History

of the

U.S. Food and Drug Administration

Interviewee:	**Garrett D. Salmon**
Interviewer:	**Suzanne W. Junod, Ph.D.**
Date:	**August 30, 2013**
Place:	**Phone interview from Silver Spring, MD to Olathe, KS**

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Silver Spring, MD 20993

CASSETTE NUMBERS

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

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Garrett D. Salmon

August 30, 2013

TAPE 1, SIDE A

SJ: Today is August 30, 2013. I am conducting an oral history interview with Dr. Garrett D. Salmon by phone from his home in Olathe, Kansas.

Mr.Salmon,thank you for joining us and sharing some of your experiences as a prominent scientist within FDA.

Tell us a little about where you grew up and how you got interested in science and your background.

GDS: Well, I was born interested in science. I was the guy that would inspect ants walking across the sidewalk and watched birds and everything else from age three or four on up. I grew up in a little town in southern Minnesota called Waterville, graduated from Waterville High in '56, and then attended Mankato State. At that time it was Mankato State Teachers College; it's Minnesota University at Mankato now. Spent four and a half years and graduated with majors in chemistry and German and minors in mathematics and physics. It was an interesting college career, but I didn't have time for much outside activities.

Went back to Waterville and worked on weekends to make enough to get through the following week or month.

I enlisted in the Minnesota National Guard when I was in high school, and that helped pay for tuition and books. I got paid quarterly, and what I made just about covered the college expenses for the quarters.

SJ: What year did you graduate?

GDS: Fifty-six. I enlisted in '55 and started accumulating service time, and then I went on active duty with the 5th Army in '57 and '58, came out in '58 and went back to school. Had strike duty in Albert Lea and other activities in Minnesota. It gave me experience with the service.

SJ: Now, what was your career after that? How did you come to work for FDA in 1961, I think?

GDS: Well, I think that was my last, by that time I had been enlisted in what they call the Minnesota Military Academy, and spent my last year learning how to become an officer.

Now, this is kind of funny in that whatever Monday it was in June of '61. I'd already committed to working with FDA, and three colleagues of mine that reported for duty. They were Richard Trauba, Don Melehior Jim Seifert. They made it okay, but a Guard unit ran in about four in the morning on Sunday and I didn't get up until well after noon and failed to call in and caught hell on Tuesday, when I finally showed up, for being a day late, ruining the pay period and being docked a day's pay, which I expected. So I had a really auspicious beginning with FDA.

SJ: And how did you get hired?

GDS: Bob Keating recruited me at what is known as a job fair now; they had on-campus recruitments.

SJ: Oh. So you were on campus when you were recruited.

GDS: Yes.

SJ: And what did he tell you about the job when he talked to you about it.

GDS: He gave me a pretty accurate rundown. He gave a good description of the variety of analyses and it appealed to me. I didn't want to end up with paint labs or drug labs that I interviewed with because of the routine analyses. I think my second choice was Federal Bureau of Investigation (FBI) special agent, and this was before the days of the Drug Enforcement Agency (DEA). That was one of the appealing things, the idea of protecting the public. I thought that was a worthy cause.

SJ: Well, when you came, the chemists in FDA had just assumed a much higher profile in 1959 with the cranberry crisis. I know you weren't part of it, but what did you hear about it when you came?

GDS: That it had happened and took a lot of resources. They were looking for 3-aminotriazole.

SJ: When you first arrived at FDA, did the job fulfill your expectations?

GDS: Yes, for the most part it did, and it got better as we went along. We had some pretty grubby experiences in the early days. We had, I think the initials were Pretreatment Engineering Platform (PEP). It was a program

to clean up the country grain elevators from rat and mouse infestation.

We ran quite a few samples, taking rodent excreta pellets out of the grain destined for human use, which, that was not very challenging. We also had a program for checking for cysts in imported white fish from up in Canada, and invariably the trucks would roll in about one or two in the afternoon so we'd be caught filleting fish looking for cysts until we got the load finished.

One other thing I forgot to mention. I thought the agency had a pretty good training program in place. It was kind of fluid and not really integrated, but we learned a lot at the microscope. Most of the chemists were not microscopists, and that's what we used for the filth and foreign material, so we learned about insect entomology and how to use the scope checking for other foreign material. Most of the analytical procedures nobody knew about. The Association of Analytical Chemists (AOAC) was brand new to us, and of course you know what AOAC is.

There was atmospheric testing of atomic bombs going on, and we monitored radioisotopes in food. And we'd ash food samples with a newly developed radar range . . .

SJ: Radar range?

GDS: Big stainless steel ovens that used "radar" to ash the samples similar to today's microwave.

Silent Spring came out in '62, and our workload increased to include pesticide analysis, in the methods being developed by Headquarters scientists at the Division of Foods. We got training out there. I did not participate in Headquarters training. We got it from others that had been out there. Vern Kamps was our lead pesticide guy at the time.

SJ: What pesticides were you testing in particular?

GDS: We started out with the chlorinated hydrocarbons, dieldrin, endrin, DDT, DDE, heptachlor, heptachloroxide. They subsequently were banned by the Environmental Protection Agency (EPA), in the early '70s. The "dirty dozen", they were referred to by that time, and enough information had been pulled together to either outlaw them completely or restrict them.

SJ: So FDA was doing the testing, but we didn't necessarily have the authority on our own to outlaw these?

GDS: That's right.

The Environmental Protection Agency (EPA) was later created. They were granted the authority to regulate the pesticide levels. And by that time we had expanded into a different class of pesticides so that when they did outlaw the dirty dozen, we were pretty much knowledgeable on the organophosphate pesticides, which those would include such things as malathion and parathion. I mentioned that I was associate referee for ethion and many of the "thion" pesticides, which by then supplanted the organochlorines for applications such as in grain, elevator grain, kept the bugs off.

And then there were problems with stockpiles of organochlorines, and sometimes a farmer would add pesticides to the whitewash for his hen houses and that would find its way into the eggs. Or pesticide powder would tip over into the cattle feed, and that would find its way into meat and milk if it was slow-acting. If it was fast-acting, like the organic phosphates, it would kill the animals right away and it wasn't near the problem to trace.

But if it got into the milk, that involved a lot of work. You had to find out the delivery routes that this was in and determine the level of the pesticides in his milk truck. And then as it went out to the dairy, how many gallons from the milk truck went into the big a tank, and

all the calculations required to find out whether it ought to be recalled. And this was later; this did not start out that way. But then final dispositions need to be made, converted into animal food or into portiliger.

SJ: How long were you involved with dealing with the milk issue? Because it persisted for many years.

GDS: Yeah. I remember doing dairies shortly after I was assigned here. It would have been early to mid-'90s -- we had episodes like that in the Missouri, Iowa, Nebraska, Kansas district.

Of course we had the polybrominated biphenyl episode while I was out in Detroit. You might recall the flame retardant PBB. It was a fire retardant for plasticizers, and I don't remember the details of how it got ground up, but it was added to animal feed, dairy feed.

SJ: Intentionally.

GDS: Yes it got into the milk, got into the mother's milk.

SJ: Now, from June '61 to March 1969, you were in Minneapolis as an analytical chemist.

GDS: Right.

SJ: But in March '69 to December '79, you were supervisory chemist in Detroit. How did that come about?

GDS: Well, they had an opening and I applied. So I interviewed and Tony Celeste selected me for a supervisor out there. And he was kind of concerned about my political correctness and such, coming from the frontier, but that was okay. We never had any problems in that area.

SJ: Are you saying you were opinionated?

GDS: He thought since I grew up in the forests of Minnesota, I did not know about many, many things: negotiating, race issues. I might have been a kid from the sticks; I probably was. But he took a chance. I did know my chemistry, and we did have some good times. I admired him as a lab director. And, of course, he went on to bigger and better things.

Cliff Shane was Director, Investigation Branch, at that time. Cliff went on to great things also.

The District Director in Minneapolis was A. Harris Kenyon and Joe Durham was the Deputy Director.

SJ: So, what was the work like in Detroit as opposed to Minneapolis? What were your assignments in Minneapolis, I mean in Detroit, after being in Minneapolis for so long?

GDS: Instead of running the samples, I would be assigning the samples, and my group was split into two subgroups, in which I tried to rotate the people every year or so.

Detroit was a big drug district, and we had the intensified drug inspection program going on at the time, which developed further. I think I was the first one to assign a chemist to a drug firm, so that whenever a problem broke out, the analysts were experienced and knew what the history was and could swing right into it without having to spend a lot of time gearing up staff and what the potential problems were. It made sense and it worked, so we did it. Had excellent drug chemists. Milda Bauzer was one of the drug specialists.

SJ: Give us a little background on the history of the Total Diet Study, for people who don't know.

GDS: Okay. It's documented in the Journal of the Association of Analytical Chemists (JAOAC). Ellis Gunderson wrote it up. I don't have the page in here, but if you've got the time and inclination, it would have been published in the mid 1980s.

SJ: I'm familiar with it, but people that are listening to this interview might not be.

GDS: One of the references I had was a five-page document that cites 10 years' accumulation of results that was pulled together by key personnel of the Total Diet results. That's for historians and people that might be interested in modifications to the Total Diet to review in depth.

But it started and was funded by three units in the Division of Foods. The Division of Nutrition was interested in vitamins. The Division of Food Contamination was interested in the findings of radioactivity from the aerial bomb testing going on at the time, and radioisotopes were being found. There were hot isotopes in different

foods. And the Division of Pesticide and Chemistry Technology was interested in pesticide residues.

SJ: The radioisotopes were coming up as a result of the testing out west, nuclear testing out west?

GDS: There and elsewhere we were finding isotopes in Minneapolis and I think Headquarters. There might have been three other districts involved in that analysis.

SJ: How dangerous? What kind of level?

GDS: Levels of concern, you would say. I don't know that tolerances had been set at that time. But that kind of work has continued.

Now, let's see. We had a meltdown in Pennsylvania at Three Mile Island that resulted in a nuclear release; the one at Chernobyl that was showing up in imported reindeer meat from Scandinavia; and I understand there's concern of the isotopes being released by the nuclear meltdown in Japan. That's in the early stages. I haven't read of any findings yet. But that happens now and then. You've got to keep the capabilities up, not only at the research level, but if there's widespread contamination, you need

widespread trained analysts to handle the workload for as long as it takes. It's the same thing with any of the national outbreaks or international outbreaks.

SJ: I have a very specific question. You worked with imported products in Detroit.

GDS: Yes. Well, in all three districts we had some imported food.

SJ: Were we able to maintain strict control, or were there times that we had to make some allowances and allow some things in with minor problems or things that could be corrected?

GDS: [laughs] I don't think we have had and won't have strict control over the import workload. We are testing what, two to three percent of the food coming in? Now, the rest of your specific question I didn't catch.

SJ: Were there times when you had to maintain an attitude of, not so much strict compliance, but of flexible compliance? If there was a small problem, you could let it in, with the understanding it would be fixed?

GDS: There were occasions like that where there was a small problem and we got it identified and controlled in a hurry. Other times there was a small problem of lingering duration. And there were times when we shut down the lab to focus on whatever the imported problem was.

SJ: And can you give any examples of any of those?

GDS: Let me think where to start.

We got into that with imported tuna fish before we discovered our domestic problem with tuna fish. It seems to me that started out with import from Asia, and the FDA halls were lined with cases of canned tuna.

New York handled the situation where mercury had been injected into oranges from Israel. I don't know how big that problem was. They're on record, the national outbreaks. There was a unit in the Division of Foods that was tracking these, mostly focused on bacterial problems, but I think it may have carried over into such things as Tylenol and other national problems that required a lot of attention. That's all I can think of just now, Suzanne.

SJ: You did a lot of standardization work, standardization analyst guides and training. You did a lot of work to upgrade the standards of the labs and train chemists and that kind of thing.

GDS: Yes.

SJ: Tell me a little bit about what you consider to be the accomplishments, the real improvements that you saw and were either a part of or helped direct.

How did chemistry change while you were there?

GDS: We started out, we had burettes and single-chain swinging balances that could measure maybe a thousandth of a gram; these were the old-time balances. You put your solid substance on one pan and the weight on the other pan and adjusted a beam across the top, and then a chain hung down to give you the fine reading. Later on we got the electronic balances where you hit a button and it tared it out, so it showed no weight on the pan. You put your analytical sample on the pan and marked all the readings, marked on the weight. You know how balances work?

SJ: I do.

GDS: Okay. When those came in, well, there was an interim period, too, when we had electronic balances and ironed out the problems with chain balances.

SJ: What time period are we talking here?

GDS: I think we were getting those in the mid to tail end of the Minneapolis period. And then somewhere in there, we got to the microbalances where we could measure tens and hundreds of micrograms on a little electronic balance, which was excellent for drug work and for the illegal drugs where you did not have much sample. We had a Division of, which started out as BDAC. Bureau of Drug Analysis and Control, was it?

SJ: Yes.

GDS: At that time they were interested in amphetamines being peddled to truck drivers, resulting in crashes and what have you.

We started getting into the street drugs, and eventually that became DEA. It was food and drug chemists

and other chemists that were taken from knowledgeable units and put together, and that turned out to be DEA.

Now, you had asked about a significant contribution with program writing. I'm kind of proud and a little bit scarred on what started out as an FDA analytical manual. I had been a drug trainer for 14 chemists, a dozen or 14 new graduates and a few from industry back in the late '60s in Minneapolis. And if you're going to train that many people, that's a pretty big workload, you can do it on a lecture basis, an assignment basis, and people work at different rates and levels and skills and such, and it did not prove efficient.

So I dreamed up this idea of creating a bunch of exercises, a couple of pages of general exercises that we learned under a tutor that involved calibration of equipment, mostly, and the literature. And then it swung off on to a chapter on drug analysis, a chapter on filth analysis, pesticide analysis, etc., throughout the workload. And what I did was kind of a one-page deal with reading assignments, referenced the method to be followed for a training sample, a place for the results to be reported, and any results as well as discussion and pitfalls. These were samples that were of unknown content to the trainee.

Okay. So the first part of it was all right, and then in 1972 we revised it. That was the first one that was published out of Washington, Division of Field Science. Hy Eiduson was Director at the time. We debated different approaches and formats and the value of this system to the lecture system, and it turns out we went with my proposed system. And then in '72, pesticides had changed enough that the original manuals (pamphlets) had been updated, so another revision was warranted, and we pretty much did it the same way. Changes happened in United States Pharmacopeia (USP) and AOAC.

Well, I got away from this project then, and others took over, which is as it should be, and it had been revised maybe once or twice more, and then it became . . . We called it the *Analyst Operation Manual*, I think was the last name for the original participants. And then I think it was associated with AOAC for a while. I can't remember that and was out of the game by then, but it kept growing by leaps and bounds. And if you get on the Division of Field Science website and look for something that looks like *Analyst Operation Manual* or *Analyst Guidance Manual*, you'll see how many pages that's grown to. It includes all kinds of additional training out in Washington and field training to assist the investigators with collection of

samples of different kinds. It's quite a change from the original one, just like with the changes to the balance we talked about.

And I don't think we ever got any credit for it other than on the front page, they may have listed the authors on the first and/or second edition.

SJ: While you were in Detroit, you participated; it sounds like, in several national emergencies. I think you mentioned the mercury in imported tuna.

GDS: Yeah. That was the first or second month I got up there, the Tylenol episode broke, and that was a domestic problem, of course. The samples were in the hallway on that one. We closed down everything, except the essential part of investigations, to collect assigned samples. Assignments were coming out of Headquarters to avoid duplication of effort. But we had administration staff and the District Director, and anybody that could open up a capsule and look for abnormalities was sitting up at a desk pulling caps apart, looking for signs of cyanide presence.

SJ: What year was that? You were in Kansas City at that point, right?

GDS: Well, I can't remember. There might have been a little episode when I was in Detroit. But this would have been a couple months after I got up here, in '79, and that lasted a good month or two. I think most of the field was in the same boat. A lot of Tylenol was examined.

SJ: We have a piece of equipment they call the twaddler. It was something someone invented to help open capsules faster.

GDS: It seemed to me that was a scanning device that showed up dark spots in the capsule. Does that sound right?

SJ: It could well be. It didn't have any electronic components, though. Well, we'll send you a picture and see if you can tell us anything about it.

GDS: Twaddler?

SJ: They called it the twaddler. I have no idea. I think the name was taken from a popular cartoon - Calvin and Hobbs . . . . What do you remember about working with

the Three Mile Island incident? We have various accounts of it, but it was fascinating as well as important.

GDS: I want to say '73. That would have been a year or two, maybe it's got the year of Three Mile Island on it.

SJ: It was 1979, but I'm interested in your memories of it and what you were able to do and the pressure you were under and that kind of thing.

GDS: Well, oddly enough, I was not under much pressure on that because what happened was that Parke-Davis was a major drug manufacturer just a few blocks down Jefferson Avenue. They were one of a few firms that made a potassium chloride or potassium sulfate solution. Potassium being an inhibitor of the radioactive isotopes, so people were getting shots of this injectable to ward off bad things, and our role was to see about increasing production to the maximum possible for protection of the citizens. I think the Investigations Branch carried the bulk of that work. I was there if they ran into problems, I could provide any technical help. They'd call on me and I'd do what I could. But as far as taking up lab time and such, I don't recall that being a problem.

SJ: Yeah. That was pretty much left to the company, with FDA supervision, I believe. I think that that was primarily conducted with supervisory work from FDA at the Parke-Davis plant.

GDS: Yeah, probably so.

SJ: In an interview that we did with Al Hoeting, he talks about a role that you played in a device investigation.

GDS: Refresh me.

SJ: It says in 1975, the Detroit newspapers had stories about an FBI investigation of the death of seven patients due to respiratory arrest at the local VA hospital. FDA became involved when it became clear that they had all been receiving IV solutions, and it says that as a supervisory chemist, you initiated a search of the world literature and located a method for determining the presence of curare in animal tissues and specimens. And it looks like you determined that there had been curare in the specimens and the tubing.

GDS: This was a tough one. I want to step outside for a minute.

SJ: There was an interruption at this point in the interview and we were not able to continue until two weeks later.

TAPE 1, SIDE B

GDS: I guess research. We were the only ones that were doing that for a while. I don't know if the other ones picked up on it or not.

SJ: The other research centers?

GDS: Yeah.

SJ: What difference did the Internet and computers, you know, the website make in your work over time?

GDS: Oh, yeah. It takes a little effort to maintain continuity or currency on it. This is the year to update it as far as your accomplishments and that kind of stuff.

SJ: Did it make it easier to communicate? I guess I'm trying to get more on the impact of computerization on FDA and how the scientists would have been influenced and in turn influenced . . .

GDS: Oh, yeah. Back in those days, when we were making the transition, computers helped us organize the results on individual foods quickly and easily, without much human drain, so that freed people up to do other work. As far as the scientific communication, sure. If you had a question, you could e-mail somebody. If a question came up at nine o'clock at night, it was really easy to hop on the computer and email and ask your question or swap information during off-hours, and you didn't have to wait for a long time.

SJ: Did you have any interactions with any of the FDA Commissioners, or do you recall any ways in which maybe the different Commissioners may have influenced the nature of your work? For example, when you first came in, I guess James Goddard was the first politically appointed Commissioner.

GDS: I'm trying to remember if I had any direct involvement, and I did with a couple of them. Jane Henney came out to the District several times. She was a Kansas City girl, real personable and such. We had a good time. I don't remember if we went out to a BBQ place. Washington folks liked to participate in one or two notable BBQ joints.

SJ: And who were some of the other people in your career that you want to mention?

GDS: I forgot to mention, in Minneapolis, A. Harris Kenyon was the DD, and Menno Voth was the chief chemist. Sol Cohen was the only supervisor at the time, and both of those guys were great in their own way. Mr. Voth was a good administrator and Sol was a good scientist.

In Detroit, Thomas Brown was the DD for a while, but then he left and Cliff Shane took over. Mr. Shane was a remarkable leader.

SJ: I think we should stop for today and let you rest. This has been a long interview. It has been a pleasure talking with you, and I look forward to cleaning up some loose ends, but this is going to be a really nice contribution to our oral history program.

END OF INTERVIEW