Dr. Mark Rohrbaugh Oral History
March 16, 2023

Valera: Hello, my name is Devon Valera, and I am the Collections Manager and Curator for the Office of NIH History and Stetten Museum. Today is March 16, 2023, and I have the pleasure of speaking to Dr. Mark Rohrbaugh. Dr. Rohrbaugh is the NIH Special Advisor for Technology Transfer. Did it get your title right?

Rohrbaugh: Yes.

Valera: Well, thank you for sitting down and talking with me today.

Rohrbaugh: My pleasure.

Valera: Our conversation is going to start at the very beginning. Where were you born and raised?

Rohrbaugh: I was born at Johns Hopkins Hospital in Baltimore.

Valera: Did you grow up in Baltimore as well?

Rohrbaugh: Yes. In the city. People always ask, “In the city?” Yes, in an east Baltimore neighborhood called Orangeville.

Valera: Did you live there from birth through high school?

Rohrbaugh: Same house, same place, the whole time yes.

Valera: What was it like growing up in the city?

Rohrbaugh: I enjoyed it. Baltimore's known for its marble steps and row homes. But we lived in a neighborhood with large yards., We had flower and vegetable gardens. I enjoyed that. When kids who lived in a row home neighborhood came over for Cub Scouts, they thought they were in the “country” when they came to our house. The 1960s were a difficult time, of course, with assassinations and upheaval in society, but we made it through that.

Valera: And it sounds like you got the best of both, city living with greenery. Turning to science, was your family interested in science? Were your parents in the field?

Rohrbaugh: My parents were both born around World War I and lived on farms in Pennsylvania. They were not able to attend high school and had to begin work on farms and in factories shortly after finishing eighth grade. My father eventually brought the family to Baltimore when he obtained a job working for the Pennsylvania Railroad as a fireman, the person who stoked the boiler with coal and assisted the engineer. They settled there right after World War II broke out. My father was very—even with his limited education—good at math and shared my interest in science. We would watch the Apollo program on TV together. My parents and I enjoyed gardening, and I explored the science of plant breeding and played with chemicals that should not have been mixed at home.

Valera: That's interesting. Do you think your parents' perspective, not having a higher education, influenced their approach to your education or your perspective on it?

Rohrbaugh: Very much. They felt that the best thing they could do for me was to give me the opportunity for a college education. Although they were quite middle class, they had saved enough money through savings bonds to pay my way through college in the 1970s. My father wanted his children to have the opportunity to work with their brains, if that's what they wanted to do.

Valera: That's a great perspective. It sounds like you had siblings as well.

Rohrbaugh: I have an older brother and my older sister died at age 35 from complications of Marfan Syndrome.

Valera: What were your early school memories? Were you a good student?

Rohrbaugh: Yes, I was always a good student. My family encouraged academics. In my neighborhood among the boys, however, I did not feel support to excel in school. I didn't talk about my good grades much with my peers for that reason.

Valera: That's interesting. Were there any subjects that attracted you when you were young? Or were you just interested in school in general?

Rohrbaugh: Interested in general. Of course, I liked science and math.

Valera: We're going to cover from elementary to high school here, are there any memories, teachers, mentors, or experiences that are still memorable and still with you?

Rohrbaugh: It was more about the care and support that teachers provided. This was post-Sputnik when support for science had increased. I benefited from those opportunities to delve more into science than previous generations might have had.

Valera: Between Apollo and Sputnik, space was really a new frontier.

Rohrbaugh: And Star Trek premiered in the middle of the 1960s, we watched that from day one.

Valera: Did you want to go to space? Was that a part of it?

Rohrbaugh: No, it was the science part of it.

Valera: Upon the end of high school, did you know you were going to go to college? Was that the plan?

Rohrbaugh: Absolutely. I never had a doubt that I would.

Valera: What college did you end up going to?

Rohrbaugh: I went to Virginia Tech, partly because they had a biochemistry major and a work study program, but I did neither. I was accepted at Johns Hopkins with a partial scholarship, but my father

would have required I live at home since it was close by. I declined because I wanted to get out of the house.

Valera: Oh really? I was going to ask, upon entering did you have a goal in mind or a plan of what you wanted to do? It sounds like biochemistry was the interest.

Rohrbaugh: I was a chemistry major. In high school, the science chair told me, “Oh, you don't want to go into biology, there's not much opportunity for jobs. Study chemistry, there is much more opportunity in industry.” Well, this was just before the biotech revolution. I was very interested in the “new” science of DNA and bought books to study on my own. I liked chemistry, but I knew ultimately, I wanted to focus on biotechnology.

Valera: That was still in high school? From a very early age it sounds like you had quite a drive.

Rohrbaugh: It was late high school and early college when recombinant DNA was in the news.

Valera: Were you able to work with teachers and labs at Virginia Tech in those disciplines?

Rohrbaugh: I did a study project with a professor, James Wolfe, who was a medicinal chemist. He was a great mentor and allowed me to work on a special project with his lab.

Valera: That sounds great. Do you mind talking more about the project or what it entailed?

Rohrbaugh: He was developing anti-seizure drugs. I just worked on a small part of it, synthesizing a labeled (deuterated) compound so that it could be used by others to investigate the chemical synthesis.

Valera: It sounds like it was a very interesting time in science, to be working on DNA and chemistry. Are there any other parts of college that were influential to your current career?

Rohrbaugh: I went to a public high school, Baltimore Polytechnic Institute, which was an all-boys school founded in the late 19th century as a magnet school for engineering and science. We had the first two girls in my graduating class of 500 in 1976. Because the program was so accelerated, I was able to get credit at Virginia Tech for my freshman year. So, I started in my sophomore year and finished in three years. Emotionally it was difficult because I was struggling with being gay in a conservative environment. I worked on the University’s first Gay Blue Jeans day in 1978 to bring awareness that lesbian and gay people were part of the university community but mostly unseen (transgender folks were not understood and often left out at that time).

Valera: That transition can be tough from high school to college, was that a sort of surprise? It sounds like you were well prepared at least.

Rohrbaugh: Yeah, I was well prepared for the academics. I was accepted into an honorary chemistry society. Had I been through a regular freshman year, it would have been relatively easy for me, and I would have gotten probably straight A's. As opposed to jumping into a second year, where it was a little more of an adjustment.

Valera: What were you hoping to do career wise? Or what were you dreaming of at that point?

Rohrbaugh: I had a sense of working in industry. I wasn't sure. Being a professor was an option. But I think I had my eye more on industry for some reason.

Valera: That's interesting, especially knowing where you are now. We did speak about mentors during your time at college. Did you work with anyone else closely or any other lab experiences?

Rohrbaugh: Other than classes, as I chemistry major, I had to take a lot of labs. At the time, my first year of labs, there was always a bottle of big bottle of benzene that we could use as a solvent to clean stubborn lipid and organic materials on our hands or the bench. So, we all had good doses of benzene but then the second year, I guess the federal government had determined that benzene was carcinogenic, and it was removed from the lab.

Valera: I was going to say I've never heard of it, and probably because of that reason.

Rohrbaugh: It's a carcinogen, yeah.

Valera: When did you decide to go get a PhD? Because that was your experience, you went from undergrad to a PhD program, right?

Rohrbaugh: Yes. As I began to understand what graduate school was about, I quickly decided that was what I wanted to do. I liked education and to do the most I could in science, I would need a PhD.

Valera: You ended up at Penn State [Pennsylvania State University], right? What made you decide on the program? Was there a particular mentor or lab?

Rohrbaugh: They had a strong biochemistry program, which not all schools had, and they were also beginning a new molecular biology program, when "molecular biology" referred primarily to DNA and RNA studies. They were hiring two professors with that expertise, and I arrived months before those professors. The first year I was taking mostly classes anyway. I did have one lab experience with cell biology, studying proteins in cultures of new-born mouse heart cells—it was amazing that as they increased in density, they would all beat in synchrony. Then, in the middle of my first year of graduate school, one of the new professors, a scientist who had just finished his postdoc in Tom Maniatis' lab at Caltech [California Institute of Technology] arrived as a professor. I was his first graduate student working on gene expression during mammalian development.

Valera: It sounds like you were really at the cutting edge, predating your professors even.

Rohrbaugh: I loved it.

Valera: What did you do during your PhD? It sounds like biochemistry…

Rohrbaugh: The program was merging biochemistry, cellular biology, and biophysics into one program. I was officially in the biochemistry program. I had to take all the requirements for biochemistry, but my research was about gene expression during development. My advisor, Ross Hardison, had worked in Tom Maniatis' lab creating the first mammalian whole genome library in lambda bacteria phage. He had started studying the beta globin locus, which is half of hemoglobin, two pairs of beta and alpha globin, and I jumped into studying how those four or five genes are regulated.

We were using rabbits as a model, looking at expression of beta-globin through embryonic, fetal, newborn and adult stages. The globin genes switch in mammals, including humans, during those periods of development. We were first exploring how [the genes] were regulated, at the protein level, mRNA, or gene expression level. I also sequencing the major beta adult gene. At the time everything was done with radioactively labeled nucleotides, and a good day, after several days of preparation, was getting a 150 base pair read. At that time a thesis could include the sequence of something like a two kilobase gene, whereas now you can do that in a few seconds.

Valera: What years were you doing your PhD program?

Rohrbaugh: I started in 1979 and I graduated in 1984.

Valera: I'm guessing your thesis covered this topic as well.

Rohrbaugh: It's several publications and the thesis. We had an interesting observation that I made. At the time people had assumed that mRNA transcription started at the beginning of the RNA (the "cap site") and then stopped at the polyadenylation site. Other labs had begun to make this finding in other systems, and I was also able to show it occurred in the rabbit globin system—that RNA polymerase extended beyond the polyadenylation tail and trailed off for hundreds of bases before it is then cut and polyadenylated, as opposed to the idea that transcription (the making of an RNA from DNA) stopped at the polyadenylation tail.

Valera: That's fascinating. That's the basic science of it, it's key.

Rohrbaugh: It was controversial at the time when we were started and by the time I was publishing it, other people had made similar observations. An interesting aspect was that a well-known scientist had published a paper claiming that transcription ended at the polyadenylation site in the mouse beta-globin system. Because of his prestige, we assumed our research result was erroneous and went on for months looking for artifacts that would explain our result. We found no artifacts, and before we could publish, that scientist published a paper explaining that his previous result was wrong and in fact his lab did observe the same result we had in the rabbit model.

Valera: Is there anything else before jumping into your postgraduate career? Reflections on your education or your time at Penn State?

Rohrbaugh: No, it was pretty much research and classes for the first year and a half, and then research, which I really enjoyed.

Valera: Did you want to continue research upon graduation? What was your plan?

Rohrbaugh: Yeah, I was going to do a postdoc. Science Magazine had ads for postdoc programs, fellowships, and I wanted to apply for a fellowship. There was a McKnight Foundation fellowship at University of Minnesota, Department of Botany, which I applied for and received. I was interested in plants and using those techniques that had blossomed studying mammalian genes and applying them to plant biotechnology.

Valera: Do you mind telling me who was the professor? And what did you guys find or discover during your postdoc?

Rohrbaugh: We had three postdocs and a grad student in the lab, the professor has since passed away. He didn't stay in academia, which I'll get to in a moment. The three of them were on the project at the time that I had just jumped into. When corn breeders want to make a cross of corn varieties, they could use a variety that was sterile, the pollen was sterile, as the recipient from the other variety with active pollen to pollinate the ears on the one that had sterile pollen. They had identified a large insert into the plant's mitochondrial DNA that caused sterility in the pollen. We were sequencing that insert, it was quite large and with the technologies at the time it took many month to sequence, really three postdocs working on that.

But, after a year, the adviser said, “My wife is at Yale, working at the library, and I haven't been able to find anything for her here. So, I'm moving back to Yale. You'll have money, don't worry.” Two days later, after he left, we met with the University budget people and they said, “There's nothing left in this fund for your lab supplies.” You're going to have to find something else pretty quickly.” We were all so mad. A colleague had been talking to someone who was starting up a molecular biology program at a local biotech[nology] company, Endotronics in Coon Rapids, MN. I talked to him, and he was very interested in having me join, so I did that.

I was the first employee in the molecular biology program, the 50th employee in this startup company. At the time [it] had already gone public, which was a lot easier to do than it is [now], even though it was less than five years old. It was a company making hollow fiber cartridges for growing cells. You would grow the cells outside the capillaries of the cartridge, such cells that are excreting cell products, antibodies, things like that. You would collect the antibodies or other products in the extra-capillary space while the fibers delivered the media with nutrients, separated from the cells.

In the molecular biology program, we were working on a recombinant hepatitis B vaccine produced by cultured cell lines that could be grown in the cartridges. I enjoyed working at the company. I thought that if you have good science and engineering’ you're going to succeed, which we did, but I never thought that the CEO and COO, which were father and son, would file an inaccurate SEC quarterly statement saying they had sold a million dollars of product to a Japanese firm. Turns out, they didn't sell it, they just had a promissory note, the promissory note fell through. They were left with egg on their faces and charged with illegal activities. The company went through major, major problems and at that point—I think we had 150 people—laid off a lot of the staff. I was laid off at the time. The CEO and the COO ended up going to the same federal prison in Minnesota where Tammy Faye and Jim Bakker were held.

Four of us in the company who were working in the same group got together with a serial entrepreneur who had founded companies like St. Jude Medical (now part of Abbott) and Cardiac Pacemakers Inc. (now part of Boston Scientific). We started a new company called Helix BioCore that would be focused on growing cells, like GMP (Good Manufacturing Practices) production of cells on a contract basis, but there wasn’t a lot of demand at the time for contract manufacturing of mammalian cells. Now there's a lot of demand for contract manufacturing of mammalian cell cultures. Primarily for secreted products, like antibodies or hormones, growth products, things like that. Out of the shell of a warehouse we built the laboratories and the GMP facility was ready to go, all the SOPs [standard operating procedures] for the manufacturing facility. We had some good trial runs, production of 1 kg of an antibody in 1 month, but we were having trouble getting contracts. The CEO was getting very impatient with the unpredictability of biology because as a non-scientist he had started companies in the engineering field, which were, of course, much more predictable. He didn't like the unpredictability of biology. Why did

something fail? Well, we don't know. We did it exactly the same way, but it didn't always work. It was too slow; we weren't getting big contracts. We had offers of $200,000 contracts and he said, “No we want the million-dollar contracts.” He decided after three or four years that he was going to just jettison all the biology and license in a technology for heart valves. All of us in the biology and engineering with the previous startup ended up unemployed. So, that was my experience in industry.

Valera: Wow, what a series of events but also what a new and interesting field.

Rohrbaugh: Fundraising, stock, stock options, all those things. I learned a lot. Being in a startup company with five people, you have to do everything. You’re not just a scientist at the bench. I was designing the facilities with others, the cell laboratory and the GMP, ordering equipment, talking to regulatory people about regulatory requirements for GMP, things that I would never have done in a larger company working at a lab bench. So, it was a great learning experience despite the disappointment.

Valera: Certainly, and you were thrown right into it, too. After this experience, is that when you came to NIH for the first time?

Rohrbaugh: Yes. I decided to look for jobs in Minnesota. I wasn't finding anything other than analysis or process control, things like that, which I didn't want to do. My mother was getting older in Baltimore and wanted me to be closer, so I started looking on the East Coast, this region, and had interviews at several companies in the [Interstate] 270-corridor, including Medimmune, which was a small company back then.

I had a friend that I did a postdoc with at the University of Minnesota (between start-up jobs) who had been a professor at [University of] Pittsburgh and had joined NIH. I was just checking in with her and she said, “Oh, why don't you stop by and talk?” So I did. She was a review administrator in the Center for Human Genome Research, at the time. And she said, “Why don't you think about a job here?” And I said, “What would I do here? I don't have a publication record to get in a laboratory because I worked for a company, and we weren’t publishing research.” Well, she said that she was working in grant review at the institute level, and would I be interested? I said, “Sure, I'd consider it.” She said, “I'll talk to my boss.” Her boss talked to somebody in the [National Institute of] Allergy and Infectious Disease (NIAID), in the grant review area, and within a month I had a job. Within another month, they had moved me, lock, stock, and barrel, to Bethesda and Gaithersburg, where I lived at the time. At that time, NIH paid for all the moving expenses. I had a house that I sold, it wasn't a tiny apartment. They packed everything, they moved everything, including a grand piano, they stored it for several months in this area until I could buy a home. That doesn’t happen anymore unless you're extremely senior. And I was like a GS-13.

Valera: So, you started in grants?

Rohrbaugh: Grant review. Most people are familiar with the NIH grant review process in the Center for Scientific Review (CSR) for R01s and most other grants. There is a parallel system in Institutes for the peer review of grants submitted in responsive to RFIs [requests for information], K awards [Career Development], T awards [training awards], program projects, and other special funding initiatives. I was the Executive Secretary of a standing committee, the Allergy, Immunology, and Transplantation Research Committee, that met three times a year.

Valera: What year was this that you first came to NIH?

Rohrbaugh: 1991.

Valera: How long were you in grant review before moving to tech transfer?

Rohrbaugh: About four years. I had decided, after a couple of years in grant review that I wanted new challenges in a different part of NIH. I missed some aspects of the business world, and I was thinking about what I might do. And lo and behold, I decided to go to law school. Nothing I ever expected, it was a difficult decision. I think I went to a lecture about patents, and I had had the experience of being an inventor, working with the patent attorney, on a patent for a recombinant hepatitis B vaccine at that first company I worked for.

I was accepted by the law school at George Washington University. I chose the evening program, a four-year plan, so that I could continue my day job at NIAID. (The day program is three years.) I had no time for anything other than those two things, NIH and law school. John "JJ" McGowen, Director, Division of Extramural Activities, at the time, was an important mentor to me in my career at NIAID. Two years into law school, I heard that there was an opening in technology transfer in [National Institute of] Allergy and Infectious Disease. I was encouraged to apply by Diane Wax and hired by Steven Berkowitz into the position of Technology Transfer Specialist in the Technology Transfer Branch in in 1995. I served as the Acting Director and then Director, Office of Technology Development until 2001.

Valera: That's fascinating. Excuse my ignorance, in law school do you also specialize in topics?

Rohrbaugh: Everyone has the same core curriculum and has to pass the same bar exam. I didn't have a lot of electives, but when I did, I chose intellectual property, patents, copyright, and health care law.

Valera: That's great. Do you mind, just for the purpose of this interview, describing what technology transfer is and the Technology Transfer Act?

Rohrbaugh: Well, tech transfer in the broad scope is the transfer of technology usually from a university or government laboratory to the private sector for further research and, when applicable, development into a commercial product or service.

When we think of a formal office of tech transfer, they help scientists understand when to report their scientific findings as possible inventions. The technology transfer office receives the invention report, reviews it, and decides whether it is patentable, and if a patent would facilitate private sector investment to bring it to market. At NIH we work with outside patent attorneys under contract to file the patent application with the U.S. Patent and Trademark Office and other foreign patent offices.

Tech transfer offices also develop scientific collaboration agreements with industry, one type of which is a Cooperative Research and Development Agreement (CRADA), clinical trial agreements with industry, and material transfer agreements to document the conditions and terms for sending biological materials such as cell lines, from one lab to another, for example, from NIH to a university or vice versa. An institution's patents are licensed to companies for internal commercial research use, or commercial development of the technology. The patenting and licensing aspect was centralized at the NIH Office of Technology Transfer under the Office of Intramural Research from the early 1990s through 2014, when it managed inventions from NIH, FDA and CDC intramural scientists. NIH went through a

decentralization process in 2015 in which the patenting and licensing was moved to the level of the Institute and Center (IC) technology transfer offices.

Although a few universities established formal technology transfer offices before 1980, every NIH funding recipient was required to engage in patenting and licensing of inventions made with U.S. Government funding after passage of the Bayh-Dole Act of 1980, which gave universities the right to own these inventions, to seek patents, license them for commercial development, and to retain royalties in return from companies which they could reinvest in research and pay technology transfer expenses. A similar law, the Stevenson-Wydler [Technology Innovation Act of 1980], at the same time gave those rights to federal laboratories, but the laboratories sent any royalty money to the Treasury. There wasn't much incentive to spend a lot of money engaging in all this work and expense only to have money from licensing to companies go to the Treasury. That changed in 1986 with the Federal Technology Transfer Act, which gave federal laboratories additional authorities including the right to keep the royalties from their own patent licensing and use it to invest in further research and pay associated tech transfer expenses. It also allowed federal labs to engage in formal collaboration agreements with industry under the CRADA mechanism, with a key authority to offer the option of an exclusive license to new inventions that might be made by the federal scientists under the project. Universities do not need a special mechanism to do this; whereas federal laboratories needed a special authority. When we want to collaborate with a company or receive their proprietary materials for research, they would typically say, “Fine, but if you make an invention, I want to be sure there’s a guarantee I can license it.” And we can do that under this CRADA mechanism, which has worked incredibly well over the years.

Valera: So, when you first joined NIAID technology transfer, you were working directly with scientists?

Rohrbaugh: Yes, intramural.

Valera: It sounds like this might have been an interesting time for technology, did any of the AIDS testing come through your office?

Rohrbaugh: At the time, and up until 2015, the patenting and licensing was all done at the NIH central Office of Technology Transfer [OTT] under the Office of Intramural Research. The institutes had offices that handled the other types of agreements: they received the invention reports and made recommendations as to whether OTT should file them as patent applications. The other types of agreements related directly to research were all handled at the institute level.

The HIV virus and AIDS testing technology was invented at the National Cancer Institute by Dr. Robert Gallo’s lab because of its association with Kaposi’s sarcoma, dark circles on the skin, that physicians first observed in young gay men in the US who were infected with HIV.

I was aware of all the issues with the HIV test kit and the controversy of whether NIH or Institute Pasteur discovered the virus. But what was coming out of [National Institute of] Allergy and Infectious Diseases were important vaccines. Rotavirus is a disease that affects every child eventually and sometimes causes severe diarrhea and dehydration. If you have access to a hospital, you can get the needed care. But in many poor areas around the world, children with severe infections die if they don't have access to a hospital. It was one of the leading causes of death in children in poor areas, as well as all the illness and hospitalization that even children in Western countries would experience. We were working with Wyeth [later purchased by Pfizer] at the time to market the first rotavirus vaccine. It was withdrawn after

several years for gastro-intestinal complications, but it really did set the precedent for other companies to develop what are now successful rotavirus vaccines.

Valera: From NIAID you then went to the centralized Office of Technology Transfer?

Rohrbaugh: Dr. Maria Freire was the director [of the Office of Technology Transfer] at the time. She went on some years later to be the Director of the NIH Foundation. But at the time she had been director for five, six years of that central office. Barbara McGarey who had been the Deputy Director joined the Office of the General Counsel at NIH. I competed for her former position and became the deputy. This was in spring of 2001. Well, we all know what happened in September 2001. Weeks before that, Maria left the NIH to become CEO of the Global Alliance for TB Drug Development six months after I joined OTT, and then I became the acting director. It took 18 months for NIH to compete the director's position nationally, and I was selected. Then we had to hire a new deputy. So it was very challenging at the time with the workload and taking on all these responsibilities.

Valera: Oh, my goodness. Yeah, certainly sounds it. From NIAID to OTT, how did your position change? Were you more focused on patents?

Rohrbaugh: Yes, we were. We had to manage the patenting and licensing of inventions from the NIH and FDA intramural research programs (and later CDC as well), administration of royalty collection, the contract patent law firm awards, and the central database to track this activity. We had a royalty monitoring group to review all licenses annually to ensure compliance with product development timelines and royalty payments, and a royalty group tracking royalties of $50 to more than $100 million from thousands of licenses, working with OFM [Office of Financial Management], so that the scientist inventors and the institutes could receive the proper amount of royalties that were coming in for their inventions.

Valera: Were at any key moments as director or deputy director that you're particularly proud of having worked on or with?

Rohrbaugh: Well, there were a number. It takes a long time from the time a patented technology is licensed until a company launches it as a product. [See here for the list of the many products developed over the years from these technologies.] When I became director, NIH was still dealing with a dispute with [Institute] Pasteur over the HIV sequence and diagnostics invention that had previously become a public dispute over who discovered the HIV virus, Dr. [Luc] Montagnier at Pasteur or Dr. [Robert] Gallo at the NCI, and which institution was due the patents based on patent law. In most of the world, between two or more parties claiming the same invention, the first party to file for a patent is awarded the patent; whereas, in the U.S. at the time [now more like the rest of the world] the first to show through lab notebooks that they invented the invention is awarded the patent, regardless of which filed a patent first. NIH and Pasteur patents were still pending in the U.S. Our two pending patents along with an issued patent for the HIV sequence from Chiron, which became Novartis during the negotiations, were declared by the U.S. Patent Office as claiming the same invention, declared as an "interference". Rather than proceed through an administrative court process at the Patent Office to determine which invented it first, the three institutions decided to negotiate a settlement. Steve Ferguson, who is still at OTT, and I managed this very challenging negotiation. We were engaged in negotiations for quite some time, over a lot of money, and we finally were able to resolve it in NIH's favor and sharing royalties with Pasteur. That was a great relief and a fair amount of money coming for that technology to NCI.

I wanted us to be innovative about how we manage licensing, new ways of doing business, so there were a couple new activities we brought on. NCI had tech transfer fellowships, like a PhD fellowship program but these people worked in tech transfer. I had to press for the OD [Office of the Director] to allow OTT to start a similar program. It was "no" initially, but we pressed and eventually got approval. These fellows were people who knew science and could be trained to be patent and licensing managers. It helped us to have additional staff to manage patenting and licensing and helped seed the HHS [Department of Health and Human Services] and outside institutions with well-trained technology transfer managers.

I also initiated some new licensing mechanisms like a stream-lined, favorable license for startup companies. I think the University of North Carolina had done this with their spin offs, but I was interested and worked with others at NIH, not just me for sure, to develop a model license that was really pared down. For a startup, you want them to succeed in the product development and initially not spend too much money. Rather than giving royalties back to the government under a license at this early stage, which would drain their research budget, we wanted to have a very low cost, $1,000-$2,000 license, for a few years to see if they could get off the ground. If they were progressing, then we could complete a license to long-term development with royalties and milestones. That's still being used at NIH.

We had a lot of interaction with other agencies, with OSTP, Office of Science and Technology and Policy out of the White House on programs to enhance innovation across the agencies. I have worked with inter-government efforts with State [Department] to visit foreign countries as part of a U.S. science and technology delegation I went to India several times, China several times, Jordan, Egypt—I had a fellowship to go to Egypt for a couple of weeks to discuss tech transfer, answer their questions—Morocco, and South Africa. It was a great experience, at least a short look at these different countries and learn from them as well.

Valera: It's fascinating how many different things must occur to facilitate this to work properly. And I saw as well that you handled some more controversial topics, like embryonic stem cells.

Rohrbaugh: Yes, that was also quite notable. The University of Wisconsin had a patent on creating human embryonic stem cells—creating them and also a patent on the cells themselves. President Bush issued a statement on August 9, 2001, stating the government could use [embryonic stem cells] in research and NIH could fund research involving the stem cells that already existed at the time of his announcement. The government had not been permitted to create any stem cell lines (because the process destroyed a blastocyst, a ball of cells at the early stage of development after fertilization of the egg and before an embryo takes shape) but had a scientific need to use them in research. We worked with the University of Wisconsin on issues in which they were using their patent rights in ways that burden research collaborations with companies and decreased the ability for research scientists at universities and NIH to utilize the Wisconsin embryonic cell lines and those created in other countries, as they were covered by the patent. We had to work out a new agreement with them, ultimately, that did not burden their use and facilitated wide research use of cell lines that fell within the requirement of the presidential order.

I sat on the NIH embryonic stem cell committee, chaired by Dr. Jim Batty, making recommendations to the NIH on implementation of the directive, and addressing IP (intellectual property) issues of the lines themselves and the Wisconsin patents. We meet with Israelis about their cell lines and traveled to India

to learn about their lines, which they never agreed to share with western countries. It was quite interesting.

Valera: That's very interesting. With our last 10 minutes, I'd like to turn to what you are doing in your current role. You were director of OTT for how long?

Rohrbaugh: From 2001 to 2014. Thirteen years.

Valera: When you came to your current role, what was that transition like?

Rohrbaugh: The Office of Intramural Research Advisory Committee was asked to review how tech transfer was managed administratively at NIH. They provided several recommended options for change, and NIH accepted the one in which the patenting and licensing would move to the Institutes, as opposed to being centrally managed. The ICs felt the arrangement was not meeting their needs.

Basically, our budget came from budget taps of institutes, depending on their use of our activity and our workload. [Institutes] felt like "It's our money, we can tell you what to do." But they didn't have the authority for final patenting and licensing decisions; it rested with me and the Office [of Technology Transfer]. Most of the time, a vast majority of time, we would agree, but there were times where we felt that something was against NIH policy or not the best direction in terms of public health, and the IC disagreed. It was just very difficult to resolve those kinds of things. [Additionally] a committee [Central Services], which was not involved in tech transfer, determined our annual budget [and] they cut our budget so slim, with not enough increases to cover mandatory increases in salary and benefits. It got to the point where we didn't have enough money to buy paper towards the end of the year for the copy machine. It was that bad. And yet, this committee didn't want to hear from me for some years to defend a budget—I wasn't given permission to talk to them some years, and when I was, nothing much happened.

It was ultimately doomed to fail. I shouldn't say fail—not be as successful as it could be. When that authority was moved to the Institutes, I said, "I don't want to be in a central office if we're not going to be doing this transactional work." I came to work under Dr. Gottesman as an advisor in the Office of Intramural Research. Kathy Hudson, who was the NIH Chief of Staff under early years of Dr. [Francis] Collins, wanted to move tech transfer policy, intramural and part of extramural, which had been in the OTT, into the Office of Science Policy. Shortly after that I was asked to start a new division within the Office of Science Policy called Technology Transfer and Innovation Policy. We have the lead within the Office of the Director of NIH on NIH-wide tech transfer policy. The Office of Extramural Research has responsibility for terms of grant award, implementation, and compliance with extramural policies, but broader policy comes with the approval of the Office of Science Policy.

I have enjoyed working in this position. We're dealing with the cost-cutting issues that reach Congress and the Administration, upon which NIH has been asked to provide input; press requests relating to patenting and industrial collaboration issues; briefing the Directors on issues involving patents or collaborations with industry that come to their attention; working with the Institutes when they have a policy issue to resolve; policies applied to licensing and cooperative agreements; march-in requests when outside groups have asked NIH to use authority to make a university patent license non-exclusive for generic manufacturing of a drug because they believe the price is too high; and many other things. I really enjoy it. As well as working with the leadership of Office of Science Policy, which had been Dr. Carrie Wolinetz, who went to OSTP and then Lewis-Burke Associates, and then Dr. Lyric Jorgenson, who

was recently named Director, OSP, after serving as Acting Director for several years. They, the OSP staff and the NIH technology transfer community, have been great to work with.

Valera: Has it been an interesting time to be in tech transfer with COVID-19?

Rohrbaugh: With COVID patent issues and with drug pricing, two major issues on our plate, as well as working remotely during the pandemic.

Valera: My goodness. I know from what we've been collecting, the movement of COVID tech from NIH to industry and back and forth has been an interesting thing to see.

Rohrbaugh: Well, an issue pending resolution for several years and was made public last year, I think, involved NIH in a disagreement with Moderna about the inventorship of the full mRNA nucleotide sequence used in their original mRNA vaccine. They believe they are sole inventors, and NIH insists that there are co-inventors that were in the Vaccine Research Center of the NIAID. We have resolved that issue by Moderna agreeing that they will no longer attempt to obtain a patent on the mRNA sequence and never assert it against any company using it for research or in commercial products. The public benefits from the open and free use of that technology.

Valera: It's something still relevant today. Looking at your role, you're on a part of many different councils and committees, working with the White House and HHS more broadly, what is that like?

Rohrbaugh: It has been interesting working in different administrations with different priorities and styles of seeking input from agencies. I primarily now work with the Interagency Working Group on Tech Transfer and some of their other work groups, usually on an ad hoc basis dealing with inter agency tech transfer issues, such as the role and impact of inventions made with NIH funding in the context of exportation and U.S. manufacturing. Sometimes other agencies seek advice from NIH if they are dealing with biomedical patented technology, with which they may have much less experience than NIH. An important issue in the political sphere now is the role NIH may have, or not have, in high-priced pharmaceuticals developed from licensing intramural and extramural inventions made with NIH funding.

Valera: Absolutely. All right, I'm going to do a bit of a wrap up. Is there anything else you'd like to say to your years at NIH or any stories that you think we've missed?

Rohrbaugh: Well, I've neglected to mention, in terms of mentorship, Dr. John J. “JJ” McGowan at NIAID, who is now retired but was the head of the Office of Extramural Activities at NIAID many years ago. He was strongly supportive of my going to law school and finding a place in technology transfer at NIAID. My colleagues and supervisors in NIAID grant review also supported my career development. And Drs. [Anthony] Fauci and [John] LaMontagne, who supported my NIH career, I owe them a debt of gratitude. In the technology transfer realm, I thank Dr. Maria Freire, who mentored me when I was still at NIAID to be in a competitive position for advancement as the opportunities arose.

Valera: Two final questions. What are your biggest professional accomplishments?

Rohrbaugh: We covered most of them, but I think I had a role, not alone, but working with other very talented people at NIH and other agencies and universities to improve our technology transfer activities to better serve the research and commercial sectors and ultimately benefit public health. There’s still always room to grow. In the last 30 years, we have collectively improved and trained a much larger

cadre of very talented, experienced people across the Institutes involved in tech transfer. We've grown professionally as a community, and I'm so very proud to be part of that.

Valera: Yeah, absolutely. My other question is how has technology transfer changed throughout your career? But what changes are you seeing and where do you see it going?

Rohrbaugh: Well, I remember NIAID leadership was supportive but did not appear certain in the mid-1990s of what the impact might be of formalized tech transfer. When the Hepatitis A and rotavirus vaccines hit the market based on NIAID research and technology transfer, people became more certain that tech transfer coupled with great science was an important part of the effort to get the technologies to the private sector and to the market. In addition, significant amounts of royalty money started coming to NIAID under those licenses. I think many people in the institute realized "Wow, this really can do some good, and we get some financial return that can be reinvested in the research enterprise." It helped open eyes to see the potential of tech transfer. We may take for granted now that the NIH research community is strongly supportive.

Valera: Oh, excellent. Before we leave any last thoughts or comments?

Rohrbaugh: It's been a great ride. When I retire, I'm not going to a beach in the Caribbean and forget about all this. I still want to be involved in in these issues, but from a different perspective.

Valera: Yes, absolutely, that's wonderful. Thank you so much for your time and for speaking with me today.

Rohrbaugh: Thank you very much.