

History

of the

U. S. Food and Drug Administration

Interviewee: Kenneth R. Feather

Interviewer: Dr. John Swann
Ronald T. Ottes
Robert A. Tucker

Date: May 7, 1997

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.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

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Kenneth R. Feather

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INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: May 7, 1997

Place: Rockville, MD

Interviewee(s): Kenneth R. Feather

Address: [REDACTED]

Last FDA Position: Regulatory Review Officer

FDA Service Dates: 1962 to 1997

Interviewer(s): Dr. John Swann, Ronald T. Ottens, Robert A. Tucker

Address: Food and Drug Administration

Number of Tapes: 3

Length: 140 minutes

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Editors Note

Shortly after this interview was held, the Food and Drug Administration issued draft guidelines for prescription drug advertising on TV and Radio. The new guidelines provided for relaxing the strict requirement of providing with the Ad a "brief summary" of important information about the advertised drug including side effects; contraindications and effectiveness. Under the new guidelines in lieu of providing a "brief summary" the advertiser would have to provide a means to ensure that consumers could easily obtain full product labeling such as through toll free telephone numbers or referring the consumer to print advertisements containing brief summary of product labeling. This is covered under 21 CFR 202.1(e)(1)

RO: This is another in the series of FDA oral history recordings. Today, Mr. Ken Feather, retired Regulatory Review Officer of the Center for Drug Evaluation and Research, is being interviewed in the Parklawn Building in Rockville, Maryland. The date is May 7, 1997. Also present are Dr. John Swann and Ronald Ottes. (Mr. Robert Tucker joined the interview after the beginning.) The transcripts and tapes of this recording will be placed in the National Library of Medicine and become a part of FDA's oral history collection.

Ken, to start this interview, would you give a brief biographical sketch of where you were born, educated, and any relevant work experience before joining FDA.

KF: All right. I was born in Lebanon, Pennsylvania, in 1940, dating myself. I went to college at Lebanon Valley College, which is a liberal arts school in Annville, Pennsylvania. I majored in chemistry and graduated in 1962 with a bachelor of science in chemistry. I joined Food and Drug [Administration] that very week, basically, in Philadelphia District as a field inspector. I worked in Philadelphia for six years doing a whole range of things that Food and Drug does really. Philadelphia District is one of those districts where you really can get to do most everything that Food and Drug is involved in. So it was great training ground. But I began to specialize more in the drug field toward the end of my time in Philadelphia.

RO: Did you have any interesting regulatory experiences?

KF: Well, I predate the '62 amendments. I began in June of '62, and they were finalized in October. So one of my first assignments along with the regular training kinds of things was interviewing thalidomide investigators for potential side effects. The side effects were just becoming known at that time, and I was interviewing several of the thalidomide investigators in the Philadelphia area, one of whom was the team physician for the Philadelphia Eagles, and some of the Eagles were actually using the

drug as part of his care for them as a sleeping drug. That's what it was under investigation for at that time, as a sleeping drug. His comment was it's a fine sleeping drug for men, because it had few side effects, you weren't drowsy the next day, it's very effective, but he said it's a great sleeping drug *for men*. So that was one of my first introductions to the agency.

JS: Just a follow-up question to that on the thalidomide investigations. One of the concerns with the way Merrell was conducting the thalidomide work was that there were just so many investigators, clinical investigators working on thalidomide, and the agency did not know how many. Do you have any sense for what kind of contact Merrell was keeping with its clinical investigators?

KF: No, I was fairly new at that time, so I knew very little about the IND (Investigational New Drug) regulations or what was involved. I, myself, interviewed five investigators in the Philadelphia area. And I don't know how many other inspectors were out doing the same at that point. So you probably are right. There probably was a large number of investigators that the thing had gotten somewhat out of control. The agency wasn't quite as tight with things at that time, as you might know, because we didn't have some of the law we do now, and I think we tended to trust people maybe a little more. But I don't know what the scope of that was, because I was fairly new at that time and had little knowledge of what was going on around the agency at that point.

I guess one of the more, if not interesting, one of the more notable things, we had a large warehouse in Philly down by the docks. It was the main cocoa bean importation point, and it was a huge dock. It was a quarter of a mile long, two buildings, three stories high, loaded with cocoa beans. One of our men went down there and opened the door and was buried in moths and larvae. So we seized the entire

pier. The marshall just tacked a notice on the front door of the pier, and then we seized the entire pier. So we had to go down periodically and watch the reconditioning of all these lots of cocoa beans, because they had to be cleaned and sterilized and repackaged, and it was a mess, because you came out of there wanting to take a shower quickly as soon as you came out of that place, because it was just terrible. But that was one of the strange things that we got involved in.

RO: Was there much insect damage in the cocoa beans?

KF: Oh, not a lot that would affect the beans after they were cleaned up. You know, they're ground up so there's . . . Whatever damage there might have been was not noticed, is not noticeable.

RO: Ground up the insects with it.

KF: Well, unfortunately, that may be true. In this case, it, you know, they were mostly moths, so it was wiping off the outside and getting rid of the webbing and things of that nature. But there's always a certain amount of natural contamination in any food product. So it's good to not remember what you know as an inspector when you're going out to dinner.

JS: Never eat that Nestle Crunch bar with the same sense of delight.

KF: You would never eat anything if you'd keep mind what you know.

One other thing we were doing was a small bakery in Reading, Pennsylvania. We were picking up samples of things, and I just happened to look at a stack of boxes of raisins and currants, and I tapped on the boxes and all the raisins moved. So I hit

it again, and all the raisins moved. So I sampled them pretty heavily, and there were more insects than raisins in the box. We sampled raisin buns and other things that had raisins in them, and they were all contaminated. The firm was put out of business. The gentleman decided he would rather go out of business than go to jail. So he shut down the place.

RT: Did you get involved in some of the court cases as a witness?

KF: No, I never actually testified in court. One thing we did do, back in I guess it was about '65, we were arguing with Cody Division of Pfizer on the status of wrinkle removers. We were calling them drugs. Pfizer was maintaining they were cosmetics. Pfizer owned a Cody cosmetic line at that point. They still might; I'm not sure. So to resolve the issue, both sides kind of agreed to go to court. So Pfizer shipped a load of what was then called Line-A-Way to their Dover, Delaware, warehouse, and let us know the shipment was made. I went down to pick up the samples. Then I went back with the marshall a week later, and we seized the shipment, which they had sitting isolated, you know, for us to do. So it was a set-up deal for us to get into court to argue this, and we lost. The agency lost. It was considered a cosmetic. So that case is in the law books. I'm not mentioned unfortunately, but it's in the law books.

You know, we did the routine things all inspectors do, such as go down to the docks. Now they have import inspectors, but back in those days, we did all the import footwork. So we went down to the docks to sample things on import assignments, which was always fun going down to the docks.

RT: Did you have any kind of formal training as an inspector when you . . . ?

KF: Oh, it was basically on-the-job. You went out with the experienced inspectors to do various things that we do, and you begin on your own doing simple things--sampling assignments, and then simple inspections, and things of that nature. There were formal courses given by the agency, by the various districts, in various techniques, inspectional techniques, and quality control techniques. You have to inspect the quality control labs of firms. As a chemist I knew a lot of that, but it was helpful for other people certainly and for myself, too, to see some of the automation. So there were formal training courses of that nature. Drug inspectional work, there was, of course, the basic drug school and the advanced drug school that were run at universities.

RO: With a degree in chemistry, I'm curious why you went in as an inspector rather than as a chemist?

KF: It sounded more interesting.

RO: That's a good answer.

KF: I heard the resident inspector from our Harrisburg post when he came to our chemistry club to speak with us at the time I was deciding what I wanted to with myself, because I was a senior at that point. His presentation sounded very interesting, the work that he did. So I applied and luckily got the job, and I've never regretted it for a moment. No, I much preferred being an inspector, frankly. Even knowing now, looking back, I was much happier as an inspector than I would have been sitting in the lab as a bench chemist.

RO: There was always a little friendly competition between the chemists and inspectors. I came up on the other side of the house as a chemist. Who was the chief inspector when you joined?

KF: Jim Greene was the chief inspector of Philly, and Fred Lofsvold was the district director--both very fine gentleman. Fred Lofsvold was a real gentleman. He was a fine man.

RO: Yes, he was. How long were you in Philadelphia? Six years?

KF: I was in Philly for six years. My former supervisor in Philly was the chief inspector in New York, and he called me and asked if I wanted to come to New York as a drug expert inspector. So I went to New York for three years as one of the drug expert inspectors, and I did foreign inspections at that time. I did an around-the-world trip, twelve weeks around the world. Left New York, came back to New York. So it was a long time to live out of a suitcase, speaking foreign languages.

RT: Was Weems Clevenger the chief inspector then?

KF: Yes, Weems was the district director at that point. George Gerstenberg was chief inspector, and George was my former supervisor at Philly. He was also a former colleague working inspector. He was one of the senior inspectors when I went there.

JS: You must have had some interesting experiences on your around-the-world trip.

KF: Yes. Well, we went to Japan first. We were doing basically bulk inspection, bulk material. But Lederle was anticipating a strike here. So they were getting a few

of their foreign plants approved to do dosage forms. We were also doing some dosage form inspections of one of their plants in Japan and one in Formosa.

It was interesting, because I went there hopefully with an open mind. I knew very little about Far Eastern culture. It was quite a learning experience. I had a good time learning about Japan, its culture and history.

The inspections were fairly straight forward, I mean, other than the difficulties with the language barriers, of trying to make each other understood in rather broken English. And we had translators, too, with us from the companies.

RO: Charlie Wayne was there then I . . .

KF: As a matter of fact, I was on the trip with Charlie Wayne, an old-time inspector in New York. So it was a very interesting trip. Although, as I say, it got long. But we went all the way down to Australia and over into Europe and did a few things in Europe, including one in Warsaw while it was behind the Iron Curtain, which was interesting. Equipment was rather antiquated in Warsaw.

JS: Did you have trouble working with the government there, getting into problems?

KF: No, not really. The company, even though state-owned, was kind of run like another company. We dealt with the manager and the quality control people and the various production personnel, and dealt with them very much like you would any other company, made our recommendations. I don't think we had anything serious to deal with them on. I don't know what would have happened had we needed some major reconstructions or major equipment changes there.

Then I did a South America inspection on my own, down to Buenos Aires and Sao Paulo, Brazil. In the Brazilian one, we had a big problem with their batch

identifications, because they were separating the batch at the drying stage and never putting it back together again.

RO: Who was the firm?

KF: I think it was Wyeth. I think it was Wyeth's subsidiary. This was back in '68. Here you're supposed to, to make a batch, you take the dried stuff and put it all back together, blend it, then sample it for certification. There they were just keeping the separate drying trays separate and just sending in one sample, but that didn't represent the batches. So . . . And it took us a while, a lot of discussion back and forth until they finally understood what I meant by a batch, and until I understood what they meant as a batch. So it took a while to get back to them. But they did buy a big V shell blender and put the stuff back together again. So it was interesting.

RO: What prompted you to come into headquarters?

KF: I was getting bored in New York. All the major firms--or most of the major firms were leaving New York. I did the final inspection of Squibb before they moved to New Brunswick, and I did the final inspection of Burroughs Wellcome before they moved to North Carolina. So the only big firm left in New York was Pfizer, because the White Plains resident post was doing the Lederle plant and some other things up in Ardsley. So we were left with basically drug sampling and small, little generic houses, and I was frankly starting to get a little bored. So some openings came up down here, I applied, and I wanted to come down here anyway eventually. Luckily I got--and I say luckily--I got the job in advertising. Came down here in March of 1970 when the division was a year old.

There had been an advertising function in the new drug, I guess Marketed Drug section--what was the Division of Marketed Drugs back then. But it was not very effective. It was staffed by physicians mainly out of the Marketed Drug Division, and the reviews tended to be more medical treatises. You should have seen some of the reviews of ads. They were like two pages long and, you know, medical discussion. As a consequence, there was not a lot of activity on ads. And I guess that the agency began to look around for ways to deal with that at the center, what was then the bureau, and the function was moved from the Office of New Drugs to the Office of Compliance to give it a more compliance-oriented function. So it was moved into compliance and staffed with consumer safety officers. Mr. Chadduck was the first director of the Division of Drug Advertising.

JS: Do you recall his first name?

KF: Harry, Harry W. Chadduck. He was a former chief CSO (Consumer Safety Officer) in the advertising function when it was in marketed drugs under Dr. St. Raymond and some other individuals back then. The regulations had been rewritten. The first set of regulations were written in '64, I think, and I think went into effect in '65, but were not found to be terribly effective.

JS: Why is that?

KF: I don't know. I really don't. But they rewrote them in 1968. It was a joint venture between FDA and PMA (Pharmaceutical Manufacturers Association). Unlike most other regulations, the advertising regulations have to go through not just publishing for comment, but there's an opportunity for an actual evidentiary hearing. Interested parties can ask for a hearing, which really throws monkey wrenches into the

works, which is why advertising regulations are modified rarely and with great trepidation.

So as a way of avoiding, in effect, a lot of challenges, a deal was worked out whereby PMA and FDA would jointly write the regulations, would work together in a committee to write the regulations. Surprisingly, the regulations are very tough, very explicit, and not well liked by the industry. But they stuck by their deal, and they didn't raise comment, they didn't ask for a hearing. So the regulations were published, comments were received, minor modifications were made, and they were finalized in '68.

RO: That probably caused some of the delay from '62 up until '68.

KF: Well, there were regulations written and in effect in 1964 or '65.

RT: Well, did those go to a hearing?

KF: I don't know. I really don't. The agency was new in advertising back at that point, and the mid-sixties were basically involved with establishing the FDA's authority over advertising, notwithstanding the law, 502(n). You still have to go to court to convince people that you have the jurisdiction and also to get agency control over things that were not advertising--meaning detail pieces, file cards, exhibits and conventions, things of that nature. They're obviously not advertisements, and that's what 502(n) addresses; 502(n) says, "Advertisements will contain . . ." And, of course, an exhibit in an exhibit hall was not an advertisement, as the world understands advertisements. There's no definition of *advertisement* in the FD&C Act. That's one of the things that Congress forgot. I guess they said everybody knows what an advertisement is. So . . . But there's no definition of *advertisement* in the statute.

So the agency began to act upon things like file cards, and things of that nature as labels, labeling, accompanying labeling. Of course, the fight was: it doesn't accompany the drug, it can't be accompanying labeling. So that's what the court decisions were about, and then the court ruled, yes, it is accompanying. Anything that discusses the uses of the drug, provides information to the people who will utilize that information in the use of the drug becomes labeling.

So that's what the mid-sixties were involved with, establishing legal authorities and legal precedents, and then the new regulations came out in '68. So our major job in the early seventies was establishing the authority of the regulations and getting industry to know what the technical requirements were of the new regulations.

JS: I know the work of the committee and so on predates your involvement in advertising, but do you know the above-board working of the agency with industry, was that unusual?

KF: I think so. There were memos of all the meetings in the central files, because in 1971, Mr. Chaddock wrote an article called "In Brief Summary" about the regulations and about the history of advertising in the agency, and another gentleman, Mr. Wilham Purvis, who's the head of advertising unit in Biologics now, and I pulled the memos out the central files and read all those memos to write a synopsis for Harry. Unfortunately, we didn't make copies of those memos. So I don't know where those memos are, but they're in the old central file volumes that dealt with '67, '68 . . .

JS: They might be . . . They might be . . . Let's hope they're in the decimal files-- what we call the decimal files now, the old, the subject files of the agency. We'll have to look that up.

KF: They might be. But they were in big bound, you know, the big bound volumes that were not bound like a book, but the big jacketed volumes down in central files on the fourth floor. And I wish to heaven we had made copies of those when we pulled them out originally, but we didn't.

JS: But these are the documents that basically document deliberations of the FDA, PMA committee regarding these regs.

KF: Right, right. Yes.

JS: It seems like a pretty important development.

KF: Yes, that's why I wish we had made copies of them. But they did exist. Whether they're still there or not, or whether they've been microfiched, or whatever . . .

JS: Maybe PMA has some. (Laughter)

KF: PMA might have, yes. But they might have lost those deliberately, see, because they weren't too happy. They weren't happy with two sections of the regulations, which are called the *per se* sections, meaning they're violations which automatically make the advertisement misleading. There's one section, 21 C.F.R. 202.1(e)(6), which says the advertisement *is* misleading, and (e)(7) says the advertisement *may be* misleading, and the one contains twenty-some and the other eleven. I think there are thirty-three points in that *per se* section that the industry was not all that happy with, because they're very explicit, and they're very detailed. They tied the industry's hands a good bit on how they use data and graphs and statistics and studies and things of that

nature. So the regulations are very good and have not needed to be modified a great deal over the years.

JS: Interesting. The industry is unhappy with these, but industry through the PMA collaborated on them.

KF: They did not fight that. When I say unhappy, they were more rigid, I think, than the PMA hoped they would or would have liked them to be and maybe more explicit than they would have liked them to be, because people like mushy language. It gives you a little more wiggle room, and there's not a lot of wiggle room in those particular sections.

So one of our major jobs at that time were establishing the meaning of what some of these sections and the regulations did, the brief summary, the statements which refer to the location of the brief summary, the fact that the brief summary couldn't be separated from the body of the ad in any way. Those things are not explicit so much in the regulations, so they had to be worked out by our defining them and then adhering to those definitions rigidly, if you will, until the industry learned them and stopped fighting them. So we weren't quite as much involved in the more technical, medical aspects of ads as we might be now. The focus has changed more to scientific medical intricacies than with the more technical aspects of ad formats.

RO: Could you kind of briefly describe the process in the division there of reviewing advertising?

KF: Well, in the earlier days, we subscribed to fifty or sixty medical journals, and we would vary that subscription list year to year to get kind of a cross section with a core of the major journals remaining. They would be assigned randomly to the

reviewers, and we'd get a stack of magazines at our desk, and we'd look through them, you know, and read the ads. It was very good, and to some extent that's been lost, because we no longer do that. We simply don't have the time now. But it was very good, because it did several things. It gave you a real feel for what products were being advertised and advertised heavily. It gave you the real world, what the ads really did look like. It gave you medical background, because we would read articles. We would read some of the research articles, and where medicine was going, and things of that nature. So it kept us up to date on medical research, and medical science, and where things were going.

Also, as part of the regulations, any product under new drug application (NDA) is required to submit all advertising and promotional material to the agency. Not beforehand, not for preclearance, but at the time of use. So we had file cabinets full of stuff that came in.

Now we didn't look at that when it came in. Mr. Chadduck felt that we didn't really have the time to look at it all, and he felt that if we looked at any of it, it *de facto* said the ones we didn't look at were okay. I'm not sure we agreed with that--we, the working level--but that was his philosophy, so we didn't really look at those things, except maybe if you're working up a case or trying to work up a case we might go back and look at that stuff.

When Mr. Chadduck left in December of 1973, and Dr. Rheinstein came on board as director in March of '74, I was acting director for those three months. We began to work at FD2253 . . . Those things are submitted on what's called an FD2253, which is the coversheet form. So we began to look at the FD2253 submissions on a routine basis. We got stacks, I mean, literally stacks, of those things every couple of days. We began to look at all of the other promotional things, you know, the paperweights and note pads and pens and key chains and videotapes and wall clocks and

wrist watches. It's amazing the stuff that's disseminated. All those things had to come in; a copy of those things all had to come in to us.

So we began to look at this stuff on a more routine basis, which was good, because we did work up several cases. Under Dr. Rheinstein we had several seizures. We seized a Sandoz product called Sanorex for misleading labeling materials.

(Interruption)

KF: We had a major seizure of a Lederle product called Zorane, which was an oral contraceptive.

JS: What year was this?

KF: Nineteen seventy-five, I would say.

What happened was in January of '74 while I was acting director, right after Harry left, an ad appeared in the journals for Zorane, which was a new oral contraceptive that Lederle marketed. They purchased marketing rights from Parke-Davis. And the advertisement was violative. So we wrote the letter objecting to it, and we had a remedial advertisement run. Corrective advertising was kind of pioneered by Harry in our division. The ad would run and we would pick out something in the ad as a visual reminder, and we'd use that in the corrective ad.

One of the first major ones was for a Sandoz product. Was that Sanorex also? It might have been. No, Serental. It was an anti-anxiety drug. The ad showed a puzzle, and one of the pieces was misshapen, it didn't fit, and that was a lady's face. The ad said, "For the anxiety of not fitting in." You know, you're new in the neighborhood, et cetera, et cetera. So the division acted upon that, called it a violative ad, and we had a remedial ad run. The remedial ad used a puzzle background as the

visual reminder of the former ad, and then gave what we objected to and what we felt the truth was. So that became kind of a pioneer of remedial advertising.

So we did the similar thing with Zorane. I mean, there were several remedials subsequent to the Serental ad, and then we had the Zorane corrective ad run. That ran I guess in March of '64.

RO: Seventy-four.

KF: Seventy-four, excuse me, the remedial. Peter Rheinstein came on board in March. In June of that year, one of the reviewers came to me and said, "Didn't we have this ad canceled?" I looked at it and said, "Yes, that must be an old magazine." No, it was a new magazine. So we looked at the ad. Here it was a new Zorane ad that looked almost identical to the one that we had objected to before. So Peter decided we should do more than another letter. We worked up the case. We had samples picked up, instituted a seizure action, and just by dumb luck, when the marshall went to seize it up in New York, Lederle had just received a whole shipment, millions of dollars worth. I think it was \$13 million worth from Puerto Rico, all interstate commerce. So the marshall seized the whole bit. The seizure totally destroyed the drug. Lederle never marketed Zorane again. We totally destroyed the drug.

But they had to run another remedial campaign, "Dear Dr." letters to every physician. The remedial campaign cost them millions of dollars. We were arguing with Lederle on another product at that time, and they caved in on that product, too, and did a remedial ad on that product and a "Dear Dr." letter--that was on Minocin--to all physicians. So that whole incident cost them quite a few million dollars, more than we ever got on fines, and luckily Lederle was good as gold for quite a number of years after that.

But those were some of the things that we were involved in at that point. We haven't had many legal actions. We haven't had to. The industry has pretty much gone along. I mean, they fight us, and they might resist a little bit, and try our patience, but ultimately they usually change their ways and do what we want them to.

JS: At this time, were you approached by firms in advance of an advertising campaign to, you know, give a look at the ad and see what you think. Not preapproval, mind you, which I assume we did not do. But did we ever give them advice in advance.

KF: Yes, not so much under Harry. Mr. Chaddock was rather close-vested. He didn't reach out to the industry much. Dr. Rheinstein was more open and involved us in more meetings with the industry. We would go out to conventions and review exhibits. We began to give speeches, which we never did under Mr. Chaddock, and we became more open. So as a consequence, the industry came to us with proposed ads, which they never did before, and had us look at ads before they ran. We can't require that. As a matter of fact, the statute says we can't require it. There's an actual statement in the law that we cannot require preclearance, except under very extraordinary circumstances which are spelled out in the regulations.

Around . . . In the mid-seventies, the division was moved from Compliance back into New Drugs, and Dr. Finkel was the head of New Drugs at that point. But I think . . . Yes, she was the head of the new drug evaluation unit at that time. She instituted a program where, for about-to-be-approved drugs, for totally new products and for major new indications for old drugs, for older drugs, we requested that the company submit their proposed launch advertising materials to us--and that was a request, although it was honored virtually universally. So we got into the business then of looking at launch campaigns, because it's felt that the initial advertising campaign is

the one that sets the tone for the drug. It's new, the doctors don't know anything about the drug, so it's the one that sets the impressions of what they know about the drug and think about the drug. So we got into the business of looking at launch campaigns, and that program expanded over the years. Until now virtually every about-to-be-approved NDA or generic or whatever, the request is there, and it's honored almost exclusively. So probably 50 percent or more of the time of the division is spent looking at launch campaigns now prior to their being issued.

RO: At one time, though, you didn't look at those promotional. I thought you said once that they were required, but you didn't look at them.

KF: Those are after the fact. There is a requirement that all promotional materials be submitted at the time of use. That is a requirement, and failure to submit that is a violation, which we can act upon and have. Not as a sole violation, but as part of a broader case. But this new program is voluntary before the campaigns are run. So now virtually every launch campaign is looked at by the agency.

JS: Just as an aside, does that material that's sent in with the new drug application become part of the NDA?

KF: Yes, technically. The submissions on the FD2253 form are also part of the NDA, but they're a portion that my division holds--my *former* division holds. The launch campaigns are submitted both to us and the New Drug Division. So technically it becomes part of the NDA. It is not an official NDA submission, because it's a voluntary submission. We can't mandate it. So it becomes an unofficial part of the correspondence files, and my division takes the lead on dealing with the company for the most part. But we work very closely with the New Drug Review Division in

discussions. Our people are now getting involved more in labeling meetings, as the labeling is being devised, and various of the other scientific medical meetings that are held with the company so we have a feel for what the science is, for what the studies support. It's a lot easier to look at the promotional material if you know what the science actually supports, not what the company wishes it would support.

So the division has changed considerably over these twenty-five years or more from rather technical aspects of advertising to much more esoteric things of hidden meanings, of implications, of trying to broaden the medical scope of the drugs, the patient populations, things of that nature.

RT: Has the staff increased substantially then over that time?

KF: Yes. Well, up until '91, the staff consisted of about four to five consumer safety officers, and I was acting director from '85 to '91--'86 to '91. When Dr. Kessler came in, he was interested in advertising, and the advertising unit was increased to fourteen reviewers and a total staff of twenty-six, I think, which is about what it has now.

RT: So apparently it was rather static in size until Dr. Kessler became commissioner?

KF: Yes, it was. Well, under Mr. Chadduck, there were four consumer safety officers, and when I was acting director, I had five consumer safety officers working for me. So, yes, the division stayed fairly constant, and the personnel was very experienced, because people didn't leave. It was a good place to work. It was interesting. Its function was different than what the agency's--especially headquarters'--functions are. We didn't just see little pieces of a pie. The division did everything. We would read the ad, determine the violation, work up the violation, write the letter to the company, deal with the company, deal with any revisions, corrections,

modifications, finalize the case, and if it involved legal action, we'd even start to work up the legal action. We would write the memos to the field districts for sampling, work with the general counsel working up the libels of information. So it was really an interesting place to work, and you got to do everything. That was great.

JS: Fascinating, considering how advertising increased, just the volume increase from 1970 to 1991, and yet your staff was basically the same size. You must have been overworked.

KF: We were that. We had more than we could do, that's for sure. I think we were fairly effective, because we . . . People kind of ignored us within the agency. We functioned out here, and what we did was kind of black magic, I think, to most of the people in the agency. So we got things turned around pretty quickly, and the industry got to rely on us as being fair and even-handed and hopefully, you know, tough, but fair. At least that's what we tried to be all the time, and I think we developed a pretty good reputation around the industry as being fair and even-handed and fairly effective. I did a lot of speeches when I was acting director. I guess I did eighty-five or so speeches to various groups around the country.

So we had a lot of visibility. For a small unit, the agency has always had a lot of visibility publicly, at least within the industry and the allied fields. So it has always been a good place to work, which is one reason I never really sought to leave, because I didn't see anything any more interesting than what I was doing.

RO: The first choice of action was a remedial ad, is that correct? If you found an advertisement . . . ?

KF: The first action . . . We had kind of an unofficial escalation. If we saw a violative ad, we would write a letter to the company saying, "We consider the ad violative for these reasons. Please stop it." We might say, "Next time change it to account for these points." If the company had a history with us of not being very dependable, we might ask to see their proposed next version.

If it was a more serious violation or if it was a repeat violation or a recidivist firm, then we might ask for a remedial campaign, both an advertisement and a "Dear Dr." letter, because the campaign usually ran across the whole spectrum of the advertising media.

If that didn't work or if it was more serious or if they had already run a remedial campaign, then we might go for potential legal action. It usually never got that far, because the companies would do what we wanted. They didn't want to go through the hassle of a legal battle with the agency over advertising. By the time you see the ad, work it up, do the actions, two or three months have gone by. No matter how fast you work, they would have gotten two, three, four months use out of the ad, which is all they usually get anyway. You know, most ads are changed every three to six months. So it was no big deal for them to stop that ad and come out with a new one for the most part, which is why we went to remedial ads if it was a serious, if it was a medical question. We reserved remedial ads for medical questions. We would never have a remedial ad run for one of the more technical aspects of things. It was used if we felt it was medically misleading that had potential for injury to patients, if the drug were misused. So remedials were basically for medical problems rather than technical violations of the regulations.

JS: Did you have any special problems with Bristol labs in Syracuse?

KF: Let's say they were one of our more familiar firms. Yes, we had a problem with salespeople. I guess that was in the mid-seventies. We began to get complaints from physicians about letters that they were getting from Bristol salespeople. We began to get collections of these things from the doctors, and we noticed that even though the letters were typed on different typewriters, had different names, and different letterheads, the body of the letter was remarkably the same, in fact identical, which led us to think that perhaps the master came out of headquarters in Syracuse. So we wrote the company a letter objecting to it, and, of course, they came in and volubly said, "No, we didn't do that, but we won't do it again." (Laughter) And they came up with, "Well, we can't really control our sales force." We said, "Well, you had better. They work for you. So fire a couple of these people if they're out of control."

That was one of the first times that we got involved with detail people and what, at least by all common sense, were headquarters directed efforts that were kind of hidden as individual actions of salespeople, if you will. They like to hide behind the fact, "Well, that's his fault. He did that." You know, the rogue salesman kind of idea. Well, if you get rogue salesmen all over the country, they're no longer rogues. Something's going on. We will accept the fact that an overzealous sales rep might do something, you know. But if it becomes nationwide and dozens of them all over the country, then it's no longer a rogue or overzealousness; that's a company directed effort. So that was one of the times we got involved with them.

We also got involved in the seventies with . . . Advertising began to change from the traditional aspects of ads in magazines and detail pieces, which still exist. That's one of those things they don't want to stop, but it began to shift more into multi-media type of things, TV and other forms of promotion, hiding it more, concealing it more as a scientific activity, scientific medical activity, educational activity, than a promotional activity.

A company called Health Learning Systems was formed in New Jersey, and it was formed by two former sales reps of Roche, and they got the idea to produce multi-media educational programs for CME (Continuing Medical Education) credit. Of course, sponsored and paid for by companies. They wanted to sell this idea to the industry. To make it viable, they came into us to work out with us the ways to do this. When we came up with a system that they could use, a program that they could use, which would, at least in our view, assure independence of the editorial content from the sponsoring firm . . . We understand the realities of the world, too, but it certainly lent itself to having an independence. So they came out with these programs. Health Learning Systems became one of the pioneers in multi-media educational programs. That was closed-circuit TV roundtable discussion, workbooks sent out monthly that dealt with those programs, test questions, answer sheet sent into a university for grading and for CME credit. So they were pioneers in that field, and they worked out that whole process with us ahead of time.

Another interesting thing in the early eighties, consumer advertising began to pick up, and Dr. Art Ulene who is on NBC TV, got the idea for a cable network of health and medical information called Cable Health Network. So Art came in to discuss with us how to do programming on his proposed network with industry funding. They had a program on Sundays that they wanted to run that would be doctor oriented, funded by ads for R drugs. One of the difficulties, one of the impossibilities for R ads on TV is the brief summary information. To broadcast that information takes minutes, so we had to try to work out some format--we didn't have to, but we did--work out some format whereby these ads could run and the brief summary information could be provided in a somewhat different form to make the ads viable and to make his programming viable. So that kind of set the stage for what currently exists in the field of R ads on TV. Those procedures were worked out with Art for his cable network, which is now Lifetime by the way. Cable Health Network was sold and became

Lifetime Network. Of course, they've switched from medical programming to other kinds of programming, but that's where Lifetime originated.

JS: You were talking about changes and trends in advertising in the 1970s, and you mentioned the rise of scientific meetings and their role in advertising, getting information to practitioners, that sort of thing, one, and the rise of video, the problem of dealing with advertising in a broadcast format, which is very difficult. Did the rise of the generic drugs and their role in therapy have any special advertising impact?

KF: Yes, in a very . . . I'd say in a very subtle way, but perhaps not so subtle. One of the things that was notable about the pharmaceutical industry and its advertising and promotion was the industry had a lock on the market. In other words, you came out with a new cardiac drug. You basically had the lock on that drug for a dozen years. So you didn't have to be so aggressive in your advertising, and you could lay back and be a little more laid back in your advertising schemes. That changed with two developments. One was the increased speed of NDA review, and the competition within the field of new drugs, as new drugs began to appear. I mean, you came out with your new cardiac drug and he came out with his six months later. Plus, now generic competition coming into what were well-established old products that were kind of cash cows, you know. You had little outgo other than production costs, but you were getting lots of money in because of the sales. Now they were threatened by the generic competition.

So, as a consequence, the market life of your product shrank from a dozen years to maybe three years or less. I mean, the real viable market life. So you had to start to recoup your money quickly. There are several ways to do that. One is to get the acceptance curve rapid, as opposed to the kind of a slow acceptance that took several

years to get your product well accepted or well used. You wanted it to shoot up right away as soon as it hit the market.

You do that by seeding the market. You do that by letting doctors know what's coming, letting them know what the research is, how wonderful the product is, and how everybody will just fall over themselves when this product gets out there. You do that by scientific meetings. You do that by seminars, by workshops, by peer influence groups. All communities have leaders in the various fields, medical fields, that other doctors look up to within their community. You approach those people, get them involved in it, so they can spread the word to their colleagues, and it's a way of getting the product accepted rapidly and get your market life extended. You hit the ground running with your product. So that's where these scientific meetings and other newer ways that industry is spending their money have come from, and what the hope is, what that is supposed to do in the marketing field.

Also, all of us are used to ads. These are some things that I learned from Dr. Morris when his group joined our group--Dr. Lou Morris. He's a Ph.D. psychologist and a marketing expert. He teaches some marketing courses, and the people on his staff are similarly trained. There's a credibility factor. We all see ads. In fact, we are so used to seeing ads that we don't see them. We don't even pay attention to them for the most part.

They need something to get your attention, so that's why certain things were done in ads to make them stand out over other ads. For instance, a couple years ago there was a lot of fuzzy focus ads being run on TV or ads where the shot was like up at your knees or something. You saw these knees walking around. Well, it was so unusual you paid attention to it. That was the reason for it. It's not that they were bad ads; it's just that these out of focus things and these knees walking around were so unusual in the commercials that you saw, you paid attention to them.

But because we are so used to seeing ads we have our defenses. So as soon as you know something is an ad . . . I mean, a Ford ad will say, "We have wonderful engineering. Our cars are well engineered." But you know Ford is putting their best foot forward, and it's paid for by Ford. Obviously they're going to say nice things about Fords, so you tend to discount what the ad is saying. If a program came on with a noted engineer, and he began to speak about automotive engineering and this kind of testing and that kind of testing, and the Ford Motor Company is a leader in this kind of thing, and they do this testing and that testing, you tend to believe it. Your defenses about advertising go down, and you begin to accept what this individual is saying to you much more readily. Now, you don't know that this guy was paid for by Ford. So as a consequence, you don't know you're listening to an advertisement, in effect, and that's where these scientific meetings come in in promotion.

You go to a scientific meeting, you go to a medical meeting, and there are four or five doctors up there discussing the drug, roundtable discussion, and you don't know that those guys are on the payroll of the company. You didn't know. So one of the things the agency is doing now is making sure that in these scientific programs the funding of the program is well known, the company funding it is well known, and any affiliations of the speakers in the program with companies is known in the program. They have to list who they're affiliated with, what their level of affiliation with the sponsoring company might be in a way of letting you know that, well, this guy might not be unbiased. You know, he's being paid for by the company whose drug he is talking about. So what he's saying, I've got to take with a grain of salt. It doesn't mean he's lying, but you just are not as accepting of his statements at face value as you might be . . .

(Interruption)

KF: If Dr. DeBakey of Houston Heart Clinic says something about a new cardiac drug or a cardiac replacement valve, you will probably accept it because you know who Dr. DeBakey is. But if you knew that Dr. DeBakey was there representing heart valve manufacturing company "X," and what he's saying about heart valve "X," you might question or you might be not as accepting of his statements about the heart valve, because you know he's being paid to be there, to say that, by the company. It doesn't mean what he's saying is wrong. It's just that your credibility level is altered, and your perception of their message is altered knowing their involvement with the person with the vested interest in that message.

JS: If a person in an academic institution might not be getting funding to go to this particular meeting from the company, but his or her research in the past has been funded by this company, would that need to be revealed as well?

KF: Yes, that's usually revealed in that the past involvement with this particular scientist with the company was as a researcher for them. That's all just to give what we call a full disclosure of your involvement with the particular companies. That's not to say that that's somehow unethical or bad or means the message is wrong or a lie. It's just that it alters you, the viewer, you, the receiver of the information. It alters your perception so that you're not as credulous. It changes your value judgment of what they're saying, which is why they're trying to hide a lot of these things if they can. It isn't always . . .

JS: I guess it's not always in the format of scientific meetings. Wasn't there a case of a famous baseball player who we realized was being compensated by a firm for Voltaren?

KF: Mickey Mantle, sure. Well, that was Voltaren, Ciba Geigy, for their arthritic drug. I mean that's more consumer oriented, but the same kind of credibility factors are involved. Mickey Mantle, well-known sports hero, idol to millions, especially millions who remember him when he was young and they were young. They're arthritic now, and here's their childhood hero telling them about this wonderful drug that saved him from being a cripple and allowed him to play golf again.

RT: What was that drug again?

KF: Voltaren. This is common practice, I mean, getting paid spokespeople. But now it's becoming known. I mean, people have to say now that they are a paid spokesman for the company. It was very subtle some of the things that Mickey did. He was the color commentator for a baseball game one time, and as one guy was running from home plate to first base, he said something about how on this new drug I could run that fast. Of course, the other guy says, "What new drug?" Mickey Mantle says, "This drug Voltaren."

So it's that kind of subtle messages that are being conveyed. I think the FTC (Federal Trade Commission) now requires that people who are paid spokesmen say so. And on infomercials now, the FTC requires that at the beginning, at the end, and every time a product is pitched, you have to say that this is a paid commercial program, paid for by the manufacturer or sponsor of the product.

JS: Was Voltaren prescription or over-the-counter?

KF: A prescription drug. So that again, his statements were not technically ads. The agency's jurisdiction over something like that is not clear. Technically he is an agent for the company, and technically the company is responsible for what he say. Are they

advertisements? That point has not been argued out. Neither side has been willing to fight that kind of thing, I don't think, because it's really a gray area and really beginning to tread on some of the First Amendment kinds of protections.

RO: Were you ever asked to look at the accuracy of some of the competitive advertising? You know, like company A asks you to look, well, what's B saying about our . . . ?

KF: Oh, sure. Yes, we got lots of complaints.

RO: What did you do about them?

KF: Review it, see if they're right. If they're right, take action. If they're not right, say, "Sorry." The fact that a company is being hurt in the marketplace is not our concern. But if the company, if the competing product is being advertised in a misleading way, that is our concern. And quite honestly, we don't object to complaints because they were helpful, because we don't get to see everything. We simply don't have time to look at everything, so something might slip by us. Certain kinds of advertising, such as letters that a detail person writes, aren't submitted to us. Now, maybe they should be in a real strict reading of the regulation, but there's no way for us to know that sales rep "X" has written a letter to Dr. Jones.

So we get those kinds of complaints in, especially homemade stuff. Sales reps are famous for making up things themselves, especially now with computers and Print Shop, and, you know, graphics programs that we all have on our computers. You can make up some pretty fancy stuff on your computer at home. We get those things in a complaint. It's a way that we get to see some of these things that we have no other way of knowing about.

We get to hear about meetings, what was said at a certain scientific meeting or a convention that we couldn't get to. Obviously, we can't get to all the conventions that are out there or attend all of the programs that are going on. So complaints are a useful source of things that we don't have routine access to and alert us to certain things that are going on.

RO: Do you monitor Internet?

KF: Yes. Obviously not perhaps as much as we'd like to, but we are . . . All the reviewers have access to Internet at their desks, and the various home pages and things are looked at periodically, and we've written some letters objecting to certain ads and messages on company home pages.

JS: There's another format for advertising that you talked about in your speech to the pharmacy group, and I wondered if you'd just say a little bit about tabloid publications and their role in getting the message across maybe in a subtle way.

KF: Well, this is something else that came to our attention more when Dr. Rheinstein first came on board. One of the definitions of labeling within the regulations deals with house organs. A house organ is a company publication. The company masthead is on it, and the company is responsible for it. If that particular publication discusses a drug, then it becomes labeling for that company's product or for that product. So we began to see sole-sponsored publications.

The one that I mentioned in the meeting was *Urology News*, and it was a tabloid form newspaper sponsored by Roche in this case, and all of the articles in the publication dealt with urology: you know, bladder infections and urological conditions, both surgical and medical, male and female. So we looked at it and said, "Well, gee,

this is sole-sponsored by Roche; it's a house organ. It's a Roche publication." Therefore, all the messages in there concerning company drugs can be regulated as labeling, and as such, they would be violative, because they were lacking certain things, if not medically violative.

So we wrote to Roche about it, and, of course, they denied that it was house organ, that they had no control over the editorial content of this publication. All they did was sponsor it. The publisher came in rapidly to deny that it was labeling, that they had editorial control over this publication. So once again we kind of worked with a publishers group to work out some ground rules of independence for sole-sponsored publications, of which there are quite a number now. They run the gamut from some very good publications that you'd be hard pressed to say were influenced by the sponsoring company to ones that you'd laugh if anybody said they were independent.

One or two particular cases . . . The one I mentioned in that talk, was one that Syntex funded, and I think that was called *Allergy News*. Well, the interesting thing about these publications is oftentimes you see Volume I, Number 1, but you never see Volume I, Number 2. We looked at this *Allergy News* publication, and it was sponsored by Syntex, and I counted the number of articles. There were thirteen articles in this tabloid. It was a four-page tabloid. There were thirteen articles, eleven of the articles dealt with Syntex products or medical conditions amenable to Syntex drugs, that were indicated for allergy drugs. I think the other two articles could be almost interpreted that way. So the whole publication was devoted to things for Syntex products.

We wrote back and said, "You've got to be kidding. This ain't about allergy; this is about Syntex products. Therefore, it's violative." Well, they denied that, but they stopped funding the publication, and I never saw another *Allergy News*.

So there are ways that we can deal with some of those things by just common sense. You know, looking at the articles in them and saying either the company has

influenced the content or the publisher is so sensitive to the interests of their sponsor that they unwittingly bend over backwards to say nice things and include all good things about their sponsor's products." Either way, it's not good and needs to be dealt with. So that's what we do with those things.

JS: Do we ever have concerns about even third party publications that might have multiple sponsorship?

KF: There's nothing we can do about it. For example, *Medical World News* is called a throwaway, and *Medical World News* is paid for entirely by advertising within it. Now we know for a fact--and I know because some people have told me this--that if they're going to run an article, let's say they're going to run an article on a cardiovascular drug, they will call the manufacturer of that drug and say, "Do you want your ad next to this article?" Now, *Medical World News* will violently deny that if you were to ask them that. If you were to write them a letter saying that, they would deny that and in fact have denied that. But we know it goes on, but there's nothing we can do about it. I mean, it's an independent publication. There's no way that we can say they're controlled by the sponsors, and they're not unique in that field. I mean, that kind of thing is not unusual in the field of publication where publishers want to be nice to the people who are, you know, sticking ads in their journals.

So, yes, there are obviously some concerns, but there's only so far the agency can go because there is . . . Even though most people or a lot of people don't believe it, we do know what the First Amendment is, and we do pay attention to it and know there is only so far we can go and should go.

So we've been on kind of the cutting edge of some of this stuff, and it's an interesting field. Computers are another field. You mentioned the Internet, but there are other computer programs that have been funded by and contained advertisements

for R drugs that we've gotten involved in, in how to format the ads, how to carry the information, how to make sure a firm can't circumvent the required information by hot keying around it. We've learned a lot about various aspects of advertising and the technical aspects of dealing with those media. I now know what story boards are and how to time commercials and all kinds of stuff.

RT: Well, videocassettes are used quite a bit, aren't they?

KF: Yes, yes.

RT: You mentioned closed-circuit TV, but videocassettes are also used.

KF: Yes.

RT: How can you monitor those? Do they submit these?

KF: If they are disseminated by the company in any form, they have to be submitted as a promotional piece. So we get those in and look at those. We have VCRs and TVs up there. The reviewers sit down, stick them in, and sit back and listen to it. Unfortunately, you have to do it real time. There's no way to skim through a fifteen-minute videotape or a half-hour videotape. So . . . But, yes, we look at those things.

They're easier to deal with the technical aspects, because you just throw a package insert in the video cassette box. It's much more difficult to deal with those kinds of things on air.

JS: I don't know if this is a change more with the 1980s; you can tell us more about it. But I know this has been a regulatory concern for the agency, and that is the

advertising of prescription drugs directly to consumers. How had and has this been a concern to the agency? And are there some cases? You mentioned, for example, the famous ad that sort of refocused our attention on these ads involving a so-called Delores ad.

KF: Yes, well, in the early eighties, the industry became interested in addressing consumers. We talked about product acceptance. Another way to get your product accepted fast is to have your patients ask the doctors about them. So you have to go to patients, to the potential patients with your message so they know about the drug, and will ask their doctor when they go to see him. One way to do that is with advertising.

One of the problems . . . One of the very great difficulties with running an R ad on TV, open-broadcast TV, is how to deal with the brief summary information. One of the requirements of the statute, 502(n), which is different from other products being advertised, is you must have information about effectiveness, contraindications, and side effects, and the statute says in brief summary. A true statement of information about those things in brief summary.

Now, as I said, ads for Ford don't have brief summaries that give the repair rate, the breakdown rate, the number of people killed in accidents, you know. R drugs have to have this information about side effects, contraindications, and a true statement about effectiveness. As the labeling has gotten larger, that has gotten more difficult to deal with. Originally it was hoped that this information . . . When the '68 regs were passed, it was hoped that this information would be incorporated into the body of the ad. It talks about a separate section, but that's what was hoped. Well, that's too difficult to do, because you've got to change it all the time. It's a new ad. So it's easier to have a separate section.

Besides that, as the labeling has gotten longer, and if you looked at a label from 1970 and look at a label from 1996, vastly different, much more information. The

amount of information required has just gotten so much that a brief summary's no longer brief. We have kind of an "in" joke, and it's been picked up by other people now and used, that a brief summary is neither brief nor a summary.

So as a consequence, as I said, on Lifetime, when they ran R ads on Lifetime in this doctor-oriented program, they would scroll the brief summaries at a certain point--not at the time the ad ran, but some other time. It took anywhere from eight to ten minutes to scroll a brief summary at a barely readable speed. Now there's absolutely no way you can do that with open-broadcast TV, because it's too expensive. No one is going to pay for ten minutes of time to run a brief summary. Secondly, no one is going to watch it. You're going to turn off of Law & Order and go watch L.A. Law or something, and the networks know that. So they would never sell that kind of time for what they would consider dead air.

So the very difficult thing for running ads on TV is that brief summary information. The regulation provides for broadcast ads that this information can be provided to the viewers at the time of showing. It does not have to be with the ad, unlike a print ad. It would have to be with the print ad. On TV, on a broadcast, it can be separated.

So how do you do that? Well, with the doctors' programs, with the closed-circuit or with the nature of the doctors' programs, it was there as a scroll. Some of the computer programs, you know who the doctors are, so you can send them the stuff. You know, it's easier to deal with. Open-broadcast TV, there's no way to do it. We thought of lots of ways. People have suggested, well, how about *T.V. Guide*? Fine, but not everybody gets a *T.V. Guide*. How about such and such? Well, not everybody gets such and such. Not everybody gets *Time Magazine* or . . . You know, there's virtually no way to ensure that every viewer of the broadcast ad will get the brief summary information, the required brief summary information, unless it's with the ad itself, and you can't do that on open-broadcast TV.

So that's the hang-up on open-broadcast TV. And the reason I say "required" is because the regulation is written to say that the brief summary has to have every side effect, adverse reaction idea. Not necessarily every one, but all the ideas. We have thought and we have suggested that that word "every" be removed from the regulation. That would then give us flexibility and the industry flexibility to determine the important information that needs to be there. What has happened is at the agency we know that the medical doctors writing the labeling feel that all the information in that labeling is a vital information. The problem is in an advertising format it is so much information it's just overload, and then, therefore, the really important stuff that people really should hear is being buried in this mass of information that you would only get if you're going to sit there and read all that fine print, which no one does anymore.

So we'd even like to have the flexibility for print media to get rid of this huge mass of information. It now takes up to a page, a page and a half of very fine print. If you get *T.V. Guide*, look at it. There are R ads in *T.V. Guide*. Look at them. There's one page of ad, and three to four pages of brief summary information. No one's going to read it. It's useless; we know it. Our own research has told us that, but we can't do anything about it, because the regulation says *every* idea. We'd like to change it, but we know if we propose to change it, people in the agency, it will open the doors to R ads on TV, and people in the agency don't want to see R ads on TV. The commissioner--the former commissioner--for one.

RO: But we have R ads on TV.

KF: No, we don't. You have reminder ads on TV that don't say what the drug does, and you have medical things that say, "If you have hypertension, go talk to your doctor." But you don't have an ad that says, "If you have hypertension, take 'such and such.'"

RT: I think you had in mind, mentioning Rogaine. That seems to be one. At first when I saw that ad I wondered, well, what's it for? "See your doctor." It's kind of provocative in that respect.

KF: Well, that's what we were hoping. Those ads are criticized because research finds out that people want to know what the product is. They don't want to guess; they don't want to go to their doctor to find out, even though they know they might have to go to him to get it. They want to know what the drug is. There's a TV commercial for Allegra. Well, what's Allegra for? They can't say what it's for, because that triggers the brief summary information, and those ads, while they are provocative, they're not really as useful in an informational sense or for a commercial sense than they could be. So . . . But we're locked with this requirement of what has to be in a brief summary.

But the division has been reluctant to propose changing it because of the feeling within the agency against R ads on TV, and this would certainly open the floodgates to those if we modified the reg. But we're going to have to eventually. I mean, it's just inevitable. The pressure's too much. Our own understanding of how useless the current brief summary is in a real informational sense, as intended originally by the statute, and we just have to do something about it sooner or later.

RO: Well, there's an ad for Claritin that surely seems to me to be more than a reminder ad. That thing is really . . .

KF: It's isn't, though.

RO: What?

KF: It isn't.

RO: It's just a reminder ad?

KF: See, a reminder ad can't . . . A lot of people think a reminder ad can only say the name of the drug, you know, Claritin, end. But there can be other stuff involved with it. As long as you don't make any representations about what the drug is used for or its dosage, you can say a lot of things in that ad, and they do. You know, art work that gets your attention and other things. And we have done some research to find out, like on that ad especially, because there was feeling in-house, does that really convey some information about what Claritin is used for? So we actually did some research, and, no, it doesn't. The problem is we, sitting in here, know what these drugs are for. As a consequence, we read into it what we know. We forget that the people out there don't know what that drug is used for--in the main.

Now, something like Rogaine, once it gets such notoriety, everybody knows what Rogaine's for, and in effect, a reminder ad really is supposed to remind you that this product is out there. That's what the purpose of a reminder ad is for. So we sometimes question why there should be reminder ads for R drugs when the consumer doesn't know what that drug is good for. It can't remind them. But the regulation's there, we're stuck with it, we have to use it, and it's a way the industry can get their information out without the brief summary information. Like the Allegra, the guy windsurfing through the field of wheat, which I think is a wonderful ad, and we tested that one too to see if that conveyed information about allergies.

Well, we had some Midwesterners on staff who are used to allergic reactions from wheat . . .

KF: Yes, but that's what I said. But we tested it, and it doesn't convey allergy. So we have to be careful that we don't read into things that don't really exist, that we're not misreading, that we're not being too rigid, and over-interpreting in effect.

(Interruption)

KF: Consumer advertising is probably the coming big thing, because the pressure for it is just so great from lots of sources, not just the industry. I mean, the consumers want more information about drugs and availability of them and information about them. So there's a lot of pressure from a lot of different sources for . . . And there's even a lot of pressure from the First Amendment kind of side, you know. Are we de facto banning advertising by certain rigidity of interpretations. So I think that's going to be the coming thing in the next couple years.

RO: You mentioned Dr. Kessler and his interest in advertising. You served under a number of different commissioners during that period of time. Did you notice any difference in the interest of the various commissioners?

KF: None of them were as interested as Dr. Kessler in the overall impact of advertising, I think, as Dr. Kessler was, and his feeling that advertising was kind of out of hand, which is why he enlarged our staff. And he was also interested in enforcement, so he was urging us to be more enforcement minded, which I'm not sure we were or weren't before, but I didn't have the staff to do some of the stuff that he wanted done--before, that he would have wanted.

None of the previous commissioners paid attention to advertising as a universal thing. If something was brought to their attention, you know, they got involved, and they were very interested. Dr. Hayes was interested in advertising. He was involved with the Delores ad and the beginnings of consumer advertising, at least as far as the agency was concerned. He was one of the more active members. I think he's the one that put the moratorium on advertising for a certain time.

JS: Why was that?

KF: Well, the interest in advertising began in like '82 really, and a number of companies came in to discuss ads with us, one of which was the famous Delores ad. That was kind of the final straw.

For those of you who might not have heard that discussion, this was Ciba Geigy again, who were really interested, really pushing consumer advertising back at that point. They came in with a proposed commercial for one of their hypertensives, and one of the supposed benefits of this anti-hypertensive drug was that it didn't cause impotence the way other hypertensive drugs did--anti-hypertensive drugs. So they had this commercial with two obviously middle-aged kinds of guys, and I thought it was on a tennis court, one of my people thought it was at a beach, but nonetheless, it was an active setting.

The one gentleman was speaking to the other about this drug that he was just put on, how wonderful it was, and how he could remain active, and it didn't interfere with his lifestyle, et cetera, et cetera, and, of course, up to him walks this very lovely young lady dressed in a bathing suit or a tennis outfit, something that made her obvious charms noticeable, and it was his new wife. So the hidden message, of course, was the fact that it didn't make him impotent.

Well, this commercial just . . . Dr. Hayes just hit the ceiling when he saw that, because the fear . . . The fear among many people in the agency is advertising on TV will tend to trivialize the importance and the dangerous nature of R drugs. The reason they're R is because (a) the conditions can't be easily diagnosed, and (b) the drugs are dangerous for a lot of indiscriminate use. So there's a feeling that it will tend to trivialize some of the important aspects of the dangerousness of R drugs and their serious nature. Of course, this ad went right along with that, this kind of sexist, frivolous kind of ad. So Dr. Hayes felt that it was time to take a step back, and he

issued a *Federal Register* statement asking for a voluntary moratorium on all consumer advertising.

JS: Do you know when this was issued roughly?

KF: Nineteen eighty-three, I think, it was issued. Except for actual price advertising, which would give the consumer information on the price of a drug which were then reminder kinds of ads, all consumer advertising was to be stopped. This was not an order; he couldn't order it. It was just a request for a voluntary moratorium, and it worked. Nobody advertised, and it gave the industry time to do some research that we wanted done. It gave us time to do some research, and we began to look at various aspects of brief summaries, and how they're read, and how best to deal with some of this information. At the end of that time, I think in 1985 or '86, Dr. Hayes lifted the moratorium with the point that it was --or whoever succeeded Dr. Hayes--that we had studied it, we felt our current regulations were sufficient, and we could deal the problem using the current regulations at this point, and therefore the moratorium was lifted.

So those were some of the dealings that we had in the eighties. Of course, advertising picked up slowly from that point until now. There's quite a number of the reminder kinds of ads and a lot of print media ads running. I mean, every Sunday in the *Parade Magazine* there are three or four $\$$ ads in there. It's going to pick up more than that.

JS: Another group that have I guess become a new focus for the industry to advertise their products to derives in part from the movement to managed care, which starts from the eighties up to the present. And we have managed care program managers who seem to be making decisions about formularies that their HMOs (Health Maintenance Organizations) and so on are going to be using. And these managers aren't necessarily

as trained in medicine as physicians are. Maybe their background is more in business. Now is this a concern to the agency as far as their ability to understand medical issues with drug advertising?

KF: There's also jurisdictional questions as to information put out by HMOs about drugs. What's the jurisdictional role? I mean, where does the agency fit into those kinds of things? An HMO, are they a distributor? They're certainly not a manufacturer or a repacker. So there are some jurisdictional questions involved. Certainly there are judgmental issues involved. Most that we're aware of, at least, there are formulary committees in these various groups that deal with this. It isn't just one individual that makes the decisions normally. I mean, I'm not saying that might not occur. But these formulary committees are staffed by pharmacists, sometimes physicians, other people who review the information, get information from numbers of sources, not just the company involved, and then attempt to make value judgments as to what product should we put in the formulary or what product should not be put in the formulary.

So those people are becoming the targets of very heavy promotion by the industry. Also, apparently--we're getting feedback from the companies about this--that various HMOs want certain information. And, of course, the industry is always willing to try to furnish that information. The problem is I don't think the HMO people understand or the health maintenance groups understand that some of that information simply doesn't exist, and to get it, to get real truthful, accurate information along those lines would be very difficult, very expensive, and very time consuming. They want comparative information. How does your product compare to his product in such and such or this and that? Sometimes that information simply doesn't exist, so the companies come up with strange studies, you know, studies that are not all that terribly valid, or, you know, almost anecdotal kinds of information to attempt to furnish these

answers to the health maintenance groups, who I think are sometimes asking for information that they don't understand really doesn't exist.

For example, new drugs are seldom tested against each other, unless it's an active control drug—one of these things that you need an active control. But most times it's all placebo control. So you when get your drug approved, you don't know how it stacks up against your competitor, not really, in a major study. They might do a marketing kind of study where they study it in, you know, two hundred patients. But there are very few studies where it's studied in a thousand, two thousand, three thousand patients head to head, your new drug and the leading competing drug, to see which one's better. Sometimes you don't want to know that answer, because if you did the study, it would be out there for the world to see, and maybe your drug isn't as good as you hope it is.

JS: Like streptokinase and TPA (Tissue Plasminogen Activator), for example.

KF: Yes, you know, so you don't want to do that study. Therefore, you gin up somebody else to answer these kinds of questions. There are a number of issues involved in dealing with the health maintenance groups and HMOs and managed care organizations that will have to sort themselves out as far as what real information is legitimate, what really exists, and are they asking for things that maybe the industry really can't furnish without an expenditure of huge amounts of money. And nobody wants to do that, because it will just drive up the cost of drugs to do some of these studies. So I don't know what the answers are to that. But, yes, it's a field that's of concern, especially in the advertising, and we are dealing with HMOs and health management organizations, managed care groups more frequently now.

RO: Do you recall any really precedent kind of case that solidified the agency's jurisdiction over advertising?

KF: Well, labeling. Although advertising has never truly been fought because the statute's pretty clear, and no one argues what an ad is. I mean, an ad in a journal is an ad, so no one argues it. The fight was over labeling, and the several precedent cases . . . One was, I guess, Hohensee Cancer Clinic, whereby he was putting out information about certain materials and certain things, and we took action on it as labeling for products, and, of course, he fought that saying it wasn't labeling, and the supreme court ultimately said, "Yes, it is." And there was another case, honey and vinegar that did some of that.

RO: Honegar.

KF: And one case that established our authority over the PDR (Physicians' Desk Reference) was an Abbott case. I think that was Eule . . . Not Eulexen, but . . . One of the E-U-T-H products that they had about like that. This was in 1967, I think. We took action on a monograph, a PDR monograph, for lacking certain information--as part of the case. There were some other things involved, too. We lost the case, but the court ruled in their decision that the Physicians' Desk Reference was in fact labeling for the products. So it gave the agency total legal authority over the PDR, and that's the one piece of stuff that has been legally mandated to be labeling under the statute. So that was kind of a precedent setting case in our jurisdictional battles.

RO: We were talking about commissioners, a few commissioners. Any differences in your bureau or center directors in their interest in advertising?

KF: They were all interested in advertising as it applied . . . It's one of those fields that the center . . . The center's main focus, of course, is approving drugs, and as a consequence, that takes up your thinking and your time, and advertising is one of those things out here until something happens that calls your attention to it. So none of the center directors were intimately involved in advertising. They did vary in their skills of understanding what advertising was doing, and their willingness to back us up in effect, in a tough meeting with the company.

Dr. Crout was very good. Dr. Crout was an excellent center director in that regard, and he . . . I think he understood some of the real subtleties of advertising, because he was the center director that took an interest in scientific exhibits. Dr. Rheinstein was interested in scientific exhibits back then. There aren't many now anymore, but there were then, and Dr. Rheinstein was interested in having them kind of independent and not look like promotion. Dr. Crout said, "Why worry about it? Make sure the sponsoring company's name is up there in big letters." You know. "Let the world know that this study was sponsored by Abbott Laboratories." Well, he understood the subtleties of what we were talking about, the so-called source of the information. By letting the world know that this study was funded by Abbott, well, it's different than if the study was funded by Tuft University. So Dr. Crout understood, I think, some of the underlying subtleties of advertising and the credibility of the message.

But Dr. Finkel was pretty good. She's the one that instigated the proposed launch campaign review procedures. So I think they were two of the more notable center directors as far as their impact on advertising.

RO: A little bit further, general counsels?

KF: Peter Barton Hutt.

RO: I thought as much.

KF: And . . . Who preceded Margaret?

RT: Was it (Dick) Merrill?

JS: (Rich) Cooper?

KF: No. Immediately preceded.

RO: Scarlett.

JS: Scarlett.

KF: Tom Scarlett. Tom Scarlett was very knowledgeable about the advertising regulations and supported us very well on a lot of things. So I think they were probably two of the more active general counsels as far as my division was concerned.

JS: I just have about two or three more questions about these sort of advertising issues, if we have time.

KF: Sure.

JS: One is . . . And in part, I talked to a couple colleagues in the field in pharmacy schools who look at advertising issues, and they tell me a couple things--not related. But a couple issues that seem to be becoming more prevalent are, one, emphases in ads on the impact on quality of life--enhanced quality of life--in drug advertising, and

secondly, a movement among chain drug stores in counter detailing. Now, these have nothing to do with each other, but what's the agency's interest in these sort of more recent trends in drug advertising?

KF: The first one was . . . ?

JS: Was the emphasis in ads on enhanced quality of life.

KF: Well, quality of life goes along with the managed care philosophy, because one of the things they're interested in as managed care people--and, of course, as patients are interested in--improving your quality of life. That's the big catch phrase now in a lot of things, you know. The problem is *quality of life is difficult to define, difficult to prove*. If you're in severe pain, and the drug takes away your pain, I guess you can say that improves the quality of your life. But does it? Can you do any more? You still might be confined to bed, or still might be confined to the wheelchair, or you can't play tennis, you can't play golf. What's quality of life to one person, is not to another. Maybe the cessation of pain is wonderful for you; that improves your quality of life. But for me, the pain goes away, but I can't play golf. So my quality of life is not improved.

So it's a very difficult-to-define term as to what is quality of life. Is the extension of life, is that improving the quality of life? To some people it is; to other people it isn't. So after you kind of define what it is, how do you prove it, in the sense of advertising that this drug improves the quality of life as opposed to this drug. How do you prove that? The testing vehicles, the testing instruments, are few and far between. There are several now which are becoming accepted as indicative of quality of life measurements, and I don't know . . . Don't ask me to name them. Dr. Morris probably can. A lot that don't. So we look at the instrument and the validation of that

instrument. Can it measure some of the subtleties involved? Some of these things are difficult to measure and involve large numbers of people to come up with it. You're not going to find it in a study of fifty people.

So that's one of our concerns is what is quality of life, and how do you really prove it. It becomes very, very difficult to prove, and it's very subjective at times.

The other . . . You mentioned counter detailing. We have noted and have taken action on certain pharmacy activities that are being paid for by companies, where in effect, the pharmacist is becoming an agent of the company, and the letters they send out are not just letters from John Brown's Pharmacy, but they're actually a letter on behalf of Pfizer Laboratories promoting their product or "depromoting" the other guy's product. A lot of this comes into play with generic competition where we'll switch campaigns to get the pharmacist to switch the patients from this drug to that drug. So that's where a lot of that comes in, and you do that by either extolling the virtues of your drug or by badmouthing the other guy's product--or both. So that's one of the chief tools in switch campaigns.

With the increasing generic competition, we had a long series of battles with the brand name industry, where they were downplaying generic drugs, downplaying the approval process, thereby attacking the agency in effect. So we had to be fairly rigid in our actions to defend the agency's procedures and the quality of the generic drugs resulting, you know, resulting from those procedures. So we had several remedial campaigns, including a "Dear Pharmacist" letter to all nine hundred and some thousand pharmacists in the country about a message that was being sent out by a company.

Those are all things of interest, but I think things that the agency can deal with as it, you know, deals with many other things. Quality of life is a problem, because they're incorporating that now with NDAs. So we're getting involved in how to design those studies, how to design the instruments to measure the results, and that's all a new field.

JS: Sort of work in progress as far as our enforcement goes.

KF: Yes. It's very much a work in progress.

JS: We also have a concern with distributing, how firms distribute reprints to practitioners about off-label use of products. Now does this come under the advertising rubric or not?

KF: Well, both. Sometimes we do get involved with off-label uses, more from the aspect of the reprints. If a company passes out the reprints, we'll act upon it as a piece of misleading advertising, because it's unapproved use. Compliance can also get involved. We have worked jointly to work up an action on those things. The actual selling of the drug or shipping of the drug for those uses becomes more of a compliance concern or a district concern than an advertising concern. The dissemination of reprints or other information is more an advertising issue.

JS: OK. I only have one other question. I don't know about Ron and Bob. But one of the proposals in, you know, the FDA reform efforts--we'll see what comes of it--has been something along the lines of this: that physicians and other health practitioners are educated, and therefore, they really don't need FDA's involvement in drug marketing issues. They can decide for themselves.

KF: It's totally wrong.

JS: Do you have any opinion about that?

KF: I have a very strong opinion, because that's the basis for the 1962 Amendments in the first place. FDA did not regulate advertising of R drugs; that was handled by FTC (Federal Trade Commission). One of the pieces of information that came out of the hearings on the 1962 Amendments--not so much the Kefauver side, but the Senator Rogers side where he was dealing with marketing aspects--was that physicians, notwithstanding their special training, were still being misled. You could mislead a physician. You might . . . Maybe you had to do it differently, but they could in fact be misled. What became very obvious in the ads was a total lack of any kind of side effect information. If you want to have fun, go to the library, and find some volumes from--well, they're probably in the archives now--but volumes from 1960 or 1958 and look at the ads in there. They're hilarious! They're a joke. They use words like "breakthrough," "miracle," "no side effects." There were some products that flat out said, "absolutely no side effects."

JS: Where was FTC (Federal Trade Commission)?

KF: FTC's concern is different than the agency's. FTC is involved in competition and fostering competition. Now if an ad is totally false, if they're saying totally false things, then the FTC will get involved, and do something about it, and ask for support, et cetera. But they think that you say something about your product, well, he'll say something about his product, and the two messages will come up with the truth. You know, the viewer or the reader can determine for themselves what's going on. So they're much more tolerant of not false statements, but puffery kinds of statements or statements which are a little bit off the wall than the FDA is.

Our concern is protection of patients. So we're coming at it from two different viewpoints. So we look at ads differently. We expect an ad to be truthful and tell the

true story, not rely upon a competing ad to furnish necessary information. Our regulations say *you* have to provide the information about your product.

So what was happening was doctor's were not knowing, did not know, the generic names of drugs. They knew brand name, because that's always been promoted. The generic name either wasn't there or was hidden somewhere. Side effects were not mentioned much at all, and efficacy was being exaggerated in the ads. The efficacy of the product was being exaggerated either by percentages or by using words like "miracle" or "breakthrough" or whatever. So the Congress realized that doctors were in fact being misled.

(Interruption)

KF: Their training did not protect them from being misled. Not to say that they're stupid or uninformed. But anybody can be misled if you're given improper information. And nobody can know everything, especially about a new drug. So, yes, doctors can be misled, were misled, and still are being misled. So the agency-- somebody, whether the FDA or whoever--but somebody must be involved in regulating marketing to physicians, because they, like anybody else, can be misled. You maybe have to do it a different way, but they can be misled. They're not protected by their knowledge. No one's knowledge is that good that it protects them from being misled by someone that knows what they're doing. Witness con men, who bilk very educated people for lots of money. So I think that's a fallacious argument. I think people need to go back and read the 1962 congressional hearing records for the '62 Amendments to find out what the world was like before the agency began to regulate advertising.

JS: And I don't know to what extent the advertising of the companies had to do with this, but if you look at the thousands of DESI products that were on the market prior

to 1962 and had no efficacy, but they were still out there, and I suppose they were still marketed because companies were selling them. They were selling them to practitioners, even though the drugs did not work.

KF: That's right. Well, luckily, most conditions are self limiting. So if you do nothing at all, you'll get better. So as long as the drug didn't harm you, you were going to get better, so you would attribute it to the drug. Efficacy is difficult to prove. I understand why the industry doesn't like the efficacy requirement, because it's very difficult to prove at times--many, many times. But I think to feel that doctors cannot be misled is just a bad argument.

We all think we can't be misled; we all think it. Watch TV and watch the ads. I have fun doing critical reviews of TV commercials just to see where the misleading aspects of those commercials are. We all feel we can't be misled, but the fact is we all can be misled by clever people who know what they're doing and know how to manipulate information. And believe me, the advertising industry is very good at manipulating information.

So, yes, doctors were misled, are still being misled in many, many ways, and will be misled in the future. So somebody has to look at the marketing. And we're the best people to do it, because we have the scientific knowledge to do it, which is the reason Congress gave it to us in the first place was because we had the database, the medical database, to deal with the realities of the drug, so we were the best ones to look at the advertising and promotion.

RO: Bob, do you have any other questions?

RT: No.

RO: I don't either.

RT: I think it's a very complete discussion.

RO: Yes. Ken, we want to thank you very much.

KF: You're quite welcome. You're quite welcome.

(Interruption)