Roumel, Theodore J. 2004

Dr. Theodore J. Roumel Oral History 2004

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Interview with Dr. Theodore Roumel
National Institutes of Health

Conducted by Jennifer Rogers
June 17, 2004

JR: This is Jennifer Rogers interviewing Dr. Theodore Roumel, June 17th, 2004. To start with, tell me about your education and career leading up to when you came to the Public Health Service?

TR: I received my undergraduate degree from Temple University, in Philadelphia, and then I went to graduate school at the University of Maryland at College Park, and received a degree in Counseling Psychology. I worked at the Counseling Center there with students as part of my assistantships. Then I was recruited into the Public Health Service, and went to work for the National Institute of Mental Health [NIMH]. That's how I got started working at NIH. When I first came to the NIMH, I had a couple of different assignments before my final formal assignment. I was working in the development of community mental health centers out in the Midwest, in a six-state area, which got me to the heartland of America for the first time, since I was an Easterner.

Then I came back and had a stint working with people in grants administration. Then it came time to figure out where I was going to go finally, and through serendipity or whatever, there was a freeze, and I had a choice of places to go. I ended up going to the Intramural Research Program for the NIMH, and worked as an executive assistant to the Director of Intramural Research Programs, John Eberhart. And John Eberhart was my mentor for research administration: how do manage research, how to deal with researchers, and how the whole program operated. He was the Director of the combined Intramural Research Program, and Director of the Division of Biological and Biochemical research. Bob Cohen was the Deputy Director, as well as the Director of Clinical and Behavioral Research.

We were involved with the clinical aspects in Building 10 at that time, where the wards were. We were also the first group in to move into Building 36. An interesting thing for me is that now that I've left the NIH, there are plans to tear down Building 36! So that gives you an idea of the expanse of time I've been with NIH and the Public Health Service. My entire career has been with the Public Health Service, by the way. So right out of school, I've always been somewhere in the Public Health Service, starting off at NIMH.

JR: You said that Dr. Eberhart was your mentor and taught you a lot about research administration. What were some of those early lessons that you learned from him?

TR: Some of the early lessons were to be patient, and always to remember that research is not programmed. A number of research findings come through serendipity, and while people may not have been very productive over a short period of time, that does not mean that they may not come up with findings. I was a little bit aggressive in trying to move resources to those investigators that I thought had the highest probability of coming up with new findings, rather than stay with investigators who were no longer as productive in their research findings. Of course, I found out you can't do that, because a lot of these people may not be that active and come out with papers, and their analysis is the thing that sparks findings. They are able to sit back and put five or six disparate pieces together and all of a sudden come up with something brand new. So I learned to be patient and give them time. That was one of the key things I learned from Dr. Eberhart.

I also learned about the overall management of a research program. I learned everything about animal care– dealing with the animal caretakers, cage-washing machines, etcetera– all the way up to playing musical chairs with the fire marshals in Building 10. We had equipment out in the hallways, and the fire marshals said, "You can't put equipment in the hallways." So we moved it around the corner. The fire marshal would come and say, "Okay, great." Then when he was gone, we'd move them back, because we just didn't have the space. Some of that still goes on today. But I learned an awful lot about the management of the facilities.

We did have one Nobel Laureate, and that was Dr Julius Axelrod. He received his Nobel Laureate in 1970—a very exciting time to be at NIMH. An interesting side story about Julius Axelrod is that they were trying to give him a promotion. Julie was a Section Chief in the laboratory. At that point in time, grade levels were attached to where you were in the organization, and he was a Section Chief, and he could not be promoted at his level. But he was an outstanding scientist and had received the Nobel Prize. Then the Head of the Office of Personnel Management at the time—his name was Macy—sent a letter to Dr. Axelrod saying, "You are the epitome of the federal employee and the highest and best of what we have to offer." So we put that in the package and sent it in, and he got his promotion. A total side story.

JR: And all he had to do was win a Nobel Prize!

TR: Win a Nobel Prize, and you can get a promotion anytime. So that was fun, working in the clinical area, and also in the biological and biochemical areas. Part of the NIMH at the time included drug abuse programs and alcohol abuse programs. They were all folded in under Mental Health, and there was legislation that was being proposed to create a new National Institute of Alcohol Abuse and Alcoholism. I was asked by the then Executive Officer and the Deputy Director of Mental Health if I would go over and start up what was to be the National Institute on Alcohol Abuse and Alcoholism. There was no—well, there was some staff. We were transferring seven people from the intramural program. It was in the Division of Alcohol Abuse and Alcoholism that was located at St. Elizabeth's Hospital.

And so they were transferred over to the new Institute. I was there, and we had two administrative people on detail. We were there when the legislation finally passed; the Institute was created, and we then brought in the first Director of the National Institute of Alcohol Abuse and Alcoholism [NIAAA], Morris Chafetz. I always used to kid Morrie that I'm the one that hired him as the Director of the Institute. So he always used to kid me about that.

So that's how we started. We started off with really no staff, and within a short period of time it became a full-service organization with a budget of more than a hundred million dollars. We went from no employees to a little more than a hundred employees in two to three years. It was chaotic; it was exciting. It was probably one of the best times I've ever had working anywhere, because everybody was thrown in to do everything and get it started. NIAAA at that time not only had an intramural program for research and an extramural program for research, but they also had extramural programs for planning grants, evaluation grants, construction grants, and service grants, including formula grants to states. Today it’s very unusual that those programs would be administered in a single entity.

We also started off a national education initiative, and I worked with the advertisements that came out through Gray North. Some people I think still know those ads: Friends don't let friends drink and drive, the Neighborhood Pusher, who is the person in your neighborhood that says, "Oh, come on in, have another drink." That's the Neighborhood Pusher. Those were the ads that came out at that time from the NIAAA, and the group just exploded. It was a fantastic time, and I was involved with a number of great activities. I worked with Alaskan natives and Indians on developing some programs to treat their alcoholism problem, a devastating problem in those communities.

I was at NIAAA for three or four years, and then was recruited to take a new position in the office of the Assistant Secretary for Health. In the Department they used to have the Surgeon-General be the head health official, but in the 70's they created a new position called the Assistant Secretary for Health and Scientific Affairs. Later it was shortened to the Assistant Secretary for Health, which was a political position, and that person basically moved in above the Surgeon-General. The Surgeon-General then became more of an information kind of person, and went around the country giving speeches about public health.

The new Assistant Secretary for Health position was setting up business, and they wanted to create an office there that would evaluate and review health programs that were part of the Public Health Service. I had been asked if I would come and do that, and I had mixed emotions about leaving. One of the other little lessons I learned: One of my mentors was Jim Isbister, the Executive Officer, and later Deputy Director of NIMH, and eventually he became the Administrator of the Alcohol and Drug Abuse and Mental Health Administration. I asked him a question: "These people are coming and asking me to go," I said. "I'm asking your opinion. Do you think I should go?" And he said, "Absolutely not. You should stay where you are." But he had a smile on his face. And I said, "Why is he smiling?" And then I said, "Hmm. Let me ask you: if it was you, what would you do?" He said, "I'd be out of here in a minute."

One of the lessons I learned is that you need to watch how you ask a question, because it will frame the answer. So the question I asked him was: what did he want me to do? What was best for him, not what was best for me. And the second time I asked the question what he would do in my place.

JR: Do you remember the rationale for creating this new Office for the Assistant Secretary of Health, and putting it above the Surgeon-General? What was the thinking behind that? What did they think it would accomplish?

TR: It was an attempt to bring in a political appointee into that position. They were all health professionals, so it was now bringing in an administrative person to deal with all the new health programs. Remember, the Public Health Service at that time included— I think there were nine—health agencies at the time: Centers for Disease Control, the Food and Drug Administration, NIH, NIMH split off. Then there was the Health Services and Mental Health Administration, and there was Health Resources and Services Administration—they split off—and then a number of programs within the Office of the Assistant Secretary for Health, like Adolescent Family Life and other programs. It was a very large area of responsibility.

So that was the rationale: they wanted to move further down into the organization, to expand their control from the political perspective, but all of those people were still public health professionals. The first one was Dr. Charlie Edwards. He was Commissioner of the Food and Drug Administration, and he came over to take that position. When I met with him, I asked what he wanted to have done in this position. He said he wanted to have his own staff to be able to go in and take a look at how effectively and efficiently various health programs were operating.

It was sort of like an internal programmatic evaluation or programmatic audit group, and we would go in wherever there was a particular issue. Let's say there were some allegations that there was a problem in a particular program. We would be sent in to take a look. Are those problems there? If so, what should be done to correct them? We came up with recommendations for changes in a number of programs.

One of the first ones was the Professional Standards Review Organizations, the PSRO's. PSRO's were the predecessor to the diagnostic groups that are used in Medicare and Medicaid for funding. They determine how much do you pay for various services. We went in and took a look at that program and found that there was a need for restructuring. I basically developed, with my group, four new models of how reimbursements should be given for the provision of health services. They were dependent on whether it was a metropolitan, inner city, suburban, or rural location, and there were different reimbursement schemes for each of those. So that was one of the first things we did.

JR: How does that compare to what the PSRO's were doing before? How did it improve the program and make it more efficient?

TR: It made it more standardized. You have to understand that most people weren't interested in developing these kinds of things. The government would go to various areas, and basically whatever the local administrators demanded is what they were given. Some places were being funded far better than others, but there was no rational basis for the different funding levels. It was just a matter of happenstance. So we put models together that could be used, and say, "Here's your model. This is what you will receive to administer your program."

JR: Now what you were doing as far as these internal program audits—was that fairly unprecedented among the health agencies?

TR: Yes. Some of the agencies would do reviews, but mainly the only reviews going on were those done by the General Accounting Office at the request of Congress. The Assistant Secretary for Health had his own group that he could send in to take a look at various programs and see what was needed for improvement. So it was a brand-new program; it had not existed in the past, and that's what was fun about it.

We took a look at how services were being provided by the Indian Health Service, Migrant Health programs, Community Health Center programs, and Adolescent and Family Life programs. There were maybe eight or ten that we did over a three-year period or so. And it was great! You learned about the programs and had an opportunity to improve them, to better utilize human and fiscal resources, and to improve the outcome.

JR: The problems that you found in the programs—were they individualized? Did you see trends emerge when you looked at the different programs? What sorts of things did you find?

TR: There were some that were localized, and some of them that were across-the-board. Usually the problems that were across-the-board involved a lack of management structure, a lack of guidance, and a lack of any kind of guidance materials. The program administrators were more interested in the delivery of services. Now if you take a look at what happened in many Community Health Centers and Migrant Health Centers, they faltered not because of a failure to deliver services, but because of poor management.

So there were trends: how programs were selecting sites, how they were evaluating sites, how they would determine continuation of funding, those kinds of things. There were certain patterns that did arise, and we saw a number of them. As I say, it was extremely interesting, and I think that we improved the quality of services being delivered to individuals. It was something that I really enjoyed doing.

JR: What were some of the management changes that you implemented in the programs?

TR: I recall there were some structural things related to reimbursement in the Community Health Center and Migrant Health Center programs. In some cases, the Centers were not even seeking reimbursement from third parties, and there was no concerted effort to ensure that they were doing so. We were able to get funding for positions at each of the Centers that would be responsible for third party reimbursement, to qualify people for Medicaid or other state aid, so that they could generate some income to help support these organizations.

It was interesting that we found not just programmatic issues, but we also documented some of the other issues that were occurring, especially with migratory farm workers. The health services that were being provided were not the greatest, but living conditions were horrendous in many cases. At that time there was also the exposé about migratory farm workers being held as slaves. They were basically chained up at night, and we saw some of this. Not exactly the chaining up, but the migratory farm workers were not allowed to go into towns. They worked down on the farms, and the crew chiefs would go into town. If you wanted groceries, you'd tell the crew chief what you wanted, and he would bring back the groceries and give you a bill. The bill sometimes had no reflection of reality, so many of these workers were constantly in debt to their crew chiefs, and the only way that they could get out of debt was to continue to work. So they were basically working for food. Some of those abuses were captured in exposés, in Florida especially, where they were chaining the people at night so they wouldn't run away.

JR: Just so I understand, what was the connection between the health agency and the workers in terms of their working conditions and living conditions? Were they supposed to be overseeing that, or were they simply there and not reporting it?

TR: Well, the health services were there to provide health services to these people. Their living conditions created health problems, and that's where some of these things had come to light. Where there were people being abused, there were problems with sanitation in the facilities—those kinds of things were being documented. A big part of it was a lack of resources for some of these programs. They didn't have enough people to oversee the activities. They wanted to get services out there; they thought they were doing the right thing, but in many cases a lot of abuses were occurring.

I learned a lot about various healthcare delivery programs, and it probably also gave me some background and feelings about a lot of public health issues, including the issue of national health services. The Indian Health Service is probably as close as you'll ever see in the United States to free care provided by a governmental agency. There were problems with that program that were easy to spot, so some of that has formed my impressions that are with me today as to how health care should be provided and reimbursed.

JR: What are your feelings on national health care?

TR: Well, one of my feelings is that if you provide free health care, people will treat it for what the value is. Since they're not paying anything for it, they have the tendency to abuse it. We had people who were coming to see doctors who should be treated at home. If you had a headache, you would probably take an aspirin, and if it was still there three or four days later you might say, "This is more than just a headache." Well, for these people that were getting free care, if they had a headache they went to see the doctor, because they felt entitled. It was a misuse of the system.

Additionally, they were given free prescriptions, so if you didn't want to go to the corner drugstore and buy aspirin, you went to see the doctor, and the doctor would give you the aspirin. So there were all those types of abuses. Even though people could treat themselves at home, they wouldn't do it, because they thought, “I can go to the doctor and it doesn't cost me anything but some of my time.” And for many people, they had plenty of time and didn’t want to spend the money.

JR: Was it completely free, or were they contributing some of their tax dollars to it?

TR: No, the Indian Health Service is totally free. The Migratory and Community Health Service had developed sliding scale fees, and your co-pays depended on your income. I believe that’s a far better system. If you're making more money, you co-pay more.

JR: So you thought that kind of system worked a lot better, and you saw fewer abuses than with the free service?

TR: Far better, yes. People would say, "No, I don't want to go to the doctor for this," unless it's something that's a little more serious. Again, some people may not go at all if they don't have the money, and that's a problem we see today. People will not go to the doctor because they have no money at all. So you don't want to keep them from coming in for services when they have a serious problem.

So those are some of the problems we found over the years, and obviously we did a good enough job that I was asked to take on additional responsibilities. I was asked to take over as Director of Grants Policy and Operations for the Public Health Service, a rather large division, because there were more than forty awarding offices at the time, including regional offices and all of the various agencies. Additionally, we were trying to consolidate operations, so that if the public applied for a grant from two different Public Health Service agencies, at least they could use the same form, the same format, but just address the different programs. We were trying to streamline activities and reduce burdens.

So I was asked if I would take that on, and I turned it down. And then I was asked by the person who was then the Executive Officer of the Public Health Service, and I turned it down. Then the Assistant Secretary asked me if I would take the job, and I turned it down. That was on a Friday, and on Monday there was a memorandum appointing me [laughter] as the new head of Grants Policy and Operations for the Public Health Service. That in addition to the duties of my old position!

JR: So the job that you were doing before didn't go away?

TR: No, it was folded into the new job. I was head of Grants Policy and Operations for the Public Health Service for seventeen years, and there were a number of very interesting things, a number of initiatives to reduce the burden on recipients. In the grants area, for example, initially when a person reported back at the end of a grant, they had to say how much money they had left. They also had to tell you exactly how they spent their money, such as how much were for personnel services. But they also had to tell you how many boxes of staples they had left, and boxes of paper, equipment, etcetera. This was very, very intensive reporting. Then in the late '60's and early '70's the number of new programs just exploded– Johnson's Great Society.

So we had these programs, all this money going out, and just a few people to administer them with antiquated administrative policies. We tried to cut those down, which we did, and change some of the prior approval items for moving money around. I think it was reduced to seven items where you needed prior approval to move money around. Whereas previous to that, if you wanted to move one penny, you had to come in for prior approval. So we had a number of initiatives, and that's one of the accomplishments I think we had in Grants, to consolidate operations across the board so that recipients of funding from multiple parts of the Public Health Service understood the package of materials they had, understood the language that was in the application, so it wouldn't be a different process for all these various programs. Additionally, we consolidated administrative requirements for the various programs.

The Public Health Service had a *lot* of programs. At one point, I think, the Public Health Service had the most grant programs of any agency in the Catalog of Federal Domestic Assistance, which lists all the grant programs and other benefit programs of the government. So you have a couple hundred programs, and you try to streamline them as much as possible. Now of course, you had resistance, and the programs still would say, "But I'm different. Our program needs this because– " And you have to work out some of those differences. Most of the time you just had to say no. It didn't win you a lot of friends in some of the programs, but it was something that was needed overall, and the programs accommodated. Programs were not less effective because of the loss of information.

Many programs would require information, data, and reports. We would ask those administrators, "Well, now that you've got all these detailed reports, what do you do with them?" They'd say, "Well, I put them over here." And you could see a stack of papers in the corner of their office four feet high, six feet long. "Well, do you read them?" "I don't have the time to read them." "Then why are you requesting them? You don't even know what's in the report, and yet you're not taking any action based on their content." We found that over and over again, and came to the determination that if we were going to require something, staff needed to read it and act on it. If you're not going to do that, don't ask for it. To require something and never even look at it undercuts your authority. You're seen as nothing but a paper tiger. You require all these things, but you don't do anything. I think of it like when you're in school and you had to write essays for exams, and you're just writing in that blue book—we had blue books at the time.

JR: They still do!

TR: They still do. And you write in your blue book and you keep writing. You're writing this essay and you're going through the entire blue book, and you say, "Now how is this person ever going to read these? First of all, how are they going to read my handwriting?" I was always tempted to just put into the middle of the essay a nursery rhyme or something, to see if somebody even read it. I never had the nerve to do that.

JR: Wish I'd thought of that! .

TR: But it's the same kind of thing—if you read and use the information, then ask for it. If you have no need, then don't ask for it, because it's a waste of time and resources for all parties. People spend a great deal of time developing applications and writing reports, and it's a waste of time and effort. So if you don't need it, don't ask for it. That was our guiding principle, and it cut out a lot of unnecessary paperwork that was a burden not only to recipients, but also to staff. Government staff were told, "You have to read these reports," but they didn't have the time, and didn't feel that the success or accountability of federal funds was being hampered by not reading them. So it was reducing the burden on our own staff at the same time.

As programs moved along, administrative resources did not keep up, and still are not keeping up in the programs. For example, at NIH the budget doubled, but they didn't double the number of people at the NIH. So when you have that, when you have an increased work load, you have to find new ways to improve productivity. You have to question: what do you really need? Let's get to the essence of what is required for you to make a determination as to whether this should be funded, continue to be funded, if there's a problem, etcetera.

So those were the things we were pushing. We did some rather novel projects that we won some awards for on creative approaches to reducing burden, and one of those led to a government wide initiative that was called the Federal Demonstration Project, FDP. It started in Florida and then expanded government-wide, and is still in existence today. We also developed training programs for grants management and program staff as to what their duties and responsibilities were. Again, we were trying to get people on the same page. It was the first time that had ever been done, and we were doing it across the board for all the agencies.

We also came up with a program for grantees: "this is what the Public Health Service is looking for in its applications. This is how it administers its programs," so that they would understand what their responsibilities were, and what the Public Health Service expected. We did the training programs ourselves. My staff and I wrote up the scripts for instructors; we did them all ourselves with our own staff, and then it became overwhelming and we went to a contract.

That training was very successful, and the Department, HHS, then picked it up as a Departmental-wide training program. That program is still in existence now, from the late 1970's, and is used by other federal agencies. So there's something that we started back then that had tremendous impact on the standardized training of staff.

JR: This training that became HHS-wide, that was . . . ?

TR: Required training.

JR: Required for staff and grantees, or more for staff?

TR: Staff had to do it. The grantee's portion is done more on an agency by agency basis, if they want to go out and do it. NIH does it; they have what they call their regional programs, in which they go out and talk to recipients about the requirements of NIH grants.

JR: Step back just a second. You mentioned the Federal Demonstration Project. You said that was something that originated with your group and then became government-wide. Why don't you tell me a little about that?

TR: Okay. We wanted to take a look at how we might be better able to reduce the burden on recipients. I called together a group of—I think it was nineteen, initially—institutions of higher education, nonprofit organizations, etcetera, that we brought together for regular meetings over about a year and a half to talk about the issues they had with the administration of grants in the Public Health Service. What were the problems? What are the things that they saw as time-wasters? And we tried to work through all those various issues. In some cases, they were regulatory issues and we could not change them. But in other cases there were some administrative things that we could change.

We went through that process, and since it was only a pilot project, it was called the PHS Pilot Project. We then tried to deal with some issues on a regulatory basis. Changing regulations was not successful because other federal agencies were not as forward- thinking as we were, and they wanted to still go back to counting the number of staples that were left at the end of the grant. The Public Health Service was way ahead in administrative implementations to streamline activities, and was looked to as the leader in grants administration. We had streamlined policies and procedures, consolidated forms, and training. We were developing grants administration as a new field apart from the contract management mentality used in other federal agencies. I, along with several others, founded the National Assistance Management Association to bring together federal grants managers to discuss issues and concerns. I was elected the first vice president of the organization. Bob Newton of the NSF [National Science Foundation] was the first president. That organization has survived and grown to become the National Grants Management Association today.

My belief was that you always want the recipient to know your requirements and objectives inside out and backwards, and to administer those grants as best they can. If you have people that are not knowledgeable on the other end (recipients), there are going to be abuses, and that's when you get fraud and waste. So I was able to persuade PHS officials to support the development of what was called the Research Administrator Certification Council, and the development of a new group, Certified Research Administrators, which is a designation given after passing a national exam. People have to take certain courses. There's an outline of the courses and the kind of information that will be on the exam. They take a national exam, and get designated as a Certified Research Administrator. There are now I think almost three thousand certified research administrators, and that's now used in some of the criteria for recruitment for positions. They'll say, "We're looking for a grants manager, and they must be a CRA."

TR: So we developed that program and it's ongoing today. It started about 1990 or 1992, and I was on the board of that organization, and applied myself, and got the designation as a Certified Research Administrator. It's like getting a C.P.A. for an accountant.

There were a number of new program initiatives that my staff was asked to come in and provide technical assistance on how to set up and run the programs, how to improve the programs. We helped develop the spinabifida program at CDC and Secretary Sullivan's Minority Male Initiative. He announced it at a meeting in April and wanted it implemented by the end of the fiscal year, which was quite a job to do. But we did it! We got the grant worked out by the end of September. There were about a dozen or more of these programs that my staff and I helped to get started

I was given a number of special assignments also. In 1980 I was assigned to the Reagan White House to assist in the implementation of what was then called Block Grants. There were a number of categorical grant programs, and they had been, by legislation, consolidated into what were called Block Grants. But it was voluntary and you had to get the states to sign off to the Block Grants. Most of the states were not interested in signing off for the Block Grants, because they were afraid the government would start taking money away and the states would then have to pick up the price tag. So we worked with the people at the White House and the state legislatures in getting them to accept the Block Grant Program. That was a very interesting process, working with the White House staff on that. So that was one initiative.

I'm not sure how it got started, but I also ended up being the head of the Public Health Service's Historically Black College and University (HBCU) Initiative. And it was very interesting. I still remember going into these meetings, and I would be the only non-African American. People would look at me very strangely and say, "Why are you here?" I think that because of my experience in program evaluation and management activities, I was better able to identify solutions to potential programs that historically Black colleges might be able to utilize. And we did a very good job. We moved it from about four million to over a hundred million in an eight-year period.

JR: Was that the purpose of the initiative? To raise the amount of funding going to those colleges?

TR: Yes, this was and continues to be a Presidential initiative, to increase funding going to traditionally black colleges and universities. As part of that initiative I wanted to run a demonstration program to show that historically Black colleges and universities could attract, use properly, retain, and obtain additional program funding. It took me three years to get this approved. We then set up a demonstration program in which we provided a limited amount of money to the institutions that were selected through a competitive process to support two positions in-house. They had to sign on for training programs, and they had to join a couple of national organizations, and they had to participate in our training program. That was for the first two years, and then we gave them minimal funding after that. It was a four-year program, and we had four institutions that were involved.

One institution had a problem in that they couldn't keep someone in the job as the sponsored programs person. So they really didn't improve. The others improved anywhere from 30 percent to 500 percent in the amount of money that they were generating, and that's like going from four million to sixteen million in one case over that period of time. This proved that as long as you have well-trained administrators who know the grants process, can identify sources, get the applications together, and manage those funds, even small, predominantly undergraduate institutions, that one would not think would be eligible or able to receive funds, were able to attract and retain sponsored program support.

Along with the training we designed, we put out a single body of policy for all the grant programs in the Public Health Service, the Public Health Service Grants Policy Statement. There were some differences, but basically all the programs operated under the same rules, which was a first, because they had been running by various rules and different application forms, as I mentioned. So the Policy Statement was a huge, huge change in operations.

My Public Health career spanned five decades, and I think there were eight Presidents, fourteen Secretaries, and I think it was twelve Assistant Secretaries. I the good fortune to work very closely with a lot of those Assistant Secretaries, and some of the Secretaries. So it was a fun ride in the Public Health Service to the early 1990's, and then I came back to NIH, which is a story in and of itself.

JR: Well, tell me that story.

TR: Let's see. In the spring of 1993, the Director of NIH at the time—I think it was Bernadette Healy—called the Assistant Secretary for Health and said they were having a tremendously difficult problem with their technology transfer operations at the NIH. The NIH had been through two General Accounting Office reviews, two Inspector General reviews, and one internal NIH review, that all had negative findings. The total number of "corrective actions" as they were called was 106. Thirteen of those were considered material, and were going to be reported to the President's Management Council. To give you some idea, most federal agencies had one or two material weaknesses. This program had thirteen.

The request came over for some help, because they did not feel there was anybody within the NIH at the time who could make people move to create the changes that were needed. I had done a government-wide review a couple of years earlier about Cooperative Research and Development Agreements, CRADA's. As part of that, I went to the NIH and did part of the study, and they knew that I had gone there, so they were asking that I come over for a short period of time. Initially it was going to be three months to get this thing started.

So in September of 1993 I went over to the NIH, to the Office of the Director. I was reporting to Jay Moskowitz, who was the Deputy Director for Planning and Evaluation. Parts of his responsibilities were the Office of Technology Transfer. There was a Director at the Office of Technology Transfer. So I went over, and was told what I would be responsible for getting the corrective actions resolved, and that I would work alongside the Director of the Office Technology Transfer, but out of Jay Moskowitz's office.

The interesting thing was, when I arrived, Jay Moskowitz had me and the Director of the Office of Technology Transfer in the office together, and he informed us that any management decisions that were going to be made by the Director of the Office of Technology Transfer had to be reviewed and approved by me. This shocked us both, because I was not aware that was the role I'd be playing at all. Basically, he wanted me to oversee that operation. I was not comfortable with that, and obviously the Director of OTT was not pleased with that either, and was moved to another position shortly thereafter and resigned from government service within a few months. Don Christoferson, who was at the National Cancer Institute, came in to be the acting head of the Office of Technology Transfer. I was still going to be responsible for the corrective action items.

Then Jay Moskowitz left, and Sandy Chamblee took his place. I worked for her doing corrective actions and a number of other projects for her and Phil Chen. Phil Chen and I worked on the GATT Treaty and some issues mainly in the area of federal subsidies. There was a proposal that federal grants be considered subsidies, and therefore any products that eventually came to the market that had at some point received federal grant money would be taxed differently for importation purposes. We were able to have that stricken, or at least delayed. Actually it was put off for a period of time, and still comes up I think every five years for review, whether it should be a green-light or a red-light trade issue.

JR: What would the adverse impact of that have been, had it not been stricken?

TR: Well, think about all the thousands of federal grants that go to support general research. If you used any of that general research to create a product that you wanted to sell, you would be at a disadvantage trade-wise, because they would charge you an extra tax since you had been subsidized with federal support. They would have been taxed on anything that had, at any point in time, been touched by government money. So we were able to stave that off.

I also worked on an issue called “Scripps Sandoz.” Sandoz, the pharmaceutical company, had provided a great deal of support to the Scripps Institute in California. I believe that part of it was for a certain amount of money, I think it was twenty-five million dollars a year, and Sandoz basically got seats on the board at Scripps. They had the right to review all publications before they went out, and could also stop publications. They also had the right to review all technologies that came out, and to take preference in licensing any of those technologies that they wanted. Well, we found out about it and felt that this was totally inappropriate, because federal money was going into that institution, and there are certain rules that went with the federal money that were being violated by the Sandoz agreement.

So there was a major to-do about federal grantees, especially NIH grantees, receiving money from other parties, and how the requirements of other money used to sponsor projects could not conflict with NIH requirements. This brought in some of my grant background in dealing with that, and I developed a document called “The Points to Consider,” the points to consider when receiving sponsored program funds from for-profit entities when receiving NIH funds. We actually put it out in the Federal Register and then published it.

That was in 1994, and my understanding is people still ask for it today because it was good guidance for when other people were coming in to provide support, and to make sure the requirements that they were placing on the institution did not conflict with those the government had placed on them.

JR: What were some of the points? Where did the conflict arise in terms of patents, licensing, and intellectual property rights with federal versus private money?

TR: You can start even earlier than that. Under that agreement with Scripps, Sandoz could tell the researchers what lines of research they should be following, and which ones they shouldn't. So the academic freedom aspect was big. So you have academic freedom to publish. Then you come to the issues of intellectual property. There was a law passed, the Bayh-Dole Act, and this agreement was contrary to the intent of that Act.

Part of our corrective action items involved revising our license agreements, clarifying the language, and instituting new procedures to ensure that we were receiving royalties. We were billing people for royalties that were owed to us, and collecting them. If we couldn’t collect, then we took action under the Federal Collection Act. The government would then go after them for the funds. Some tasks were minor, internal procedures, like writing up internal procedures. Some of the internal procedures weren't even in writing. A new data system so that we'd be able to track our technologies, because with the old paper system one could not track what the technologies were and what happened to them.

There were thirty empty positions in the organization, and they had to be filled with qualified people. There was a whole initiative just to hire new people, and bring them in and train them. There was an effort to develop a well-substantiated budget for what we were doing. I can't think of all of them now, but the situation when I came over there to Technology Transfer, as many of the scientists would say, was a black hole. They would send over documentation about possible new discoveries, and you'd never hear anything back. You never knew what happened to them.

JR: Let's see if I'm understanding this correctly—research being done at NIH was not making its way into the private sector?

TR: Right. They were sending it to that office and then not doing anything with it, or not communicating what they were doing with any of the technologies. It was a very difficult thing, and the Scientific Directors at the NIH wanted to close down the office. There was a big move to decentralize the whole technology transfer operation to the various Institutes at the NIH, because they weren't getting any satisfaction from the central office. The GAO was on them, "What are you doing to correct these actions?" The Inspector General was on them. So the whole office was under a great deal of pressure, and the whole process was about to collapse.

That's where we were coming in. That was the nadir, you couldn't get any worse than all of those things that were going on at that point with the Tech Transfer program. This was 1993-1994, and we started making a number of corrections in 1994. 1995 is when Dr. Varmus selected a new director for the Office of Technology Transfer, Maria Freier, who came in February of 1995. I was still working on corrective actions; however, I was asked by Maria and her deputy, Barbara McGargy, to join the office as the Assistant Director and basically be, as Maria liked to call it in business terms, Chief Operating Officer for the organization.

At the end of February, beginning of March, 1995, I left the Office of the Director for the Office of Technology Transfer. I gave Maria the advice that she should concentrate on meeting with the Scientific Directors from the Institutes, because they were the ones that could close down the office. She also received from Dr. Varmus an agreement not to discuss anything about decentralization for at least two years, to give her a chance to get the operations back up and running.

She embarked on that, and was a whirlwind when she came in. She's an amazing woman, probably one of the most capable people I know. She is remarkable at reacting to things on her feet. And she had to do that, and did it very adeptly. We had a number of issues that came up right away when she was there, such as the reasonable pricing clause. This was a requirement that had been put into some of our agreements from about the early 1990's. It was supposedly an innocuous term that basically said to our licensees that should a product ever come to the market, it would be reasonably priced. Well, what did that mean? Nobody really knew.

In the early 1990's, there began to be a great deal of concern about this, starting around 1993, 1994. You have to remember that the Clinton Administration came in, and one of the first things they wanted to do was health care reform. And this part of health care reform was taking a look at how can we get our hands around drugs and drug prices. One of the ways to do this was to use reasonable pricing language, to specify that anything developed using technology from the NIH had to be reasonably priced. Companies were very much afraid that this was going to be price controls and intervention by the government. They stopped cooperating with the NIH and stopped licensing technologies from the NIH, mainly in reaction to that kind of language.

So we had hearings; we had various groups come in to talk about the issue, and I think the patient advocacy groups swayed the discussion. The patient advocacy groups were not in favor of this language, and believed that it would create impediments to the creation of new discoveries and treatments. They were supportive of getting as many new technologies out and into products as possible with as few strings attached. The issue of pricing would need to be addressed once a product got into the market. You have to understand that few technologies [discoveries] get to the marketplace. Some of them are going to fall out early, and others fall out along the way. Few of them may make it to the marketplace. So the argument from the patient advocacy groups swayed Dr. Varmus, and he removed the reasonable pricing clause, to the consternation of several members of Congress, including Congressman Wyden. It got some traction from others, some liberals, some conservatives, but most people understood that you're talking about an NIH technology which may be one of a dozen technologies that eventually end up in a final product. For instance, because you're providing the battery, are you then going to control the total price of the car? The drug companies weren't going to let the NIH or anybody else do that either, when a government-funded technology was only a piece of what was going to be the final product.

However, it became very clear, that Members of Congress and even some members of the public didn't understand that there is a difference between having a technology and having a product. When someone says, "Oh, this product was developed with an NIH technology," the immediate thought is that this is something made with government money. And that's not the case, just like with the battery in the car. They can't understand, or they don't want to understand the difference. So we had all of those legislative issues and others come up in 1995 to about 1997.

From 1997 to 2001 was probably the hottest time in tech transfer. We started licensing a great deal, and revenues from royalties shot up tremendously in the mid-nineties. Last year, in 2003, the NIH brought in fifty-four million dollars in income. That may not sound like a lot, but the NIH royalty income accounts for 70 percent of the total amount of royalty income for the entire Federal Government.

When compared to the university community, you have to remember that the university community has numerous types of activities to create income, including copyright and distance education programs that they license. NIH usually ends up being fourth or fifth amongst all the institutions, including the University of California state system. So they do very well. It's a very successful program. It's wildly successful for the government and the envy of every government around the world.

One of the things that occurred is that our successes became known far and wide. I don't know the exact statistics, but in a two-year period, I think it was '98 to 2000, we had more than two hundred groups talk to us about our process and how it could be duplicated. This is not only universities and nonprofits here in this country, but *mostly* entities in other countries. Other countries take a look at the United States and want to be like the United States. I helped the Japanese government write a parallel law to Bayh-Dole.

In the nineties, the U.S. system of biotechnology and small molecules technology exploded, and still is the envy of every other country in the world. And they were coming to us saying, "How can we do it?" So we helped the Japanese write their law; we worked with the French to redo part of their laws, the Germans to do some of theirs. We also started working with the Dutch and the U.K. We started doing a lot internationally. I used to laugh that when I first started working in the government, I was rarely allowed to get outside of Rockville Maryland, and here I was in this time period, 1997 to 2001, and I'd been to almost every European country, visiting there and talking to their officials. And they came to visit us to talk about technology transfer. I discussed that before.

TR: Our participation in a global research enterprise had many positive and negative sides. One issue that came up was a project that was going on in Papua New Guinea in which researchers were taking blood samples from the population there and trying to possibly develop some antibodies. These people weren't getting certain diseases, and the researchers were trying to figure out why. The government of Papua New Guinea wanted a share of any royalties that were generated from the project, and began a campaign that said that the U.S. Government was conducting genocide on the people of Papua New Guinea. So the project was dropped. Nothing came of that, and who knows if something should have come?

The key thing is that technology transfer in the mid-nineties became international. It became extremely complex. It was maturing as a field. When you get the State Department involved in your deals, you know that you've got complexity. There were issues with China and others because they were taking technologies that belonged to American companies and exploiting them within their countries, and not paying any royalties. Well, it's kind of hard when somebody takes something, like a vaccine, and is using it to save children's lives in China, and you're going to tell them to stop doing that until they pay this company money. It's not a very good public policy.

So there were all those kinds of issues that would come up, and they still are. But technology transfer was becoming far more complex. The deals were getting far more complicated. The international aspects of it were often mind-numbing. You had to deal with foreign laws, where you didn't have to deal with that in the past. Many of the foreign countries wanted to be players in biotechnology, so they were playing different games, and you had to be aware of what was going on.

NIH was given the lead for HHS technology transfer policy by the Office of the Secretary. At the same time internally, as I mentioned, in 1996 through 1998 there was a great deal of Congressional interest in what was going on at the NIH: Who were you licensing to? How much money were you getting? Who do have Cooperative Research and Development Agreements with? Are you subsidizing private industry? All of these kinds of things were coming up. The Office of Technology Transfer was given responsibility for providing technology transfer policy guidance to the extramural community, started dealing with the grantees and contractors, talked about technology transfer problems, and worked with that entire community. Also coming to the fore in the mid-1990's was an issue about research tools. Scientists were complaining that they couldn't get access to certain research tools that were being developed with public funds, NIH funds.

So Dr. Varmus had a group take a look at that. They came out and said yes, there were some problems and asked our office to develop some guidelines on how to use and share research tools. Now the Public Health Service had a policy going back into the early '80's about sharing biomedical research resources, so this was not a new policy, but an amplification of that earlier policy.

There was a great deal of resistance from tool companies, companies that sold reagents, that said, "You're going to put us out of business." The Biotechnology Industry Organization came out against the research tool guidelines. We kept saying, "These are all myths. These are not issues. They are not going to be problems. Actually, it's going to be more helpful to the small companies. And what we want to do is ensure that recipients have access to these research tools without encumbering any kind of future product." Just because you have a Sony tape recorder, if you come out with something that's copyrightable, that doesn't mean Sony can come out and say, "Oh, we want a piece of that, because you used our equipment." It is a tool that you use. You either licensed it, or bought it outright, or whatever. But it's a tool, and therefore they should not have any rights to what comes out of its use. It's the same thing with some of these biological reagents and other resources: cell lines, mice, etcetera, that are tools in and of themselves. You use them to get to another point. There should not be reach-through into those areas.

TR: In 1999 the NIH issued its policy on the use of research tools, and it came out as a voluntary, not a regulatory, document. Some institutions liked the idea, and took it as part of their own; the University of California system made it institutional policy. Some other institutions said that they wouldn't go near it, and they said we had no authority to enforce it.

Also in 1999, Congresswoman Morella had a bill called the Technology Transfer Commercialization Act that had a number of real problems that we spotted first. We then got a number of other agencies, through the Department of Commerce, to meet and try to come up with an alternative piece of legislation. We proposed a number of changes to existing policy, and one of the things that the Senate put in, at our request, was some language in the Bayh-Dole Act. It is the only change that's ever been made to the Bayh-Dole Act. This was put in to give us a place to hang our hat on the research tool guidelines and legislation, which says that the purpose of the Bayh-Dole Act is to develop technologies and move them into products for economic benefit, but not to adversely affect future research. That was the key to what we were talking about.

So we and our attorney said, "Well, you now have something in legislation. If you want regulations, you can go after regulations." Many people were very upset that our change got into the law, and the Department of Commerce didn't even know it got into the law . But we were very pleased that it did get in there, because it gave substance to our research tools policy. The research tools policy has become extremely effective, and most institutions now use it as institutional policy. They use it as basically a floor, and say, "Here are the rules; we will not abrogate any of these rules." They're now an NIH policy in that they've been applied to all the grants and contracts that NIH issues, and are part of the terms and conditions of the award.

Companies are now changing the way that they do business with universities because they know that universities, if they're getting NIH money, have to follow this policy. So it's changing some of the ways that they're interacting with companies, and the companies are telling this to NIH. So here's something that started off as trying to do good from the bully pulpit, and has really turned into something that's been a major impact on the way that research is being administered throughout the country. And it started from this program on research tools that Dr. Varmus started up in 1995. So that policy has been, as I said, very successful.

The Technology Transfer Commercialization Act passed, and we got in language that supported the research tools policy. We also had some other changes in there which allowed us to retain more of our royalty income, to change the formula. Previously, if a laboratory received more than 5 percent of its budget in royalties, it had to give some to the Treasury. We changed it from the laboratory to the agency, so now NIH can generate up to 5 percent of its budget without giving money back to the Treasury, and use it for further research. 5 percent of the current budget would be 1.4 billion dollars in royalty income. And as I said, there was 54 million last year, so they have a long way to go before they run into any problems

JR: What were some of the problems in the original legislation that concerned you?

TR: The way the bill was originally designed, it said that the government would have no responsibility in administering its technologies once they were licensed. Basically, it proposed that the first Monday of every month the agency would put out a list of technologies that it had to license, and it would license it to the highest bidder. Once that bidder took it, that's it; there were no additional requirements.

We felt that was counter to the intent of the Bayh-Dole Act, and counter to the best interests of the American public. Let me give you an example. Suppose I had a technology that would supercede a technology that your company currently has on the market. It would knock you out of the marketplace. You're now selling a billion dollars a year worth of your technology, your product. This would take that market away from you. If I sold it to you, to the highest bidder, how much would it be worth to you? Probably it would be worth a heck of a lot of money. You'd give me 15 million dollars in royalties. You'd say, "Here, I'll give you 15 million dollars for that technology." Then what would happen to that? You would take it, sit on it, not necessarily bring it to the marketplace.

You have to understand, the intent of technology transfer is to get as many technologies out into the marketplace as quickly and as unencumbered as you possibly can, to give the public more choices of treatments, to provide treatments that maybe weren't in existence before—so, as we're moving to more "designer drugs" as we call them, that fit your particular genetic makeup, it's going to be more and more important that those technologies get out into the marketplace that are going to help you.

I use the example of Cipro. My wife can't tolerate Cipro, yet if you recall, during the anthrax scare, everybody was going to be given Cipro. What other alternative would she have, if we just said that there was only going to be this one drug? So those people that can't tolerate it—what happens to them? There has to be another alternative. Then there are those populations that need treatment for a rare disorder, or whatever. There may only be a million people in the world that may want that particular product. You still want to get it out, so you can help them.

The whole idea is to get as many products out as possible in technology transfer, and we said that the proposed Act was counter to that intent. Well, that resonated. It was probably, in all my years of government, the fastest development of an alternative piece of legislation that I've ever seen. It went from drafting to agency approvals to OMB approval to being introduced in Congress in a matter of a couple of weeks. And Ms. Morella, when she saw the bill, threw out her old bill and adopted the new one! It was only because we were able to spot those problems and marshal the other agencies to get involved that the legislation got changed.

We were also starting to get involved with the human genome project, and you may recall that there was a great deal of controversy and competition between the public and private sector, with Drs. Francis Collins and Craig Ventor going at it, almost physically at times. The OTT also became an essential part of the implementation of the President's stem cell policy. Additionally, in 2002, the Office of Technology Transfer became the first government agency that had a group totally devoted to monitoring their licenses. Usually what occurs is that you have one person that handles their license from cradle to grave, from the time any technology comes into the office to the time a license expires. But in most cases the pressure is on getting new licenses.

So once a license is signed, basically nobody pays attention to it anymore. But the whole thrust is: get it to the marketplace. Are people moving on it, or aren't they moving on it? If they aren't moving on it, why aren't they moving on it? Do we need to go in and take the technology back from them? Sometimes companies get bought out by other companies. The person we licensed it to, it may have been their number one priority, but they've now been bought out by another company. It's now 200th on their priority list, and it will be developed. So do we take the technology back and try to license it to someone else? You have to stay on top of those technologies to make sure they're moving forward. If you don't do that, you're going to lose an awful lot.

So we've done that and have staff devoted to it, two excellent guys that we were able to recruit. They are doing a wonderful job, and are also picking up on royalties that weren't being paid to us that should have been paid to us, called benchmarks. Sometimes royalties are attached to meeting a certain milestone in the development. Well, they weren't being reported to us. Our people were going back and saying, "Where are you in the process? Oh, you've met that milestone, therefore you owe me." And within the first year, they accounted for almost four million dollars in income. Their salaries were well-reimbursed for the money that they brought in!

We also had a special initiative with Ireland, and I worked with the Irish government to help them develop their biotechnology infrastructure and bring companies over to work on cooperative projects. We got a great deal of attention and kudos from the Secretary for carrying out that activity. Another project was the Greater Washington Initiative, which is an economic development initiative. I had spoken to and represented the NIH at a number of economic development groups, and whenever that type of issue came up at NIH, it usually came to OTT and to me.

The Greater Washington Initiative was an economic development initiative for Washington, Maryland, and Virginia, and they asked us to write up something about technology transfer and what the NIH had to offer. So we did that and they put it in what's called the *Washington Flyer*, which is a magazine given out at the airports in Washington. It has a lot of information about Washington, where to eat, things like that, and they also showcase some of the companies. We were showcased in that for a month, which was tremendous advertising for NIH and its technologies.

JR: What's the connection between NIH and the local economic initiative?

TR: Okay, good point.

JR: Why do the two necessarily have a relationship? I'm just curious.

TR: It's an excellent point. Again, we're talking about licensing technologies to companies, many of them small companies. Where are the small companies? Where are they located? Many of them are located around large areas where there's a critical mass of universities or other research-intensive activities. NIH is a huge one. You've got Navy Medical, Walter Reed, and other federal research places here in the Washington area. So it is a major draw for companies. The local governments like to bring people to visit the NIH and say, "See, if you bring your business to out state/city, you can have access to the NIH. You can talk to their scientists, you can do this, you can do that, and it will help you in developing your activity." Also, it's a great recruitment tool, because NIH has a number of post-docs that are constantly moving through the organization, so they're well-trained, experienced researchers who are now looking for jobs. It's a great job market for companies. The companies can see that they have a pool of well-trained people coming out of the NIH that are looking for jobs. That's going to help them find good people.

In some cases, researchers have left the NIH, licensed back the technology that they developed as a government employee, and are now running a business with it. So economic development is important; a lot of jobs are associated with the licensing of technologies, development of products, and sale of products—a large number of jobs associated with this spin-off of research. That's why it's an economic development issue. That's why all the states want it—they see jobs. That's why all the foreign governments want it—they see jobs, they see income, they see prosperity. The U.S. has been wonderful at it, and foreign countries want to emulate what we've got here.

You remember I mentioned that Congressman, now Senator, Wyden, asked us to put together a report to Congress on how the NIH was protecting the taxpayers' interests in any technologies developed with federal funds. That study was issued in July 2001. I was the one that put that report together for the Office of Technology Transfer, but with input from a lot of other people! All of the various interest groups were gathered at a meeting, and Senator Widen went around the room— there must have been twenty-five groups, from universities, companies, whatever—and said, "What do you think of the NIH report? Fair or unfair?" Everybody thought it was a good report except him. It did not come out how he wanted it.

JR: What was his complaint?

TR: He thought NIH should get more money for its technologies. But again, you're talking about early stages of activities. We could go on—I could give you a whole lecture on technology development. NIH usually will have something, a mechanism of action, maybe a compound, a theory, or a concept, which you can patent. Then somebody has to take that and say, "Well, let's do a proof of concept, and then try it out and see if we can develop something to put it in a clinical trial," and so on, through the entire process. It takes 12-15 years to bring an idea or new therapeutic innovation to the public.

There are numerous steps in the process. Let's deal with the formulation. How are we going to deliver this medication to the right place in the body? Are you going to put it in a pill, are you going to put it in a liquid? You know, how are you going to deal with this? Will it be reimbursed by Medicare if I put it in this form or that form? So all of those kinds of things come into play. That is not what the NIH does. The NIH does the basic research, comes up with the ideas, and then hands them off to, in most cases, biotechnology companies and pharmaceutical companies.

JR: So he had unrealistic expectations of the amount of money that you could collect at that early stage?

TR: At that early stage, yes. If you could know it was going to be a drug that would some day sell a billion dollars, how much should you get? Well, the process from the time that we license, until something hits the streets as a product and incorporates our technology, can run anywhere from 12-15 years. So if you knew 12-15 years ago what the value of something would be today, you could have probably negotiated something, but we don't have that knowledge. But in most cases technologies don't go anywhere. They fail. So one has to be very realistic in how they approach the issue, and there isn't a lot of money in these things up front. The closer you get to coming out with a product, the more you can get. It's the same thing with the drugs; most of them do not make it. So the people who've invested in this process are taking a big risk, and one must understand that. It would be nice to be able to say, "Oh yeah, now it's on the market and selling, so we should have gotten more." I don't know if we should have gotten more. We were only one piece.

JR: And as you said, it's not NIH's job to take it that far.

TR: Right. NIH is not in the development business. Applied research and development is totally different from basic research. You have to have totally different skills, and basic researchers like at NIH don't have those kinds of skills. They may be able to learn them, but there are already organizations out there that can do it, and the best thing to do is to go with your strength, and pass it onto people who have the skills to develop it for the marketplace.

So I guess those were some of the highlights of my career. I have to say it was great to have technology transfer support from Dr. Varmus, and now Dr. Zerhouni, and of course from Ruth Kirschstein, who is extremely supportive of technology transfer activities at the NIH. They were just absolutely fantastic to deal with. So that's the story, nearly 40 years of activity, starting off very innocuously, going through a lot of twists and turns.

But I have to say that when I got to the Office of Technology Transfer, a lot of my skills and experience sort of came together. I was dealing with companies, the extramural community, and NIH internally, looking at effectiveness and trying to improve efficiency. All of those things really gelled together in one place at one time, and that's what made it so much fun during that eleven-year span.

JR: Making things more efficient seems to be the major theme of your career.

TR: It probably is. I started off learning by doing, and then taking those experiences and applying them as I kept moving onto new programs. Taking things that I picked up here, and using them in a new place, picking up things from there, and moving on, and accumulating all those experiences and tools. So it's been a great learning process, and fortunately I think I've been able to do what's important to me, and that's helping other people. Looking back on it, I hope I did that, and people tell me that I did. So that's always nice to hear.

JR: So you retired on May 1st of this year, right?

TR: Right.

JR: If this is a personal question, you don't have to answer it, but was there anything that prompted you to decide that this was the time?

TR: Well, I think there may be. You know, I was looking at where I had been and all the things that I've done. Here was technology transfer, and we went from the nadir to the zenith, because NIH is now looked at as the gold standard for technology transfer operations. So you went from some place with 106 corrective action items to a place that's considered the gold standard. I thought it's far better to go out at the top while things are going great, so you can look back on it and say, "Gee, wasn't it wonderful?" And I have to say I've been fortunate to deal with a lot of very bright, capable people. That's made my job far easier and more fun. There was always something that would keep me going.

JR: What are you doing now?

TR: I am now working at the Pharmaceutical Research and Manufacturers of America, a trade organization for the largest pharmaceutical firms in the United States. I'm what's called a Senior Advisor here, and I advise various groups within the organization on a variety of issues, like intellectual property, legislative issues, international relations, policy, science and regulatory issues—a wide variety of items. I'm primarily working on developing relationships with educational institutions and nonprofit, working on what I call very upstream activities.

I think the most interesting thing is that many of the positions that NIH took on various issues are the same as here at PhRMA. So while one may think that they're antithetical to one another, they're really not. They both want a robust research enterprise. They want to move as many technologies from the bench to the bedside as possible, with as few encumbrances and hindrances as possible. They're both coming from the same perspective. The companies want to make money and improve the public health, and NIH wants to improve the public health.

So they're moving in the same direction; they have the same objective. Their goals are a little bit different, but they're still trying to improve public health. So for me it's a very natural place to come. I'm sure that some people thought I was moving to the dark side in coming to the pharmaceutical companies, but it's not like that. There may be some places that are that way, but this is not one of them.

. So there were a lot of firsts, a lot of firsts, and that's what made it so exciting. Chaotic, but exciting.

JR: Okay, well thank you very much.

TR: Well thank you Jennifer. I appreciate your coming down and doing this, and I hope it turns out well.

JR: Me, too!

End of Interview

[Note: After this interview, the French Government named Dr. Roumel as a Chevalier of the French National Order of Merit. This prestigious award was bestowed on Dr. Roumel by order of Jacques Chirac, President of France, and presented on September 15, 2004, by Jean Francois Boittin, French Minister Counselor for Economic Development and Commerce. The award recognized Dr. Roumel for his work while at NIH with the French Government, private industry, and academic institutions to improve France's health-related research, development, and technology transfer.]