## History

of the

## U.S. Food and Drug Administration

Interviewee: Arvin Shroff, Ph.D

Interviewer: Robert A. Tucker

Ronald T. Ottes

Date:

July 18, 2000

Place:

Rockville, MD

## INTRODUCTION

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

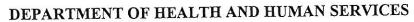
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Food and Drug Administration Rockville MD 20857

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

Date: July 18, 2000

Place: Rockville, Maryland

Interviewee: Dr. Arvin Shroff

Address:

Last FDA Position: Deputy Director, Office of Enforcement, ACRA

FDA Service Dates: 1974 to 2000

Interviewer(s): Robert A. Tucker, Ronald T. Ottes

Address: Food and Drug Adm. .

Number of tapes: 3

Length: 50 Minutes

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RO: This is another in the series of FDA oral history recordings. Today we are interviewing Dr. Arvin Shroff, retired deputy director of the Office of Enforcement of ORA (Office of Regulatory Affairs). The date is July 18, 2000, and the place is the Parklawn Building in Rockville, Maryland. Interviewing Dr. Shroff is Robert Tucker and Ronald Ottes.

The transcription of this interview, together with the tapes, will be placed in the National Library of Medicine and become a part of the FDA oral history collection.

Arvin, in order to start this interview, would you give a brief biographical sketch of where you were born, raised, educated, and any relevant work experience prior to coming to FDA, and what brought you to FDA.

AS: Sure, Ron. I'm from India. I was born on July 2, 1933, in a place called Surat, India. I received my undergraduate training in India and my graduate training in the U.S.

I went to M.S. University in Baroda, where I received my Bachelor of Science degree. For two years after that, I was in my own business in India.

In 1956, I came to the United States and enrolled at Duquesne University. I was there for two years and received a master's in pharmaceutical chemistry. I went to the University of Maryland for graduate work, and in 1962, I received my Ph.D. in medicinal chemistry. I taught at Maryland as a instructor and as a post-doctoral fellow for a year. I was an instructor at University College, University of Maryland for a year. In 1963, I went to work for Ortho Pharmaceuticals in Rariton, New Jersey. I was there for eleven years as a research chemist and as an analytical chemist. I have about eighteen U.S. patents and over thirty international patents.

One of the patents became an oral contraceptive called Ortho Cyclene.

RO: Ortho what?

AS: Ortho Cyclene. After I retired, I got a call from one of my former colleagues who told me that its sales are now close to \$400 million.

I was with Ortho Pharmaceuticals for eleven or so years working in pharmaceutical chemistry doing formulation stabilities, helping quality control folks. I also served as a group leader in analytical chemistry, where we analyzed products and developed new methods and did stability testing.

I was involved with preparing submissions for NDAs (New Drug Applications) and had come to FDA a few times as part of the submission and meeting with FDA review chemists.

In 1974, I decided that it was time for me to move on. Dr. Kumkumian, who was in charge of the chemistry portion in the New Drug Evaluation at the time, had also gone to the University of Maryland at one time. He suggested that I may want to think about FDA. Fortunately, there was an opening in the review group of Anti-Infective Division at that time. I applied for the job and was accepted. In 1974, I came to Parklawn, and reported to Dr. Casola in the Anti-Infective Division.

On my first day, Dr. Casola came in with six or so volumes of NDAs and transferred them to me. He said, "Here are your NDAs to be reviewed."

I promptly reviewed them and found out how some of the deficiency letters and other regulatory communications are written. Within three to four weeks I went through all those NDAs. Dr. Casola and the other people were surprised that I was able to review them that fast and identified so many deficiencies.

I was in New Drug Evaluation for about sixteen, eighteen months and then went to the Office of Compliance as a GS-14.

RT: Did you come to FDA as a GS-13?

AS: Yes, I did.

I went into Office of Compliance as chief of the Product Surveillance Branch.

I was there for probably four to five years before moving to DFS.

One of the programs we initiated had to do with collecting drug samples from warehouses to do surveillance work at the testing laboratory in St. Louis.

RO: Was the testing laboratory a part of the Bureau of Drugs?

AS: It was run by Thomas Layloff. It was a mechanism by which we obtained surveillance samples from pharmacists and warehouses so you would have an idea of what's on the market after having gone through all kinds of transportation, storage, and warehousing problems.

RT: When you came in to FDA, did you come in on an open vacancy announcement?

AS: Yes, there was an open vacancy. I had to apply for it.

My practical industrial experience of working with the quality control people on pharmaceutical formulations regarding bioavailability, stability, etc. was helpful when I came to FDA. It helped in knowing the significance of an item on a FD483 other than it being a technical violation of the law. It was especially helpful when I was in Compliance in meetings with company officials about the significance of certain violations of the law.

RT: So that elicited greater cooperation on the part of industry than otherwise?

AS: That's exactly right.

I was in Compliance for about four or five years. Then there was an opening in EDRO (Executive Director of Regional Operations) in the Division of Field Science (DFS).

I thought it would be a nice challenging place for me to go. So I did a detail, and when a job opened up, I applied for it and was chosen.

RO: Before we get to that, there were some problems with bioavailability between some of the generics and the brand names, and FDA started trying to devise some methodology to be able to determine this without in vivo testing.

AS: Right. Dissolution testing was one of the things that they had done.

RO: Was that while you were still in Compliance or was that after you came to EDRO?

AS: No, while I was in Compliance. I was still a review chemist.

RO: So then you came to the EDRO organization.

AS: I came to the EDRO organization as Director of the Division of Field Science.

At that time, research centers—then called centers of excellence—were being formed. There were about seven of those research centers. Each of the research centers would have roughly four people. So we were only talking about twenty-eight people. They were not new positions. They were going to be carved out from what was called FD1609 Research and put into that.

One of the things involved in establishing the research center was to get the peer review system organized for a selection of the research center directors and all.

I was involved in that, along with the EDRO, Don Healton and the RFDDs (Regional Food and Drug Directors) where the seven centers were going to be established. I didn't have as much authority as I thought I did.

RO: Do you recall whether the directors of the research centers were for the most part hired from outside FDA or if they came from within?

AS: I think they were both. Most of them came from the outside, except, if I recall, two of them.

RO: At that time, I believe we still had science advisors assigned to each one of the field laboratories. What role did the science advisors play in these research centers?

AS: Some played more active roles than others. Dr. Caruso in Cincinnati played an active role in the formation of an analytical research center at the time, but most of the others played a passive role.

The science advisor program was really a good program. At one time I had advocated that we use the science advisors to do training and other things that are needed in the analytical or microbiological areas and to bring the level of science up.

RO: All of the district laboratories at that time did not have a research center.

AS: That's right.

RO: But those laboratories that didn't have a research center were able to do some "method development" or research.

AS: Yes, that was the FD1609 Program that I mentioned earlier.

That was one of the issues that had come up, if you remember, Ron, whether these research center people would be considered a cut above the research analysts in the district laboratory. That was an issue that we had to tackle.

RT: You've mentioned the FD1609 Research a couple of times now. What does FD1609 Research mean? How do you define that?

AS: FD1609 refers to a form number. It is a mechanism by which district analysts can propose a research project that is needed or would be helpful to do analytical work at the district level.

RT: I see.

RO: But the 1609 requests came to the Division of Science for review and approval. The districts couldn't just initiate something on their own.

AS: Everything that went into an FD1609 Research project allowed people to do a certain part of research and then publish it in a peer group journal, or they can publish it in the *Laboratory Information Bulletin* that was issued by DFS.

RO: These research centers weren't well accepted by a number of the centers or the bureaus, were they?

AS: That's right. Most of bureaus wanted to have the control over the research centers. One objective was for them to manage the Centers; secondly, to have an input in what kind of research was to be conducted. That was contrary to the charter that was

established for the research centers. One of the compromises that we came up with was that EDRO would continue to manage the research center; however, we would consult with individual centers on some research projects in terms of determining the priority and needs of the agency.

RO: Were some of the centers a little bit easier to work with than others?

AS: Yes. Foods always wanted to control things, and even if a research center came up with a better or new idea, it was hard to get Center approval.

RO: With the Bureau of Drugs and their St. Louis laboratory, what was the difference as far as that operation doing research as opposed to the districts doing research?

AS: The research at the St. Louis laboratory was targeted toward a request either from a review chemist or from the ANDA folks. In some cases, Tom Layloff would initiate a research based on the survey samples that he did; whereas, the district laboratories did research based on their findings based on samples they collected under a compliance program.

RO: In your judgment, Arvin, were those research centers of value to the agency?

AS: They would have been of value to the agency, except for the way they were set up and managed. They had the name of research center, but a lot of the work that they did was very similar to that being done in the district laboratory.

RO: I thought when the Centers were established, the work was to be controlled so the research centers didn't get bogged down in some special analytical regulatory problem.

AS: I think the problem they ran into was that the people they hired in the research center had a somewhat limited knowledge of research. What they brought with them was method development research experience they had acquired in the district laboratory.

Research, unfortunately, in the field laboratory kind of . . . I mean, it's a fancy word for methods development. OK? Which is nothing more than a glorified quality control system. OK. It's really not a research. It's called research because we want to pat everybody on the back, but it's really not research. Those are the people who went into the research centers. So if you have a people with very limited knowledge, they're only going to use what they have.

RO: How many research centers are there today?

AS: Probably the Elemental Analysis Research Center is the only one left.

RT: Now beyond the methodology aspect of research, what are the parameters or what is the definition of research that you're speaking about? The intellectual pursuit of what kinds of issues or problems?

AS: Research, as you know, entails more than doing something by a different method. What it means is the ability to dig into different and new things to advance knowledge in a particular area.

RT: That may be helpful to the reader of the transcript.

RO: You've mentioned before that you felt the science advisors were of value to the field, but the field probably didn't use them to the fullest extent possible. And in the same manner, the research centers or the Centers of Excellence served a purpose at the time.

AS: They did.

RO: Not only from the morale standpoint, but it gave some of the analysts a little more of a flare for doing method development work to advance their careers. Does the field still have science advisors?

AS: Yes, I believe they still do.

RO: One of the other things about this time that was talked about was laboratory specialization. The analytical equipment had become rather sophisticated, and with budget restrictions there was the feeling that you couldn't support all of the laboratory sophistication in all of the eighteen or so laboratories. So management started talking about laboratory specialization. Were you still in DFS when they started to discuss moving to specialization and consolidation?

AS: Yes. I was directed to look at those things. We've always had problems of getting new equipment for the laboratories. According to the requirements that we have, the laboratories are expected to use certain kind of methodologies for doing either it's surveillance work or compliance work. For those methodologies, we need all the types of equipment.

RT: In management of a regional laboratory staff, is procurement of laboratory equipment a particular problem? Does everyone think they need top of the line stuff? Is it difficult to convince some you don't need that?

AS: Oh, yes, it's very, very difficult. You can come up with all kinds of justification for what you think you need.

RT: Well, that's the catch, the problem in government administration, both at the regulatory and political arena, everybody wants the best as long as someone else is paying for it.

AS: Yes, that's right. If you compare the industry equipment to that of FDA laboratory equipment, you will find not much difference.

RT: That's interesting.

AS: Where are we now?

RO: We were talking about laboratory consolidation.

AS: Yes, we were talking about laboratory consolidation. I really don't know why Paul Hile wanted to do the laboratory consolidation.

I guess he had a few people who did costing and stuff like that. Anyway, he decided that we should look at laboratory workload and cost analysis. I was involved only superficially. As you know, laboratory consolidation did not occur at that time.

RT: Was the relocation of personnel a factor?

AS: Well, yes, a number of factors were involved, such as relocating personnel and work.

Everything revolved around the district's work plan and what the district director wanted. We've had problems all along when we sent samples, pesticide samples from one laboratory to another laboratory, or from one district to another district's laboratory.

That continues when you consolidate since you're taking away somebody else's work. All of a sudden they don't have a laboratory, and they know the other laboratory is not going to pay as much attention to their samples.

RO: Well, some of those laboratories have been closed now.

AS: Yes, a number of them have closed.

RO: I guess we've got to separate consolidation and specialization. For example, Philadelphia is a drug specialization laboratory. Is that successful?

AS: Well, beauty's in the eye of the beholder. Probably it is.

RO: I guess you should separate out compliance samples and surveillance samples. To me, a surveillance sample would lend itself to let's say a place like Philadelphia. There should be some economy of scale of collecting a whole series of surveillance samples, for example aspirin samples. They can set it up on an automated system.

AS: Yes, you can do that. That's what Tom Layloff's Bureau of Drugs laboratory in St. Louis was doing. For surveillance samples, they would get samples from all over the country and run the analysis.

RO: What I hear from you is that you are not necessarily in favor of what is happening now as far as a lot of the laboratories closing down.

AS: I was not in favor of laboratory consolidation.

RO: But it's here.

AS: It's here, and people will have to live with it.

RO: Let's move on from field science. Then you went into ORO (Office of Regional Operations).

AS: I went from field science and became deputy to Ron Chesemore when he became the director of ORO.

RO: When you went there as the deputy ORO, Hile was still the ACRA, is that right?

AS: Yes, he was here.

RO: How long were you in that position?

AS: I was in that position until 1991.

RO: Well, Ron Chesemore left before that.

AS: Before I did, yes.

RO: Did you become the director or the acting director?

AS: I became acting for a while. It was during that time we had the Tylenol episode, and we had the generic drugs scandal. I had worked pretty closely both with Dr. (Frank) Young and Jim Benson, when he became the acting commissioner. Then came the grape situation.

RO: Tell us about the grape situation.

AS: In the grape situation, there was a senior staff meeting in Frederick, Maryland. John Taylor was the ACRA (Associate Commissioner for Regulatory Affairs) at that time. All the senior managers from the field, the RFDDs, office directors, and John were at this meeting and I was in charge. I got a call that night from (Dick) Swanson that the district laboratory in Philadelphia had found cyanide in grapes.

RO: This was imported grapes?

AS: That's right, Chilean grapes. As called for by the procedure, Dick Swanson had notified Dr. Frank Young, and the commissioner wanted to have a meeting at 7:00 the following morning. I called John and Ron to let them know what had happened to see if they wanted to come back for the meeting with the commissioner. They said, "Go ahead. Attend the meeting in the morning."

We had a meeting in the morning at which time Dr. Young decided that this was a very serious matter. He wanted certain things to be done by Fred Fricke's laboratory and CFSAN (Center for Food Safety and Nutrition). He did not want to wait; he wanted to move on this thing.

RO: Let me ask you, it used to be the policy in the field that you had the original analysis and then you had a check analysis to confirm the result. Had this been done in Philadelphia? Did you have two separate analyses?

AS: There was a check analysis, but from the same aliquot. Only one or two grapes in the lot were suspect and the amount of cyanide was very small. On the basis of the presence of cyanide, the commissioner decided there might be a health hazard.

RO: Were the grapes detained?

AS: Yes, they were detained.

RO: None had gotten into . . .

AS: Commerce. The commissioner decided to brief the Secretary and the Assistant Secretary. I went with him for the briefing at the department. The Secretary accepted what the commissioner said. The Secretary indicated he would notify the Department of State and the Defense Secretary.

RO: I've forgotten the final outcome. Did they ever find any more contaminated grapes?

AS: No, however, a lot of stability and other analyses were done by Fred Fricke's laboratory.

RT: When was the decision made for the two FDA people to go to Chile?

AS: It was made during the time the analyses were being done to find which Chilean farms may have been involved. Since the government of Chile was cooperating with us, they suggested that FDA send some people to examine the procedures their government had put in place to monitor the situation.

RO: With having had the recent Tylenol episode, was it suspected the grapes could have been contaminated here rather than in Chile?

AS: The whole shipment came from Chile. The question was, did the contamination take place in Chile or did it take place on the boat? Also, how long ago did the contamination take place? That is why we needed to know the stability of the cyanide. Knowing the stability of the cyanide would probably tell where the contamination took place. If it was determined the contamination occurred on the boat, it would narrow the number of people who may have caused it and you could direct your investigation accordingly.

RO: What else exciting happened while you were on that watch?

AS: One other exciting thing was when we had the generic drug scandal. One of the issues that came up at that time was whether generic drugs are safe. In order to determine whether generic drugs are safe, it was decided to have fifty or a hundred of the most frequently prescribed drugs analyzed in our district laboratory.

The results of these drug analyses would be made available to the public to assure them that these products are good.

RO: Were the drugs sampled on the market found to be satisfactory?

AS: Yes.

RO: It was my understanding that one of the things that happened was some of the generic manufacturers were not submitting their own product to FDA.

AS: No, that's a different thing. You're comparing two different issues.

RO: OK.

AS: The fifty or the hundred most prescribed drugs sampled were to assure the public that the products made by these manufacturers are safe and effective.

The issues that we had with a number of generic drugs were that during their approval process, some companies switched their sample for a form that was already on the market in order to get a faster approval. The idea was to take care of the scandalous firms in a different manner, but at the same time assure the American people that the products that are prescribed by their physicians are satisfactory.

RO: What was the time span for collecting and analyzing those samples?

AS: I think it was about three to four months. Many of the district laboratories were doing just those samples.

Part of my responsibility at the time was to collect and tabulate the results of the analyses.

RO: While you were still in ORO, Ron Chesemore was selected for the ACRA (Associate Commissioner for Regulatory Affairs) position.

AS: Yes, Chesemore got selected to become the ACRA. I had applied both for the ORO job, as well as for the deputy ACRA job. I had learned indirectly at that time that Jim Benson wanted somebody from the field to come in to the ORO position. He had also suggested to Chesemore that he should try to better integrate ORA with the centers. It was Benson's feeling at that time that ORA was just doing its thing and not working with the centers. In order to achieve better integration with the centers, Ron Chesemore selected Gary Dykstra from CVM (Center for Veterinary Medicine) for his deputy and Gerry Vince from the field for director of ORO. These selections were made in response to the Benson request.

So I decided at that point that I needed to have some other experience. Adam Trujillo was the deputy in OE (Office of Enforcement). He was on some training assignment and might not come back. So I asked that I be assigned to OE. (Al) Hoeting was more than happy to have me.

Dealing with the district director and the regional director was part of the ORO responsibility. I had a pretty good relationship with most if not all of the field managers and that was one of the things that I brought to OE.

Naturally, Hoeting's relationship with the various district directors was very different, even though he came from the field as a district director. Hoeting's nature was very different, being somewhat authoritarian.

RO: The role of OE then was probably different than what you just left?

AS: Yes.

RO: At that time, a lot of the field's regulatory recommendations came in through OE, didn't they?

AS: OE played a very, a different role. The generic drug scandal had just closed, and there was an order of doing a lot of prosecutions. Therefore, you needed to have a lot of "ad hocs."

RO: Describe ad hocs for the record.

AS: Well, ad hoc is a mechanism set up by which a district or a region can ask that the center, the Office of General Counsel, and naturally the Office of Enforcement all get together and come to a consensus decision on a case.

RO: Go or no go.

AS: Go or no go. Many times the ad hocs were used as a part of an appeal of a turn down, but in many other cases it seemed expeditious to come to a consensus decision in one initial meeting.

We had almost thirty-nine ad hocs the first year I was there. Soon the districts realized that ad hoc was not the easiest thing, because you can start prosecuting people, but then you've got to follow up, and that takes a lot of resources.

The other thing that is different now than it was then was that (Representative John) Dingell had a hearing where they exposed that the agency was overloaded with reviews and we were not able to take any actions on many of them. At that time, Dr. Kessler was commissioner, and it was decided that we would streamline our procedures and practices.

So in streamlining, it was decided that among a number of things that OE was doing, it did not need to look at injunctions: or warning letters anymore. In some other cases, we would provide whatever resources or advice we were asked for but not to routinely review the proposed regulatory packages.

Unfortunately, we were not involved in the review, but we were often asked for information on pending cases. In case there were center or district problems with a proposed action, we would have to ask the field for a copy of the injunction to see what the issues were. In some cases, there were policy or precedent issues that we needed to know in order to assist in resolving the problem. Most of the people in OE are senior people who have a lot of institutional memory and to cut them out of the loop was not the best thing to do.

RO: I had talked to Al about a month before he finally retired. Al had indicated to me in our earlier conversation that he had no intentions of retiring, and all of a sudden-rather abruptly to me anyway--Al was retiring. He had tried, I think, a partial retirement or something? He decided he liked it, or am I wrong?

AS: I don't think he had--at least not to my knowledge--tried partial retirement. Actually, I was surprised when he decided to retire, because at that time, Al was heavily involved in certain legislative efforts that were being put up by OLA (Office of Legislative Affairs) and the department. Like a lot of things, Al would like to take the bull by the horn and do it himself.

RO: What was the legislative initiative that he was working on?

AS: There were a number of FDA proposed amendments to the Food, Drug and Cosmetic Act. Some had to do with imports and others with enforcement authorities. He was very actively working with the department and some of the congressional staffers.

RT: Do you think there was some departmental influence with regard to his decision to retire when he did because of his independent legislative initiatives?

AS: I would think so.

RO: Didn't he come back and testify after he had retired?

AS: Yes, Senator Kennedy had a hearing after Al retired. Mike Taylor attended the hearing to represent the agency, and I went with Mike as a backup, a support person. Al was there to testify after FDA's testimony.

RO: Didn't he testify?

AS: He did, but no new authorities were granted as a result.

RO: And you stayed in OE.

AS: I stayed in OE, and Dan Michels came in as Director.

RO: Dan came from the Bureau of Drugs.

AS: Yes, CDER (Center for Drugs Evaluation & Research). I had worked with Dan before, when he was Ted Byer's deputy.

RO: There used to be a Compliance Policy Council that had been set up I think back when Hile was the ACRA, and there were some that thought it was a great thing and others that wondered if it was a waste of time.

AS: That's right.

RO: What's your feeling?

AS: I think things have to change according to circumstances and people. When the compliance policy was set up years ago under Paul Hile, he used to manage it, and all the compliance directors of the centers participated.

After Paul left, the management of the Compliance Policy Council seemed to be in the Office of Enforcement. So Al Hoeting became the chair of the Compliance Policy Council. Situations started to change within the centers. The new compliance directors coming into the centers were very different. Some were compliance oriented and others were not. So the philosophy of compliance was changing.

By the time Dan came on board, the Compliance Policy Council just became another meeting. By then, some of the center compliance directors were more tuned to what their needs were within the center.

RO: The role of the ACRA changed since Hile was there, because that used to be considered the number three position in the agency, and under Dr. Kessler, the ACRA was submerged.

AS: Yes, a lot of philosophy changed, and many of the new center directors were not compliance oriented.

RT: When you say they weren't compliance oriented, how would you describe their orientation?

AS: Compliance was an unnecessary evil.

RT: They believed that the center should be doing what?

AS: More product approvals.

RO: What is the role of OE now as far as the whole agency compliance policy is concerned?

AS: The role of the OE now is to broker a lot of problem issues between the centers, between the district and the centers, between the centers and general counsel, or between the other factions even of the Commissioner's Office, like Office of Policy.

RO: What influence does the Office of Policy now have in the Commissioner's Office? From what I read in the organizational chart, that office is to provide a uniform enforcement policy for the agency.

AS: Yes, that was when Mike Taylor was there.

RO: Well, in the scheme of things in the present structure, who is supposed to see that there is a uniform agency compliance policy? Does one center take the same action on the same kind of a violation as that of another center?

AS: Theoretically, there is no one. From a practical standpoint, that's when OE comes in to play.

RO: You retired within a month after your boss, Dan Michels, retired. What prompted that?

AS: I was ready to retire.

Last year, I had trigeminal neuralgia, and it's a really painful disease, which I was out for three months.

When I came back, which was in March, I was contemplating when I should retire.

Then Dan surprised me by making his announcement. I did not want to make an announcement at the same time.

I waited for a few days, and my wife convinced me that it would be good for me to retire during the summer months so I would have time to play golf and do other things.

RT: I know some other retirees who made such a decision during the winter and they got cabin fever.

AS: I have to thank my wife for it.

One of the other reasons why I decided to retire was that if I'm going to do anything else after retirement, this is the time for me to do it. I'm sixty-seven years old, and so I have a very small window to fool around with. If I was lucky enough to get the OE job, it would be just another pain in the neck for not too much money.

I look forward to keeping myself at least intellectually stimulated.: I'm going to do some consulting if I get the type of things I want to do. I'd like to paint. I do some oil painting. So will resume doing that. I like to play golf. I like to write. Most of my writing is in technical writing. So I'll probably do that.

Being a chemist, I use my kitchen as my laboratory, so I've been fooling around with vegetarian cooking for some time. I've been thinking about writing a book on it.

RO: Your wife hasn't thrown you out of the kitchen yet?

AS: No. She's very good. She eats it, and then tells me what I should do to improve and what I should add or subtract.

RT: Well, as long as you don't do like a state chemist I worked with years ago. When his wife was away one time, he reorganized all of her kitchen cabinets as in his laboratory. She was not pleased.

AS: Oh, yes. Well, that reminds me. When I used to work for Ortho, we had a chemist, Les Bane, a very intelligent person, but he wanted certain things in certain places. He lived in New York and didn't know how to drive a car, so he used to come on the train and walk to the plant. He would not go home every week. Most of the time he would sleep on the sofa in the waiting room at night. He would work for eight, ten hours, or more depending on his project.

But he didn't like the way our library was kept. He thought that it should be organized better.

One night, he spent the whole night rearranging the library. The librarian came the following morning, and she was, I mean, teed off.

And then another time, his mother took him on a cruise. He loved cats, and on this ship there were nice paintings. He went and painted cats all over the paintings and rearranged those pictures. The captain came in and wasn't too happy. His mother had to pay some money to get those things cleaned up.

RO: Well, Arvin, is there anything that you'd like to add to this? We appreciate your time.

AS: No. The only thing I would like to end up with is to say that I've really enjoyed working for FDA. It was time for me to move on.

RT: Well, thank you for the interview.

RO: Yes, we appreciate it very much.