

WMR: Okay. I'll begin at the very beginning.

I was born September 23, 1947, in Berea, Ohio, a small town outside of Cleveland -- and I was raised in that area, went to grade school in Berea and then high school in Cleveland. Then I went to the University of Notre Dame in Indiana for my bachelor's degree, which was in political science. I graduated from there in 1969 and went into retailing, but was soon drafted into the Army. This was during the Vietnam era, of course. I was fortunate I didn't go to Vietnam, but served my time in Texas, in Fort Sam Houston, as a chaplain's assistant and was discharged in 1972; and went back into retailing, but soon decided to pursue my interest in journalism, and so I applied to Ohio

State University and was accepted into their journalism program, and in 1974, got a master's degree in journalism from Ohio State.

And then I went to work for a small newspaper in Ohio, a daily newspaper in Elyria, the *Elyria Chronicle Telegram*, worked as a reporter and as the business editor there, and then decided to give a try to the federal government and got a job in the communications office at Eisenhower Army Medical Center in Fort Gordon, Georgia, and this was, we're now talking 1975. And I worked in their Public Affairs Office, put out the newspaper for the medical center, and did that till 1977, when I came to FDA.

JS: Did anything in particular interest you in going to work for government, given your background?

WMR: Well, I, of course, had a degree in political science, so I was always very interested in government and politics. I hadn't had an opportunity to really use that, a little bit in my journalism job, but my journalism job was more covering business and labor. It was a very highly industrialized town that I worked in. So I thought that this might be an opportunity to get back to where I had originally had an interest.

And at Fort Gordon, I first got exposed to the public health arena because it was an Army medical center, and I got to work very closely with the doctors and the other healthcare providers there, and that interested me a great deal. So when I began to look for something else in government and the opening appeared at the Food and Drug Administration, I found that very interesting, plus it was in veterinary medicine, and I had been raised on a farm. My dad had a middling-sized farm in Ohio, and I had some

background in that area that tied in nicely with the Center for Veterinary Medicine's activities. They seemed to think it was a good fit and they asked me to come on board, and I was happy to do so.

JS: Had you any familiarity with FDA?

WMR: Very little. I remember, on my trip up to Washington to interview for the job, reading in the paper about FDA moving to ban red dye #2, and that was really the first interest that I had had or the first real attention that I had paid to FDA. But that changed drastically over the next 30 or so years. I got to learn an awful lot about a lot of awful interesting things.

RT: Who did you interview with in FDA when you came in?

WMR: Dr. William Bixler. Bill Bixler was the -- I'm trying to remember titles now -- I think he was the director of the Animal Food Safety staff. And I also interviewed with the head of Surveillance and Compliance, Dr. Philip Cazier, and, frankly, with a whole bunch of people.

I was a little intimidated because, well, it was a difficult trip when I got up here. There was, we were talking early January, and I arrived right along with a major snowstorm, and they called me at my hotel room the morning I was to come over to Parklawn Building for the interview and said they weren't sure they were going to be

able to get together, and I had driven up all the way from Augusta, Georgia, so I was afraid I'd have to turn around with nothing to show for the trip.

Luckily, later in the day, they cleared the roads, things were fine, and they got into the office and called me and said, "Come on over." And when I got there, I sat down in a conference room with about six or seven or eight people from the Bureau of Veterinary Medicine, and it was kind of intimidating for a young guy. I was only 28 at the time.

But they apparently were satisfied with my background and my experience, and it sounded like interesting work. It was industry information specialist, working as part of the Animal Feed Safety staff. They had a very active outreach, and still do, with not only veterinarians, but with feed producers and with individual livestock producers as well, trying to get them to use animal drugs responsibly and safely. And I thought that that was a very interesting program, so I was glad to be part of it.

JS: Was there any recent major change in statute or regulation that affected these, that led to them bringing you on?

WMR: No. A woman who had worked with them for a long time was retiring, and they were looking for people to replace her and another vacancy as well.

Interestingly enough, the other guy they hired at exactly the same time was also a Notre Dame graduate from 1969. I had worked at the student radio station on the AM side, where they played all the rock-and-roll; he had worked at the student radio station on the FM side, where they played all the classical music. We had never met, even

though we had been just one wall apart for all those years at the radio station. But we then worked together for the next couple years. Leo MacNamara was his name, a good guy.

No, there were no new regulations at the time, but the big concern was the proper use of antibiotics in animal feeds. The issue about antibiotic resistance had already raised itself up into our consciousness and the consciousness of other people that were concerned about that. Of course, that issue continues unresolved to this day, and I've always found it fascinating how long some of these public health issues can percolate along before they're finally resolved.

JS: You were there for a couple of years.

WMR: In CVM, I was there for two years, almost exactly two years.

JS: You've mentioned a little bit about what an industry information specialist did in your area, but did you go out into the public, work with firms directly?

WMR: I didn't work with firms directly. The Compliance Division did most of that work. But we did work with media. There are a lot of specialized media, as you probably know, that cover agriculture, and one of the big ones at the time was *Feedstuffs Magazine*. I guess it still is. And, of course, every small farming community throughout the country has its farm radio station.

One of the first adventures I had at FDA was to travel out to the Midwest, where one of our fine public affairs specialists, then known as Consumer Affairs Officers, Blanche Erkel, who worked out of the Minneapolis office, had arranged for me to travel across Wisconsin and Minnesota over a few days, stopping at what seemed like every small town, small crossroads, across those two big states. And she had set up appointments with the farm reporters or farm editors at these stations to do interviews, and the subject was antibiotic use in animal feeds.

The message that I was carrying was to make sure that you follow the proper withdrawal times for the use of these medications in feeds before the animals were taken to slaughter. It's still a concern with the agency today. We were trying to reach out directly to the farmers, livestock producers, who were feeding these drugs to the animals, to make sure that they knew what their responsibilities were.

Blanche was a ball of fire. She was middle-aged, I was young, but I could barely keep up with her because she just was very energetic. She met me in Green Bay, and from there it was just one town after another for several days.

We finally ended up in Minneapolis, where, in addition to the radio stations and some newspapers, I also met with people from the headquarters of *Feedstuffs Magazine*, which was *the* big communicator with the animal-feed community. I'm not sure I was able to convince them of FDA's viewpoint, but they were gracious enough to hear me out and publish what I had come to say to them. So I think the trip worked out well.

As an aside, Blanche was at my retirement go-away. I didn't recognize her at first, but I was glad to see her there, and she's still going strong. I still don't think I could keep up with her.

RT: Did the county extension agents of USDA become involved at all in educational activities regarding drug usage?

WMR: They used our publications. We put out a lot of fact sheets, we put out a newsletter, all to do with safe use of animal drugs. And I believe that they used those to hand out because they had the grassroots connections much more effectively than FDA did because of their very strong local organizations across the country. So they used our materials that way. In fact, my boss at the time was John Arnold, and he had previously worked for USDA, so he had good connections there too, and that was very helpful.

JS: Did you have any other adventures like this? Was this fairly early in your FDA career?

WMR: Oh, yes. This was within just a few months of my arrival. I think it was during the summer. I joined FDA, as I said, late January of '77, and I got my feet wet, got to know the issues for a couple of months, and then this trip was arranged at the request of the folks in the Minneapolis District. So, yes. That was one of my early baptisms by fire. The trip went well.

I did do other trips over the remainder of my time in Vet Medicine. I covered trade shows where there were a lot of agricultural interests represented, and that was the audience that we were looking for. So I did a fair amount of traveling. And, of course, we also had events here at headquarters that I helped set up, and put out the newsletter.

FDA Veterinarian was the main communications vehicle. That spoke mostly to the veterinary professional community. But then we also had publications that were more targeted to feed producers as well, and that was what I spent most of my time, writing for those, putting out the messages on those.

RT: Did you get into the issue of misuse or off-label-use-of-drug education?

WMR: Yes. Off-label use was very important because there was a lot of that going on, some of it out of ignorance and some out of a feeling, I believe, that people should be allowed to use these drugs for their livestock in the manner that they saw fit, and there was a real philosophical difference there.

We tried to impress upon our target audiences the safety issues, not only for the animals, but, of course, for the people that were consuming the meat and dairy products that came from that livestock. And it was a hard sell. I think if you talked to the folks in the Center now, they would probably say it continues to be a hard sell. But it's a very important public health issue.

But I think that the one that was the most fascinating for me was the issue of the antibiotic resistance, which was just coming to the fore at that time. The scientific knowledge about it, how it worked, was becoming more well-known, and we could see that there were serious dangers with that. That is when FDA published some proposals about limiting the use of different antibiotics in animal feeds. I think it was the first time FDA had ventured into those waters, and, of course, this caused quite an uproar because farmers had come to depend on those drugs.

Frankly, I can remember -- and maybe it helped me with my ability to communicate on this -- is I could understand the point of view because my dad never raised a lot of livestock, so he wasn't a big user of medicated feeds, but he did grow crops that required the use of a lot of pesticides. At that time, DDT was the pesticide of choice. I remember how upset my dad was when the decision came down to ban DDT for environmental reasons. Maybe I shouldn't be telling tales out of school, but he knew the ban was coming. He stocked up on it so that he'd have a supply even after the pesticide was banned, and he continued to use it for as long as he was able to keep that supply going. He would probably say that it never killed him, and that was, frankly, the attitude of an awful lot of people who used pesticides and medicated feeds for their livestock as well -- commercial interest butting up against scientific and public health interests, which is where FDA finds itself time and time and time again -- not just on the veterinary issues, but on human health issues, too.

JS: Were there any major enforcement issues connected with livestock feeds during the time that you were in CVM doing this?

WMR: Not at the time I was trying to do this. I think that the Center -- there were, of course, inspections of feed mills, but they were trying to rely on voluntary compliance and education, and I think that was a good approach.

Later on, of course, there were enforcement actions as we got into issues like BSE [bovine spongiform encephalopathy], with the use of ruminant tissue in animal feed. But at that time, the emphasis was on voluntary compliance.

RT: Was there an effort at the Bureau to engage state regulatory people in this problem at that phase?

WMR: Yes, there was. We had agreements with states to carry out a lot of the inspections because there are thousands and thousands of feed mills producing medicated feeds. And, of course, state people and USDA people were also involved in inspections of slaughterhouse operations and things like that. It was the kind of cooperative arrangement that FDA uses in other areas, as well.

RT: In your role, were you involved in any of that liaison with other agencies?

WMR: Not so much with the states. They did use our information materials. We distributed copies to them for them to distribute. Of course, this was in the days when everything was done by paper.

We also produced public service advertisements that were run in *Feedstuffs* and other trade publications that reached the veterinary community and the medicated-feed community and livestock producers. A lot of the farm-oriented magazines that I had been familiar with when my dad was farming were publications that we were trying to reach and that would agree to run our public service ads advising on the proper use of medicated feeds. So it was an interesting time. It was a bit of a flashback type of thing for me at that time.

RT: You mentioned your father, understandably, laid in a little advance supply of DDT. Not your father specifically, but for producers generally, do you think there was an inclination to use more of some of those pesticides than maybe the label prescribed; in other words, a little will do some good and a lot more might do more?

WMR: I imagine so. I can't point to any evidence of it, but I'm sure it was a concern.

I can remember coming out of -- pesticides again, not animal feeds, and this is really not FDA, so it's probably a digression -- but we used to apply that to corn. We grew a lot of sweet corn, and the way we applied it, this wasn't a big operation where you'd come in with crop dusters, but you'd do it by hand, and you'd put on the heavy suit, rubber suit, and a hood and a mask. You looked like something climbing out of the trenches in World War I. Then there was a big metal canister in front of you full of whatever the pesticide was. It wasn't always DDT, thank God. We used Malathion and Sevin and others. But it was hot, sweaty work, and you'd be going through, cranking between the rows of corn, and you'd come out of there and take off the rubber suit, and wherever your skin had been exposed, you were just totally white, covered with this powder. I'm 57 now. I don't know whether this is going to come back and haunt me maybe in 10 or 20 years, but the exposure level must have been awfully high. Whether that was the way it was supposed to be applied, I think back at that point, there wasn't a lot of regulation or guidance as far as that goes. The EPA [Environmental Protection Agency] hadn't even been created yet. I'm talking back in the '60s. OSHA didn't exist either.

JS: So, in 1979, you moved to the Press Office, and I wonder if you could take us through how that move came about, why move to the Press Office, what was there, and what you did when you moved there.

WMR: Well, while I was working in Vet Medicine, I soon found out that FDA put out an outstanding publication, *FDA Consumer*, and I was able to write for that magazine about veterinary issues while I was working in Vet Medicine. In fact, I remember one article that I did about pet health with Dr. Catherine Carnevale, who at the time was working in CVM (then known as BVM). She now works in the Center for Food Safety and Applied Nutrition. Not only was Vet Medicine concerned with livestock issues, but they also have a responsibility for pet health as well. So we did an article together for *FDA Consumer*. The editor at the time was Roger Miller. He liked the article and thought that my writing style wasn't too bad. So he met with me and asked if I was interested in coming to work in Public Affairs, and I thought this would be a great opportunity.

At the time, Wayne Pines had recently taken over the job of Assistant Commissioner for Public Affairs after Jack Walden had left the agency, and I met with Roger and then with Wayne, and they were both interested in having me apply for vacancies in both the Press Office and the Publications staff. I asked, "Can I do both?" because, really, I liked the idea of doing press relations, since my degree was in journalism and I had been a reporter. I also liked the idea of writing for that fine magazine.

So what happened was I was hired into the Press Office, but in the time that I could find, I was able to continue writing for *FDA Consumer*.

My beat in the Press Office was Medical Devices and Radiological Health, which at the time were still two separate centers, or bureaus. I covered those areas for the Press Office and also wrote on those subjects for *FDA Consumer*. Both of those jobs got me interested and involved with the folks at both the Bureau of Medical Devices and the Bureau of Radiological Health, and that's what eventually led to me going over to work at the Center for Devices and Radiological Health.

JS: Right.

What things were going on in the agency at the time that stand out still in your mind that had an impact on what you were writing about in the *FDA Consumer*, and what were you working on in the press relations area?

WMR: I happened to hit the Medical Device area at a time when a lot of issues were coming along, and also the Radiological Health area when there were a lot of big issues there, too.

Radiological Health in a way was very similar to Vet Medicine in that they were very strongly into voluntary compliance. John Villforth was the Director then, and he strongly believed in the power of education, and they had an enormously strong and, I believe, successful educational arm. And to this day, I think, it's one of the best in FDA.

Their objective was to go out and try and educate, in particular, health professionals, radiologists and other folks using radiation-emitting devices in the medical environment to alert them to the hazards of excessive radiation. These devices were great advances in medical science, but they had to be used responsibly with an awareness of

the dangers if they were misused. So we had a very active educational arm. We worked very closely with the American College of Radiology at that time, and with the American Dental Association, to educate about the risk of overuse of dental x-rays, of overexposure in medical x-rays and CAT scans. Our partners in the public health arena helped with that.

So I was involved in writing about those radiation issues for *FDA Consumer* magazine and also when there would be something of news interest in those, when we'd put out new guidelines or something, those were the kind of issues I handled in the Press Office.

In the Medical Device arena, Dalkon Shield intrauterine contraceptive device had been a recent concern because of serious health risks to women who used it. It wasn't too much later that toxic-shock syndrome became a public health issue. When it became linked to the use of menstrual tampons, that, of course, was within the bailiwick of our Bureau of Medical Devices, and that was, of course, a big, big public health issue. This was in 1980-81.

The press coverage on that was enormous, and that issue alone kept me and other press officers and folks in the Center very, very busy for a long, long time. CDC [Centers for Disease Control and Prevention] was also involved in that from an epidemiologic aspect as well. I was not only covering this for the Press Office, but then it was a very logical and relatively easy next step to take that knowledge I had gained and then put it into the form of a magazine article for the general public in the *FDA Consumer*. So we were getting extra mileage and, in a way, double duty, but I really enjoyed it. It was a great way for me to capitalize on what I was learning at that time.

Emil Corwin, who was a press officer at FDA for decades, had said late in his career that he felt he owed the government a payback for the education that they had given him over the years. I have always felt that way too. I have learned so much about medicine, about science, about public health in the three decades I was here. I feel the agency has given me a terrific education in fields that I otherwise probably wouldn't have been familiar with, and it's been a terrific learning experience. Until the day I walked out the door, I was still learning new things every day.

JS: I want to ask you a question about the work on the *FDA Consumer*. But before I do that, I wonder if you could just characterize for us what the press relations officer does and how they work with the press as far as the agency is concerned. It's very possible people don't really understand how that works, because FDA, being the very visible institution that we are, the press is constantly interested in what we are and what we do.

WMR: The press operation at FDA is absolutely fascinating because FDA is one of the most visible federal agencies, and impacts people's lives every day. There is always something in the news, whether it's a controversy or a crisis or just something routine that people are interested in as new products are approved.

Each press officer is assigned a "beat," just as if they were reporters for a newspaper. My beat, as I said, happened to be Medical Devices and Radiological Health. Other folks cover human drugs. In fact, that area is so busy, it usually has several people, as does food; and, of course, Biologics and so on.

The press officers need to establish a strong working relationship with the people in the Centers. That needs to be a real hand-in-glove type of relationship. They need to know what's going on on a day-by-day basis. They need to gain the trust of the people in the Centers so that the scientific and medical experts can feel confident and trusting when they talk to the press officers about these issues, and know that the information will ultimately be conveyed to the press and to the public accurately and without factual mistakes and without bias. It takes an interesting combination of skills, I think, to be a good press officer.

Communication skills obviously are important. You need to know how to write because you're writing the press releases that the agency issues; you need to be able to communicate orally because you spend a great deal of your time every day talking to the reporters who are calling in to ask the agency what the latest is with whatever the issue of the day happens to be. You also need to be able to gain the trust of the people back in the Centers and be able to get the information from them that they naturally impart in scientific and technical terms and translate it into information reporters and the public can use and understand. That is, I guess, a fairly rare combination of skills, and it does take a rather unique person to be able to fill that kind of a role. The agency's been lucky in that it's had a lot of good people who can do that over the years. I've seen a lot of very good, very dedicated press officers.

TAPE 1, SIDE B

WMR: Press officers typically put in pretty long hours and lots of weekend work because reporters are working at all hours. You're dealing with media deadlines, not only across the country, but around the world in a lot of cases, since many public health issues aren't confined to the U.S. borders.

With the growth of more diverse media over the years, it's become even more difficult for press officers, because you're dealing with cable stations on television, you're dealing with niche publications, you're dealing with publications with a preordained point of view, and oftentimes those are very difficult to work with. Most reporters for major media come at it with an objective point of view and are willing to hear what we have to say; others, not necessarily so, and that can be very challenging, very difficult. I've got to say, though, that most of the reporters who I dealt with were always trying to get the story right, and in most cases did so. That may not have always set well with FDA because oftentimes what was printed was somewhat at odds with what we thought and what we would have liked to have seen. But I think reporters do try their best and usually succeed in producing an unbiased account of the facts, trying to represent all sides of an issue.

Press relations was always exciting work, and you always felt that you knew what was going to be in tomorrow's paper before anybody else did. You got to meet with officials at the highest levels of the agency, and in some cases even the Department, because those were where the decisions were made, and you needed to know about those decisions and you needed to know the background that went into them. I think sometimes maybe today, some of our press officers are at a disadvantage because they aren't privy to the decision-making and the debates, the internal debates that go on, and if

you don't know about that, it's very hard to convey the information with the right background to it.

JS: Well, is that relationship, then, between the press officer and the beat they're covering in the agency ever formalized, or is it just worked out sort of however the press officer feels it needs to be worked out?

WMR: The latter. Press officers work very much like reporters do. When a reporter is sent out to cover a story or to establish a beat, they have to find their sources, they have to establish the trust, open up the lines of communication, and really, a big part of it is winning the trust. There are no set rules as to how you go about it. If you're a press officer, your boss, the head of Public Affairs, may introduce you to the Center director or a couple of other people and say, "Here's your new press officer. Please do what you can to make him welcome, and good luck." But from then on, it's up to you. You have to win their confidence.

I was very fortunate in working with people like Dick Zafra and David Link at Medical Devices, and with John Villforth and Jim Benson in Radiological Health. I was invited to attend their staff meetings, their own senior staff meetings. They expected me to tell them what was going on in the press and what issues reporters were showing an interest in. I, in turn, was able to hear what the Center's top officials were talking about, and that enabled me to be prepared when reporters started to call. I felt like I was part of the Center's team, and that's the way it needs to be. Even though you're assigned to the

Office of Public Affairs and the Office of the Commissioner, you are every bit as much a member of the Center you're covering as your beat.

RT: Historically, referring to years ago, the agency wasn't really that well known by the public. What, in your recollection, were the issues that really brought the agency to the fore? I know there are probably many, but was it in the drug area or foods or something else?

WMR: Well, unfortunately, I guess, it's always the public health *crises* that get the biggest headlines. That trend had already started at FDA when I arrived in '77. I think a big part of it was the rise of the consumer movement itself during the late '60s and into the '70s. That was reflected in FDA itself because the predecessor to *FDA Consumer* was called *FDA Papers*. It was more of a scientific, technical publication, and it was begun in 1967. In '72, the name changed to *FDA Consumer*, reflecting a change in society at large.

The big issues, of course -- and it will always be this way with FDA, I'm sure -- are food and drugs. Lately it's been mostly drugs, but food issues in the past, and, of course, we're talking mostly food *safety* issues. There were the problems with red dye #2 and other food additives; saccharin was one of the biggest, of course. About the time I was coming into the Press Office, those were the kinds of things where FDA was in the media, and not always favorably.

To this day, it amazes me what you hear people talk about. For example, when FDA attempted to ban saccharin, people would say, "Well, they fed 800 cans of diet soda

to a bunch of lab rats. Who's going to drink that much soda?" It's a way to ridicule the agency and our scientists because people don't understand the science behind that kind of testing. The quick, glib joke or headline will stay with people, but not the details and the real scientific data that take a bit of work and thinking to understand and appreciate.

JS: How often was it necessary, in response to a story that the agency just had a serious problem with, to turn around and ask for a correction or a response, letter to the editor, that sort of thing? Did that happen very often?

WMR: No. It was rare, and it still is rare. I think the main reason for that is the original news story is going to get all kinds of attention; the correction the next day isn't. And this is true despite the fact that newspapers are much better at running corrections than they were in the past. I think that they have become more willing to acknowledge that they themselves make mistakes, as we all do, and they have an obligation to their readers to issue corrections.

For example, look at the *Washington Post* today. On page two, you will see numerous corrections every day. That didn't used to be the case. On the other hand, I don't think many people read them, so they probably don't do a lot of good. So it's usually not worth the effort and worth getting bad relations with an editor to continually insist on corrections.

Letters to the editor do have more effect, I think. You save those for the big mistakes.

Frankly, most reporters who cover FDA don't make a lot of mistakes. There have been cases over the years where there have been reporters who just weren't up to snuff and didn't get it, and I think there may have been one or two times when the head of Public Affairs would talk with an editor about a reporter who just either seemed to approach the issue with a bias or just didn't have the journalistic skills to communicate effectively. But those also were rare.

I think letters to the editor and seeking opportunities to write op-ed pieces are more effective because those do get more exposure than just an ordinary correction. But, again, you have to choose your battles carefully, and I think the agency has done so.

JS: Now, when you were writing for *FDA Consumer* at the time, this was on the heels of the medical devices amendments. Were there issues that came out of those which might have found their way into some of the articles that *FDA Consumer* would have written about at the time, issues on the regulation of different classes of devices, say? Is this the sort of thing that *Consumer* might have been attending to in any way when you were writing for it?

WMR: The Medical Device Amendments were passed in 1976, and FDA was still issuing implementing regulations, so we were trying to write "primer" articles about how FDA's regulation of devices was going to work.

But we also saw a need to educate consumers about specific types of devices that they were using themselves every day, such as contact lenses or eyeglasses. Those were

products that that FDA was now able to write about because we were applying the new device amendments to them.

Another important type of medical device at that time was intraocular lenses. They were very new, and an important medical breakthrough in the treatment of cataracts. Surgeons would remove the natural lens with the cataract and implant a permanent plastic lens into the eye. It was a tremendous advance over the previous treatments of very thick, as they were called, “coke-bottle” glasses that cataract sufferers used to have to wear after their surgery. Of course, there was concern about their safety because they were permanently implanted in the eye.

At one advisory committee meeting, the manufacturers tried to garner press for their point of view by bringing in Robert Young, who played Dr. Marcus Welby on TV, to testify. Mr. Young himself had recently had surgery to have intraocular lenses implanted.

Reporters were everywhere because they knew the famous actor was going to be there. He told about how, after he’d had his surgery and removed the bandages, he was able to see across the hospital room and the beautiful flowers in the vase that somebody had brought him, and how amazing these lenses were. Of course, that may not have been the kind of scientific data FDA’s advisory committee was looking for, but it certainly helped the proponents of the lenses win over public opinion.

JS: Did I hear you say he was working for a firm or a firm employed him?

WMR: I don't know what financial arrangement there was, but he had been asked to come and speak by the manufacturers, and he was very effective, as you can imagine, Dr. Marcus Welby telling us how wonderful intraocular lenses were.

At about the same time, FDA became deeply involved in one of the biggest radiation-related public health emergencies in our history. The incident at Three Mile Island nuclear power plant occurred just a month or two after I joined the Press Office, and FDA had a major role to play in monitoring the safety of the food in the area around the plant after the accident. The safety of milk was a special concern because Lancaster County and that area of Pennsylvania has a very large number of dairy farms. We had our folks up there checking the milk to see whether radioactive contaminants from the plant had gotten into the milk. Luckily, the milk was safe.

John Villforth, then Director of FDA's Bureau of Radiological Health, was appointed by Health, Education and Welfare Secretary Joseph Califano to be the coordinator for the entire Department on all the public health issues resulting from the incident. I was sent to Pennsylvania for several days to act as the on-site public affairs officer for the Department.

When I reported up there, a number of people from CDC, EPA and countless other federal and state agencies were assigned there, and they would get together every afternoon to talk about their progress and what they had found. I attended those discussions and sent information back to the Public Affairs Office at FDA and the Department.

At one point, one of the state fellows asked me if I wanted to go up in his airplane over the Three Mile Island plant, and, foolishly or not, I said, "Yes, let's go for it." So he

took me up in a small, single-engine plane, and we flew over those big cooling towers of Three Mile Island a couple days after the incident. Everybody kidded me about coming back to FDA and glowing in the dark. I don't think that happened, at least not for too long. But it was a great experience to be a part of what was *the* story at the time.

RT: I recall that this individual also used his plane to ferry samples down to the laboratory to expedite the analysis. This fellow actually was an FDA Baltimore District staff member, Bob Brands, the shellfish specialist there.

WMR: There was a lot of camaraderie at the time. You know, when FDA becomes a part of these kinds of things, it's almost like a small military operation, and you do have that feel of it. Everybody working extremely well together, putting aside their "turf" issues as best they can and really working for the public health. I was really excited and proud to be a part of that. It was good work.

JS: Many times in our history we've, as you said, put all those things aside, whether it's a public health crisis or a natural disaster or something like that.

WMR: Yes.

JS: And this has been going on throughout our history, throughout FDA's and even the Bureau of Chemistry's history.

WMR: Yes. On a day-to-day basis, there's plenty of squabbling and bickering and turf battles and so forth, but when push comes to shove, everybody knows what's really important. My experience has been FDA and other agencies are able to work together very well, when the public health is in jeopardy.

JS: Well, with this background, with this turf that you developed -- your specialty that you developed in Public Affairs -- you then moved on in, I think, 1983. Was it 1983?

WMR: Yes.

JS: To the Center for Devices and Radiological Health. What were you doing when you moved to the Center?

WMR: I worked in their Technical Information Division. A gentleman named John Bailey, a member of the Commissioned Corps, a wonderful guy, had headed up their technical information staff, originally with the Radiological Health part, and then, after the merger, took over the whole area. He had headed that up for many, many years, but he was getting ready to retire, and they were looking for someone to be able to step in, and they asked me if I wanted to give it a try. So I came over there as his deputy and learned the ropes.

It was somewhat different work. It wasn't the consumer-oriented work that I had been used to. We were preparing technical documents for publication by the Center. They had a very big, very active publishing operation, originally in Radiological Health.

They were expanding that into Medical Devices as well. They also helped Center scientists prepare journal articles for publication. There were a lot of very good technical editors working over there. Betty Facine was the leader of the editing team, a very talented person.

We also had the libraries as part of our responsibilities, the Radiological Health library, under Bud Smith, and the Medical Device library under Harriet Albersheim. So it was a pretty big operation, and it took me a good while to learn the ropes. This was a new area for me, but it was interesting work.

However, after I was in that job about a year and a half, the editorial director of *FDA Consumer*, Harold Hopkins, retired after many years with the magazine. Roger Miller, who was the editor of *FDA Consumer*, asked me if I'd be interested in the position. Even though there was more career growth potential in CDRH if I were to stay there, I really missed and loved the writing and communicating to the general public that I had been able to do with *FDA Consumer*, and I decided I wanted to go back. So I told Roger yes, I would love to do that, and said goodbye to my colleagues at CDRH.

JS: This was in what position, then?

WMR: I was leaving the job of Acting Director of the Technical Information Staff to move to, the title was Editorial Director of *FDA Consumer Magazine*. Roger was the editor, actually what you would call the editor-in-chief. My job as editorial director involved more of the day-to-day, hands-on working with the articles, editing, making

story assignments, doing some writing myself, coming up with story ideas, things like that, but Roger had the overall responsibility for the magazine.

But it was a GS-13 position, and I really didn't expect to ever rise above that, because Roger was in the position above, and I didn't think he'd be leaving anytime soon, and he didn't, thank God. But I enjoyed that kind of work so much that it didn't matter; I just really wanted to get back into those activities.

JS: How big was the staff at the time?

WMR: Those were the heydays of FDA's public communications. The office at that time was probably 20; I know at one time it was 22 people. They were involved not only with *FDA Consumer*, which was then the flagship publication for the agency, but they were also producing exhibits for use by FDA's Consumer Affairs Officers around the country and by headquarters people as well. They were producing radio and television public-service announcements, print public-service ads, brochures, reprints of articles from *FDA Consumer*. The budget was more than two million dollars. We had broadcast specialists, a staff photographer, slide-show producers -- this was still when slide shows were state-of-the-art technology -- just doing a little bit of, a lot of everything, frankly, and doing it very, very well.

Roger Miller was an extremely talented, creative person, and came up with just one good idea after another for the Agency's public communications. I learned an awful lot from him.

Also at that time, the Office of Public Affairs had a far greater role in Agency communications, not just press. Of course, it still leads the press-relations effort for the agency. But at that time, the Centers were not doing as much of their own independent public communications. It was, by and large, coming out of the Office of Public Affairs and out of the communications staff under Roger Miller. He worked closely with the Centers, especially with the public affairs liaisons in the Centers, but his office was the driving force and was very effective.

For example, we did public education campaigns against steroids abuse and about the health risks of excessive salt in the diet. In fact, then Commissioner [Arthur] Hull Hayes adopted salt/sodium as his big public health message

RT: What did you attribute the reduction in staff size to from that high level to the relatively small cadre now?

WMR: Certainly the main factor was the overall budget problems that began to affect the entire agency. That office took its share, and probably more than its share, of those cuts, and I witnessed a gradual pullback in a lot of areas.

Also, the pendulum swung toward where the Centers were taking on direct responsibility for more of their own communications issues. For instance, the Center for Drugs began doing more such educational work -- and they still do, and they do quite a good job -- on the proper use of medications and use of generic drugs, and so on. While the OPA Communications Staff had been doing those kinds of messages, now the Center for Drugs.

JS: OTCOM [the Office of Training and Communications] was taking on more of that work.

WMR: Likewise, the Center for Food Safety and Applied Nutrition began to bring in its own people. For example, Marjorie Davidson in the food safety area. That started to happen during Dr. [David] Kessler's time. I think the Office of the Commissioner was more focused on a couple of really big things, like tobacco regulation and, of course, the new food label, and the Centers stepped in to fill a void in the other areas. Also, some centers had more money; with user fees, they were able to fund the communications issues better than Public Affairs was.

JS: So, prior to the late 1980s or so, as far as Center communications efforts themselves, those weren't quite at the level witnessed later on?

WMR: With some exceptions, such as the former Bureau of Radiological Health, they weren't as robust as they are today. They certainly were not competing with what was done centrally through OPA at that time. I would maybe put it more toward the '90s when the pendulum really started to swing, early '90s, because even the food label, while we worked very closely with CFSAN [Center for Food Safety and Applied Nutrition] on that major, major public education campaign, that was done, by and large, out of the commissioner's office. In fact, you can't even say it was done by OPA. Dr. Kessler

brought in new people, not part of OPA, for example, Sharon Natanblut, to work on the communication campaign for the Nutrition Facts label.

JS: We're going to get to Dr. Kessler. I know that's a huge endeavor there.

So you're with *FDA Consumer*. You're working under Roger Miller at the time.

WMR: Yes.

JS: Now, at what point do you become editor of *FDA Consumer*? How does that come about?

WMR: Well, it came as a great surprise to me because I didn't expect that it would happen at all. Roger actually held three titles at that time. He was the Deputy Assistant Commissioner for Public Affairs; he was the Director of the Communications Staff; and he was the Editor of the *FDA Consumer*. That was a lot of work, as busy and active as that office was back in those days with so many different responsibilities, *Consumer* being only one of them. He finally realized that it was probably more than one person should try to take on, so in early 1985 the position of editor of *FDA Consumer* was made separate and a vacancy announcement was put out.

Quite honestly, it was like a dream come true from when I first picked up a copy of *FDA Consumer* when I arrived at the agency in '77 and saw how good it was, and, frankly, couldn't believe that the government could put out such an outstanding

publication, an award-winning publication. That magazine is really a national treasure. When I was able to become the editor, I was just overwhelmed.

JS: How did *FDA Consumer* get to the kind of status that it did? Was it just a commitment by the agency from the top to create a publication to serve the needs of the consumer? Obviously, good direction always helps too.

WMR: Well, I think there was a convergence of several things: very good people got it pointed in the right direction. Wayne Pines was the editor who repositioned it from *FDA Papers* to *FDA Consumer*, and Wayne has a very strong journalism background. He knows how to communicate effectively with the general public, and I think that's the forte of *FDA Consumer* and always has been -- its ability to communicate to the public in terms that they understand about issues that they deal with every day. We always are proud to say, and it's true, that FDA is a science-based agency. But someone needs to translate that science into terms that consumers can understand and make sense of. Wayne Pines was able to do that, along with the people that he had working for him. Ellis Rottman was also an editor, just before Roger Miller, who was very effective at that; and then, of course, Roger as well. These people all had a journalism background, had all been reporters, and knew how to write a good story.

One of the testimonials -- and we used to use testimonials quite a bit when we would promote the magazine -- was the statement from one prominent subscriber that it "read like a novel." And it did. We had excellent writers.

That's another thing people need to remember, that *FDA Consumer* was and is a paid-circulation magazine. People actually spend their own good money, of their own free choice, to buy it and read it. Even though it's now available online for free, there are still many people willing to pay for it.

Annabel Hecht worked on that staff for years and years, and she was a prodigious and very talented writer. Evelyn Zamala, Harold Hopkins. Harold Hopkins wrote an article for the magazine based on personal experience. It was called the "Jake Walk Blues," a fascinating first-person story about his father's addiction to an illicit drug back in the 1920s.

JS: Jamaica ginger extract.

WMR: Thank you. And the Jake walk was the shaky-leg condition that users would get from being addicted.

JS: There was a poison that was introduced into this product, this prohibition-era product . . .

TAPE 2, SIDE A

NOTE: ON THE FIRST PART OF TAPE 2, THE VOICES SOUNDED VERY MUFFLED AND COULD NOT BE COMPLETELY TRANSCRIBED.

JS: I was just mentioning as an aside that Bill mentioned the ginger Jake story. This related to an incident back in 1930, when a firm in Boston put out an additive in a preparation of ginger extract and ended up poisoning many, many thousands of people across the country. The effect of that was to cause a neuromuscular disease manifested in part by a gait, and they called it the Jake walk, and it actually gave rise to a variety of blues music known as the Jake-leg blues. As a matter of fact, the Northeast regional office researched one particular song that the Allen Brothers came out with around this time. They changed the arrangement of it, slowed it down. They performed what I think was called the “Jake-Leg Blues” at the New York Region’s centennial celebration. And we loved it so much that we brought them down to the ORA headquarters centennial celebrations eventually; they did a wonderful job. It’s an important part of FDA history that they brought to life for the agency.

So, you were editor beginning in 1985 until 1989?

Well, after you became Director of Communications in 1989, David Kessler arrived a few years later, which I’m sure created many, many opportunities for communications under Dr. Kessler’s tenure, certainly one of the most visible and communicative commissioners that FDA had had in a long time. But certainly, there was a major issue just before his arrival, the generic drug scandal. Can you say a little bit about the impact that generic drugs had on FDA’s communications responsibilities?

WMR: Well, it was a difficult situation because one of our main public health messages at the time was the benefit of generic drugs. The scandal made it difficult to convey that message with credibility.

RT: Communications work involves liaison with the press. Did communications staff have a similar rapport with the press, as did the Press Office, per se?

WMR: No. We did not conduct press relations in the Communications staff.

JS: During your tenure as Director of Communications, which included Dr. Kessler's time here as Commissioner, did that pose any special challenges to FDA? Not challenges necessarily, but how did that have an impact on the Communications Office in FDA?

WMR: It had a very substantial impact. Dr. Kessler was the most effective communicator of all the FDA commissioners that I've known and worked with.

I think he understood instinctively how to get public health messages out effectively, and he knew how to work with the press. Let's face it, for all its excellent writing and communication, *FDA Consumer's* peak circulation was about 22,000. Now, it reached many more people through reprints. We would reprint hundreds of thousands of copies of the most popular articles. But, nonetheless, in a nation of this size, that's still a drop in the bucket.

I think Dr. Kessler understood that to get his messages out, you needed to reach the people through the mass media, and he knew how to do that very well. But he didn't rely solely on the Office of Public Affairs to help him do that. Needless to say, we were very busy during his entire tenure. But he brought in his own folks, reporting directly to him, who were trained, seasoned professionals in communications and public relations,

and he kind of had a shadow public affairs office. This was certainly true during the tobacco years, and in the food-labeling years, when FDA published regulations mandating a new, more consumer-friendly nutrition label on foods. That was, to my knowledge, the biggest public communication campaign the agency ever undertook, and it was massive, it went on for years, and it employed communication ideas and media that we had never dreamed of before. We had never thought of having the Goodyear blimp carry a message saying “Read the new food label,” but that was one of the ideas that the agency managed to put into play. Sharon Natanblut, whom I mentioned earlier, was a public relations professional that Dr. Kessler brought into the agency, and that was one of the ideas that she employed.

The food-label message was also put on the giant Jumbotron scoreboard at Yankee Stadium during one of the Yankees’ games -- just numerous things like that. Not only at those events -- I mean, at Yankee Stadium you were reaching, what, 50,000 people, whatever, but it got media coverage because this kind of thing had rarely happened in government public-health communication before, so there were news stories the next day about that, and that reached millions of people.

Dr. Kessler was very, very good with the press. It started with his campaign about misleading food labels. I think he knew darned good and well, when he held up a carton of orange juice misleadingly labeled as “Fresh” before an industry group, that it was going to reach more than just the industry people in the audience, that it would become a national news story, which it did. He was a very effective communicator.

I learned a lot from him, too, even though he was the Commissioner and not a public communications professional. But in a way he was, more than many.

JS: It was probably toward the end of his time here that you got involved in the website. Is that right? About 1996 or so? Was that about . . .

WMR: Was he gone then?

The website, we launched the website in March of '95. I can't remember when Dr. Kessler left.

JS: Nineteen ninety-seven.

WMR: Do you want me to talk about the website a little bit? I need to, in 10 minutes, I need to go and feed the parking meter.

JS: Well, let's go ahead and get started with it.

RT: We can always pick it up again later.

WMR: I'd be glad to. If I'm not boring you guys here . . .

JS: Not at all.

RT: This is great.

As far as the website goes, nobody had heard of the Web or the Internet in 1994 at all, and I remember Don McLearn was the Deputy Associate Commissioner for Public Affairs at the time, and I reported to him. He came to me one day and said there was a fellow down in the IT office that wanted to show us something, and we went down to this fellow's office. I can get his name, but I do not remember it right now. He had on his computer screen something in the Mosaic browser, which has come and gone, and it was a graphic image from NASA; it was NASA's home page. Of course, we didn't know what a home page was then, but it gave information about NASA and you could click on links, and it would take you to more information. These hyperlinks were something else we had never heard of. But it was fascinating.

It wasn't too much longer before HHS said that they expected every agency in the Department to develop a home page on what was called the World Wide Web. So we had to educate ourselves pretty quickly, and none of us, of course, had any knowledge about computers or IT, so we had to hook up very quickly with the CIO's office. At that time it was called Office of Information Resource Management, and we partnered with those folks, and they were responsible for the technology behind it, while Public Affairs was responsible for the content. I was put in charge of this because of my role as Director of Communications. It was viewed, and rightly so, as another communications vehicle for the agency.

We scratched our head as to what we would use for content. At the time, there was a publication called the *FDA Almanac*, which was kind of a primer on the agency. It had a lot of background information about FDA, and was also kind of an annual report with a lot of statistics and data about the Agency's programs.

JS: Very useful.

WMR: It was useful. It originated when Gary Fendler was the head of Public Affairs. He got the idea for it, and my staff put it out.

But we thought, well, here we've got all this content. Let's see if we can't put that on the World Wide Web. So that was the original content. We designed a home page that, as you look at it now you would laugh because, of course, you'd look at any home page from 11, 12 years ago and you'd laugh. It had little icons for each of the Centers. There was a drop of blood for Biologics; there was a mortar and pestle for the Center for Drugs; and so on, and we considered that extremely clever at the time. If you clicked on one of those, it would take you to some information about that topic area. There were no more than a few dozen pages at the time. But it was our start, and that was the beginning of what became the FDA website.

I should mention, though, in deference to the Center for Food Safety and Applied Nutrition, that while the FDA website went live in March of 1995, CFSAN had already gone live with their own website in late 1994. Larry Dusold, who is still their web manager, launched their site before the agency overall did.

JS: Okay. They win.

WMR: They win.

JS: They went to start?

WMR: That's right. But that was the beginning of it, and now it's huge.

JS: You know, I don't want to hold you up, and I certainly don't want you to get a ticket.

How did we get to be where we are today with the Web? We started out with maybe a dozen pages; today we have how many pages?

WMR: We can't even count them all. Literally, we can't count them all. But there seem to be somewhere about 800,000; it could be as many as a million pages. They get put up faster than we can count them. About 300,000 individual visitors every day to the FDA Website, which means, of course, tens of millions every year. It is the only communication vehicle the agency has that really does challenge the impact of working through the mass media.

Before the website, we had to rely on the press if we wanted to reach millions of people at a time. But now, we can reach that level of magnitude on our own with our own website; in fact, we do, day in and day out. It is enormously influential. It has visitors from every one of our constituent groups: consumers, health professionals, regulated industry, students, teachers, reporters, anyone you can imagine.

And our visitors come from over a hundred countries around the world routinely. Truly, it is an international public health communications vehicle.

JS: Each of the agency's components, of course, are loading thousands of pages up on the website.

WMR: That's really how it attained critical mass, because when it started, it was just public affairs and we grabbed the *FDA Almanac*, and here's some information about FDA, and, okay, we made our presence known.

But then, with CFSAN first, and then the other Centers soon thereafter saying, "Hey, we need to be a part of this too," they got their own staffs and created their own websites, and we linked them together, which of course is the whole idea behind the World Wide Web -- that it's all interwoven. Then you really started to get some important communications material out to the world. In fact, to this day, it is run in that kind of a decentralized fashion. It's kind of a federation of websites. Each Center has done a great deal; in fact, the bulk of the material comes from the Centers. The Office of the Commissioner itself, aside from the Dockets Managements Staff, doesn't have nearly as much material on the site as the individual Centers do, and that's the way it should be, because they're the ones developing the information, and they know what they need to say, and they're saying it very effectively.

JS: Is one Center or one Office dominating, putting up the most information?

WMR: Well, mentioning Dockets, they account for about a third of the website. That is because of the enormous number of public comments the Agency receives, virtually all of which the Dockets office posts on the Website. The agency has decided that it will post

all the public comments it gets on all of its open dockets, and that means every day, hundreds, if not thousands, of individual items are being put on the website, so much so that it becomes enormous just to manage it. It's really a difficult thing to control.

JS: In terms of volume, there's no doubt, and it's also been an award-winning website as well.

RT: You've given us a very good interview, Bill. We really appreciate your input.

JS: Really do.

WMR: Thank you.

END OF INTERVIEW