

History
of the
U.S. Food and Drug Administration

Interviewee: Robert J. Nesselhauf

Interviewer: Robert A. Tucker

Date: June 23, 2006

Place: St. Louis, Missouri

Interview with Robert J. Nesselhauf

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TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, the interview is with Robert J. Nesselhauf, who was an Investigator Specialist in Biologics operating out of the St. Louis District. The interview is being conducted by Robert Tucker at Mr. Nesselhauf's home in St. Louis, Missouri. The date is June 23, 2006.

Bob, as we begin these interviews, we like to have a brief personal history of the interviewee and then go on into the professional aspects, such as where you were born, educated, any employment you might have had other than FDA prior to your career with the agency. So would you begin in that way.

RJN: I'm a lifelong native of St. Louis. I was born and raised here. I attended the University of Missouri at St. Louis, and, after graduation, went into the Army for two years. I got out in 1972 and was shortly thereafter hired by FDA as part of what was called Project Hire, and served with the agency from July of '72 until I retired in October of 2004.

During my years with FDA, I did a broad range of FDA inspections, everything from food to medical devices to drugs, and the last 15 years or so of my career, I specialized primarily in biologics. I did a lot of work also in bioresearch monitoring, and those were the focus for the most part in the last several years of my career.

RT: You entered the agency at what level?

RJN: I started as a GS-5, worked my way up to a GS-11, and then became a GS-12 specialist, and then ultimately was a GS-13 specialist.

RT: We'll perhaps get into that as we go along.

You initially began in St. Louis District?

RJN: Correct. I was in St. Louis my whole career. I traveled some, but I was in St. Louis my whole career.

RT: Who was the director at that time? Do you recall?

RJN: Well, St. Louis was not a district when I started, never really became a district. It was a district until the '60s. When I started, it was called an Inspection Station. Then we became what they call a Branch Office, and I don't remember exactly what we were called. I think we were still called St. Louis Branch when I left.

RT: So your supervision was with a resident in charge?

RJN: No. I always had a supervisor. There were always supervisors in St. Louis. It was a large post. It had been a district office until they did some realignment under the old Health, Education and Welfare, and then there was a supervisor, and then ultimately there were plans at one point to put it back to a district office, and they brought a director in, and we had a director of the branch. For many years, we had a director, for more than 15 years.

RT: Who was the person who was put in charge?

RJN: The first one was Ron Johnson, and then, after he left, Ray Hedblad. And then the last one was Charles Breen.

RT: That's okay. I'm just kind of trying to put it in the context of time when these managers served.

RJN: Yes. We had a director, an office director, from '79 until about 2000, about 20 years.

RT: Now, in your early career, what did you initially work in? Usually, new personnel are assigned to filth and general inspection work.

RJN: Correct. That's what I did initially, did a lot of food work initially, and then got into doing a lot of pharmaceuticals. At that time, St. Louis had a lot of small drug manufacturers, and I did a lot of those.

RT: Were there any investigations that you were involved in which led to significant regulatory actions, seizures or anything of a formal nature?

RJN: Oh, yes, I was involved in a number of seizures. I was involved in some of the peripheral investigations of a firm in St. Louis that was making counterfeit drugs called Jamison and McKames in the '70s, and was involved in a couple of injunctions.

I had two small blood centers, actually three, but two small blood centers that started up in St. Louis that essentially were put out of business because of our efforts. That was in the '90s, when I was a specialist here.

RT: Did you move into the biologics area after the Office of Biologics, or whatever, was merged into the Food and Drug Administration?

RJN: That was '72 or '73. They trained a limited number of investigators at that time, I was still fairly new, and they trained a number of some of their senior drug people to do biologics work, and they then trained us. I was part of the second group that got trained to do it. And I always did biologics work from about '73 on. I was doing some every year. I always tried to keep my knowledge up in doing biologics work.

And then there was a combination position for a Drug and Biologics Specialist, and that individual left in the late '80s, and then I was given that position.

RT: Now, in addition to drugs, there are probably other areas of investigative interest or regulatory oversight for biologics. Can you differentiate a biologics field investigation from, for example, one involving drugs? Are there some unique areas of interest and expertise required in that area?

RJN: Well, biologics is in itself somewhat unique because it is considered both a biologic under the PHS Act and a drug under the Food, Drug and Cosmetic Act. Biologics has its own set of regulations in the CFR, but they also have to comply with good manufacturing practice regs that are listed for pharmaceuticals, and you have to balance those. It's a unique area that the agency regulates, always has been, because of the nature of the product and the nature of how it's manufactured as opposed to pharmaceuticals, which are made in a different way. They're a more bulk kind of manufacturing process.

RT: Now, at the time of the merger -- what was the Biologics group called? How were they identified in the Public Health Service before they came to . . .

RJN: FDA?

RT: Yes. Was it a bureau or . . .

RJN: It was a long time ago. Actually, it wasn't regulated by FDA until about 1972 or '73. It was regulated, for the most part, Biologics was regulated by the National Institutes of Health, I believe.

RT: Yes.

RJN: And that was brought, Congress decided -- NIH regulated the licensed facilities, ones that were licensed under the Public Health Service Act.

RT: The reason I raise that is because I recall when the Biologics operation came under the aegis of the Food and Drug Administration, some of the professionals who had been Biologics licensers or so on were more prone to the education-of-industry approach of industry oversight.

RJN: Yes.

RT: Rather than the regulatory approach. So that marriage was . . .

RJN: Very difficult because they weren't really regulators. They were not enforcers. And to be fair, I don't believe they had really good regulations. They had guidelines; they didn't have good procedures and regulations. I wouldn't call them educators exactly, but many times, at least from the early training that we had, they would go out and, rather than try to do something from

a regulatory standpoint, they would try to persuade the licensed facilities to comply with whatever. And some of the stories they told us were frightening. They regulated a lot of plasma centers.

RT: Now, you essentially used more of a voluntary compliance stance than our agency. Did you hear them tell you how they dealt with recalcitrant firms?

RJN: Not really. I think they just kept trying to persuade the people that weren't doing it correctly. Occasionally they would encourage them to shut their operations down and fix everything and start back up again. They didn't talk about regulatory actions at all, about anything.

I suppose that they always had the power to pull a license, but I know that was never done ever at NIH.

RT: So it was a matter not only of FDA investigators' orientation to this field, but somewhat of a requirement for the predecessors coming to the agency to learn our ways.

RJN: Yes. And we had to write a set of regulations as well. There were no regulations to specify what needed to be done. Everything was kind of incorporated in those license applications, and you couldn't get your license approved unless you agreed to do certain things. But then

there were no regulations. The only commitment you had made was what was in your license application.

So FDA wrote, probably about 1973, I think, the first set of regs were written by the agency to specify exactly what firms in the business of manufacturing biologics had to do.

RT: Within the FDA, who was the writer or creator of those regulations? Was that a . . .

RJN: That was a Washington function. That would have been what was then called the Bureau of Biologics. They wrote those regulations.

RT: And, of course, they went the regular route of publication in the *Register*.

RJN: Exactly. They promulgated those regulations the same way that any regulation would be promulgated.

RT: Now, you got into the biologics area, as I recall, because of your prior experience and interest in drug investigations. Was that the background of others that got into this activity?

RJN: I think there was a lot of internal politics going on. These people coming over from NIH were from outside FDA. The Biologics people have always been a little different than some of the other Centers, formerly called Bureaus. They had a hard time with regulations in

the beginning, I think, a very difficult time; they were, holding onto that program pretty closely. I felt in the early days, they didn't do a really good job of training us just in the science of blood that they should have. You kind of had to learn it on your own, which we obviously did. Ultimately, FDA did have courses later on, but in the early days it was a very difficult situation.

In the early days, we were regulating only non-licensed facilities. NIH only regulated licensed facilities. That means ones that shipped blood products across state lines.

It was Congress that desired to regulate the entire blood industry, and in the early days, when I started, there were a lot of hospitals that had their own blood program. Very few of them collected enough blood on their own to provide all of their needs. They still relied on the Red Cross or community blood centers to collect for them. But I think we had lots and lots of small hospitals that collected blood, and I think what happened was, after those regulations were written and they specified what you had to do and what tests you had to do, a lot of those hospitals decided to get out of that business. And so, then, for a long time, a lot of the facilities, the hospitals we regulated, had blood banks, but they weren't

collecting blood, they were just purchasing it, taking it from their local supplier, and then they still had things they had to do. They had to make sure they're giving it to the right person, make sure it's the right product, and do some testing.

And then in, I think in the Carter administration, the decision was made that a lot of these hospitals that didn't collect blood, that we were inspecting them, and so was another federal agency. I don't remember which agency it was, and it's changed names a number of times since. But the decision was made at that time, if a hospital only purchased blood from a Red Cross or community blood center, a local blood supplier, and all they did was really cross-match it, and gave it to their patients, that that would not be regulated by FDA; that would be regulated by the other federal agency, and then we would only inspect those facilities that actually manufactured products.

RT: Now, the folks that were in the Public Health Service, were they primarily commissioned officers in that Service?

RJN: As far as I know, that would be correct. If not all of them, then most of them were. Every one I ever worked with was a Public Health commissioned officer.

RT: We've had, of course, a lot of those folks in our drug activities, and our food programs, for that matter, too.

Again, that presented a little bit of a management dilemma on performance evaluations.

RJN: Nightmares.

RT: The management-by-objectives program, of course, came in. Did that have unusual effects on the field personnel of the two disciplines as far as the biologics and blood area was concerned?

RJN: No more than anybody else. That was one of those things where they had concrete, you were supposed to have very clear goals and objectives and measuring criteria. Is that what you're talking about?

RT: Yes.

RJN: Yes, hard to do. It was always hard to do because there's a mandate under blood as well as -- and for blood, we were always held pretty much to the two-year requirement. They were very stringent about that, particularly after, of course, AIDS hit. That changed the whole world.

RT: Right.

RJN: And after that, we were -- well, for a long time we were inspecting every facility every year.

RT: The AIDS problem certainly caused a lot of concern by persons affected with it, to the extent that they had a demonstration or two at the Food and Drug headquarters.

RJN: Oh, yes.

RT: Former Commissioner Frank Young had to field some of the uproar about that in one-on-one meetings with those groups.

RJN: Yes. It was a bad time.

RT: But I think in one meeting that I recall, the Commissioner just opened up very honestly with them and, to an extent, won them over to a recognition that FDA wasn't really trying to ignore their problem but were following established drug approval procedures.

RJN: Right. Well, the first identified case of AIDS, when it was identified as this agent, was 1979, and the industry in general, the health industry as well as just the biologics industry itself, worked very hard very quickly to try to determine the cause of AIDS. I lived through that so I remember it very well. At one point, there was a discussion of calling AIDS the gay disease, because that's what most people were who had the disease initially.

RT: Right.

RJN: And they weren't sure initially what the mechanism of infection was. It was believed pretty quickly to be a virus, but then they had to identify that virus. I believe that the virus was actually identified in 1982, which is pretty quick turnaround when you consider that in those days we weren't very good with viruses. We were pretty good with bacteria, but viruses were still a puzzle to us.

And then the first test for the antibody to the AIDS virus was licensed in 1983, which was first generation, and, of course, it's gone from there. But it was a tough time for the industry in general. It was a very unknown time until that test was approved. A lot of people came up eliminated on the first go-round, lots and lots of people that were tested positive.

RT: Now, you mentioned, I think before we started the tape, that you also did some overseas work.

RJN: No, I've never done any overseas work.

RT: I'm sorry, I misunderstood.

I've done an interview or two this week that involved folks who had done that, and maybe I just attributed such experience to you in error.

RJN: Most of the overseas biologics work, which was where my specialty was, is done by headquarters people, or

was, anyway, for the most part, very selected people. They don't do as much of that. There's not as much of that kind of work as there is in, say, the drug work or the device work or the food work, which you would expect. Most of it is involved in the fractionators, the people that take the plasma and break it out into the various portions of it, and so there's not as many of those. That combined, I guess, with the military program. They inspected those. But most of that was done by headquarters personnel.

RT: As far as the management of your work, was that also headquarters directed, or was that more local management decisions?

RJN: That was mostly local, I would say. I mean, you know how the system works. It's like a pie. They keep subdividing the pie, the pieces of the pie up. But when it came down to district work -- and for many years, for over 10 years, I pretty much did most of the work out of the St. Louis office. We covered half of Missouri, half of Iowa, and then our district office was in Kansas City, and so I would help them occasionally. And then a few times I helped out our regional office in Dallas and did a few things for them over the years. They were shorthanded occasionally.

RT: Were there personnel in other regions doing similar work to what you were engaged in?

RJN: Oh, yes. Most regions have a biologics specialist. It just happened that in the Kansas City District, we had a regional specialist in Kansas City and a regional specialist in St. Louis just because of the volume of work that we had.

RT: I see.

RJN: The St. Louis office had a larger portion of the work than Kansas City in terms of just sheer volume because I had one of like the fourth largest Red Crosses in the country. And out of the territory we covered, I had three medical schools that also ran blood collection programs. I also had some community blood centers. A number of Red Cross sites had collected large volumes of blood, that kind of thing, so it covered a lot of that as well.

RT: Because of your expertise, were you called upon to provide training for other field personnel?

RJN: Yes, all the time; I trained lots of people. In fact, last year, before I left, before I retired, I went over to Kansas City and did training for people over there as well, our District office.

RT: Was there ever a standardized or formalized training course developed in this area, or was it kind of left to individual trainer discretion?

RJN: Headquarters has one that they've done. They have a couple of standard courses, of course. I hope they're better than they were when they started, because when I took them was a long time ago, standard headquarters courses.

RT: Bob, you earlier mentioned AIDS, and how it had a tremendous impact at one point. Was there a long-term impact on the agency?

RJN: Yes. Prior to AIDS, the biologics program had kind of become a minor program within the organization. And, in fact, what used to be called bureaus -- they used to call them the Bureau of Biologics and Bureau of Drugs -- the Bureau of Biologics was actually absorbed into the Bureau of Drugs prior to AIDS. And it was a very, I would say, a low-priority program for the agency.

And then when AIDS hit, of course, that changed the face of everything. And as a result of that, the biologics program was broken out again from drugs, and by then they were calling them Centers instead of Bureaus, and so it became the Center for Biologics.

It changed a lot of things. It changed the way the new organization, the Center for Biologics, worked compared to the way they used to work. Because of the health impact, the Center began writing regulations, which is always a difficult process. It takes usually two years to write a regulation. They began using a provision that the agency had in, I think it's 21 CFR 10, about writing guidance documents and began putting out memoranda to the industry. That's in fact how they originally put out the first one for HIV, saying, we've identified the fact that it's caused by a virus, and as soon as the test was developed and licensed, there was a recommendation then -- not a requirement, because it was a recommendation on the part of the agency at the time of the memoranda was written -- to say you should do this. And, of course, the industry as a whole, everybody wanted that test, and so everybody started testing for HIV.

As a result of that, it changed the way we began doing work. We began focusing more on that. And, of course, we began focusing as well on the testing. And along the way, a lot of other change is occurring. The industry began testing, not just for HIV -- originally they called it HTLV-3 and then changed it to HIV-1 -- they began testing for other things as well. They had always tested for

hepatitis virus, but the tests weren't very good, so we began improving those tests. They also began testing for some of the antibodies to the hepatitis virus, again trying to find people that perhaps were at high risk and to screen out those people.

RT: You mentioned a moment ago that everybody was interested. Now, what did you mean by everybody? Do you mean entities other than the agency?

RJN: Oh, yes. Everybody would be the blood industry as a whole, all the community blood centers; all of the hospitals that collected blood. I mean, this was a big deal because, first of all, it protects their patients; but, secondly, it's just a clear economic sense. Nobody wants to put their patients at risk. And so when the agency said we think you should do this, even though they didn't make it a regulation, clearly, it would be very difficult to defend not doing it when it was available and clearly was in the best interest of the patients as well. So all the community blood centers, all the hospitals that collected blood, they were all testing for AIDS right from the start. As soon as the test was available, everybody began testing for it. And the same thing when these other tests became available and the agency recommended everybody put them in place, even though at the time we were doing

it, there wasn't a clear regulation until, I think, oh, I don't know, maybe even early '90s before they actually made it a regulatory requirement. But the industry was very responsive in following the recommendations that the FDA put out.

As that progressed and the agency began learning and FDA began learning, because the technology was changing.

You know, in the pre-AIDS days, the only thing we really tested for, other than that we would cross-match -- we tested for blood type and that kind of thing -- the only infectious disease we were testing for was hepatitis B, which is a blood-borne pathogen, and for syphilis, and those, by today's standards, were pretty crude. But when you start adding more tests on, you have to put in new technologies, you have to put in some automated technologies, because now you're running a lot of tests and you have to be able to do them.

And so, as a result of that, in the late '80s, I think the agency was learning and the industry was learning. We were beginning to find problems across the board. In '88, FDA entered into an agreement with the Red Cross because of some compliance issues that they'd had -- not everywhere within the Red Cross, but in a lot of places. We had troubles here in St. Louis; we had troubles really in a lot

of big centers that were processing a lot of blood and testing a lot of blood.

I believe it was in 1988 that the agency did something they'd never done before, and that is they suspended the license of a community blood center -- never happened before, but they were really bad.

RT: That probably had an expanded beneficial effect, didn't it?

RJN: Oh, well, everybody knew we meant business, the industry as a whole. Again, because it was something the agency had never done before, it was just unheard of. I mean, people had surrendered their license before when they were going to go out of business, you know, they were closing operations or whatever, or merging with another facility. They would, we would say, "Well, we're going to have to suspend that license." But in point of fact, it had no effect because they were going to not have the license anymore. But it was the first time the agency suspended a license for regulatory reasons and compliance issues.

RT: Was there in that action a punitive measure or fine?

RJN: I don't believe so. That was done in the Kansas City District, but removing your license is pretty, in

itself, punitive. That means you can't ship products across state lines. And if you have any customers that are outside of your area, then you cannot ship.

Most community blood centers -- how to say this correctly -- they do what we call resource sharing. The concept is, if you can collect enough blood for your own community and have some left over, then you can ship it to people who aren't able to collect enough for themselves. The plus side to that is that, first of all, by doing that, you make sure that you are able to meet all of your hospital needs because you always have the blood types that they need. In addition, by selling that product to other people, then it brings income. It helps you to be able to not have to throw stuff away that you might otherwise have to throw away, plus you're able to impact on your own costs for your own customers. So, when you can't do that, if you're collecting and you can't ship it anymore, then it has an impact economically.

I think that particular community blood center, I think they got their license back within about a year and a half. They worked very hard to bring themselves back into compliance. But it had an impact on the industry as a whole because it, by doing that, FDA told the blood industry we are serious, we mean business.

And then a lot of things came. Computers began coming on the market. People began using computers to control their processes, to manage a lot of their donor files, who is deferred and shouldn't be. This had a big impact on the industry as well. So it is, as I think back to the very early days, 30-plus years ago, the industry, it is dramatically different. And I know that's not unique to the blood industry, but it is tremendously different today. It's a different world. We've learned a lot.

RT: Now, I suppose there were some new entrepreneurs in this area as you went along, too.

RJN: Yes. I had a company started in the early '90s. I remember when the individual called me for the first time and told me that he was thinking of starting. And it happened. Other people would call. I think I can remember two or three other times over the years when people would call and talk to me about starting a blood center because they'd read something in the paper and they thought maybe it was a good industry and very profitable. But I don't think they had any concept of the regulatory responsibility and the difficulty. It looks easy, but it's not. It's a very complex process.

At any rate, I remember this individual. And at the time, there's a thing called autologous blood, which is

basically donating blood for yourself. And it became a big issue, particularly at the early AIDS days, and it still is a fairly significant issue. People want to donate blood for themselves because if they have planned surgery, then they can get their own blood back. They feel like that's the safest thing. That doesn't always work out. Some people are not good blood donors, and blood is only really good for six weeks, so it's hard sometimes to schedule enough. You're really only supposed to donate every eight weeks, although, for yourself, you can donate more often, but you have to be pretty healthy to do that otherwise.

But, at any rate, this individual is talking about frozen blood. Frozen blood has been something that has never been terribly successful in the blood industry. The military does a lot of it, and they use it on submarines and they use it on battleships and aircraft carriers, where they almost have their own little blood bank there for emergencies. But it's very complex. In order to freeze it, you have to add the chemical called glycerol to it in order to not destroy the cells; and then, before you give it, you have to thaw it, and then you have to wash off the glycerol with the saline, and then, the blood is only good for 24 hours because it's done in an open system, so it potentially could be contaminated with bacteria.

RT: Have you encountered difficulty on -- you mentioned the six-week shelf life, I guess I could call it, for blood?

RJN: Yes.

RT: Has that been a problem of persons keeping it or using it?

RJN: Beyond the six weeks?

RT: Yes.

RJN: No, not really. Not in my experience.

But you're talking about entrepreneurs, I had this individual call. He was going to collect and charge people for collecting their blood for unplanned surgeries. In other words, it would just be someone like myself, let's say, "I want my blood stored away in case I need it someday in the future." And frozen blood is good for 10 years. So it can sound good, but the problem is, you'd have to charge an exorbitant amount of money for doing this. Frozen blood, again, because of the complexity -- and I don't know about you, but I don't have any planned surgeries in the future. He had a lot of trouble finding staff to run the operation. And that's part of the industry problem, finding qualified people to run the operation.

He was in business about a year and a half. He ended up on the news because he had difficulties. Besides just

the blood issues, he was misrepresenting some of the things he was doing.

I ended up, I took another individual, another investigator, with me, and we looked at -- and I never did this in my entire career, ever -- looked at every record he ever generated. That's how scared we were. I was really afraid he was going to hurt somebody. And just got some interesting stories about that guy.

And, finally, he was having difficulties, not just with us, but he was getting some bad press. I think he was misrepresenting some things to both his customers and to his donors, and ultimately, thankfully, he went out of business. We hammered on him pretty hard, sent him a couple of warning letters and he went out of business.

But as a result of that, in less than six months, two other blood centers started in St. Louis, because they thought that if he could break into this field, that maybe they could too.

One in particular actually started with a number of people who had actually worked for the Red Cross and came and started, and they were backed by a California company that was involved in the blood industry. So they had a pretty good track record. They had some issues along the way.

But the other firm that started was, they were in existence for about two and a half years. They were always on the edge of everything. I mean, they didn't really have a clue as to how to operate. The stories I can tell you, the stuff they did, it was just unbelievable. Some of them are technical, but this one I think is best.

They came in on the second of January one year, the one year they were in business, and their alarm was going off on their refrigerator where they stored the blood products, the whole blood. And what had happened, over the New Year's holiday, they had two compressors that operated, and they cycled. Well, one of them quit, and the other one came on, trying to keep this refrigerator -- it was a walk-in, so it was very large -- refrigerator cool enough to maintain the blood at the appropriate temperature. And it cycled so much, it kept coming on, that it actually got stuck in the on cycle and just kept running, to the point where, instead of a refrigerator, it was a freezer and froze the blood solid, which destroys the cells, because without that preservative in there, that glycerol, to protect them, the cells just explode.

So they came in on the next workday, and their alarms were going off. Now, they had a system where, when the temperature even came close to being out of specification,

they had a system that was supposed to phone. They had a list of people it was supposed to phone. For whatever reason, it did not. They thought it had something to do with the change of the year and messed things up. They had to throw the blood away. And that's the kind of stuff that happened to them over and over and over again.

It's a very difficult industry to operate. You have to know what you're doing.

RT: What kind of professional disciplines do persons usually have that attempt this kind of operation? Are they medically trained, or just kind of business folks?

RJN: That's a good question.

The first guy that I told you about, the little firm that I hammered on for a year and a half, he had an interesting history. I learned that you couldn't trust what he said because he would tell you a story, and then you would find out other things that what you understood the story was.

He was in business in a community not too far outside of St. Louis, just over the river, where he was in an older community and they were doing a bunch of rehab work, and he was in the construction business. And his goal was to retire young, and so he did. He retired; I think when he was like 50, he retired. And he'd had a timeshare in

Hawaii, and they decided they wanted to live in Hawaii. So they went to Hawaii to live, and I think what he found very quickly was that he hadn't saved up enough money to live in the kind of lifestyle that they wanted to live in Hawaii, because they had no income coming in anymore; he was retired, so just whatever he was living off of in savings, whatever he had.

So the story that he told me was that he ended up back in St. Louis to -- I think he was trying to do a business deal, and he had a heart attack and he ended up in the hospital. And somewhere in the hospital along the way, he didn't get blood, but he must have been talking to people about blood, and he thought, "You know what? That's an industry I could run; I could do that." And so he had no medical background whatsoever, knew nothing about manufacturing or anything, had a very difficult time hiring people for him. He hired people that would work for him for a short time, and they just would leave. He had a very difficult time with his payroll, making his payroll. He issued a lot of bad checks to people.

I know the laboratory, I inspected the laboratory -- it was in another state -- that had done work for him, and when he went out of business, he owed them over \$20,000 in unpaid debts. And he kept calling the president and

pleading with him. He'd send him another check. And he had like three bank accounts. People learned that the way to get your paycheck for sure was the day you got your paycheck, you went to his bank immediately and cashed it. That was the only way you could be sure, because if you sent it to your bank, chances are it would bounce within a few days.

So he was an interesting character, no background whatsoever, and, again, had a hard time hiring anybody with any background.

The other ones, the one started -- there was a really good one. Those people were all blood bankers, and that was a good operation for a number of years. They had financial difficulties, which is what caused them to go under. It really wasn't regulatory issues.

The other one, businessmen. It was one guy that had worked for the Red Cross but really didn't know much about blood products, and he convinced his boss, and his boss got some other investors, and they invested in this company and just started it up. And they did hire some people with blood bank experience, but somebody told me that worked there, described it as the interpersonal dynamics didn't work. Basically, they all had their own agenda and they

had their own reasons for being there, and they didn't work together well.

It's hard to say what motivates people. Again, I've talked to a number of people who have called me on the phone over the years and thought that getting in the blood business would be real easy.

I remember having a doctor call me one time. He was retired. And he said he used to run a blood bank at a local hospital many, many years ago, probably 40 years earlier. And he said he'd been thinking about starting one up and he wanted a copy of all of the Red Cross procedures. And I said, "Well, first of all, we couldn't provide that to you anyway." Under the Freedom of Information Act, it was not permitted. We don't provide people's procedures.

But I said, "Do you have any idea what you're asking for?" Even if he could, we're talking about volumes. It would probably be a hundred binders.

"Oh, no," he said, "it can't be that much, probably only a couple hundred pages."

"No, it's not. It's very complex."

It's a very complex industry. But I liked the work, and I enjoyed doing it for a number of years. And I was fortunate to work for people that allowed me to have the

freedom to do a lot of my own scheduling and to make a determination.

I said early on, in the early AIDS days, particularly after the mid-'80s, we began inspecting every blood bank, every hospital that collected blood, every blood center in the Red Cross, every plasma center every year, so it was pretty intense. It took a lot of, it took more than just me, you know.

RT: The American Red Cross did enter, I think you mentioned earlier, into a voluntary agreement.

RJN: A voluntary agreement in 1988, and then they signed a consent decree in 1993.

RT: Those problems were apparently sporadic rather than everywhere under the aegis of the Red Cross. Is that correct?

RJN: Well, yes. You know, they're a big organization. They're the largest blood-collection facility or system in the world, actually. And they represent roughly half of the blood collections in the United States. It's not an easy organization to regulate or to manage.

You know, I work for them, now, so I see them from the inside. There are a lot of complex issues. You know, as we try to write procedures for across the country, it's

very difficult to write procedures that everybody can implement the same way. It's not an easy process.

RT: I'm sure the organization is glad to have someone with the background experience you have to guide them in proper directions.

RJN: Hope so.

RT: Do you sort of travel nationally?

RJN: Yes.

RT: So you're sort of the national expert or consultant?

RJN: I'm on a special audit team. There are six of us, and a supervisor. There's what they call a regular audit team that do the more routine kind of audits of all of the regional sites and all of the fixed sites and all of the -- everywhere, all the labs, everything. We go in and do special things. We do follow-up audits, we do special audits, we do all the headquarters audits because we do audit the parts of the headquarters, and that's what I'm doing. I'm part of that special audit team.

Yes, I travel all over the country. I've been to California and Montana a couple, three weeks ago; and, obviously, back East. I was up in Upstate New York and Pennsylvania and Ohio and . . .

RT: Well, you probably enjoy some of that.

RJN: I love the audits. I always liked inspecting, and it's a lot like being an inspector, you know, an investigator for FDA. It's a different, it's more intense because of the way it's done and because I'm looking a lot at internal procedures as well as just the regulations. But I don't like to fly.

RT: That could be a problem, all right.

RJN: It's no fun. We're talking about going to the airports, and they don't have as many flights as they used to. The week before last I spent eight hours in an airport waiting for flights, trying to get on an earlier one. So you get home late and, you know, you get home about 8:30 at night, and after spending an entire day at the airport. Looking back, I would have done it differently, I wouldn't have sat there all day, but hindsight is always wonderful.

RT: That's true.

Are there any other things you'd like to speak of during our interview here?

RJN: Well, just to say that it's an ongoing process with blood. I don't think it'll ever be over.

I have to tell you honestly, 15 years ago, if you'd asked me, I thought I would have been out of a job in five years because I thought we're going to find ways to do this

differently. And the truth of it is, we're not any closer today than we were 15 years ago, not really.

There are a few products on the market that are being tested in clinical trials for artificial blood, but there are four being tested. Three of them are manufactured from blood itself, so we have to have that supply to make this product. It's called artificial blood. And you have to collect two units of whole blood to make one unit of artificial blood. It's really just a hemoglobin-based process. There is one non-hemoglobin product on the market.

But, you know, blood is just a unique substance. I've told blood centers for years, someday, hopefully, future generations will look back at what we do, and they will look at us like we look at the people that were bloodletters and we'll say, "What a barbaric process. These people took body fluids from one person and put them in another." But in our state of medical science today, this is the best we have. We could not operate most of our hospitals very well without blood banks, without the blood products. Cancer treatments today, for the most part, are very much dependent on being able to give patients blood products to sustain them when they're getting chemotherapy or radiation, because their own body is not manufacturing

the red cells and the white cells and the platelets that they once were, and you have to sustain them until their body restores that function.

You've got emergency rooms -- and, granted, a lot of emergency rooms aren't about blood -- but automobile accidents and any kind of major trauma where there's blood loss, it would be very tough for those people.

And so it's really a very necessary thing, and I really do enjoy that industry and I appreciate all the hard work that goes into it on the part of not just the Red Cross, but a lot of blood centers that work very hard to make the product safe and available.

RT: I assume that the Department of Defense really has their own program.

RJN: They have their own program as far as I know. I don't think it's changed substantially. I think I mentioned earlier, red cells are good for about 10 years. They have their own program. They collect from military personnel. They freeze that product. I think they have a few blood programs around the country where they actually collect blood. They don't freeze it, but they just use it. But for the most part, most military bases rely on local Red Crosses or community blood centers to provide for them, and many times it's a cooperative agreement. They permit

the blood centers to come on post and to draw from their staff, and then, in turn, they get some of that blood back in their own hospitals that they have. So it's kind of a mixture on the part of the military, the Defense Department.

RT: Well, Bob, we really appreciate your granting this interview, and we'll get the transcript back to you for review.

RJN: Okay. Thank you.

END OF INTERVIEW