Dr. Kathryn C. Zoon

Oral History

This is an oral history with Dr. Kathryn Christine Egloff Zoon on February 27 and March 6, 2023, about her career at the National Institute of Allergy and Infectious Diseases (NIAID). The interview is being done over Zoom and the interviewer is Dr. Victoria Harden, Founding Director, Emerita, Office of NIH History and Stetten Museum (ONHM), National Institutes of Health (NIH).

Dr. Kathryn Zoon, Director of NIAID Intramural program, 2006.

Harden: Dr. Zoon, would you please state your full name, that you know that this interview is being recorded and that you give permission for the recording?

Zoon: Yes. My name is Kathryn Christine Zoon, and I know that this is being recorded, and I give my permission.

Harden: Thank you. You were born in Yonkers, New York as the only child of August Robert Egloff, who worked in the fuel oil business, and Violet Teresa Pollock Egloff, a homemaker and small business assistant. Please tell me about growing up through your high school years, and I note that you graduated from Roosevelt High School in 1966 as salutatorian. I'm especially interested in knowing if there were particular family members or teachers who nudged you towards a career in science.

Zoon: I was born in Yonkers, New York in St. John's Hospital, and grew up on a dead-end street called Jessamine Avenue. My family lived in a duplex that my grandfather owned. His name was August Ernst Egloff. His wife was Kristina Cadre and she died at an early age prior to my birth. We lived in the top apartment, and my father's brother, Robert Egloff with his wife Margaret (nee Pisco) lived in the bottom apartment. My two cousins, who were the children of my uncle, lived downstairs. They were Robert (Bobby) Egloff, and Marjorie Egloff (now Spina). Marjorie and I are three months apart and have been very close—like sisters all our lives, and we still get together quite often. Unfortunately, my cousin Bobby died at an early age of leukemia.

Later on, my grandfather moved to another section of Yonkers, not far from our home. My mother's parents, Katherine (nee Oravec) and Emmerant Pollock lived in what was then called North Tarrytown, New York; now it's called Sleepy Hollow. My Aunt Kay (Katherine Krolicki nee Pollock) and Uncle Bob (Robert Pollock) lived there as well. They were both very influential in my life. My Aunt Kay was a very independent woman whom I admired (tough love), and my Uncle Bob was a chemist for General Foods in Tarrytown, New York. He bought me my very first Gilbert Chemistry set and inspired me to have a career in science and in particular, chemistry.

Even though I was an only child, which suggests that one would think, "You must have been quite spoiled," I really wasn't. Both my parents were sergeants in the Army during World War II, so they were regimented and had great expectations for me. They taught me a lot about time management and commitment. I think that was quite important, especially the fact that my mom was in the Women's Army Corps and was involved in riveting airplane wings and taking care of wounded soldiers. She did whatever needed to be done, and that became my philosophy in life. My dad was in the Army in a division under General George Patton. He fought at the battle over Ludendorff Bridge at Remagen, Germany during which he was injured and earned a Purple Heart. Both my parents were committed folks and important role models in my life.

I went to Public School no. 5 in Yonkers, New York, which was about three or four blocks from my house. My father had also gone there, which may or may not have been a good thing, because he didn't have the best reputation. I came in with a little bit of baggage and had to prove myself. It was an interesting experience, following in the footsteps of my dad, who was quite the "getting into trouble" type. He could be a great kidder.

I was very interested in science, even when I was going through grammar school. One of the things that I remember is that an eighth-grade science teacher named Mr. Schwartz told me, "You're never going to be a scientist." And I said, "Yes, I am, Mr. Schwartz, I'm going to be a scientist." I thought that was quite interesting because in some ways, his assessment that I would not be a scientist actually made me want to be a scientist even more.

When I got to high school, I did extremely well academically. In New York at that time, you went through eighth grade in elementary school. Then I had a year in what was called junior high school—ninth grade in Walt Whitman—which was a separate school from 10th, 11th, and 12th grade (Roosevelt High School). I did very well in school in ninth grade and continued to be in advanced classes all through my years at Roosevelt High School.

One of the people who had the biggest influences on me during my high school education was my chemistry teacher, Ms. Catherine Russell. She was very tough. She believed that you had to have quizzes every day and she would give you 10 questions and if you got one wrong, you would get 75%. If you got

two wrong, you would fail. So, she made you work really, really hard in order to succeed, and I'll never forget this because by the end of the year, we had the New York State Regents exams. These are standardized tests across the state of New York. I got a 98 on my chemistry exam, which someone told me was the highest grade anybody got that year. So, I guess Ms. Russell's method of teaching was successful—to scare you half to death to study as hard as you could, and it apparently worked for me.

Another major influence in my life in high school was my German teacher Dr. Kaufmann. He was quite a strict fellow, but very encouraging. He really encouraged me to go after my dreams in science. I graduated from my high school as salutatorian which made my parents very proud. At this point in time I became very interested in being an organic chemist.

Harden: In high school. Wow.

Zoon: Yes.

Harden: Go ahead.

Zoon: During my high school years, I had some summer jobs, but when you're in high school, you have to resort to jobs that you can get, and they were not in science. I tried my hand working in a grocery store, but that didn't work very well. I ended up working for an individual in our neighborhood who was blind. I would read him all his mail and help him with his business items. It was a rewarding experience, and I felt that it gave me some responsibility. I also recognized that we often have to do things to help others when they need it and be available to them. I thought that was a good first start.

Harden: Indeed. It sounds to me like the teacher who told you that you couldn't possibly be a scientist might have said that because you were a woman. If so, I suspect he may have been just the first of many.

Zoon: Yes.

Harden: Tell me about applying to college and why you chose Rensselaer Polytechnic Institute.

Zoon: I really had my heart set on MIT [Massachusetts Institute of Technology] because it was supposed to be the best science school going. So, I applied to MIT, and I also applied to Rensselaer Polytechnic Institute (RPI), and Stony Brook [State University of New York at Stony Brook], but I really wanted to attend a strong science school, with MIT being my first choice. So, I went through all the application process for MIT and was granted an interview with an alumnus of MIT. I went for this interview, and the gentleman who interviewed me was probably somewhere in his 70s or 80s. At the end of the interview, he said, "You would've been great if you were a boy." And I didn't get in. So, that was my second

experience with being told I couldn't do something because I was female. But I did get into RPI which turned out to be the best choice for me because it was academically excellent, and I met my wonderful husband to be, Robert Zoon [Robert Alan Zoon], there.

There had previously been women graduates at Rensselaer Polytechnic Institute (RPI), but they were part of the Russell Sage College-RPI special program where the women attended classes—and I wanted to emphasize this—and got their degree from RPI but lived at Russell Sage College. I was in the first group of women who lived on the RPI campus. There were approximately 25 of us in total, and the rest were men (approximately 5000) on campus, so you can do the math for the ratio of men to women. We became a sisterhood because there were so few of us. We were very supportive of each other.

We obviously needed somebody to show us the ropes and guide us at the beginning. Mary Middaugh was my big sister who was very helpful orienting me to life at RPI. Thasia Goodwin was a good friend who introduced me to the Phi Kappa Tau fraternity, which is where I met my husband, Bob. We started dating when I was a freshman. He was a junior, and we dated throughout my college years. He was always very supportive of my career goals. When I graduated from RPI, we got married. That fraternity was a really important part of our social life at RPI because there were no sororities. And it allowed us to build relationships that still last today. There were not a lot of extracurricular activities for women at RPI. For example, the only time they would let girls use the gymnasium was on Sunday nights.

Harden: Wow.

Zoon: You could not go to the gym any time except Sunday nights because none of the boys wanted to go then. They were all studying on Sunday night for what they hadn't done over the weekend.

Harden: There were just 25 of you, and this was the very first time there'd been women on campus. How did the professors--

Zoon: As I stated earlier there had been women at RPI who came from Russell Sage College, also in Troy, New York, to take some classes, but this was the first time that there was a structured program and housing for women at RPI. The reactions of various professors were interesting. One in particular was Dr. Stanley Bunce [Dr. Stanley C. Bunce], who, I believe, was assistant chairman or deputy chairman of the chemistry department. He was amazing. He took me under his wing. I had limited finances, so I had to do a work-study program to earn money to cover some of the bills for food and other items while I was there. I worked probably 20 hours a week in the chemistry department. Dr. Bunce assigned me to assist one of the graduate students. I also worked with Dr. Bunce on my senior thesis in chemistry, doing a project in organic chemistry, which was then my major. He was an example of somebody who was very supportive and tried hard to make me successful.

Some of the other professors were quite different. A couple of them would try to date you, which was weird. Some wouldn't look you in the eye because they couldn't handle the eye contact with a female student. It was quite funny The graduate students taught some of the classes, and they were more receptive to having female students because they were younger, and they didn't have any biases in their

thinking such as, "You're at RPI, so you should be a boy and not a girl." Overall, I think most of the professors were pretty neutral.

I was the only female chemistry major in my class. The other 39 were men. But I have to say, they all treated me like an equal. We would work together on projects when we had to. My love for organic chemistry was always there.

I also fell in love with biology while I was at RPI. With the advent of biochemistry, the integration of chemistry with biology, I knew it was for me. I ended up with a major in organic chemistry and a minor in biology, and I think that was where I saw myself going as I evolved through my college years and into the future.

RPI was a tough school because, particularly as a chemistry and biology major, there were a lot of courses that were mandated. You had to take calculus through differential equations. You also had to take four semesters of physics and many chemistry courses. These courses all had laboratories. You were in class from 8:00 in the morning until 6:00 at night and then had your homework to do. It was pretty intense for all those years. I did manage during the summers, however, to get some great science-related positions. One was with Burroughs Wellcome in Tuckahoe, New York, where I got to work with Alan Conney [Dr. Alan H. Conney] and Wayne Levin [Wayne Levin], studying the effects of phenobarbital and alcohol using an animal model. Another summer, I worked with Union Carbide, doing X-ray diffraction of molecular sieves, which was totally different. But I also enjoyed that. They wanted me to stay there and work permanently after I graduated from college, but I had my heart set on going to graduate school. So, I said, "Thank you very much," and declined. It was also probably a good thing because several years later, Union Carbide had a terrible chemical spill accident in India and ended up closing the plant in New York where I would have been working. So, sometimes things work out for the best, even when you don't know it.

Harden: They do.

Zoon: At that point, my experience at RPI, while exhausting, was very, very productive. I graduated *cum laude* with a B.S. in Chemistry and won the William Pitt Mason Prize in chemistry as the best chemistry student that year. I wasn't planning to go to graduation, but Dr. Bunce convinced my soon-to-be husband as well as my parents to make me come so I could get this prize. I'm glad I did it. Hindsight is 20/20, but in my early twenties and with the Vietnam War still ongoing, it wasn't a time in which people thought much about the pomp and circumstance of graduations.

Harden: In 1970, after you graduated with your B.S. degree *cum laude* and the prize in chemistry, on August 22nd that year you married Robert Alan Zoon, and then you entered Johns Hopkins University to work on your Ph.D. But before we talk about your graduate school work, tell me more about what was happening in your personal life. You said your husband was two years older than you. What was he doing after his graduation before you married, and was he in graduate school at Hopkins? Just set the stage for me.

Zoon: Yes. He graduated with a B.S. degree in physics from RPI in 1968, and then he went to NYU [New York University] where he got a Master's degree in nuclear engineering. By the time I graduated, he had just about finished up that degree. He was potentially going to be drafted and go to Vietnam when he found out about the U.S. Public Health Service [PHS] as an alternate way to satisfy his military obligation. So he joined the PHS and went to Maryland in February of 1970 to work for the Bureau of Radiation Health. His location in Maryland was one of the reasons I applied to Hopkins. We knew at that time we were probably going to be married, and it would make sense to be located in the same state. Back in those days, your mother wanted you to be married if you were going to live with somebody.

Harden: Correct.

Zoon: In 1971, after we had been married about a year, he got transferred to work with the Environmental Protection Agency and reviewed nuclear reactors for several years. Eventually, a position opened at NIH, and he came to NIH while I was a postdoc there.

Harden: Before we get to your postdoctoral work, let's drop back. Tell me about your graduate school work at Hopkins. This was in organic chemistry or biochemistry, I believe.

Zoon: Biochemistry. I was in the Department of Biochemistry and Biophysics. It was led by Roger Herriott [Dr. Roger M. Herriott], who was a member of the National Academy of Sciences. This department was in the School of Public Health and Hygiene (now the Bloomberg School of Public Health) at that time, but we also had close ties with the School of Medicine. Because of this, a lot of courses I had were in the School of Medicine, but some courses were in the School of Public Health. My thesis advisor was John Scocca [Dr. John J. Scocca], who was at that time fairly junior in his career. He was an assistant professor, and I was maybe his second graduate student.

I was very interested in biochemistry and John Scocca and Roger Herriott were very interested in studying bacteria and how DNA got repaired in bacteria, as well as how bacteria could exchange elements of DNA among themselves to get different traits.

Harden: And your first paper, in 1974, was on deoxyribonucleic acid uptake by transformable *Haemophilus influenzae*. This is what you're talking about, I believe.
Zoon: Correct.

Harden: It must have been a very exciting time because in the early 1970s, people were just learning how to cut up DNA and splice it back together.

Zoon: We were like the pre-biotech, pre-restriction enzyme folks. In fact, we were studying these factors at the same time as Ham Smith [Dr. Hamilton O. Smith], who actually won one-third of the Nobel Prize for the discovery of restriction enzymes. He had a graduate student, Kent Wilcox [Dr. Kent W. Wilcox], on the original paper with him. While they discovered the first restriction enzyme, which

was obviously very key, our studies on the DNA uptake was integrally related to that because the question remained as to how these bacteria processed getting nucleic acid and incorporating it into their genome. It was really exciting when we put everything together, and then when Kent and Ham found the restriction enzyme, it all made sense. It was super exciting.

Harden: Is there any particular reason you chose *Haemophilus influenzae*?

Zoon: Well, it was an important bacterium that caused disease. And so, we were very interested in that. It was also a system that the lab already had set up to use, quite frankly. Roger Herriott had a number of both *H. influenzae* and other organisms in the lab that we had available to study. So it was a matter of convenience, as well as of interest because of the nature of these organisms and their ability to take up DNA (termed competence development) and cause disease.

Harden: In 1975, you joined Chris Anfinsen's [Dr. Christian B. Anfinsen] Laboratory of Chemical Biology as a postdoctoral fellow at what was then called the National Institute of Arthritis and Metabolic Diseases [NIAMD]. But before we get into your research there, would you describe the lab for me? Who was there? How did everyone work? What was Dr. Anfinsen like as a mentor?

Zoon: First of all, he was great mentor and he taught me many, many important things, some of which I am happy to share because if ever any students read this, some of the insights that he gave me were very important. Roger Herriott and Chris Anfinsen together were the bridge for me to go to NIH. Roger knew Chris from the National Academy of Sciences, and they were both interested in enzyme structure and activity. Chris was working on RNase, and Roger was working on an enzyme called Old Yellow, which he worked on for a number of years. When I decided to come to NIH, I applied for a postdoc position in two different labs, those of Bernie Moss [Dr. Bernard Moss] and Chris Anfinsen. I was offered positions in each lab, and I ended up deciding to go with Chris's offer because I felt like I could learn some fundamentals in protein chemistry. Chris's research better aligned with my interest in biochemistry and protein chemistry.

The part about Chris that I always loved was that he always treated everybody with respect and never pretended to be better than anybody else. He would thank the trash people. He appreciated everything that everybody did for him. That was an important lesson for me: To be successful, you need to respect people at all levels and work with them, because they're important for helping you to do your job. Chris would go across campus with me, pushing large bottles filled with Namalwa cells across campus from Buildings 10 and 5 to the pilot plant in Building 6 to further grow hundreds of liters of cells.

The people in Chris's lab at that time included Urs Rüegg [Dr. Urs Th. Rüegg] from Switzerland, Dalia Gurari-Rotman [Dr. Dalia Gurari-Rotman], and his technician, Lila Corley [Lila Corley], who had been with Chris a very long time. They pretty much made up the original folks in the lab. And then, Pam Bridgen [Dr. Pamela J. Bridgen] and Mark Smith [Dr. Mark E. Smith] joined the lab.

In the meantime, Urs had gone back to Switzerland and Dalia went back to Israel. Chris at that time was very interested in purifying interferon. It was a tough project because people had been trying to purify interferon for many years and were unsuccessful. One of the folks in our lab, Urs, had been assigned to

that project earlier, and he did a lot of work on the purification of interferon, but in the end, only got a sequence for, I believe, myoglobin, not interferon. That was a big disappointment for the lab.

Many people thought I was crazy to try to join a project like this as a postdoc. But one of the things that I think is really important in training is perseverance and taking on hard problems. If something's too easy, you may get a paper out of it, but what's the impact of it? Chris could pick hard things to do because he had already won the Nobel Prize. He didn't have to prove himself and could take on difficult research.

When I arrived, I was eager to get on with the project. And we made progress over time. The key to the progress was being able to grow large amounts of cell culture and infect it with a virus that induces fairly large amounts of interferon, although what we got was still only small amounts of interferon. We started with tissue culture in small flasks and bottles and eventually worked our way up to an 800-liter fermenter.

Christian Anfinsen's laboratory, L-R: Mark E. Smith, Kathryn Zoon (back to camera), Pamela J. Bridgen with Dr. Christian B. Anfinsen seated on stool behind the others.

Harden: Wow.

Zoon: We had worked out a purification program as a team in the lab. I did a fair amount of the work at that time because of the situation where people were coming and going. I was there from the beginning

to the end, and it was quite a project for four-plus years to purify human interferon from human lymphoblastoid cells induced with Newcastle Disease Virus. Once we successfully purified the interferon we then collaborated with Michael Hunkapiller [Dr. Michael W. Hunkapiller] and Leroy Hood [Dr. Leroy E. Hood] to do the first sequencing. They had developed a spinning cup micro-sequencing technology and we were eager to try it out on our purified interferon. I went out to Caltech [California Institute of Technology] to work with them to do the sequencing because from that 800 liters of tissue culture material, we ended up with one milligram of pure interferon. So, it was a really small amount that required this special technique.

Harden: Let me ask you two tiny questions before I move on here. What building was Chris Anfinsen's lab in?

Zoon: We were in Building 10, in the North Wing, on the ninth floor.

Harden: Thank you. Was Alan Schechter [Dr. Alan N. Schechter] in Chris's lab at this time?

Zoon: Alan was a separate investigator in the Laboratory of Chemical Biology. There were also Ed Steers [Dr. Edward Steers], Hiroshi Taniuchi [Dr. Hiroshi Taniuchi], and Irwin Chaiken [Dr. Irwin Chaiken]. They were all Section Chiefs, each with his own research program.

Harden: In September 1980, you gave birth to your first child, Christine Zoon. That was also the year that you made a key career move to the Food and Drug Administration [FDA]. Before we talk about the FDA, would you tell me how you and your husband managed what is today called work-life balance with a young child?

Zoon: Oh, I can. I was very, very, very fortunate. Once I knew I was going to have a child, my parents moved down from Yonkers, New York, and we all lived as one big family here in our house that we still live in on Culver Street.

Harden: In Kensington, Maryland.

Zoon: My mom and dad were really instrumental at that time. I was transitioning between finishing up a senior staff fellowship at NIH and then going over to FDA. I had just started at FDA when I was in my ninth month of pregnancy. Chris really wanted me to stay in his lab as a tenure-track investigator. I gave a seminar, but Ed Rall [Dr. Joseph E. Rall, NIH Director of Intramural Research at that time] was not receptive to adding a woman on the intramural tenure track.

Harden: I remember Dr. Rall.

Zoon: Be it as it may, life sometimes turns out that when one door closes, another door opens.
Harden: Indeed.

Zoon: FDA needed somebody who knew cytokines such as interferon, which were small cellular signaling molecules, in order to regulate them as medicines. Once we had the initial protein sequence of interferon, people then used recombinant DNA technology to clone it. That meant that firms were going to make a product in bacteria in large quantities. The FDA needed to understand the structure and biology of these molecules and review how they would be studied in clinical trials. There was a big need at FDA because at that time because they did not have a lot of people with expertise in biotechnology, e.g. purification, characterization, cloning and sequencing of these proteins. That was something that I brought to FDA. It continued to be an area of interest at FDA for many years to come.

Harden: I want to read into the oral history record the bureaucratic placement within FDA of the department where you worked from 1980 to 1983. You were a senior staff fellow in the immediate Office of the Director of the Division of Biochemistry and Biophysics, the Office of Biologics Research and Review, the Center for Drugs and Biologics of the U.S. Food and Drug Administration. Whew.

I also want to ask, whereas you were not given the opportunity for a tenure track position at NIH at this time in the intramural program, did the FDA have any problem with a woman who had such expertise?

Zoon: No.

Harden: Thank you. According to your biography on the Office of NIH History and Stetten Museum's website documenting Buildings 29 & 29A, during the 1980s (https://history.nih.gov/display/history/Building+29+and+29A+Biologics+Exhibit+Home), you were a "crucial part" of the development of quality control standards for alpha interferon and participated in the reviews of the first alpha interferon products, Schering-Plough's Intron A and Hoffmann-La Roche's Roferon. Tell me about this work.

Zoon: When I got to FDA, my job was to do part-time research and part-time review. But to do review, we had to write guidance documents or points to consider for the industry so that they knew what to expect when they wanted to do an investigational new drug (IND) application, which meant that they wanted to do early clinical trials in humans. So, part of my job was research on interferons, which was continuing to do purification and characterization of interferons and their receptors. I was also reviewing and helping to develop policies for interferon, for recombinant DNA technology, and to a lesser degree for monoclonal antibodies. I was also reviewing submissions from drug companies that wanted to do clinical trials.

There were many different sources of interferons, some from natural sources. The Finnish Red Cross came in with a partially purified interferon that they were studying in the clinic with other investigators. Burroughs Wellcome had an interferon that they were producing from a Namalwa cell culture that was partially purified and that they were using in clinical trials. And then, as time went on, Hoffmann-La

Roche (HLR) and Schering-Plough (SP), the two early developers of recombinant interferon alphas, submitted data to also do clinical trials. Eventually, HLR and SP showed that recombinant interferon alpha 2 was very helpful in treating hairy cell leukemia. When those two products came to fruition and the companies submitted information for a biological license application, I chaired the committee for one of those applications and was on the committee for the other application review. Thus, I was involved in the review through their development, as well as through their final applications for commercialization.

Harden: Beginning in 1983, your title changed from Staff Fellow to Research Chemist in the Cell Biology Branch of the Division of Biochemistry and Biophysics. And then, in 1984, you became Chief of the Laboratory of Immunology in the FDA Division of Virology. In your CV, I can see regulatory papers being published, but also research papers on alpha interferon, which has been your focus all the way through.

Zoon: Correct.

Harden: What would you like to tell me about this period in your career?

Zoon: My research on interferon continued to be productive and I collaborated with many NIH investigators. I was very fortunate to have Dorothy Zur Nedden [Dorothy Zur Nedden] and Renqui Hu [Renqui Hu] working with me in the laboratory to further study the structure and function of the interferon alphas and their receptors. In 1983, I was tenured by the NIH Board of Scientific Directors which was the process all tenured investigators at NIH had to go through at that time. The reason for my dual FDA/NIH tenure status relates to the history of biologics control, which was under NIH from 1902 until 1972. In 1972 when the Division of Biological Standards was moved from NIH to FDA, it was then called the Bureau of Biologics (BOB). Its physical infrastructure—the buildings with the labs—and the scientific staff stayed on the NIH campus. A decision was also made that although we would be part of FDA, our scientists would go through the same rigorous review process for tenure as NIH institute scientists. In addition, the BOB Director (and subsequently the Center for Biologics Research and Review Director) would be a member of the NIH Scientific Directors. Thus you will see me in the 1992-2002 photos of the NIH Scientific Directors until I moved back to the NIH to become Principal Deputy Director of the Center for Cancer Research for the National Cancer Institute in 2002-2003. Then starting in 2005-06, I again became a Scientific Director when I was first Acting Scientific Director and then permanent Scientific Director for NIAID, from 2006-2015.

This was also a period of rapid growth in biotechnology, and I was involved in working on policy and research, as well as doing a lot of review of submissions. During that period, interest in recombinant DNA and cytokines, cell signaling proteins, was increasing. As a result of that, we had more people coming into the agency to review those products. My responsibilities had grown, which included recruiting and training scientists and doing more research in that area. That's probably fair to say what I was doing, up until 1984.

Harden: In 1986, you gave birth to your second child, Jennifer, and you also added Acting Deputy Director of the Division of Virology to your responsibilities. And the next year, they promoted you to

actual Deputy Director. Then, from 1989 to 1992, you went through a similar process, acting-to-full Director of the Division of Cytokine Biology. It looked to me, reading this, as if the powers needed to check you out first as acting before they trusted you with full responsibility. And, of course, the easy conclusion there is that it was because you were a woman. Is this correct?

Zoon: I don't know about that. I think it's just that the government wanted to see how you performed before they made it permanent. There was also a fair amount of work required to recruit for these positions—advertising the position and all the "government-ese" things that need to take place before they can take somebody from acting into a permanent position. I never thought of these acting-to-permanent promotions as having anything to do with my being a female at that point in time. I felt it was just the administrative processes that had to go through and getting the best person for the job.

The one difference in the process of my promotions was when I became the Director of Cytokine Biology. That was different. Frank Young [Dr. Frank E. Young], who was the FDA Commissioner at that time, was a real advocate of biotechnology for the FDA. As Commissioner, he saw the growth that was emerging in this area. He also appreciated and thought highly of the work I was doing. So instead of going through the normal administrative course of action, he actually created the Division of Cytokine Biology and asked me to lead it.

Harden: That's very interesting. As Director of that division, you coordinated the reviews of further indications for the interferon products, which included AIDS-related Kaposi's sarcoma, genital warts, and more recently, hepatitis C. Tell me about this work.

Zoon: There are many cytokines, interferon being one of them, but there are also granulocyte-colony stimulating factor, granulocyte-monocyte-colony stimulating factor, and macrophage-colony stimulating factor. There were a variety of different cytokines being cloned and developed and tested for cancer, for infectious diseases, for a variety of ailments. The one I worked on was interferon. It eventually got approved to treat a number of different types of cancer, as well as hepatitis B and hepatitis C. And back when it was approved for hepatitis C, it was the only known treatment for hepatitis C. Now we have much better-targeted drugs for the enzymes involved in the replication of the hepatitis C virus, but back at that time, interferon as therapy was really quite an important discovery because hepatitis C is a major public health issue in the United States. Today, IFN [interferon] is still used to some degree to clear the virus completely. During the course of looking at blood safety and overseeing the blood supply, having interferon to help treat people was important for hepatitis C. But interferon also had side effects, so it was not an ideal drug, but the risk-benefit was such that it was important to treat people who had hepatitis C so that they wouldn't progress to cirrhosis and renal cell carcinoma and spread the disease. I think it was important for a number of different cancers; chronic myelogenous leukemia was another one. There were a variety of different cancers for which it had some activity and some efficacy. It wasn't the magic bullet that everybody had hoped it would be, but it did provide a clear clinical benefit. It is still in used for some cases today.

Presentation of Reinventing Government award, 1992: L-R: Mac Lumpkin, Kathryn Zoon, Vice President Al Gore, Janet Woodcock, two unknown people.

Harden: In addition to running this division, you had your own section on cytokine research in the Division of Cytokine Biology. So you were running an FDA division, doing your own research, and also teaching pharmaceuticals at the University of Maryland School of Pharmacy in Baltimore. How did you manage all of it?

Zoon: While I didn't do a whole lot of teaching, I was quite busy with all the responsibilities of running a Division and a research program.

Harden: In 1992, you were named Director of the FDA Center for Biologics Evaluation and Research or CBER, the first woman to be director of a center at FDA. Would you tell me about the process of becoming CBER director? Were you recruited? Was it advertised? Who interviewed you? Who made you the job offer?

Zoon: This is an interesting story. At that time, Paul Parkman [Dr. Paul D. Parkman] was the head of the Center for Biologics, and he was going to retire. The person who was most likely to succeed him at that

time was Gerry Quinnan [Dr. Gerald V. Quinnan]. So, when the job was advertised, there was a search committee. I can't remember now who was on the search committee, but I know that Ruth Kirschstein [Dr. Ruth L. Kirschstein] was chair of the search committee. I knew Ruth, obviously, from my days at NIH, as well as because she used to work for the Bureau of Biologics. And actually my first lab in Building 29 was the lab that Ruth had worked in, which is interesting in its own right, following Ruth's footsteps there.

Gerry applied for the job. I did not apply the first time. Gerry was not selected, and then they advertised again, and he applied again. I didn't apply the second time, and Gerry was not selected the second time, either. On the third time, I said, "I'm going to apply because clearly what we expected is not working out." Everybody encouraged me to apply, so I did and had a number of interviews with David Kessler [Dr. David Kessler], who was then Commissioner of the FDA, and Jane Henney [Dr. Jane E. Henney], who was Deputy Commissioner of Operations at that time, and with the search committee. I was then offered the position of Director of CBER, the Center for Biologics Evaluation and Research.

Harden: Your Wikipedia page said you emphasized three things as director: policies to facilitate the development of biotechnology products, advancing the approval of a number of vaccines, and working to achieve a safer blood supply. Would you tell me about what you did to implement these three things?

Zoon: Yes. Back in the 1990s, there were still HIV [Human Immunodeficiency Virus] and HCV [Hepatitis C Virus] contamination issues with the blood supply and with some plasma derivatives. I was instrumental in overseeing the work to make the blood supply safer. I didn't do the work; I had wonderful people who did. When you're head of an organization, it's really the people in the organization who have the knowledge, and as a leader you support them and oversee them. The new tests detected with high sensitivity and specificity the presence of HCV and HIV in blood. The staff developed new standards, working with the blood industry to test for HCV and HIV in the blood supply so that infected blood units wouldn't be used for transfusions. We also had to deal with the issue of TSEs [Transmissible Spongiform Encephalopathies], the infectious proteins known as prions which cause Creutzfeldt-Jakob syndrome with a deterioration of brain tissue and ultimately death.

As a result of that, we made the blood supply and plasma derivative products much safer, developing new methods to inactivate viruses that might be in plasma and plasma derivatives to make sure that those products were safe, and also screening the plasma donors. I felt that we had done a great job. Jay Epstein [Dr. Jay S. Epstein], who was Director of the Office of Blood Research and Review, provided excellent leadership of that office. We worked very closely together.

There's a funny story around all this work on making the blood supply safer. When I first became CBER director, we had to testify before Congress in hearings about the blood supply. John Dingle [Representative John D. Dingle, Jr.] was really on us about the safety of the blood supply, let's put it that way. He raked us over the coals at the hearings. But several years later, when he was retiring, there was a special dinner in his honor, and I was included in the guest list. We were both leaving at the same time, and the Congressman said, "You know what, Dr. Zoon, you did a good job on the blood supply." And that was the biggest compliment I could have received from him.

Harden: Tell me about the new vaccines that you were able to get approved.

Zoon: Vaccines were another interesting and important area. Carolyn Hardegree [Dr. Carolyn Hardegree] at that time was Director of the Office of Vaccines Research and Review. I worked very closely with Carolyn and all the other scientists in her office. We were involved in approving several new or improved vaccines. A new one was the vaccine for chickenpox. An improved one was the vaccine for pertussis. We also worked to make combinations of vaccines that were safe and effective without reducing their efficacy or having any untoward side effects. Then came the time where we were dealing with the anthrax attack after the September 11, 2001, terrorist attacks, and I don't know if you remember, but we had already been worried that perhaps Iraq was preparing anthrax for a biological warfare.

Harden: I want to interrupt for a moment because I'm going to come back to your role after the September 11, 2001, attacks and the anthrax letters. Before we finish this overview of your goals as Director of CBER, however, were there any other policies about the development of biotechnology products that you haven't already talked about that you should add?

Zoon: We were developing new policies for recombinant DNA technology derived products, monoclonal antibodies, xenotransplantation, and cell and gene therapies. Guidance documents were prepared for the development of new medicines. Many of these products were reviewed and approved for clinical trials and eventually for commercial use. And I was very proud of that contribution.

Harden: So now let’s come back to everything surrounding bioterrorism that you dealt with at CBER. During your CBER directorship, which I understand you celebrated with a license plate that said CBER-1, you published a paper in 1999 about vaccines, pharmaceutical products, and bioterrorism as challenges for the FDA in a special issue of the journal, *Emerging Infectious Diseases*. Now, this is 1999. This is before the attacks of September 11th, before the anthrax letters. You were also on an advisory committee to DARPA, the Defense Advanced Research Projects Agency, and presumably that was about bioterrorism. And, finally, you got a Distinguished Service Award for this work. Why were you and the FDA interested in bioterrorism before the attacks of September 11th?

Zoon: That concern was related to the Iraq war and the fact that we already thought Saddam Hussein might be preparing biological agents for biological warfare.

Harden: So, this would be during the Bill Clinton [President William J. Clinton] presidential administration, when in 1998, Iraq refused to admit weapons inspectors into the country. And then, on September 11th, 2001, Al-Qaeda terrorists attacked the Pentagon and the two World Trade Center towers in New York. One week afterwards was when the envelopes containing anthrax spores were mailed to news media and to Democratic senators. After all this, CBER must have been even more intensely involved in the federal government’s planning for a possible bioterror attack, along with NIAID.

Zoon: Absolutely.

Harden: Please tell me more about this work.

Zoon: When the anthrax letters were intercepted, there was one approved anthrax vaccine. It was made by the Michigan Department of Public Health, which was not the best venue for making a vaccine on a large scale. That organization was bought out by BioPort, a private-sector firm that took over the production of the facility in Michigan to make anthrax vaccine. We worked very closely to get that manufacturing site in Michigan in order so that they could make a safe and effective anthrax vaccine product. This was quite important in terms of treatment for people exposed to anthrax as well as pre-exposure prophylaxis for anthrax.

But this also raised a number of issues under George W. Bush [President George W. Bush]. There was an understanding that preparedness across the board for bioterrorism was not very good. And so, interest in smallpox also surged. It was a disease that had been eradicated, but the question arose about what would happen now that people for years now hadn't been immunized for smallpox if terrorists had obtained and grown vats of smallpox virus and released the virus. Smallpox was a very communicable disease. So there were concerns about smallpox and about anthrax. And then, there were other select agents that were of also equal concern.

We worked very hard to develop criteria about what we were going to do about smallpox, because there was no smallpox vaccine currently available. This is an interesting story in its own right, because the only place that there was any smallpox vaccine left—Dryvax, it was called—was in Wyeth's [Wyeth pharmaceutical company] basement. That was the original smallpox vaccine that was given using a bifurcated needle. You probably remember that, Vicky.

Harden: Yes, I do. I have my own smallpox vaccine scar.

Zoon: So, what to do about that? It turned out that the small amount of stock that they had in their basement was still active. And what we ended up doing was working with NIH, in particular NIAID, to do a dilution study with that vaccine so that there would be enough for 300 million doses. We found that this old vaccine was effective, even after having been diluted. In the meantime, people were making new smallpox vaccines. That was an interesting time. Dick Cheney [Vice President Richard B. Cheney] was very involved. He came to NIH, and I briefed him about smallpox. We were working very hard on anthrax and smallpox vaccines, and then on deterrents for some other select agents that could potentially be used for bioterrorism.

Harden: In 2003, the year you received the Distinguished Alumni Award from the Bloomberg School of Public Health at Hopkins; the year after you were elected to the National Academy of Medicine; and three years after you had become the first female president of the International Society of Interferon and Cytokine Research, you left FDA to move to the National Cancer Institute [NCI] as Principal Deputy Director of the Center for Cancer Research. I was surprised about this and wondered why you made this move. Would you tell me about it?

Zoon: Sure. In 2002, I was inducted into the Institute of Medicine, which is what the National Academy of Medicine was previously called for my public health contributions to biologics and biotechnology. And then, at the beginning of 2003, I made a transition from FDA to NIH. I don't want to go into too much detail except to say it was not because of the science. It was more the politics surrounding certain decisions being made in the FDA at that time that I didn't agree with. And so, I decided that from a career point of view, it would be best to leave.

Harden: And why the Cancer Institute?

Zoon: Why the Cancer Institute? At that time, Carl Barrett [Dr. J. Carl Barrett] was the Director of the Center for Cancer Research. I knew Carl from my time at Hopkins, even though he had been in a different department. He was looking for somebody to be his Principal Deputy to help him and the Cancer Institute come up with procedures and policy to streamline interactions with FDA. The goal was to get new cancer medicines through FDA more efficiently. He also wanted the Principal Deputy to help him oversee the clinical and basic science programs of the Center for Cancer Research.

Harden: In 2004, you published an article on the impact of the completion of the human genome on the future direction of cancer research, especially on, "the design of new diagnostic tools and therapeutic or prophylactic agents." What can you tell me about that?

Zoon: There were many exciting discoveries going on at that time, and I was grateful for the opportunity to influence and help direct how we could get new medicines approved in a faster way. I had some experience with this when I was at the FDA. I was involved with overseeing the review for Herceptin for breast cancer. We were able to complete that review at CBER in three months. And that was astonishing in terms of the approval of a product in that short period of time because it included a diagnostic for detecting the receptor, as well as the drug, and we had to work with the Center for Devices and Rad Health [FDA Center for Devices and Radiation Health] for the diagnostic part. So it was indeed astonishing to get the drug approved in three months, but the data were so compelling about the effectiveness of Herceptin, a monoclonal antibody to treat certain breast cancers, everybody pushed 200% to try to get it approved as quickly as possible. Knowing that it could be done, I wanted to bring that enthusiasm and excitement to the Center for Cancer Research to see if there were other things that we could do to promote medicines quickly to patients.

END OF INTERVIEW 1

This is the second sitting for the oral history with Dr. Kathryn Zoon. The date today is March 6, 2023. The interview is being doing via Zoom, and the interviewer is Dr. Victoria Harden.

Harden: Dr. Zoon, when we stopped last week, I believe that you were about to tell me a story about FDA and human cloning.

Zoon: Yes. This was an interesting story. After they cloned Dolly the sheep, there was a lot of interest in cloning and obviously people were interested in whether or not you could clone human beings. There

was a group called the Raëlians, which is a UFO religion. It was founded by Claude Vorilhan, who believed that the Raëlians came down from outer space and founded this religion. I think the religion base is still located in Canada. After Dolly's cloning and some other experiments with cloning, the Hill [U.S. Congress] was very interested in who has authority if somebody wanted to clone human beings. So they had a hearing downtown, and apparently the Raëlians claimed they were cloning human beings. At that time, I was the CBER Director, so I was asked to come testify. The Raëlians claimed that they were working on a human cloning program.

Before I went to Congress to testify, we had a discussion at FDA and agreed that the Center for Biologics would have jurisdiction over human cloning because we had jurisdiction over cloning other things. So I went down to the Hill, and there were the Raëlians. This guy was dressed in this white outfit, like something from Star Wars. His scientific director was there. She was a little woman. They made claims about cloning. But in the meantime, I sent a team of people to inspect a facility where they claimed they were going to be cloning. It turned out to be an old high school, and there was no way for them to clone anything there.

This episode revealed the first indication that there were going to be people who claimed to do human cloning. And we were clear that FDA would have jurisdiction over this. This was also probably one of the most interesting hearings I had ever been at. I thought you might find that kind of an amusing/interesting story.

Harden: Well, it is. And yes, I mean now especially that one scientist in China manipulated germ line genes in twin babies. He got in deep trouble and went to prison for doing that.

Zoon: Right. I think most people are looking at cloning for what would be somatic cell cloning of genes in order to do disease correction. But once you get into the germ line cells, that's where the issues become very dicey, making sure you're doing no harm. Obviously, moral and legal and other issues surrounding that come up. I think society has not yet been able to navigate that.

Harden: Right. The science and technology are ahead of ethics and politics.

Zoon: Yes.

Harden: In 2004, you left NCI and moved over to NIAID as Deputy Director for Strategic Planning in the Division of Intramural Research. And once again, I wonder why you made the shift. Can you tell me how it happened?

Zoon: I enjoyed my time at NCI very much. I still have very close connections to many of the PIs [Principal Investigators] in NCI. They're good colleagues. But I missed the infectious diseases area of science, especially after my time at CBER. So I had a conversation with John LaMontagne [Dr. John R. LaMontagne], who at that time was Dr. Fauci's [Dr. Anthony S. Fauci] principal deputy. And I said, “John, I'm really interested in going back to my roots here in infectious diseases. Do you think there is a

position in which I can contribute to NIAID?" He said to me, "Kathy, Tom Kindt [Dr. Thomas J. Kindt], who was then the Scientific Director of NIAID [Director of Intramural Research] was planning to retire in another year." He said, "Why don't you talk to Tom and see how things go?"

And so I did talk to Tom, and he was excited about the possibility that I should apply to be the next Scientific Director. He said, "Why don't you come over as my Deputy Director for Strategic Planning? That way you can get more involved in the Institute's scientific program and understand what we're doing here. Then you can apply for the position when I leave." And that's exactly what happened. Tom retired, and I applied for the position. Fortunately for me, Dr. Fauci selected me. I told him this was my dream job and I really wanted to do this. I think with that in mind, and my experience at FDA, my experience managing large groups, and having my own scientific program, I was a good fit for NIAID. They wanted to continue the tradition of having a Scientific Director with an active research program, and interferon was still important at that time, as it still is today.

Harden: Thank you. I want to step sideways and say that I noted that your entire career has been physically on the NIH campus first as a postdoc in Building 10, and then you moved to Building 29, one of the Building 29s—

Zoon: Yes I am an NIH nomad: Bldgs. 10 (Chris' Lab); 29, 29A, 29B (FDA labs); 50 (NIAID) for my lab; and then 31 (NCI); 10 (NIAID); and finally 33 (NIAID) for my office. I know every tunnel and every bowel of NIH after all those years. So getting from point A to point B was a major accomplishment at first but easy after just a little while. I can be an NIH tour guide.

Harden: And the fact that your husband was a Radiation Safety Officer at NIH, yours was an "NIH family"—dinner table conversation tended to be about NIH, correct?

Zoon: Yes.

Harden: You lived in Kensington, Maryland, which is not far from the NIH campus, and with two children to raise, your work and non-work life must have flowed together. Would you talk a bit about this before we get back to science?

Zoon: We were like many couples at NIH who are married and spent the majority of their careers at NIH. When I started out in my postdoc at NIH, Bob and I lived in Columbia, Maryland. And after Bob moved to NIH, we were both on campus at that time. We said, this is crazy, spending two hours each day driving back and forth on the Beltway and I-95. It was insanity. So we decided to move to Kensington. And that was great because we were only a mile from work. It really made life a lot easier for me scientifically, getting back and forth to the lab. And for Bob, if there was any kind of a radiation safety emergency, he was available to go back and forth quickly. In 1980, when I had my first daughter Christine (Chrissy), my mom and dad (August and Violet Egloff) lived with us. I was breastfeeding my baby, so I would come home at lunchtime to breastfeed and then go back to NIH. It was quite a challenge, but my mom was great, helping out and taking care of Chrissy. And then five and a half years

later, in 1986, I had Jennifer (Jenny), and that was a busy time when I was at the FDA. And so again, my mom and dad were terrific in helping out with Jenny. By that time, Chrissy had started Holy Redeemer School in Kensington. It is a small Catholic elementary school in the Holy Redeemer Parish. Eventually, both Jenny and Chrissy went to Holy Redeemer. And that made it a little bit easier for my parents, because by then they were getting tired.

We had bought a condo in Delaware on Bethany Beach. My parents would spend the summer there with the two girls, and Bob and I would come out on weekends. Bob and I would also talk a lot about business at NIH, and he was part of my aspiration to apply for the FDA CBER directorship. I'm very thankful to him and to my parents, who gave me so much support to take on these challenges, which were quite time-consuming. They had to give a lot in order for me to do what I did.

Kathryn Zoon and husband, Robert Zoon, at the Gonergrat in Switzerland, 2012.

Harden: I think your story is very interesting to hear, especially for young people. Women talk a lot about family arrangements when I interview them. Until recently, men have generally not worried much about their non-work lives and let their wives take care of things. And yet both men and women must have support if they plan to raise a family while pursuing a career in science. So thank you very much for talking about it.

Turning back to science, when NIAID made you a Section on Cytokine Biology in the intramural program as you moved from NCI to NIAID, is there anything in particular that you would like to get on the record about your research at this time?

Zoon: My interest in the alpha interferons had been evolving over time: first the purification and sequencing of human interferon alpha, then its receptor, then its mechanism of action. There's just not one human interferon alpha. There is actually a family of 14 interferon alpha genes and 12 unique proteins. I was interested in studying the question, “Why did Mother Nature give us so many of these interferons?” My lab was also interested in how these interferons interacted with their receptors and whether we could make hybrid proteins from the interferons, either the alphas themselves or some

alphas and gammas, which could facilitate certain activities. I was very fortunate to have wonderful laboratory support personnel over the years to work with me, Joseph Bekisz [Joseph Bekisz], my lab manager, Dorothea Miller [Dorothea Miller], my technician, Hana Schmeisser [Hana Schmeisser] and Tom Zhou [Tom Zhou], my staff scientists, and numerous students and postdocs. I also had many outstanding collaborators from NIH which led to some very important findings. We found that each of these alpha interferons, when we purified them and tested them in a variety of systems, had a different biological fingerprint in terms of their antitumor activity, their immunological activity, and their antiviral activity on a variety of different cell types.

Clearly, Mother Nature gave us this diversity because she saw a variety of different challenges to the human body. Interferons are found in all vertebrates, but I studied human interferons. A certain virus will induce cells to produce one spectrum of interferon alphas, while another virus will induce a different set of interferons. We learned that depending on the virus, they can induce different fingerprints of Interferons, which then have different fingerprints of biological activities. And that's where we focused our research. If I were still doing research, I would probably still be trying to figure it all out.

Another thing that we did was look at signaling pathways of these interferons to see what they signaled. And then finally, we worked with Sam Baron [Dr. Samuel Baron], who was a volunteer in my lab, doing a lot of work on human monocytes and their ability to kill cancer cells. In particular, we were interested in ovarian cancer. We (Daniel Green [Dr. Daniel S. Green]) had developed some in vitro models and organoids to show that interferons, alpha and gamma in combination, could stimulate human monocytes to kill tumor cells, both in culture as single cells as well as in organoids.

At this point we went to Christina Annunziata [Dr. Christina M. Annunziata], who's an investigator in NCI, and we set up a collaboration to develop a product, which would be taking the patient's autologous monocytes and stimulating them with alpha and gamma interferons and administering intraperitoneal via this combination to see if they would affect the ovarian cancer cells. So we did a phase one study, which we completed probably a year ago and have written this up, and it just got published the past year. So I still talk to Dr. Annunziata even though we don't collaborate as closely now, but we still interact and talk about possible next steps. [Dr. Annunziata has left NIH and is now at the American Cancer Society.]

Zoon lab group in Oxford England, 2007, celebrating the 50th anniversary of the discovery of Interferon: FR: Hana Schmeisser, Kathryn Zoon, Robert "Bob" Zoon, Carolyn Goldman (not in lab), unknown person. BR: Josef Mejido, Angel Morrow, Joseph Bekisz, Neil Goldman, Joseph Orndorff (not in lab).

Harden: Thank you. Let's go back to when you were officially appointed as Director of Intramural Research at NIAID, the "Scientific Director" as the DIR is known—and especially as the first female Scientific Director. I want you to give me an overview picture of what you found in the division when you took over.

Zoon: I just want to note that in 1974, Ruth Kirschstein [Dr. Ruth L. Kirschstein] was the first woman to serve as director an NIH institute, the National Institute of General Medical Sciences, and in 1987, Ada Sue Hinshaw [Dr. Ada Sue Hinshaw] was the first woman to lead an NIH Center, the National Center for Nursing Research, that later was upgraded by Congress into the National Institute for Nursing Research. There's a great photograph of Ada Sue and me with all these men and Cathy James [Catherine P. James], who was the assistant to the Deputy Director for Intramural Research [DDIR] for NIH. It's a great picture. If you don't have it, Michael Gottesman [Dr. Michael Gottesman] has a copy and I think it might be hanging in the Building One DDIR office there.

Harden: Thanks, and correct me if I'm wrong, but I believe that you were the first woman to oversee an intramural research program. Both Drs. Kirschstein and Hinshaw oversaw institutes with only

extramural programs. And when you became NIAID Scientific Director, there was just one female laboratory chief, Susan Pierce [Dr. Susan K. Pierce], and I know about only one female section chief, June Kwon-Chung [Dr. June Kwon-Chung], although there may have been others about whom I am not aware. I'd like to know what your goals were for the Division of Intramural Research, what you saw, how things were organized at the outset, and the challenges that you may have faced to begin with.

Zoon: There were several challenges. The first challenge when I took over was that we were building a BSL-4 [Bio-safety level 4] facility out at the Rocky Mountain Labs [Rocky Mountain Laboratories, NIAID] and a BSL-3 facility on the NIH campus that was about to open. There were a lot of public issues and concerns regarding the buildings themselves and the experiments that would go on in these buildings. So a part of my job was to ensure as much as possible that these buildings were safe, that the research in those buildings was conducted safely, and that we did everything by the book to assure the public that the research we were doing was important and done carefully and well. As I said, the building on campus, the BSL-3 facility, was just about to open when I took over. But the BSL-4 facility at the Rocky Mountain Labs required me to spend a lot of time working with investigators and with ORF [NIH Office of Research Facilities] and others to make sure that it would be safe. There was a lot of community interest and concern in Hamilton, Montana, about the new building and the infectious disease research that would be done there. Everything had to be just right in order to do the work out there, and so I spent a lot of time on that project.

Harden: Marshall Bloom [Dr. Marshall E. Bloom] told me a lot of detail about that from his point of view.

Zoon: Right. And bless Marshall, because he took on a lot of the community interaction there, but ultimately I was responsible for it, so I was out there quite often. I also had to recruit personnel to work in there, and I had to get the very best people to work in that facility. You didn't want to have just anybody working in there. So getting that facility built and staffing it was one big challenge. And that took a lot of my time.

Another one was to work with scientists, especially those who were developing products for use in human clinical trials. Because of my experience at FDA, I could help our staff in that area and oversee the importance of immunology research.

At that time, we were doing a lot with systems biology, and it was becoming an important, innovative field. I established the Laboratory of Immune System Biology and recruited scientists in immunology and systems biology. I also established the Laboratory of Malaria Immunology and Vaccinology. We had a very strong contingent in malaria, and I was able to recruit Patrick Duffy [Dr. Patrick E. Duffy] to lead that program. I also recruited Carolina Barillas-Mury [Dr. Carolina Barillas-Mury], who is an excellent scientist and now head of the Laboratory of Malaria and Vector Research. I was very proud of that. I also recruited a number of other women tenure tracks and men who have now advanced to become lab chiefs. That was another priority, to develop a cadre of individuals who could then take on leadership roles as people retired.

Another challenge that I had was the budget. We were either flat budgeted or had a declining budget, and I had to deal with the allocation of resources to established investigators while trying to support our

junior staff. It was very important to me that we made sure that our tenure tracks had the resources they needed to be successful and have a fair shot at becoming tenured. And so some of our senior investigators were not quite as happy because they got budget cuts. But that allowed some of the junior people to have a full budget so that they could continue on and advance. Balancing those demands was a challenge. But we got through it, and people in general were supportive of my priorities.

Harden: During this time, in addition to all these things you were juggling, you were also teaching as an adjunct professor of biochemistry and molecular biology at George Washington University, as well as being a member of the Office of Research Advisory Committee, the NIH Facilities Working Group, the Dual Use Committee, the Women in Biomedical Research Committee, and on and on and on with additional committee assignments for the NIH Scientific Directors. How did you juggle all these responsibilities in addition to running the Division of Intramural Research for NIAID?

Zoon: It took good program management skills, which I learned at FDA, because to run a complex group like CBER required time management and project management skills. You learn to allocate time but not too much time to things, but enough time to be useful and help things through. As far as teaching goes, I gave a lot of lectures, but I never taught a full course. I would give lectures and seminars but not actually design and implement a formal course.

There are two areas on which I had a significant impact. One was the World Health Organization (WHO), in which I was actively involved for many years on the expert Committee on Biological Standardization. Globally, we developed documents and standards not only for developed countries, but for all the developing countries. That dealt with all kinds of biological medicines, vaccines, blood and blood products, some of the newer technologies, recombinant DNA derived medicines, monoclonal antibodies and cell and gene therapies, et cetera. The other one was the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, especially on specific biotechnology documents, which harmonize regulatory requirements for the development of biotechnology products and good review clinical practices and animal testing information.

Harden: I don’t think that most of the world understands how all this happens and how much attention to detail it requires to try to make it safe for people around the world.

Zoon: Yes.

Harden: I want to ask one more question in terms of things that emerged during your leadership that I have heard in interviewing other people for this project. There seems to have been a burst of new technology during your tenure. I'm too ignorant to be specific, but I’m thinking of things like microscopes that enable you to see things in real time that you couldn’t before.

Zoon: Correct.

Harden: Would you talk a bit about that?

Zoon: When I was at NIAID, Bob Hohman [Dr. Robert Hohman] was the head of the Research Technologies Branch in Bethesda, and ultimately, he also took over the Technologies Section for Rocky Mountain Labs. We were developing and accessing all kinds of new technologies, including the Titan electron microscope. It was a high-powered cryo-microscope that could look at individual molecules. It has been a big asset in understanding the structure of viruses, proteins and other molecules as well as how they interact with each other.

There were a lot of new immunology techniques for detecting cytokines and growth factors in minute amounts, gene expression microarrays, sequencing RNAs [ribonucleic acid] and RNAi [RNA interference], single cell analysis, flow cytometry etc. These technologies were instrumental in moving the field forward. They were incorporated into the NIH Center for Human Immunology, Inflammation, and Autoimmunity (CHI). Initially, Yasmine Belkaid [Dr. Yasmine Belkaid] was the lead of that initiative for NIH, under the auspices of NIAID. Now it is led by James Cherry [Dr. James M. Cherry].

We also looked at antimicrobial resistance and set up working groups, because there are very important problems with resistance to antibiotics that have been developing over the years. We needed to think about how we could develop new medicines to counter antibiotic resistance or develop new antibiotics. And then there are serious drug resistant fungal infections, so again, we recruited a number of scientists with background in fungal infections, and they're going to be very important as we go forward in understanding new fungal diseases and developing new medicines for drug resistant fungal diseases.

Harden: Tell me about how you as Director of the Intramural Research Program interacted with Dr. Fauci, the Director of NIAID, and his staff.

Zoon: Dr. Fauci was a very hands-on person. I met with him one-on-one once a week on Friday afternoons. That's how I ended my week: at four o'clock, a one-on-one with Dr. Fauci. But it was good. We could deal with complex topics, but because it was a Friday afternoon, it was a little less tense, I guess you could say, as it sometimes could be, especially with Tony. We also had weekly executive committee meetings, which included all the directors from all of Tony's divisions. Of course, if there were special initiatives going on or other important issues, Tony would call everybody in, and we would meet with him. But he was always available. If there was an issue I needed to discuss with him, he would always make time to talk to me. I was also always mindful that he was a very busy person.

As far as working with his staff, I loved his staff. They were great people—Patty Conrad [Patricia Lynn Conrad], Jill Harper [Dr. Jill R. Harper], and J.J. McGowan [Dr. John J. McGowan]—and we interacted in a positive way. We also worked with the finance people. Overall, the way NIAID operated, there were some territorial issues. There always are at NIH, I'm not going to lie, but if you had a look from the "20,000-foot level" overall, I think we did a great job.

I also haven't mentioned that NIAID has many sites overseas. We had sites that I was responsible for in Cambodia; in Chennai, India; in Mali; and in Uganda. I had to oversee the research going on there as well as overseeing the intramural labs.

Harden: That's very interesting. I know about the malaria work in Mali but tell me about the work in the other overseas places.

At the NIAID International Center for Excellence in Research (ICER) site in the Rakai district of Uganda: Edward Mbidde, head of the Ugandan Virological Research Institute; Kathryn Zoon; Thomas Quinn; Steven J. Reynolds; Mark Pineda, 2008.

Zoon: In India, NIAID had interests in two areas. HIV was one area, and the other was parasitic diseases, especially those transmitted by sand flies and other parasites transmitted by other vectors that are prevalent in the area. That was very important in our India facility. In Uganda, we studied HIV and some sexually transmitted diseases. HIV had been devastating in Uganda early on, and once the antiretrovirals were put in place via PEPFAR [the U.S. President's Emergency Plan For AIDS Relief], we worked to improve access for those infected. We had clinics there as well as our work with Makerere University on virology research projects. And one of our investigators, Tom Quinn [Dr. Thomas C. Quinn], was interested not only in HIV, but also in sexually transmitted diseases in general, and they were a key area of research in Uganda. In Mali, we studied malaria, and we still are there, believe it or not, even with all the political strife. But the research in malaria, into malaria vaccines is very, very important in Mali because they have seasonal malaria, so you can really follow the impact of vaccines and other interventions as well as the ecology and entomology of the mosquito. In Cambodia, we also studied malaria. And the interesting fact about Cambodia was that it had both *Plasmodium falciparum* and *Plasmodium Vivax*. Having two parasitic malaria organisms was very important for studying the disease.

And Cambodia was also showing signs of becoming Artemisinin resistant. So Cambodia became an important place to study that resistance.

Harden: Indeed. One quick follow up question. Did NIAID collaborate with private sector initiatives like the Gates Foundation [Bill & Melinda Gates Foundation] work?

Zoon: Yes. We had several grants from the Gates Foundation. Cliff Barry [Dr. Clifton Barry III], who studies tuberculosis in Bldg. 33 and South Africa, got a Gates Foundation grant for studying TB in a marmoset animal model. He also was interested in working with the Gates Foundation on new anti-malarial drugs, and I believe he still may be doing some work on them. Mal Martin [Dr. Malcolm A. Martin] got a big grant from Gates for research on HIV using the African Green Monkey. We were also a collaborating center with WHO in several different areas within NIAID, some on cytokines, some on infectious diseases. In addition, we collaborated with a number of NIAID's extramural groups on some of the initiatives on vaccine development, et cetera.

Harden: I want to ask one more question about women leaders at NIH. Ruth Kirschstein obviously comes to mind, and she told me about numerous battles she had to fight as she ascended the NIH administrative ranks. So please tell me who were your closest female colleagues at NIH, the women with whom you could share problems and achievements? And was there an “old girls club” to help each other and mentor young women comparable to the “old boys clubs” that have existed for centuries?
Zoon: No. There was no “old girls club.”

Harden: Were there even enough women at NIH to comprise an “old girls club”?

Zoon: There were not enough women at NIH to make up an “old girls club” in my time. It got a little better later on when there were a few more women as Scientific Directors. But other than interacting with Ruth a little bit when she was still there, I didn’t have any female peers. She would be my go-to person if I had a problem. But I ended up interacting mostly with male mentors because there weren't that many women in senior positions. And sometimes you just have to suck it up and do your best.

Harden: There were certainly male mentors for women. I remember some years ago hearing women saying that no men ever supported women, but that was simply not true.

Zoon: Yes, there were indeed men who supported women’s careers.

Harden: For people like you, who were the first women in any scientific field, you must have been promoted by men who had faith in your ability to achieve. Were there any-

Zoon: I have just thought about another woman I want to mention who supported me: Jane Henney [Dr. Jane E. Henney], who was David Kessler's deputy when I arrived and later she became FDA Commissioner herself—I would consider her, even though she was my boss, a really good mentor as well.

Harden: As a side note, when I was preparing for your oral history, I found it impossible to find a complete list of all the female Scientific Directors who came after you. You can find all kinds of other lists, and I thought that such a list of women luminaries would be something that NIH would maintain.

Zoon: Maybe we should start one, Vicky.

Harden: Well, perhaps you might pass such a suggestion on to Nina Schor [Dr. Nina F. Schor], the new NIH Deputy Director for Intramural Research.

Zoon: Oh, yes. I will. I think she would be very receptive to it.

Harden: What about appointments during your time at NIAID—your efforts to get women promoted to section chiefs and lab chiefs?

Zoon: It was rough road to success. NIAID is the oldest institute, and there were men who had been in these positions for a very long time, with the exception of Dr. Sue Pierce, who was the only female lab chief. And the men were not about to retire. They all seemed ready to die at their desks. Thus the most I could do to influence this was to hire really good women scientists at the tenure track level and bring them up in the organization, get them tenured, and get them ready to be competitive to apply for lab chief positions when they were available. This worked out pretty well, because Pam Guerrerio [Dr. Pamela Guerrerio] is now the Chief of the Laboratory of Allergic Diseases, and Yasmine Belkaid is Chief of the Laboratory of Host Immunity and Microbiome as well as the head of the NIH Center for Human Immunology, Inflammation, and Autoimmunity [as of January 2024, Dr. Belkaid has departed NIAID to become President of the Institut Pasteur]. Carolina Barillas-Mury is Chief of the Laboratory of Malaria and Vector Research, and Irini Sereti [Dr. Irini Sereti] is Chief of the Laboratory of Immune Regulation. And at RML, I appointed Patti Rosa [Dr. Patricia A. Rosa], as Chief of the Laboratory of Zoonotic Pathogens. She thus became the first female lab chief at RML (she is now retired). Also at RML is Sonja Best [Dr. Sonja Best], who is Chief of the Laboratory of Persistent Viral Diseases. I did a lot of the groundwork for raising women up in the organization, work of which I'm quite proud. I also did that at FDA when I became a head of CBER. I had the ability to take women who were tenured and make them chiefs of their labs or divisions within FDA. And when I left FDA, 50% of the leadership was women, which I was very proud of.

Harden: You continued to collect awards and to serve on more committees and even to become deputy editor-in-chief of the *American Journal of Clinical and Experimental Immunology* beginning in 2012. In 2015, you officially retired. But the very next year, in 2016, a report was issued that recommended

administrative changes in the Clinical Center [NIH Clinical Center] as a result of, and I'm reading this into the record, “contamination of biological products found in the Clinical Center compounding pharmacy.” This report was known as the Red Team Report, and it resulted in—and now I'm quoting from an *NIH Record* article—“luring you out of retirement" to become interim director of a new Office of Research Support and Compliance, which was formed to set policy and standards and assure quality with oversight responsibility, not just for the Clinical Center, but for the entire NIH intramural research program.” Would you tell me about what you did in this position?

Zoon: What happened is that I had talked to Tony in 2015 and told him that I had plans to retire, but that I wanted a year to close down my lab and get everybody jobs who needed jobs and get my postdocs and students all taken care of. Tony agreed and said that that would be fine. I was still head of the Cytokine Biology Section at that time. So I had just gotten back to my lab and was having a great time, finishing up some experiments, when I got a call from Francis [Dr. Francis Collins, NIH Director]. Francis said, “Kathy, I really need your help. I got the Red Team report, and we're really concerned. Can you help?” At that particular moment, Tony was out of town or at least unavailable, so I called Hugh [Dr. Hugh Auchincloss] because Hugh was his deputy. I said to Hugh, “Francis called and asked me if I would do this. He's the NIH Director, so I don't feel like I can say “no,” but I want to check since I'm still under the auspices of NIAID, just to make sure I have your blessing to help him out.” And Hugh gave me the permission I felt I needed from NIAID.

So I took on that job, and obviously there were numerous issues in that report that needed attention. Valerie Bonham [Valerie H. Bonham], the DHHS [Department of Health and Human Services] attorney for NIH, and I were assigned to work together on this. The two of us set up this new Office of Research Support and Compliance under the auspices of Michael Gottesman. I never worked so hard as in that one year to establish this office—inspect all the labs, work with investigators, work with the FDA, work with NIH.

It was a huge job. And Larry Tabak [Dr. Lawrence A. Tabak], who was Francis's deputy and right-hand person at that time, had been delegated to oversee this project, so we worked closely with him. There were a number of investigators and pharmacy staff involved in the investigation, to be sure. There was an NCI investigator, several folks in Mental Health [National Institute of Mental Health], and the pharmacy in the Clinical Center that had some issues. We worked to resolve all the space issues with ORF under Dan Wheeland [Daniel G. Wheeland] and worked with the labs to get their procedures in compliance so that problems got corrected.

And then Larry wanted me to continue to do this. He said, "We can put you on a contract." I said, "That's not what think I want to do in my retirement, Larry, but I'll help you find somebody to take over.” And we found Bruce Burnett [Dr. Bruce K. Burnett], who now is working with Ginny [Dr. Virginia A. Guptill] in the Clinical Center under Gilman [Dr. James K. Gilman, Director, Clinical Center] to run the office. I think we got NIH out of a lot of trouble at that time. And NIH really appreciated the work I did for them on that. I felt it was an honor to help NIH.

Harden: With all your different skill sets, you must have had a number of offers through which you could have left NIH, with all the rules that you have to deal with being a federal employee and gone to academia or industry and made a lot more money. What kept you at NIH?

Zoon: I always felt public service was very important, and I have dedicated my career to it. While there were opportunities to leave, I was careful not to pursue any of them because, of course, even contacting a company could be a conflict of interest. I was also on the NIH ethics committee, so I knew the rules. I decided that once I retired, then I would think about what I wanted to do afterwards. But I was really dedicated to public service, and I felt that's where I belonged and what I should be doing.

Harden: Now that you have retired, tell me about what you are doing. Are you and your family traveling, for example?

Zoon: I'm on several boards now, and that keeps me quite busy. I'm on the board of Emergent Bio Solutions Incorporated. I'm on the board of the International Biomedical Research Alliance, which is a nonprofit board that works with NIH on the NIH Oxford-Cambridge program. It is a really wonderful program, working with Oxford and Cambridge to grant our students a four-year Ph.D., which is phenomenal as you probably well know.

I also help out Johns Hopkins University. I'm on a malaria advisory committee for the Bloomberg School of Public Health right now. And I am also a special advisor for the International Alliance for Biological Standardization, which deals with standardization of biologics. I'm there for advice on the big picture, strategic input, maybe once or twice a year. I go to the annual meeting and review their programs. But I spend a lot of time on the first two.

And I get to travel more except during Covid, which was a bummer. But now I travel together with my family. We were able to take several trips. I visited my cousin down in Florida, who lives in Tampa, and I get to see her more. I also get to play with my grandkids. Get to do things with my husband. We're like crossword puzzle nuts now. We spend time together, go out to lunch, do nice things, and garden. I like to garden, and I have 15 or 20 Bonsais that I care for.

Harden: Oh wow. That's impressive.

Zoon: So I stay busy.

Harden: These are all the questions I have. Is there anything else you want to get on the record before we stop?

Zoon: I think I gave you as complete of a picture as I can. I am honored to be one of our female scientists who are being recognized, and I hope it will be inspirational to some of the young people coming up.

Harden: It will. Thank you so much, Dr. Zoon, for such a fine oral history.