History

of the

U. S. Food and Drug Administration

Interviewee:	James Ritz
Interviewer:	Ronald T. Ottes And Robert A. Tucker
Date:	May 9, 2001
Place:	Rockville, MD

INTRODUCTION

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

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

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James Ritz

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INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Administration

Date: May 9, 2001 Place: Rockville, MD

Interviewee(s): James Ritz

Address: [redacted]

Last FDA Position: Compliance Operations Specialist, Office of the Associate Commissioner for Regulatory Affairs

FDA Service Dates: From: December 1976 To: December 31, 1999

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

Address: The Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

Number of tapes: Two Length: 90 Minutes

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RO: This is another in a series of FDA oral history interviews. We're interviewing Mr. James Ritz, who is a retired compliance operations specialist. The interview is being conducted with Ronald Ottes and Robert Tucker at Mr. Ritz's home in Rockville, Maryland. The date is May 9, 2001.

Jim, we like to begin these interviews with a brief history of your background, your place of birth, education, and any pertinent employment that would relate to your subsequent FDA career.

JR: I was born in New Brunswick, New Jersey, in 1944, and educated in New Jersey. After high school, I served four and a half years in the United States Navy, and subsequently served four years with the Department of Police, Montgomery County, Maryland. In 1970, I left the Department and returned to the University of Maryland full time, receiving my bachelor of arts in law enforcement.

My federal service began in December 1972 as an investigator with the National Aeronautics and Space Administration. I served four years with NASA, joining FDA in December 1976 in what was then known as the Policy Management Staff, under the Associate Commissioner for Management. I remained in that position until December 1990, when I joined the then Generic Drug Task Force at the Office of the United States Attorney for the District of Maryland, investigating allegations of fraud in the generic drug industry. I remained with that task force through its evolution and name changes to ultimately a task force under the Office of Criminal Investigations, although I was not an OCI employee. I remained with Office of Enforcement, which I was transferred to organizationally, probably 1993. I just don't recall the exact date.

RO: Can we back up a little bit and cover some of these positions that you held? When you first came into the agency, you were in the Policy Management Staff, which, as I understood it, conducted internal investigations of maybe wrongdoing as far as employees were concerned, and whether or not any of our investigators were threatened in the course of doing their work, and things of that nature. Is that right, Jim?

JR: Yes. There was an investigations group. It was a small group, three or four investigators, and we conducted investigations relating to allegations of impropriety of all kinds on employees of the agency, at all levels of the agency, both in Washington and throughout the field.

We conducted investigations that involved violations of standards of conduct, administrative procedure. There were criminal investigations, although in point of fact, our authority to conduct criminal investigations was limited. That was technically reserved to the Office of the Inspector General for the Department. What we would do is, in a criminal issue, we would talk to the IG people and then in almost all cases we would do the investigation, ultimately referring it to them. But the vast bulk of cases were handled administratively. We did a lot of time fraud cases, you know, that kind of thing.

We did a lot of work in the field, as you well know, Ron. You and I were involved in a number of cases.

RO: The time fraud, just to clarify what you mean by that, was that misuse of time by staff?

JR: Yes, it involved a number of kinds of cases. It might be somebody who was engaged in an outside activity, an outside employment, if you will, or a private business venture that they were performing on government time.

There were a number of cases we did of that nature that involved physicians who were

employed in the bureaus or centers and who had outside practices that, while technically they were on the government payroll, they were visiting patients in hospitals, conducting office hours, seeing patients in a private practice. I can remember one case where we had a physician who actually performed surgical procedures at a hospital while he was in a pay status on his review position in Parklawn.

RT: What was the ultimate penalty or outcome of those kinds of malpractice?

JR: Well, the way things worked, whatever the case was, we conducted the investigation and prepared a report of all information, evidence, whatever we had determined, which would either support or refute the allegation or the allegations. It would then be referred to the supervisory level of the employee's organization, whether it was a district or a center or what have you. That would be reviewed with the personnel people. The Employee Relations Division would, in concert with management, determine what the appropriate action would be, if any. That could be handled in the normal course of personnel rules and regulations, sometimes up to and including termination of employment. That was not an uncommon sanction for fraud cases, time abuse in particular.

Another example of time abuse cases was falsification of time records by timekeepers. Maybe they were sloppy or maybe they were padding their own records or padding records of somebody else. We had cases where we got into outright theft, personal property in an office on occasion. We had a number of cases of impress funds, where funds were embezzled. Unfortunately, we did see a few of those. On occasion we had government checks that were stolen.

RT: You mentioned earlier that this was done under the aegis of the Inspector General. What

you're telling us now seems to indicate that the resolution of many of these problems were administratively conducted by the agency itself, is that correct?

JR: The vast majority of cases within the agency were handled administratively. There were very few cases that were ever criminally prosecuted. Now, the cases that would go to prosecution were clearly those that related to allegations of bribery.

We had instances that we worked where complaints were lodged with the agency against, for example, a field investigator, where it was alleged that the investigator solicited something in return for not doing or not taking an effective action during an inspection, what have you.

Most of the instances were where our people encountered an offer, a solicitation, if you will, or an outright bribe. Now, in those cases they were immediately referred to the Inspector General's office. We would work on them in most cases, but they assumed the responsibility for the case.

There were a few prosecutions of people in the industry who out and out made bribes to our people. Fortunately, we heard of small numbers of instances, and hopefully we heard about all of them. There were a number of times where we had an allegation that an employee of the FDA made an overture; very, very few over the years. I worked those cases as internal investigations for fourteen years.

RT: In the case of those who were prosecuted, what were the range of claims or actions against industry?

JR: I don't remember specifically, but I know there were a couple of cases where people actually got a couple of years in federal prisons. There were some cases that were brought, I think, that there may have been a "not guilty" finding or what have you, but there were at least a couple of

cases I can recall where someone actually went to jail. And fortunately, if we had any where our people solicited, and there may have been a couple over those years, they just don't stand out in my mind. It's amazing how many cases I can remember, but fortunately we didn't have much of a problem in that regard.

I guess the truth is, you never really know, because, unfortunately, we did have an investigation that developed into the prosecution of five Food and Drug employees, and we'll probably talk at some length on that, the generic drug scandal in the late eighties.

RO: Jim did you ever get involved in the investigation of the doctors that were doing the clinical investigation of drugs where the agency suspected the doctors were padding the results? Did you get involved in those, or were they handled by some other unit?

JR: We had investigations that we got into in terms of the process of review, allegations of impropriety in the review. We had all sorts of conflict-of-interest allegations, because we did all the conflict-of-interest investigations, which could include an investigator or a reviewer, rather, who had a financial interest in a particular drug company or what have you. There were so many of these investigations, I just can't even recall specifics at this moment.

But in terms of the specific nature of the question, I don't think we really did anything like that. I don't think we really had any cases. We may have, but I'm just trying to think. Gosh, I thought I had a better memory of some of these things.

RT: Occasionally the agency took some action against some of these doctors that were investigating drugs and found out that they didn't have the patients that they said they had.

JR: And some of the actual clinical studies.

RT: That's right.

JR: Yes There were some cases that we got involved in that where, in fact, the data could not be supported. Most of that kind of thing, though, I mean, that was extensive in the Generic Drug Task Force, but in terms of the old internal cases under DEPI [Division of Ethics and Program Integrity], if you will, we really didn't. We didn't have the manpower. We didn't have the coverage.

RO: One of the other things that Policy Management did at one time was to have what they called, I think, on-site audits of some of the field.

JR: The On-site Review Program. That was the positive operation. You know, the nature of the work that I did for the agency was never really what people considered the good kind of work. I mean, I had the reputation--the only time people ever saw me was if there was a problem. And that was the truth, because we showed up when there were allegations of impropriety. Period.

But the On-site Review Program was one of the other functions of the staff or division as it was known, and those of us that were in the investigative group ultimately got into assignment of on-sites, and that was a good program because it was keeping the house clean, if you will. The field offices, regions, and districts were set up on roughly a three-year rotation, such that there was a one-week review. A team was established and managed by our office. It included representatives of physical security, property management, safety, contracting officer, an accountant, maybe a travel audit person, and eventually got even bigger than that. We had a number of different specialists.

A team would go out, begin on a Monday morning and conduct an audit of the field office

to ensure that proper procedures were followed as it went to various administrative responsibilities primarily relating to fiscal matters. The accounting, procurement, contracting, impress, and money handling, what have you.

RO: Those were, I presume, as is the practice of the agency on making industry inspections, unannounced.

JR: Actually, these were announced. The offices knew well in advance. In fact, the schedule was published for a fiscal year. The design was that you would go out and look through everything. We had people who knew what they were looking for. Could you look at everything? No, but they knew how to do spot checking. There was some sound basis. It just wasn't totally random. We could get a good feel for how things were going. You could clean your own house and make sure it was kept clean before you had somebody from the outside coming in and really find problems.

The other thing was, the field operations and the centers, to a lesser degree, but I think it was primarily a field benefit program, they knew that there were internal controls, and if you found problems, you brought them to the surface, you dealt with them and corrected them. It wasn't a program designed to go out and beat on people. This was a program designed to go out and make sure that things were being done correctly, and if they weren't, get them corrected.

You found the run-of-the-mill kinds of problems, and we concluded the review at the end of the week with a sit-down written report. We went over all findings with district management point by point. The report would almost always have a requirement, a finding, and the corrective action that could be taken, how it could be taken, and in most cases we could get that corrective action effected while we were there. That was the idea. And if it couldn't be effected while we were there, the means by which it could be set up would be provided as quickly as possible.

We had a thirty-day review where the field would respond with corrective actions. The headquarters person would work with the field office counterpart to effect those corrections. It wasn't a case that we went in, prepared a laundry list, walked out and forgot about it. It was followed up and made certain that everything was corrected.

Eventually that program got to the point where for various manpower and cost limitations the three-year cycle was changed. Some offices were considered better than others. Better offices were reduced to a four-year cycle and others were moved to two-year intervals, and if we had certain problems, in particularly the big offices where you really had so much volume that you needed to do a little more close scrutiny, we went in annually. There were even a couple of times when we went in and the review revealed serious problems to the point where we terminated the review. Extensive headquarters group assistance was provided to bring administrative operations up to standard.

RT: Was there ever any oversight by GAO [General Accounting Office] or congressional committees that called your attention to problems?

JR: Sure. GAO had its authority to go anywhere it wanted when it wanted, and primarily at the direction of the Congress, and that happened. Over the years there are any number of specific issues that they went in and looked at. If they found problems, it was referred, and we did not necessarily get involved with effecting their recommendations. We were aware of it. I think our reports and the on-site review program was made known to GAO, but they had a more defined, decisive role. I think the general perception of the GAO is, they'd come in and hone in on particular issues.

RO: Were the auditors on this team all from your staff, or were they drawn from other

headquarters?

JR: They were drawn from various elements of Office of Administration--including financial management, whatever it's called today, personnel. We ultimately got personnel people involved and they would review personnel procedures, contracts and grants, procurement, the safety office, property. Six, seven areas. Which, you know, was a fair number of people to take in and in many cases it was kind of disruptive to an operation. We tried to do it in a positive mode and be as least disruptive to the office as we could. I think we did a good job.

RT: As far as staff was concerned, I think that program was discontinued from your staff then?

JR: Well, it was run by our office up to--well, past when I left the end of 1990, and it continued. Did it ever end? I really don't know. I don't remember. Because from the end of 1990, when I went to the task force in Baltimore, I was pretty much out of operations. Ultimately that division, as it was known, Division of Ethics and Program Integrity, was reorganized. I'll say in the mid-nineties, the investigative function had been absorbed by the Office of Criminal Investigations. The conflict-of-interest operation was moved over to personnel. The physical security group had been moved over to--gee, I can't remember where. It went over Voyce Whitley, whatever that part of the--OFAC, whatever they called it.

RO: Facilities.

JR: Yes, facilities. So, I mean, the organization as it as known and I worked in, was disbanded. I wasn't directly involved.

RO: Was the disbandment a result of a reorganization?

JR: The internal investigations function was transferred to OCI because the then deputy commissioner decided that it would be moved--well, OCI had come in and was operating by 1995, and the deputy commissioner--I can't think of her name--ordered that the function go to OCI. None of the people in the old DEPI group were carried over. They wanted their own people.

Paul Lancaster was moved out, so he didn't really have a job. Paul and I'd worked together since 1976. In fact, I brought Paul up to the task force in Baltimore, and he worked his last year and a half with us before he retired. A couple of the people that were in that investigative group, two of them died. One of them was hit by a car and killed out on the Beltway. The other guy had some serious health problems and died. The organization was being broken up, and all of why, I'm not so sure, but there were problems in that organization, effectiveness problems and they reorganized it.

RO: You mentioned the Generic Task Force. When you went to that Generic Task Force, were you still a part of that Policy Management Staff?

JR: Yes. I was on the rolls of the Division of Ethics and Program Integrity. I was loaned under authority of Sharon Holston, the Associate Commissioner for Management and Management Operations. Sharon said it was okay that I would be loaned to the Office of Enforcement under ORA.

In the late eighties, when the generic drug scandal hit, the big criminal probe by the Office of the Inspector General, the United States Attorney for the District of Maryland created a task force at the Federal Courthouse in Baltimore. It was comprised of some agents of the DHHS

OIG, some CSOs [Consumer Safety Officers] from the Baltimore District, and I think a couple of people, at least one that I can recall by name, Carl Sharp, from the Office of Compliance, Center for Drugs.

Dan Michaels, the then head of Compliance in Drugs, and Al Hoeting, the Director of Office of Enforcement, detailed people to the United States Attorney. Then Commissioner Frank Young ordered the field to conduct intensive investigations of the top thirty generic drug manufacturers in the country. These assignments went out and they were completed as a priority action. They moved people from all over the country, put them in these drug houses primarily up in the Northeast, New York in particular, and performed extensive inspections.

The extensive reports were sent to the task force in Baltimore, and reviewed. The task force started digging in and conducting criminal investigations of fraud in the drug approval process. The U.S. Attorney's Office for the District of Maryland, and the Office of Civil Litigation, Headquarters Justice Department in Washington, assigned Assistant United States attorneys and trial attorneys to these cases, working very closely with the investigators. They developed criminal cases resulting in Federal prosecutions of a number of generic firms and a number of employees and officials of these firms.

I went to the task force January 1, 1991, and I teamed with Jim Tessmer, from the Center for Veterinary Medicine. The number of prosecutions in cases was quite low in the first year because these cases are so labor- and document-intensive. You have tremendous--and I mean tremendous--volumes of records to review. We would develop the cases of fraud and seek indictments by grand jury or file information against individuals, and it was an impressive record.

By the time I retired, we had prosecuted in all 140 people. Well, let me characterize it this way. We had probably 140 prosecutions of individuals. Unfortunately, some of those were the same individual that we prosecuted for other charges in earlier investigations.

The number of firms we prosecuted was probably thirty-five or so.

RT: Are there some of those that have been adjudicated so you could tell us a little bit about the nature of them?

JR: The first big case was the star, the flagship of the generic drug industry, Bolar Laboratories in New York. Bolar was from the name of the two principals, Bob and Larry, and I forget their last names. But to give you some idea of the scope of the fraud, this was the flagship of the generic drug industry. I'll never forget, when I got there, this case had been ongoing and it was nearing indictment. I remember when we were trying to develop figures as to what the extent of the fraud (loss). The figures were astounding, $140 million.

[Begin Tape 1, Side 2]

JR: ...in one product. That astounded me, because before I went up to the Generic Drug Task Force, I didn't work directly in the day-to-day operations of Food and Drug Administration. I didn't know a whole lot about the drug industry or drug manufacturing, but I learned. So it was fun in that way. It was all new to me.

But it just blew my mind the kind of money we were talking about. I mean, these people were making product, and what they were doing is--you know, a generic drug has to be a bioequivalent, and they were falsifying biostudies. They would get an approval of a formulation, and the manufacturing, the application, which, as you all know, specifies everything. I mean, they would do R&D [Research and Development] batches, and when they went to scale up at manufacturing, the product wouldn't work.

If they were doing tableting, they had problems, like they would fall apart in a press. So what they'd do is, they would just grind up the tablets that they had pressed, add some more

magnesium stearate, or other excipient binder, reblend it, put it back together. Then they would run it through the tablet press again, and the tablets would not crumble. Well, if you make any change to the formulation, you have to do a new study to ensure that the product is what it is supposed to be. And that's the kind of thing that was going on.

These people had product that didn't work. Now, was it dangerous and kill anybody? No, we don't know that. But if you have the amount of active ingredients that's supposed to reach a therapeutic level in the blood and maintain it for a period of time, and you dilute, if you will, the formulation, then you have a question of whether you get the therapeutic value for the therapeutic level and time it's supposed to be maintained.

If you're talking about a common variety pharmaceutical, is that going to be an absolute critical issue? Maybe not. But if you have a narrow therapeutic product such as a cardiac drug, and we had a narrow therapeutic window--there were some thirty-two listed drugs. The list changed. But you take a particular cardiac drug. Well, if you drop down below the established therapeutic level and you're not getting enough, that's one kind of problem. The drug is not effective. What about if you get too much? And there were problems with these products, the way they were altering the manufacturing, the formulation, affecting the therapeutic level. Too much active ingredient could be toxic.

Now, I can remember a case where we had wired a guy and sent him into the company to have a chat about what they were doing and the double books they were keeping. In some of these companies, they were very creative. I mean, they had two sets of books, if you will. They had a batch record for a given batch of product. That was the record that was there. If anybody asked, that's what they saw. But the real pages of what they did, in fact, were phonies, and they were kept out of sight.

In one case a firm owner said to an employee that if the product involved, a cardiac drug, and the alternations being made to it was "A business decision. That's all it is." If you're

punching tablets and the things are capping, and you can't ship the product because somebody's obviously going to see it looks terrible--nobody likes to take ugly pills. They would just regrind it, reblend it with more magnesium stearate. It was a very common practice. They regrind, run them through the process. Simply punch and go on.

The fraud perpetrated there is that you have a misstatement, a misrepresentation of fact in an application, because many times the applications were wrong. How they claimed to make the product was not, in fact, what they were going to do, because they realized they couldn't do it that way. So they created a fictitious application, if you will.

The other thing was, when the product was actually made and sold, the consumer was not getting what they were led to believe and what they paid for. If you bought a pharmaceutical product manufactured by a given company, you had a right to expect that it was a wholesome, safe, and effective drug, manufactured in accordance with an approved ANDA [Abbreviated New Drug Application], in this case. And if that's not what they were doing, then that's a misrepresentation.

The consumer is defrauded and the government is defrauded because the government has a right to expect that the application, the data that are submitted in an application is factual, true. On the submission form, an official has to sign and say, "This is a true and accurate statement." And they just blatantly submitted false applications.

Well, when we could prove all of that, we sought indictment on various charges. 18 USC 1001 was a common charge: misstatement of fact, false statement.

RO: Of the initial thirty generic drug houses that the Commissioner said they were supposed to look at, how many of those did you find problems with?

JR: Every one of them.

RO: Every one of them?

JR: Every one of them. Was there clearly fraud in every one of them? I can't really say. I don't remember. Did we prosecute all thirty? No, because there was so much of it, we didn't have the people. The first assistant at Baltimore and the Deputy for OCL [Office of Civil Litigation] in Washington, made joint decisions of which ones we were going to go after, and we just couldn't do it all. There was just too much of it. It was that simple.

RO: What started this whole thing? There was the internal, as far as FDA is concerned, generic scandals. Did this task force result from that internal problem with generic drugs, or what came first?

JR: Well, the Inspector General got into it in 1988, I'll say. What happened, an official owner--I don't remember, but some ranking individual of Mylan, which was one of the big generic houses, contacted the FDA Headquarters. He had information that a reviewer in generic drugs was involved with somebody in a pharmaceutical company and there were serious questions as to the propriety and indications of payoffs, what have you. Now, I heard about it because Paul Lancaster and I and one or two others were in the investigative group. The Director of DEPI, John Reed, told us, and we thought we'd be talking to the guy.

Well, actually, I have to correct myself. It wasn't the individual; it was a representative of the owner. It was a third party who had contacted the agency and may have contacted Reed directly. I'm not sure if I ever really knew for sure. Reed was going to talk to him. We wanted to talk to him, let us handle it. No. We were told no; that Reed would do it. I don't know how many times he talked to this person, but exactly what happened we never heard. We weren't

apprised of what was going on.

The long and short of it is, some of which I learned after the fact is that this information had apparently been passed around to some others in the agency. For whatever reasons, somebody made decisions they didn't take an action or never got around to it or what have you. Well, the complaining people apparently got tired of it and sensed that FDA wasn't going to do anything, so they went elsewhere. They went to Congress, and Congress jumped on them with both feet. The IG got pulled into it.

They started their investigation, and one day they swooped in on Parklawn and seized the office of Charles Chang, who was a reviewer in Generic Drugs Division. Charlie was arrested. I don't know if he was arrested that day or the indictments were later, whatever, but Charlie Chang was the first Food and Drug employee in that series of events. Others, I think it was five Food and Drug employees, ultimately were criminally charged as an outgrowth of the generic drug scandal.

Dr. Young ordered the investigation of the thirty big generic drug houses. The task force was formed, I believe that was early '89 or what have you. Once started, it just grew in scope. I mean, it was just like the more they dug, the more they found, and it just went on.

To this date, that task force still exists, although it's very different. Originally, it was the generic drug industry. Quite frankly, in the early nineties we got into cases that were not generic drug houses, they were the originators [innovators], the brand-name houses. We prosecuted some big companies, Warner Lambert for one. If I'm not mistaken, Warner Lambert paid an $11 million fine in our case.

RO: What was the problem there?

JR: Falsification of applications in product.

RO: In some of those instances, it was alleged, anyway, that some of these houses were not submitting their own product to FDA for approval, but rather--

JR: In Bolar, that's exactly what happened with the samples submitted. When it came time for the FDA to have a sample of the product, Bolar substituted the brand-name product for their generic product. When FDA tested it, lo and behold, it was bioequivalent to the brand. Now, if you're going to ask me the name of that product, I can't remember, but I'm glad you reminded me. Did it happen in other cases? Yes. Could we prove the substitution? I don't think we did. But in Bolar we did.

RT: In those investigations, I assume there was voluminous document review required.

JR: In these cases what you'd have is hundreds of thousands of pages of documents. A banker's box, a standard banker's record box will hold 3,000 pages of paper. It was not at all uncommon in these investigations to have 6 to 800 or 1,000 boxes. In the breast implant case, silicone gel breast implants, I think we had 1,400 boxes of records in that case. It was incredible. I mean, you just can't fathom the volume. These cases were so tremendously document-intensive. We literally looked at every page of paper. Now, were lots of things duplicates? Sure. You would see a batch record, I don't know how many copies of the same batch record of an R&D batch, say, or a production batch record.

But when you went into these companies, when we issued the subpoena, it would read "any and all manufacturing record for any and all drug product within this specific drug product," or whatever. Well, that meant any and all documents that related thereto. If you created a memo and it went to Bob and it went to me, that subpoena covered his copy and my copy, and if mine

was written on or his was amended and yours wasn't, we would compare them, because your document may have nothing of consequence, but Tucker's copy, where he had written and drew a circle around something that related to the manufacturing and said, "No, do it this way," or, "Change this," you could look at several copies of the same document that were different, and it may have evidentiary value.

It was just incredible. I mean, we would work day after day, week after week, month after month, looking at documents. It was enough to drive you nuts. These cases took, on average, two years' investigation.

RT: How many FDA staff or investigative staff would be involved?

JR: At the outset it was primarily two people per case, and that was nice. Then it got to the point where we'd get two cases per team, because you would have peaks and valleys. Eventually we had so many cases there were no valleys. When you issued a subpoena, it took several weeks to receive the documents. There could be several weeks where you had a light load. When the documents come in, you were up to your elbows. You would have to review these documents for months and months to prepare to see what was going on, develop a theory as to what they were doing and how could we show it. Then we needed to identify who to interview. The interviews of individuals in these cases would go on for hours and hours. We would interview many, many people.

RT: What was the case with the breast implant, silicone breast implant?

JR: That was a little bit outside of the generic drug and brand drug arena, but it was originally started in the Center for Medical Devices. It similarly grew. The Commissioner then was [David]

Kessler, I think. He was deeply involved in it. This case was actually moved under the umbrella of the task force. We moved to Beltsville [Maryland] in August of 1994. We pulled that case under the task force in the spring of 1993.

The whole issue was whether there was fraud in the application. Well, that was a long story. It ended with no prosecution. There were problems and questions, and it was just such a mess, they could never really get to the point of conclusively establishing criminal culpability on the part of a particular individual and prove it at a felony level.

You have to understand, misdemeanors were a common garden variety thing. We could make misdemeanor cases by the thousands. We prosecuted. Did we ever press a misdemeanor charge? Yes, we did, but mostly, if we couldn't make a felony case, we just didn't go forward. We had too many cases and too few people.

In the Quantam case, the first case that I did. We only prosecuted three individuals in that company. One of them went to jail. Actually, we only prosecuted two. The other one had long since fled the country and was in Taiwan where there was no extradition, so we couldn't get him back. Shortly before I retired, the U.S. Attorney directed a review of all outstanding warrants in the District of Maryland. That indictment and those warrants were quashed because we returned those indictments in, I think, 1992, and at the end of 1999 this person was still in Taiwan. He was never going to return to the United States, so they dropped it. This is a guy who left the country and I'm sure he took more than $14 million in illegal gains.

RT: Did you say that was the Quantam?

JR: That was the Quantam case, yes.

RT: And that involved what type of preparation?

JR: Quantam was one of the smaller houses up in Long Island.

RT: Generic?

JR: A generic house. You'll remember the Premo case up in New Jersey. Remember the family involved? Seymour--oh gosh, what's the name? Seymour was the old man, and John was the son. John left after the Premo case, and he opened Quantam on Long Island. He got Jin Shun Chang, who was his scientist. Chang was Charlie Chang's godfather in the scandal in the early eighties when we had the first generic drug problem.

Around 1980 there were allegations of improprieties in the Generic Drug Review Division. DEPI got into it. We looked around, and it was Charlie Chang, Marvin Seife, and some others. There was no question--no question--that there was too cozy a relationship between the people in that review division and the people in the generic industry. Jin Shun Chang had been Charlie Chang's professor in college, and they were close. Then Jin Shun Chang and John--(I can't think of the name, that set up Quantam). They were the two principals.

What the agency did in the early eighties with that question, that cloud, and clear indications of problems, was they just kind of glossed over it. They didn't effectively deal with it. So in the late 1980s you come up with all these proven cases where reviewers in that division took kickbacks, they got paid off by the generic drug houses.

There was a day one guy walked into a reviewer's office in Parklawn, dropped an envelope on his desk. When he left, the reviewer discovered $20,000 in it. That employee called right away and reported it. I mean, he opened that envelope. He left it there. The guy left, and a few minutes later he thought--he didn't even look at it, and then he looked at it, and the guy almost had a heart attack. I mean, the reviewer was so shaken. And I know the man. Years later, when

I would deal with him, up until I retired, every once in a while it would still come up, and the guy would literally shake. It shook him up, it really scared him.

I can't remember the name of the guy who dropped the money. We prosecuted him. He had another company on Long Island. He was involved in all this stuff, and we prosecuted him. I just can't remember their names.

RO: Going back to this original complaint or one of the complaints, anyway, that came in from industry to the agency about the problems--

JR: In the late eighties.

RO: --I suppose that they were complaining that other generic houses were getting favored treatment in the agency rather than they.

JR: Yes. I never had the benefit of talking to these people myself, but it was that people had one reviewer in generic drugs. Chang by name was really close and it was obvious he was getting some payoffs. And the issue, whether it was specifically stated or by inference, it was clear that certain generic houses were getting priority in review. In theory, everything came in and it was reviewed in its received order. Well, there's no question that Charlie Chang and others were switching the order. Faster reviewers got certain applications by certain companies, and more sluggish, less productive reviewers got the others.

And here's the key to the generic drugs. The bottom line goes back to this. There's two points here. The first generic application approved gets the money, because they get the generic product out, it gets picked up. The brand has been on patent, it's been expensive. Now this equivalent product is available at substantially lower cost. It gets market share. Even if it's a

month later, somebody else comes and gets another generic ANDA approved, they're not going to get (the first one to get approval gets the market share) the bulk of it, and they'll get the entire generic market share. And when somebody else comes along, they'll chip away, but they'll never get a lot of it. It'll always be the first one.

When you talk about the generic money, we're not talking $100 million. We're not talking hundreds of millions of dollars here. We're talking billions. And I mean billions with lots of Bs. I mean, $100 million in product sales on a generic product is simply minuscule. It's drumbs. Chump change.

Now, the Food and Drug Administration and the United States Government is not without fault in this drug scandal. You have to look back to the political situation in the early 1980s and look at the changes instituted by the administration in power at that time. Get the government off people's backs. The [Ronald] Reagan Administration made a lot of changes.

The authorities, manpower, budget, and other elements of the Food and Drug Administration were greatly strained. We didn't have the oversight--and this is my opinion--we as an agency couldn't keep as close a watch as we should have. The emphasis was "Get the generic drugs approved." When you look at the 1984 Waxman-Hatch Act, what does it say? That is the pivotal point. And you know who the single largest buyer of generic product is?

RO: Defense.

JR: The government. DOD. What are all your state programs? What is all the Medicaid/Medicare drugs? They're all generics. I mean, the approval of generic product is--I mean, the money is just incredible. There's truth, money makes the world go round. Now, do I say that in the sense of, you know, it's a horrible thing, payoffs? No. But it is a fact. It is a simple fact, when you look at what the states and the federal government puts out monetarily for

pharmaceutical products for government-funded programs, it is absolutely astounding.

When you cut back on the number of staff you have in an agency for review, and you put a greater emphasis on review, and you have a greater number of applications coming in, something's going to give. And this whole scandal was part of that "give." It's just a fact. The government contributed to it. Whether anybody likes to hear that or not, that's the truth of the matter.

RO: Is it true that Congress passed legislation in this area as a result of all this background?

JR: Yes. When this scandal hit in the late eighties, you're talking like 1988-1991, there was legislation developed. In 1992 it was enacted, and it is a direct result of this scandal and the task force.

RT: What was the title of that statute?

JR: I can't remember. [Tape recorder turned off.]

JR: There's no question, one of the earliest effects of the generic drug scandal and the special prosecution staff cases, that's what it was known as in the early nineties, it evolved from the generic drug staff to the special prosecution staff. But the SPS cases, and the direct result legislation established additional sanctions for violations of the Food and Drug Act and related statutes in the production of generic drugs. This was the Generic Drug Enforcement Act of 1992, which established authority for FDA to bar individuals and companies convicted of crimes pertaining to the regulation of drug product, prohibited them. You could bar the individuals from working for companies that manufacture and/or distribute such products. Or in the case of the

companies, you could bar them from submitting applications.

There was the application integrity policy in the Center for Drugs, although it was not a punitive program by design. The idea was, if you could prove fraud in an application, and that it wasn't an isolated instance and could prove it in more than two applications, there's a term for it, an established practice. You could then suspend all approvals of all applications for all products pending review, including independent review or certifications before any approvals could be reinstated or any pending applications would be reviewed. In addition, the company could not submit any new applications.

You think about that for a second. You have a company that's got approved ANDAs, and you suspend their approval. Those products are no longer lawful in interstate commerce in this country.

[Begin Tape 2, Side 1]

RT: The Waxman-Hatch Act of 1984. That's different from the Generic Drug Enforcement Act. Could you speak to the first Waxman-Hatch Act for the moment as to what its purpose was?

JR: Let me just make one point about the 1992 Act before I forget. It established debarment of individuals and companies. It was a pivotal point in the authorities of the agency, because now you had people who were convicted of crimes related to an application, and you could bar them from being involved in any new applications. You could also bar their employment in the industry. A company that knowingly hired a debarred individual under the 1992 Act could then have all their applications suspended.

RT: Was there a mechanism for checking that?

JR: Well, I'm not so sure the agency has yet established an effective mechanism. From the time of its inception until when I retired, it was still a questionable issue. Raj Matkari was an Indian national who had been convicted early on. He had set up some kind of company or was working for a company and the issue came up. Could this company even submit applications under the 1992 debarment provision, given that Matkari had been previously convicted of crimes related to false applications?

RT: How do you spell that, Jim?

JR: I think it was M-A-T-K-A-R-I. If I'm not mistaken, that's who it was. There were a lot of Chinese and a lot of Indians in the industry, and, frankly, the names run together after a while.

But that was an important piece of legislation. Procedurally, I don't think they had refined procedures. Did they have a monitoring program that they could actually say, "All these people have been convicted." Under Center for Drugs they had some small office that did debarment; a group in compliance. Every time we completed an action, I would send the judgment and commitment documents from the U.S. District Court on a given individual or a company to these people. They could then initiate a review, determine whether or not debarment was appropriate under the act, and if so, initiate the actions. Then you had a whole administrative, typical bureaucratic government action, for which FDA has always been well noted. But the 1992 Act was very important.

To get back to the Waxman-Hatch Act in 1984, this is the point where generic drugs had been around for a long time. There keeps a push in this country to establish a means by which generic drugs could be approved and manufactured, and you could cut the cost. I mean, here we are in the year 2001 and everybody's screaming about the cost of pharmaceutical product, and

certainly there's a legitimate basis for that.

Twenty years ago, people were screaming about it, and that legislation made it that generic drugs could be proven safe and effective and marketed, and it established the mechanism of an Abbreviated New Drug Application. An ANDA, which in essence says a drug comes off patent, I can make this drug and I can make it doing it this way and it is safe and it is effective, and it is bioequivalent to the brand-name product.

Now, the generic drug manufacturer doesn't have to pay the--who knows, hundreds of millions of dollars in research and development costs that the innovator had. So they can make it much more cheaply without all that cost. Now, they could make it a little bit differently because they wouldn't have the innovator's formulation. They had to come up with a development formulation. But if they could make it bioequivalent, well, that was the critical issue.

RO: Of course, now, Jim, the innovator manufacturer is seeking patent extension.

JR: Absolutely. Also going on back in the eighties, the innovators weren't stupid. These are good companies. I mean, sometimes the toughest generic competitor to a brand-new drug was manufactured by the brand-name company. Incest is best, you know. Altruism is wonderful, but bear in mind, pharmaceutical houses are a business. The primary objective of any business is profit. If they don't make a profit, why are they in business? And pharmaceutical product is money, capital. And we are a pharmaceutical nation. We love our drugs, you know. Go to a doctor, get an ouch, get a pill. It's just that way.

RO: Is this Generic Task Force still in existence?

JR: Well, not in that sense. All the people that were in Baltimore, the IG people pulled out,

people started retiring, some of the older people. I stayed with the operation through various stages of evolution. When OCI came into existence and took over management of it, it was managed by OCI. It had some OCI people and it had some Office of Enforcement people. Well, people get jobs, they go different places. One investigator transfers, gets tired of the operation, didn't like the way it was being run. He transferred to a district office, took a job in another part of the country. Another guy gets transferred here, somebody retires, and the first thing you know, you have nothing but OCI people left. To my knowledge, I don't think there's anybody in that group that is not OCI now.

The nature of the operation moved away from strictly--that operation was created to investigate fraud in drug applications, specifically generic drug applications. It has moved on, and OCI does lots of other investigations in that operation.

I retired sixteen, seventeen months ago. In all candor, I have no idea what they're doing. I do know of one case that is continuing because it was a case I worked on for three years before I retired. It was not complete, and it's still under way. Technically I am privy to some information on a limited basis because sooner or later--once in a while I get a phone call because they need to know something that I was involved with, because I was the one who did it. I know that case is not resolved, and when it is, I'll know that. But other than that, I have no idea what they're working on. It's none of my business.

RO: For the record, Jim, tell us a little bit about the creation of OCI, because that came about, I think, back when there were some problems in FDA and Congressman [John] Dingell thought we needed some--

JR: Here's my understanding. Was I directly involved in these things and am I an authoritative source of information? No. But it's another of the outgrowths of the generic drug scandal.

Dingell, who was in a very powerful position in the Congress back in those days, looked into it, stating, "You mean to tell me you don't have criminal investigators in the Food and Drug Administration to conduct criminal investigations?" And Congress started beating on the agency, and, as far as I'm concerned, that's why there is an Office of Criminal Investigations in the Food and Drug Administration.

Congress beat the agency to the point where it had to put one together. It did. So they went looking for somebody to set it up. They did. They found--and I think it was in 1992--they hired the director, who's still there. They created an agency within an agency, is what they did. Want me to tell it like it is?

RT: That's the first time that FDA field staff was authorized to carry firearms, is that correct?

JR: I don't think that's quite accurate. Prior to my time in the agency, back in the sixties, because there's another agency, the Drug Enforcement Administration in the Department of Justice, that evolved from FDA. It came out of the old Bureau of Narcotics and Dangerous Drugs. Back in the sixties, there were people in FDA who did criminal work. Of course, there were always people in FDA doing criminal work.

One of the most serious issues I always had with this agency is they never truly looked at the field investigators for what they were really doing. Some of them were investigators in the true sense of the word. They went out, they looked at a company, and they had no idea what was going on. They just did a rote investigation. But there are a lot of field investigators, truly, who actually went out and did criminal work, whether they realized it or not, and many of them did, and over the years it became more and more.

FDA investigators have always been doing criminal work, in my judgment. But back in the sixties, particularly, and Ron, you'd be more knowledgeable than I am, but I think there were

times when FDA investigators, as they were known then, were authorized to carry firearms, but I think it was in very limited circumstances.

RT: Was that the Bureau of Drug Abuse Control?

JR: Yes, I think that's what it is, BDAC, and I didn't remember that name. Then it became the BNDD [Bureau of Narcotics and Dangerous Drugs], because I remember when the DEA was first set up, it was not the DEA, it was the BNDD. That's what it was. It came from BDAC. That was the Food and Drug part.

Now you have this Office of Criminal Investigations, which is a subset of the agency, and originally, when they first staffed their offices, when they set up their six field offices around the country, I mean, from Terry Vermillion on down, they didn't have 100 people. I don't know how many people they have now. But you had this mass--and I mean mass--infusion of money staffing, and a tremendous amount of resources, the Food and Drug Administration going into this new Office of Criminal Investigations. This thing was like a sponge.

And there was a lot of resentment in this agency, a lot of resentment, because now all of a sudden you had these special agents, and they said to the inspectors, "Get the hell out of my way." That was the way they operated and that was known it was going to happen. People knew that would happen. They tried to warn them it would happen, and there was no way you could avoid it.

Now, the OCI is an organization that treats its people as an elite. It is geared for one reason: it supports the agent. That is something the Food and Drug Administration, in my opinion, never did. I will never forget when I saw people come in from the field and they would look at these word processors and stuff we had back in the eighties, and then when computers first started showing up, "My God, every moron in the world's got one of these, even idiots that

don't know how to turn them on. We're sitting out in the field and have nothing." I used to see the money spent at Headquarters, the equipment that went to people, and these folks out in the trenches doing the day-to-day work didn't get any.

Well, that's not the way OCI operates. OCI has everything it needs. Those people lack for nothing, from their hard hats to the steel-toed shoes, to their jumpsuits, their shotguns, their 9-millimeters, you name it, they have it. They lack for nothing, and when they go to do their job, they have everything. And the reason is, Terry Vermillion sees that they do. A lot of people can say what they want about Terry, but Terry knew how to put an organization together and he knew how to do what this agency had never done, in my opinion.

Quite frankly, does OCI justify all the money it's had? I have no clue. I really don't know what they do. I was not an OCI person. I was not involved. There were meetings in operation that I wasn't involved in because I wasn't in OCI. And there were guys that were on that task force that were not OCI. As it began to change, they up and left. They just couldn't take it. They were excluded. They felt like their FDA knowledge, experience, judgment was not taken into account because they weren't a special agent, and they were bringing young agents in there who knew nothing about drug manufacturing, and they weren't going to understand it, but they were agents that, in their opinion, counted. There were all sorts of hostilities.

I just didn't let it bother me, because I figured, what the heck, I was in the last couple of years. I was on a downhill slide. I just thought, "Hey, I'm going to do my job and do it as well as I can." I just couldn't get an ulcer over it.

RT: While you were in that task force in Baltimore for a while, did the U.S. Attorney had some staff there, too?

JR: Originally it was in Baltimore at the courthouse, and then it grew and we were across the

street, where we had U.S. Attorney space. The U.S. Attorneys had their offices and we had ours. Well, it was great, let me tell you, when these attorneys got some time, they'd walk out of their office and they'd go 100 feet and they would sit down and go over records with us and we could talk, we could do things. Well, we were right there in Baltimore. Everything worked.

Then came the time when the new courthouse was going to be built in Greenbelt. The Southern Division of the District of Maryland was created. For three years, the agency had been sending people to Baltimore. Nobody wanted to go to Baltimore. Everybody lived down here and they were schlepping up to Baltimore every day. They put people in hotels for a year up there, because they wouldn't drive from Bethesda to Baltimore every day. I lived in Laurel. It was nice for me because it was no farther than Rockville. I just went up 95. It was great.

So we had this nice working relationship. Well, it was getting tougher to get people to agree to go to Baltimore. It was getting costly. They were going to build this new courthouse. Carl Chancey was in charge of the task force, and he lived in Germantown, and he didn't want to be driving up to Baltimore every day. So what a surprise. Let's move the task force to Rockville. Now move this operation to Rockville. There were several places considered. You can't see it because of the trees, but that building right over there on Rockville Pike, the Rockwall Building, the first building over here on Executive Boulevard, probably four or five other places, we went through all this bullshit. Oh. I forgot about the tape.

I mean, the move, the money, and we've got to move to this place. Do you have any idea, if you stack paper eight feet high, how much it weighs? And do it over several hundred square feet. Every time they wanted to put us somewhere, the floor wouldn't take the load. So we would get these moves, and they spent all of this money. Now they've got to do a study. They were going to put steel trussing under floors. It was lunacy.

Finally, when Chancey left and I was in charge, and I didn't care where we went--Rockville, whatever, just get it done. Then OCI takes over and Jud Bohrer is in charge, and Jud

Bohrer lived in Laurel. Now how much do you think they wanted to put that operation in Rockville? So now the cost of space in Beltsville is a third what it is on Rockville Pike. Where do you think the task force is? Off 95 and Powder Mill Road.

But we had to go through two buildings there because they wanted us on the third floor. I told the guy who represented the company, who had never leased to the government, I said, "Tell you right now. Day one. You guarantee me 95-foot pounds per square foot. If you can't give me that load factor on this floor, don't even think of us moving in." We had these trolleys, these big file cabinets that were 16 feet long. They were six shelves high on each side. I put 26 of those carriages in. I had 6,100 shelf feet. How much load do you think that was going to put on there?

When we built that place in Beltsville, when I laid it out and built it, 6,100--over a mile and a half, almost, of shelf space of paper. I mean, we had to build it on the ground, finally, because you couldn't get a place that could handle it. It was lunacy. That was another part of the trials and tribulations. So the task force was over there in Beltsville, and it's now a subset of the Washington field office of OCI.

RT: Very interesting.

JR: Hey, you know, it was a good operation, and I say with pride that I was a part of it. We did a lot of good work. The guys that preceded me in the early days, Stan Johnson, Bill McConnell, Carl Sharp, I can name a lot of guys. They got into the first of it and I didn't get there until a year after they started it, but we did a lot of good work.

I think when you look at the mission of the Food and Drug Administration to protect the public health, the first fourteen years in the agency I had no feeling that I was in any way involved with what the Food and Drug Administration did, but when I was up there, I felt like I had

something to do with protecting the public health. I really do. I feel good about what I did.

RO: Where do you think this whole thing is going to go, Jim?

JR: That operation?

RO: Not only that operation, but the agency.

JR: Well, in terms of that operation, in my opinion, it will just become another field office of OCI. It will not be application fraud; it will just be another criminal investigative group of OCI that will do some application fraud.

Quite frankly, OCI agents do not understand and do not care. It's not what they want to do. These criminal investigators are involved in doing traditional criminal work, and learning about drug manufacturing and regulations and how and what FDA does, they're not interested. They are not interested in climbing into paper bins and living there for years. There's no excitement in doing this. It is boring. It really is.

And there's no question in my mind that operation will just fizzle as it relates to doing those kinds of cases. It just fizzles, because when you look at the Food and Drug knowledge that OCI agents do not have, okay, on that task force right now, as far as I know, there are only two people left there who came from Food and Drug Administration, that were picked up with OCI. One of them runs it; he's the agent in charge. As long as he's there, he's going to try to keep that going, but he's also going to do what OCI wants done. I mean, that's the nature of his job. He's in his mid-forties, maybe forty-seven now. There's no question in my mind, if he gets a chance to get a promotion which would take him out of that job, he'd go. He's a guy who wants to get ahead, always has, he's very sharp, and he's a good guy. I hope he makes it and gets another job.

If he goes out of there, there's one of the working agents, if you will, is still there, who was an old CSO. A year from now he's probably going to retire.

RT: Who's the guy who's in charge?

JR: Kim Rice. Kim Rice is the agent in charge. He had twenty years as a CSO before he got picked up by OCI. Kim's a good guy. He's very knowledgeable. But when he goes and when John Lanksford goes, that's it. There's nothing left. All the others are OCI agents, they're all young, they're all kids, every one of them, and they don't have the knowledge and understanding. They don't.

There is one non-OCI person there. That's right. I just thought of that. There's a pharmacist over there, a young woman. What they don't appreciate is, they have a pharmacist there. When you're dealing with pharmaceutical, the wealth of information and knowledge this woman has was not capitalized upon. The knowledge and experience of the CSO, no. But, hey, that's the real world, and that's not going to change. What started in 1988 was there in the nineties, through the first half, no. In 1995, it was dramatically shifting and it has just continued, and it will go by the wayside, that's all.

RT: I think we've covered a pretty broad range of information.

RO: We appreciate your permitting us to do this interview with you, Jim. You've talked about some things that I don't think is in the oral history to date.

RT: That's right.

RO: That's why we wanted to get you.

JR: As I told you the first time we talked about it, I thought, what can I really contribute, because I wasn't involved with the day-to-day FDA, but I guess I really was involved.

RT: You're part of the history of the agency.

JR: I did twenty-three years in the Food and Drug Administration. It's hard to believe. Twenty-three years I spent in that office.

[End of interview]