History

of the

U.S. Food and Drug Administration

Interviewee: Richard Merrill, Esquire

Interviewer: Suzanne W. Junod, Ph.D.
Robert A. Tucker

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Richard A. Merrill

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TAPE 1, SIDE A

RT: This is a continuation of a taped interview for the Oral History Program with Richard Merrill, former General Counsel of FDA. The initial interview took place on July 12, 2004. Today, November 12, 2004, the interview is taking place at the law offices of Covington and Burling in downtown Washington, D.C. Present are Mr. Merrill, Dr. Suzanne Junod, and Bob Tucker of the FDA History Office.

So, as we now resume the interview, Richard, would you like to proceed with any thoughts that you have for continuation?

RM: I think I would rather respond to questions that you'd like to pose or topics you'd like to bring up.

SJ: Well, we left off with Mac Schmidt and Don Kennedy. Why don't you just review your experiences working with them.

RM: Well, I spent a year and a half with Dr. Schmidt, who was a cardiologist. He was also a Utahan, as I am, and he'd grown up and been educated in Ogden, Utah, which was the center of railroad operations in that part of the American West. It was also the center of non-Mormon population in the state of Utah. Mac and I had a lot in common, friends in common, experiences in common. He had a family place on Hebgen Lake, which is

just outside Yellowstone National Park, where he spent summers as a kid and then later as an adult. My family spent time there as well with friends. So while I had no prior connection at all with Dr. Schmidt on coming to FDA, it was as if we'd known each other all our lives within twenty-four hours of our meeting.

I think Mac found the job wearing. It was a time when the agency was under a fair amount of public criticism. Press coverage was unflattering. The tenor was, "why aren't you doing more to protect the American public?" And, of course, Mac had just weathered the second in a series of pretty hostile hearings chaired by Senator Edward Kennedy in which the agency's drug-approval process was held up to criticism, even ridicule. And I think Mac felt responsible for the conditions complained of, but even more responsible for seeing that there was a forthright response. So it's fair to say he was on the defensive.

SJ: Had you helped prepare the testimony for those?

RM: I had not. There had been a hearing in early May 1975, and there had been an earlier hearing the previous summer, August, I believe, 1974, which was really the session that highlighted the sharpest criticism. It's the hearing that featured Dr. John Nestor and several other FDA reviewers who complained of pressure to approve drugs that they thought had not been fully demonstrated effective, and, worse, had been shown to be unsafe.

Peter Hutt was on vacation at the time of the 1974 hearing, so the Commissioner, Dr. Schmidt, Dr. Crout, head of the Drug Center, and no doubt others appeared with

counsel, but not with the agency's senior counsel.

RT: I think in our earlier interview session, we affirmed at that period there was a different administration in the White House than in Congress.

RM: That's correct. Democrats, by substantial margins, controlled both House and Senate, and they of course chaired the committees.

RT: Dr. Schmidt was appointed by a Democratic administration?

RM: No, no. He was appointed by a Republican administration.

RT: And carried over.

RM: Well, no. There was no carryover. The Republicans were in charge of the White House from 1968, when Nixon was elected, through 1976, when Carter defeated Ford. So he was appointed, I suppose, technically by Charley Edwards, who had by that time become Assistant Secretary for Health, although maybe the form called for the appointment to be by the Secretary of HEW, which would have been Casper Weinberger.

SJ: That was probably the formal part, yes.

RM: Yes. We now know who has the appointment authority, the President does for the

Commissioner. But in those days, it was officially somewhere below the President.

RM: Schmidt was a Republican. There was no doubt about that. And he owed his appointment to Republicans. He therefore was a sitting target for Democrats in Congress.

RT: That's true. In the previous part of our interview, we touched on the Dorsen Panel, so perhaps more could be added to that, if you would, Richard.

RM: Dorsen was a law professor at New York University, who is prominent for his work in civil liberties, and justifiably praised for his work in that field. He was appointed by Secretary of HEW David Matthews, who succeeded Weinberger, to an outside panel that was instructed to study the processes by which FDA evaluated and approved drugs, to evaluate the charges that Senator Kennedy and the committee staff had levied against FDA in the hearings we've talked about.

Dorsen gave his name to the panel because he became its chair after the original chair, Dr. Tom Chalmers, who was, I think, on the medical faculty at Mt. Sinai in New York, resigned. Chalmers felt that he was under too much pressure to produce a report that verified the charges made by the witnesses that the Kennedy hearings had put forward. Chalmers in effect said, "I'm not going to be directed in what I end up finding and recommending."

In any event, the committee, now with six rather than seven members, proceeded over the course of about a year to study the FDA approval process and produced a series

of reports that did two things. One of them was to explore and, to an extent, validate the accusations made by the witnesses at the Kennedy hearings. The other was to make a series of recommendations about the drug-approval process, focusing particularly on the private interactions between drug companies and FDA reviewers. The Dorsen Panel recommended a much more arm's-length kind of dealings between the agency reviewers. Drop-in visits were to be forbidden; all communications would be on the record; all oral communications would be committed to writing. In short, the idea was to sanitize the drug-approval process and dilute the influence of representatives of the drug companies that were seeking approval.

I think the process recommendations were far less troubling to Schmidt and Dr. Crout than were the committee's acceptance of the testimony that had been offered by John Nestor and his colleagues. Drs. Crout and Schmidt to some extent felt that they had been unjustly accused of misconduct and both of them felt a desire to respond on the public record. Mac Schmidt spent a very substantial part of the next year preparing his own report on the accusations and taking issue, in many instances, with the account provided by Nestor and the other witnesses. He felt it was important, as a matter of personal privilege, to get on the public record his view of the true facts. I think it may have been a mistake for Mac to devote as much of his mental energy and effort and attention to this project. It was the thing that, more days than not, preoccupied him.

The "record" consists of the investigations of the Dorsen Panel and the reports of the Dorsen Panel and Dr. Schmidt's and Dr. Crout's rejoinders. I suppose one could say that the truth of the matter with respect to specific episodes is for readers of those documents to judge.

RT: As a result of this Dorsen Panel report, was there some tempering on the part of the congressional oversight committees?

RM: Yes, I think so, but that was not so much the result of the report itself, but the result of the passage of time that was required to produce the report. By the time that Dorsen finished his work and Crout and Schmidt finished their responses, we were in the middle of 1976; there was a presidential election, and lo and behold, the new President was a Democrat, and the officials that were going to run the agency were going to be appointed by a Democrat. The Democrats retained control of Congress, so there was less of an incentive on the part of members of Congress to embarrass the agency's administration.

RT: And, of course, that was President Jimmy Carter.

RM: That's right, who appointed Joe Califano, who in turn chose Donald Kennedy to be the Commissioner.

SJ: They were both Californians. Did they . . .

RM: Who?

SJ: Califano and . . .

RM: He's not a Californian.

SJ: He wasn't Californian?

RM: No. He's Harvard Law and New York or New England.

SJ: Okay.

RM: I know that because his granddaughter plays with my granddaughter.

SJ: [laughs]

RM: I only discovered that this weekend.

SJ: I guess all I was asking was, did they know each other?

RM: I don't know that. Kennedy is a New Englander by birth, and Harvard educated. But he'd been at Stanford for many, many years and is back at Stanford today. So he's a California transplant. I don't know whether they had any connection.

SJ: I think that's why I associate him with California.

RM: Schmidt was not ousted. I think he submitted his resignation in anticipation of the election and in order to meet the academic calendar of the University of Illinois, to which he was returning. I think he became vice-chancellor and Professor of cardiology. I think the truth is he'd been worn out, worn down, and surely would not have been continued in the job because the Democrats, Califano in particular, would want their own person. It wasn't a case of Califano saying to Schmidt, "You leave, I've got my own guy." There was a hiatus during which Sherwin Gardner, for the first of several times, served as Acting Commissioner.

And it's during that window between Schmidt's departure and Donald Kennedy's arrival in March of 1977, that Canadians produced the results of their study of saccharin and set in motion FDA's attempt to ban saccharin and Congress's passage of legislation to prevent it. Sherwin was not simply a caretaker; he had more than one hot potato on his desk during the period of time he was Acting Commissioner. He served as Acting Commissioner between Kennedy and Jere Goyan, and at least one other time.

SJ: We've got the records and officials online.

RM: Sherwin probably logged more months as Acting Commissioner than some Commissioners logged.

SJ: That's right. We've got to see how he's doing with Dr. Crawford, in competition with Crawford. The competition's heating up.

RM: Yes, I think that's right. I think Les may have the longest single period of service as Acting Commissioner.

SJ: Yes, I think at this point he probably does.

RM: I don't think Sherwin ever had the six or seven or eight months.

SJ: Yes. We want to get an interview with Sherwin soon.

RM: You should.

The Dorsen people made a number of recommendations having to do, the central theme being, deal with these companies at arm's length on the public record, no private conversations, no private deals. And for a significant period of time, that atmosphere characterized the dealings between drug companies, applicants for drug approval and the FDA reviewing officers and offices, and I think indirectly fueled the complaint that the United States was falling behind other industrialized companies in the access patients had to new medicines, the so-called "drug lag."

RT: Now, this period that we're speaking of, wasn't that during the post-generic drug problem, when we had some indiscretions in the handling of generics?

RM: Well, I think they're coterminous; that is, I don't think the generic drug issues loomed large until the late 1970s. They were not issues that I dealt with.

I bet that Rich Cooper probably did, during the time he was Chief Counsel. I associate the issues more with the Goyan administration than with Kennedy's administration.

RT: Oh, okay.

RM: But, of course, it was later charged that some generic companies got special favors from FDA reviewers in the generic drugs office. This was an important episode, I think, but not of great practical importance for the American patient because there weren't many drugs for which generic copies could be approved under the prevailing law.

SJ: I was going to say, I still have always felt like it was a bit of an anomaly that they had made it an orphan out of the program.

RM: Yes.

SJ: And under the normal CDER processes, that would have never -- it was a sign that the agency was lax in overseeing the . . .

RM: No question about it. It was not a big deal from the agency's standpoint because there weren't many drugs that were eligible for generic approval. There were enough, however, the incentives were substantial for those drugs that could lawfully be copied.

And I'm sure there was strong pressure on the reviewers of those applications, pressure or inducements that . . .

SJ: Well, it was so easy to manipulate. All you had to do is put one application in front of the other.

It was just, whichever one came out first. So all they had to do was shuffle papers on a desk, and that was very hard to document.

RM: Yes. It's an episode that I know about only through press coverage. I was long gone from the agency. I wasn't engaged in law practice. In 1980, I became dean of the law school. My attention was fully occupied with that chore, so that I was as far removed from what was happening in Parklawn as I have been at any time since leaving FDA.

SJ: Well, let's get back to your work with Mac Schmidt once you came on board, because you said that the Kennedy hearings had pretty much ended. What did you work on after you came in?

RM: What did we work on? One thing we worked on extensively goes under two or three different names. Aspartame is one of them, or bioresearch monitoring, or Searle, and they're all linked because the agency's justifiable concerns about the integrity of the scientific data that it received in support of product applications. Particularly toxicological data. Those concerns surfaced late in 1975 or early 1976. Just how it came

to light, I'm not sure.

The Searle Company was a major focus of the FDA's interest in the possibility that data submitted to the agency had been cooked in some fashion. This fire was fed by another set of Kennedy hearings in which the agency's handling of applications for three products -- Flagyl is a prescription drug for the treatment of feminine disorders; I can't remember the name of the second drug; and the third product was aspartame, an artificial sweetener that appeared to be a possible substitute for saccharin. Because of concerns that saccharin might be proven to be an animal carcinogen, there was a lot of interest in aspartame. No doubt there was a lot of interest on the part of Searle, the maker of the compound, for they could anticipate a very large market if saccharin fell and theirs was the only artificial sweetener standing.

RT: May I ask you, the Canadian studies that identified saccharin as a potential carcinogen, was that research done by the Food and Drug Directorate of Canada, or was it done by a private researcher?

RM: The Food and Drug Directorate sponsored it. I don't know whether they conducted it.

SJ: I talked with Ben Oser before he died. He ran the Food Research Laboratories, and he says it was his lab that conducted the study, but that they made it quite clear when they turned over the evidence that they had used a saccharin-cyclamate mixture. But I never had a chance to really document that . . . .

RM: I think one needs to understand, there were three studies of saccharin, three animal studies over a decade.

SJ: So he may have just conducted one of them.

RM: I think the first was completed in the mid-1970s, before I was at FDA. I don't know who did it. It raised questions about carcinogenicity, but it left in doubt whether the excess tumors were produced by saccharin or by a contaminant that was an inevitable production byproduct of the manufacture of saccharin. I believe that first study was sponsored by the U.S. sugar industry, and I believe it was done at the University of Wisconsin.

Then a second study was done, because the effort was to try to isolate the effect of saccharin alone, and that may have been the Ben Oser study. There was the potential for confusion because one of the dose groups in animals received both saccharin and . . .

SJ: Cyclamate.

RM: And cyclamate, another substitute for saccharin. And so you didn't want to approve a new compound -- you didn't want to get rid of an old compound if there was a new compound that was going to be more risky. And who paid for that study, I don't know.

As a result of the second study, suspicions that saccharin was a carcinogen were,

if anything, heightened, but whether it alone acted, or if it was something else that produced the tumors, or whether there was a synergy that produced the tumors, there was a desire to have another study done that would clarify those questions.

I think there is no doubt -- Charley Edwards as much as admitted it at one time -- that FDA was happy to have another study done so the agency didn't have to make a determination that the compound was a carcinogen and, under the Delaney clause, had to be withdrawn. This left the ball in the Canadians' court. But the two countries were working in tandem, collaborating, at least at an intellectual level, and the Canadians, as I understand it, said, "We'll get one more study done, and we will administer to the animals pure saccharin, and we'll administer one group OTS" (orthotoluene sulfonamide), I think was the acronym for the contaminant, "and we will see if the contaminant alone can produce tumors."

Well, the results of the study were that it was saccharin alone that produced the tumors. It produced tumors only in male rats, and only at the highest level administered. But that was the news that came to FDA in early 1977, when Sherwin Gardner was sitting in the Commissioner's desk.

I remember two or three folks went from FDA to Ottawa to meet with Ian Munroe and others from the Canadian Food and Drug Directorate and to talk with the scientists who'd done the study about what they found.

The meeting itself was sort of hush-hush. The people at FDA did not want the press to get word that there was this study that had been completed that looked like it might indict saccharin. If saccharine had to be removed from the market, the diet-food industry was in deep doo-doo, because aspartame, while it had been approved by FDA as

safe, the final decision had been challenged. Thus aspartame couldn't be substituted. And cyclamate had been effectively banned by FDA around 1969. So saccharin was the last man standing as of 1977. A lot rode on that decision.

But that, in some sense, takes us away from the Searle investigation, which goes back to the fact that FDA had not conducted these studies themselves. It had commissioned them to be done by private testing laboratories, one of which was Industrial, I think Industrial Bio-Test in Chicago, and . . .

TAPE 1, SIDE B

RT: Industrial Bio-Test Research Labs was headed by, who did you say?

RM: Steven Carson.

RT: Thank you.

RM: Who I

Just how this focus fell on Industrial Bio-Test and on the Searle Company's products is unclear to me.

It's quite clear that there were people in the agency who had suspicions about the integrity of IBT research and had already begun investigations into the workings of the testing laboratories generally and IBT in particular. Word of those investigations got to the Kennedy staff. Kennedy had a man named Walter Sheridan who had worked for the family for a long period of time, and who spent most of his days in the Parklawn

Building talking with people about what work they were doing. So in a real sense, Kennedy knew before Schmidt or Gardner or Donald Kennedy ever knew what was happening in the agency with respect to this investigation.

But I think it is probably just coincidence that several, three in number, Searle products which had been tested under a cloud of scrutiny in the middle of 1976, early 1977. Because Industrial Bio-Test not only did testing of food chemicals but also of pesticides. FDA and EPA were jointly led to conclude, "We may have a problem on our hands. We may have more than one laboratory that may be cooking the books." And, quite clearly, Industrial Bio-Test did.

It became quite clear that some of the studies that IBT claimed to have run, they never did. It was possibly the case that, with respect to at least a couple of compounds that they tested. They tested them on the same laboratory animals, so it would not have been possible to disaggregate the effects of one agent versus the other.

And FDA became suspicious that other companies were engaged in, if not quite so blatantly, fraudulent activities, at least shoddy scientific activities.

The result was the formation of an FDA-EPA task force to undertake the investigation, an FDA-centered investigatory task force. I'm trying to think of the name of the fellow who chaired it. I can picture him now. It may come to me. Arthur Levine was the lawyer from my office who worked with the Searle task force and did most of the legal analysis.

Several important developments came out of this. One was the creation of a bioresearch monitoring program at FDA that encompassed oversight of all of the generators of scientific evidence on which the agency's approval decisions were going to

be based. Initially, this included a set of regulations called Good Laboratory Practice (GLP) regulations, the functional equivalent of GMP regulations but for testing laboratories. Those live to this day, and both agencies -- FDA and EPA -- insist on compliance with GLP's on any laboratory study that is going to be submitted in support of a product application, either under the pesticide law or the Food and Drug Act. And I think it's fair to say that, if GLP's have not transformed, they have powerfully affected the business of toxicology in the United States and across the world.

Companion regulations for which Bill Vodra, along with Dick Crout, was centrally responsible and focused on clinical investigators. They, after all, are produce the data on human subjects that parallel the data Industrial Bio-Test was producing on animals. And then FDA added regulations governing institutional review boards, which had some quality-control responsibilities for clinical trials. Three sets of regulations, in updated form, continue to be part of FDA's research oversight effort today.

When things settled down and the Searle investigation had run its course, I believe it was Dr. Francis Kelsey who was made head of the operation from the drug side.

So you could say that the Searle investigation created a whole new area of intense regulatory activity involving substantial numbers of people.

There was also pressure from the Kennedy committee and others for FDA to do something to punish the people responsible for the research frauds. Industrial Bio-Test and Dr. Carson were prosecuted and convicted. I don't know whether it was on a plea or whether it was after a trial. There may have been other convictions.

The question was what to do about the sponsor of tests that turn out to be

fraudulent. One of the major focuses of the investigation, which now shifted from toxicological laboratories to sponsors of research/ The question was whether Searle knew that the data that it had submitted to the FDA was cooked? And if it did, shouldn't the firm be prosecuted?

I think it was fair to say that the agency -- this would have included the Commissioner, certainly, and Gardner, very definitely, and Dr. Crout -- felt some pressure to explore the possibility that Searle had committed fraud very deeply. And the investigatory task force -- it was Ernie Brisson who headed the Searle investigation -- Ernie and Arthur Levine put together a very detailed report for the U.S. Attorney in Chicago which said we think there might be fraud here, but we can't be sure.

SJ: The people certainly knew that they were getting cut-rate deals.

RM: Probably right.

I think -- Arthur could speak for himself -- that Arthur was more suspicious than I was that there was real culpability on the part of Searle. Whatever the truth, the people at FDA did not feel that they could have dropped the case without further effort. But at the same time, they did not feel that they had clear evidence in hand that would justify a recommendation of prosecution.

So we crafted a very careful and detailed letter to the United States Attorney, a man named Sam Skinner, who later served as Secretary of Transportation in the first Reagan administration. The lengthy letter that I signed said, in substance: "Here's what we found. Here's what we don't know. We think that you ought to investigate using

your powers of subpoena," to see whether there was genuine culpability on the part of Searle. It was not a recommendation Searle be prosecuted. It was a recommendation that the U.S. Attorney complete the investigation that FDA had begun, but using tools FDA does not have, which is the power to subpoena witnesses and materials. In fact, no prosecution was ever brought.

In the final analysis, Skinner concluded, I think on the record, that there wasn't evidence that would justify a prosecution of the company or of anybody at the company. But it was a close call, and a lot of people thought, first of all, that we failed in our responsibility, that we knew but didn't say that there had been culpability. And for years afterward there was criticism of Skinner for dropping a case that would have been brought against an important constituent, namely the Searle Company, located in Chicago.

I have continued to get calls from newspaper reporters, one as recently as last year, asking me, "What's the truth about Searle?" Aspartame is usually the product of interest, because aspartame, of course, has made its way into the American diet. Nobody remembers Flagyl or what the other Searle product was that might have been tested shoddily or possibly fraudulently. But suspicion remains in some quarters that the Searle Company got away with something, maybe through the complicity of FDA or, more likely, through the complicity of the United States Attorney in Chicago, Mr. Skinner. Occasionally you'll see press stories conveying that charge but without the supporting detail. I think nobody has the supporting detail.

There is one other interesting anecdote resulting from this episode. Months after the letter we wrote to Skinner and the wind-down of the United States Attorney's

investigation, Donald Kennedy, now the new Commissioner, got a call from Searle's new head , seeking a meeting. The new head of Searle wanted to know how the company ought in the future engage with FDA. What had gone wrong? What steps should be taken? Don called me to say, "We've got a meeting with the new president of Searle. I want you to sit in on it." The new president of Searle was Donald Rumsfeld. We spent an hour and a half talking with him.

SJ: What was your impression of him then?

RM: He is a very impressive guy.

He was much younger then, of course. We're talking about 1977, June maybe. That's twenty-eight years ago. He was not as avuncular or as amusing in a sardonic way as he is now on television. He didn't carry that heft and weight back then. He seemed eager, conscientious, smart. Whether he was genuinely interested in what Donald Kennedy had to say and the question that purported to be the subject of the meeting is another matter. I don't know.

SJ: Well, he was brought in, I guess, precisely because they wanted to impress FDA with their sincerity.

RM: I think that's probably right. But I exhibit a little bit of skepticism. Rumsfeld may have known the answers to his questions without coming to see us. I think he felt it was important to be on the record that he had come to see us. Whether it was important

to shareholders or the board of directors or the company employees is not clear. What I don't know is whether it was important to him.

However, it was a very sensible gesture.

Aspartame has an interesting dimension to it. It's been, of course, a fabulous commercial success because, while the original approval was quite narrow, over time that approval got expanded for many, many other foods, including soft drinks, in which Nutrasweet is by far the dominant non-nutritive sweetener available to American consumers.

Its approval was controversial as a scientific matter. A university-based scientist, whose name I can't recall, was convinced that the stuff has the capacity to cause brain tumors. I don't think he claimed that there is clear and convincing evidence from the animal studies that it does, but that there was hints in the animal studies that would support that hypothesis, and FDA would be wrong to approve it.

He was represented by a man named Jim Turner, who is here in Washington and is notorious for a gadfly role in the life of FDA. He wrote a not-unimportant book called *The Chemical Feast* in 1972, when he was one of the early Nader Raiders. *The Chemical Feast* did for foods what some say *At Any Speed* did for the automotive industry. Turner became a convert to the view that aspartame was a problem, and so it was his pen generally that was used in the submissions to the agency, which ultimately took the form of formal objections to the approval of aspartame. Under the law, an objector is entitled to an evidentiary hearing at which the scientific questions raised by his objections are to be resolved. It's like a food-standards hearing before an administrative law judge, featuring live testimony and cross-examination.

Peter Hutt had, sometime earlier, amended the FDA regulations to provide for an alternative to an evidentiary hearing when the issues in dispute were fundamentally scientific. He said, "What we ought to have is a panel of scientists who judge that evidence." Hutt was enamored of the concept that Arthur Kantrowitz had put forward in *Science Magazine* that what we needed to resolve fundamentally scientific disputes that had enormous social consequences was a "science court." FDA's regulations providing for a public board of inquiry were Peter's way of saying, "And we're going to establish a science court for disputes that will make available to parties who under the statute would be entitled to a formal evidentiary hearing." There followed extensive negotiations to reach agreement on the details of a public board of inquiry for aspartame.

Searle had to be consulted because it was Searle's product that had been approved. So in a sense you have a four-way proceeding: FDA as the administrative decider, the Bureau of Foods as author of the initial approvals; the sponsor of the product, Searle; and the objectors to approval of aspartame, including Turner and his client.

It took months to get in-principle agreement among the parties that instead of going before an administrative law judge, we'll put the issue -- is aspartame safe -- before this public board of scientists.

All of these plans were put on hold when the Searle investigation broke, because nobody -- when the safety issues surfaced -- had any inkling that the data weren't reliable. As soon as the data were called into question, FDA said, "Our approval is on hold. The board of inquiry is on hold. We must first get to the bottom of the truth of the studies." And that's what we spent the next two years trying to get to the bottom of the

truth of the studies. So the board of inquiry that Peter had got the parties to agree to was on the back burner.

By the time I left FDA, the Searle investigation was winding down. It was quite clear Sam Skinner wasn't going to do anything.

And in late 1977, Searle said, "We're ready to market aspartame, which you approved several years ago. Now you've confirmed that the data are honest. But there is this pending commitment to have a hearing."

To make a long story short, after another year's wrangling, the scientific board of inquiry met. The scientists made a decision adverse to Searle, as I recall, saying there are enough questions about safety that the agency probably shouldn't have approved aspartame. Don Kennedy overturned that decision; he thought that the agency's approval decision was, under all of the circumstances, correct.

There has not since been another public board of inquiry at FDA. So far as I know, the public-board-of-inquiry process is an empty shell in the FDA regulations. I'm not suggesting that it was a bad idea. It was quite an inventive idea for the time. But it shows how difficult it is to persuade lawyers, who know what an evidentiary hearing is like, to trust their client's interest to an unfamiliar process over which they don't exercise as much control.

In a formal trial-type hearing, the lawyers know how evidence comes in. They know how evidence is going to be evaluated. They know what their opponent is going to be allowed to do. But with three scientists as "judges," you have no way of knowing whether they're going to share your understanding of the laws of evidence, for that matter, or the rights of cross-examination.

SJ: Okay.

RM: So it's not that you control the outcome, but you . . .

SJ: Control the process of reaching it.

RM: You know how to influence the process. In some sense you share control with the lawyers for the other side.

Here, the lawyers -- I think the FDA's position was the least compromised, but the lawyers for Searle and Jim Turner -- even though they had agreed to the concept -- were quite uncomfortable trusting this dispute to not only to people they didn't know, but to a kind of decisional process with which no one had ever had experience.

SJ: And you're right. In the end, there's no yes or no. In other words, the benefit of the doubt, does it go to the sponsor and the company? Who has the burden of proof?

RM: The lawyer would say that's clear. The maker of the product has the burden of proof. But you can't be sure that is a meaningful statement to a trio of toxicologists. Actually, the board included one toxicologist, a neurologist concerned about the brain, and a third of another discipline. I have no idea what their names were. Again, this was a proceeding that went on after I was back in Charlottesville.

But FDA's experiment intrigued administrative lawyers because it represented

one of a handful of innovations that were attempts to see if there's not a better way to resolve scientific disputes than going to a court of law or to its equivalent, an administrative law judge.

SJ: You may be able to answer a question I've been carrying around for years. What is the evolution of an administrative law judge? Did that come in the '30s? Was it in the '38 act, which I don't think it was.

RM: No.

SJ: Or was it part of all those changes made in administrative law during that period?

RM: There was nothing in the 1938 FD&C Act about who presided at the hearings that it provided for.

SJ: Food standards hearings and others?

RM: Hearings were provided, but the details were not spelled out. However, I think it was understood that the presiding officer would be what was then known as a hearing examiner.

SJ: Right. I've heard that term used.

RM: That term got codified in 1946, when Congress passed the Administrative Procedure Act. Not only did the Administrative Procedure Act provide for hearings that were to be presided over by a hearing examiner, but it described the legal status of hearing examiners and their rights, their independence, vis-à-vis the agency for which they performed hearing-examiner work.

By 1960, the United States government employed hundreds of hearing examiners. Most of them, a majority of them, worked for the Social Security Administration. But there were hearing examiners at the FCC, at the SEC, and many other agencies. These were the cadre of individuals who provided, you might say, quasi-judicial services to agencies across the government. Individual hearing examiners were anchored to the agency whose cases they helped decide. They were on the agency's payroll, but they were structurally independent, cut off from the ordinary lines of communication and free from direct oversight by the agency head. The agency head couldn't say, "I want the case to come out this way."

RT: Isn't that somewhat the structure of the Office of General Counsel in FDA?

RM: I don't think so. The lawyers in the Office of General Counsel, at the end of the day, do what the Commissioner wants to be done so long as the statute permits. The Commissioner cannot tell the hearing examiner at the aspartame hearing how he wants the case to come out or what he thinks. Indeed, it would be inappropriate for the Commissioner to call up the hearing examiner and ask something so innocent as, "Can you tell me how it's going?" or "When do you expect to finish?" The hearing examiner

is supposed to be as independent of the agency as a federal district judge would be, even though he or she is being paid by the agency.

Sometime in the 1960s, this cadre of hearing examiners, who were increasingly influential because they processed a lot of the major decisions of the Executive Branch, got Congress to change their title to Administrative Law Judge.

SJ: That was in the '60s. It's just really a name change.

RM: It is a name change, but the title "judge" was very important, and had a powerful allure for the hearing examiners.

SJ: Sounds like a clerk.

RM: It does sound like a clerk. "Judge" sounds important, and the hearing examiners felt important. They wanted to be viewed as important. They remain an important force for their own self-aggrandizement.

SJ: [laughs] They have to protect themselves like everybody else.

RM: That's right. But they've enjoyed more success at doing that, at elevating their status, their prerogatives, their titles. I'm not sure it's in law, but it's not uncommon for them to wear robes. Indeed, they would think it would be entirely appropriate. And they like to be addressed as "judge" or "your honor." As you can see, I have some skepticism

about this. Administrative law judges have not loomed very important at FDA in recent years because the agency has gotten out of the food standards business. It has held few proceedings that, under the law, require an administrative law judge to preside. When I came to the agency, Commissioner Schmidt hired the first administrative law judge who had been on the agency payroll for several years, Daniel Davidson. I believe he is still there.

SJ: Yes, he's still there. I'm looking to interview him at some point.

RM: Now, he's handled some high-profile controversies, DES being one.

RT: As we close this second interview with you, Richard -- again, our thanks for your participation in and significant contributions to the agency's oral history program.

END OF TAPE

END OF INTERVIEW