Dr. Michael Lauer

August 12, 2022

Barr: Good afternoon. Today is August 12, 2022. My name is Gabrielle Barr, and I am the archivist at the Office of NIH History and Stetten Museum. Today, I have the pleasure of speaking with Dr. Michael Lauer. Dr. Lauer is the Deputy Director for Extramural Research with the Office of the Director. He is also a board-certified cardiologist, an elected member of the American Society of Clinical Investigation, and an elected fellow of the American College of Cardiology and the American Heart Association. Today, he is going to be speaking about his career, his training, and, most importantly, about his experiences with COVID-19. Thank you very much for being with me.

Lauer: Thank you, Gabrielle.

Barr: So, for your early life and training, will you please describe your upbringing and what ignited your passion for science and medicine?

Lauer: I grew up in Philadelphia. I am a second generation American. My parents were refugees from Nazi Germany. My father came to this country when he was 18 years old, and despite not knowing a word of English, he became a highly successful scientist within a relatively short period of time. He received degrees in physics and chemistry and went on to have a distinguished scientific career. That, certainly, got me very interested in science.

Barr: Was his family, back in Germany, into science and medicine?

Lauer: No. He came from Vienna. His father was an attorney, and his mother was a musician. So no, not at all. But for some reason, this is what he did. My mother grew up in Berlin, and she left in 1938, shortly after the Kristallnacht pogrom. She found refuge in England, got interested in theater and literature, and came to the United States in 1945. My parents were married in 1955. It was an arranged marriage. They were different people from different backgrounds, but it worked. They both inspired me. My father was a scientist, and my uncle, my father's brother, was a cardiologist. He is the reason why I became a cardiologist.

When I was in high school, I had two interesting experiences. One was an NSF [National Science Foundation] funded program at RPI [Rensselaer Polytechnic Institute]. At that time, my father was on the faculty at RPI, and he told me about the NSF program and said, “You should do this.” It was a summer program, and I joined a chemistry lab that was doing work on the interactions of DNA and anti-cancer drugs. I stayed in that lab through college and medical school and had a fantastic experience, and for that, I am forever grateful to the National Science Foundation. Another interesting experience I had in high school was volunteering for the 1976 Jimmy Carter Presidential campaign. I got to see a bit of the political process up close. I met some fascinating people, and I remember, one day, telling my father that I found politics interesting. I could see myself going into politics or going into government. My father had a fit. This was one of the few times that he really, truly, completely lost it. He made it clear to me that I was going to medical school, and that I was to get these silly thoughts out of my head. I also enjoyed my government courses in high school. I took economics courses in college. Now here I am in government, and I am doing it as a trained scientist and physician. It all worked out.

Barr: Yes, definitely. Do you have any siblings, and are they in scientific careers?

Lauer: I have a younger sister. She is not anywhere close to being a scientist. She is an artist and an artistic photographer. She also teaches yoga. She does fancy photography using high-tech equipment. She is one of the few photographers who uses film, and she is doing some interesting work, but yes, she and I went in different directions.

Barr: Yes, what an interesting family. There are so many different interests.

Lauer: Yes.

Barr: Can you talk about how you selected the six-year accelerated program where you obtained your bachelor's at Rensselaer Polytechnic Institute and your medical degree at Albany Medical College, and what you felt you gained from each of these institutions that you have applied to your career?

Lauer: I was a junior in high school when my father lost his job. He was working at Sun Oil company in Philadelphia, and it is a long story, but he wound up at Rensselaer Polytechnic Institute, at RPI, in Troy, New York. He told me about their six-year medical program, and he made it clear that I was applying for it. And he made it clear that if I got into it, that is what I was going to do. I had these ideas of all these other various colleges I was going to possibly go to, and he said, "No, this this is where you are going." Anyway, I did get into the program, and I had a fabulous time. The way the program was structured, as long as I maintained a B-plus average, I was guaranteed a spot in medical school. I never had to go through the whole process of applying to medical school. The result was that my academic college experience was intense, but not so stressful because there was no anxiety about whether I was going to get into medical school. As long I did my work, I had a spot in medical school. I think I received a fabulous education there, and although we do not think of Albany Medical College as being one of the top tier medical schools, I received a fine education there. Part of the reason I know that is because I wound up doing my residency at Mass General Hospital in Boston. I'm alongside these Harvard graduates, one of whom, by the way, I wound up marrying. But I am alongside all these Harvard grads, and I remember that one of the residents came to me and said, "Now, you probably think that you got in because of the computer error, and that you are a total idiot. Wait till you see how you compare to the Harvard grads."

Barr: The emphasis at RPI is the hard sciences. How do you think that has affected how you have approached certain issues in your career? A lot of people are just straight bio majors coming into medical research.

Lauer: That is a great question. At the time – I do not know if this is still true – RPI's motto was, "We train people to solve problems." That is what we do. Of course, RPI is an engineering school. I was one of the minority of students who was not an engineer. The interesting thing is, I think, that I incorporated that problem-solving philosophy into my work in clinical and academic medicine. I was solving problems then, and today I am solving problems in my current job. Basically, my job is to figure out which problems I am supposed to be dealing with, and either solve them myself or help others solve them.

Barr: Before we go into your internship and residency, you are part of the orchestra which I think is interesting. You talked about your mother being a musician. What instrument did you play and how has music continued to be a part of your life?

Lauer: I played piano and viola. I played viola for quite a long time. I was in a chamber music group through college and medical school, and I did pit orchestras. There were various college musical productions: *Oliver*, *Kiss Me Kate*, and *Cabaret.* I was never particularly good. I think I was a fairly mediocre, but nonetheless, I guess I was competent enough. I love music, and I listen to music as often as I can – all kinds of music – classical, opera, operettas, musicals, early jazz, and ragtime.

Barr: As you said, you went on to do an internship and residency at Massachusetts General Hospital in Boston. What is it about cardiology that excited you and led you to become a clinical fellow in medicine specializing in cardiology at Beth Israel Hospital, and then serving as a research fellow in the Framingham Heart Study at Boston University Medical School?

Lauer: The reason I became a cardiologist – I could say that I thought that the field was intellectually interesting, and I enjoyed the physiology, but the real reason I became a cardiologist is because my uncle was a cardiologist. Uncle Kurt was a cardiologist. He was one of my role models. I greatly respected him. He was an amazing doctor and I wanted to be just like him. That is why I went into cardiology. I have no regrets. I love cardiology. In many respects our field was way ahead of everybody else in evidence-based medicine, generating evidence, and using the scientific method to solve clinical problems. I did my fellowship at Beth Israel Hospital, and Bill Grossman, who was the Department Chair, made it clear to us that we needed to pursue a research career. He said, "If you are going to live a worthwhile life, you have to pursue a research career. What I am going to do is help you do that. I will help you figure out what your niche is, but you have got to find it." So, I wound up going to the Framingham Heart Study and working there for Dan Levy who is now still at NHLBI [National Heart Lung and Blood Institute]. I had an amazing time there. I learned a huge amount, and those skills then took me through a research career going forward. One of the reasons I went into a research career was because Bill Grossman drilled it into our heads. He set up the fellowship program in such a way that we could spend a maximum amount of time in research. He also made it possible for me to go to the Harvard School of Public Health. I was a graduate student at the Harvard School of Public Health in epidemiology and statistics and had an amazing time there. I would have to say that the skills I learned there I am still using today.

Barr: Did you have any particular formative experiences during your training that had a big impact on you that you would want to share?

Lauer: That is an interesting question. Well, we will get back to that. Keep going.

Barr: Okay, we are going to move on to your career at the at the Cleveland Clinic. What were some of your clinical and teaching roles that you held while at the Cleveland Clinic, which is renowned for cardiology and its cardiac surgery programs, when you were there from 1993 to 2007?

Lauer: I did a mix of things. I had a fairly large outpatient clinical practice, and I saw inpatients. I ran the exercise laboratory. Actually, that is where my research came from, the exercise laboratory. We developed a research program, and I guess I would say one interesting formative experience I had was that I got to meet Gene Blackstone. Gene Blackstone was recruited as a surgical researcher at the Cleveland Clinic, and I am not quite sure exactly how we found each other but we did. He was doing outcomes research long before anybody thought that it was interesting. We were both physicians. We were both interested in solving clinical problems. We both liked to do statistical coding. Through him, I was able to develop a deep connection to the surgical program there. We set up a research program that was quite successful. We were funded by NIH at various points along the way. Then, we were asked

to set up a master's program in clinical research. At one point, I was asked to essentially create a program from scratch, and I made it very clear that that was not possible, but nonetheless, we would do what we could to help support it. Eventually, under the leadership of Eric Topic, Cleveland Clinic set up a new medical school (as part of the Case Western Reserve system). It was an interesting place, because it was a medical school designed to train physician scientists – people like me. One of my roles was to develop a clinical research curriculum, a curriculum in epidemiology and statistics for medical students. This was not the typical kind of epidemiology and statistics which is watered down, but much higher level, almost like a Ph.D. level graduate program. I remember saying, "Well, let us look around at other medical schools around the country and see how they do it." Nobody else was doing it. Nobody. So, we created this from scratch, and it worked out quite well. Those were some of the things I was working on.

Barr: It is quite a lot, creating a medical school. It is a huge endeavor.

Lauer: Well, let me not exaggerate this. I was one of many players. I think that if there is any one person who really made it happen it was Eric Topol who was the chair of the department. I was there in a supporting role, but I did my part.

Barr: Can you talk a little bit about some of your research initiatives during your time at the Cleveland Clinic. One of them that you had already mentioned was looking at heart rate recovery after exercise and mortality, but you were a part of a lot of others.

Lauer: Right. Our exercise lab was unusual at the time because it had a fully electronic system. When I came to Cleveland Clinic I was told, "Well, our exercise lab has a fully electronic system. Everything that we do in the exercise lab is digital. We have an electronic health record." Now this was 1993. And they said, "Well, you trained at Framingham. You could figure out how to use this and do some research." It took a long time to figure out how to use it. It was not all that simple, but it was. We had a fully electronic system, and the result was that we had rich, robust, standardized digital data on every patient who came through our exercise lab.

Barr: That is incredible.

Lauer: We were doing tens of thousands of these every year, so we had an absolutely massive database. I had been interested, from an intellectual point of view, in how heart rate and blood pressure are regulated and somewhere along the way it occurred to me that we had a laboratory here. We were measuring heart rates. As part of our routine clinical care, we were measuring and systematically recording resting heart rates, exercise heart rates, and recovery heart rates. We had read some literature that recovery heart rates might be actually more informative than exercise heart rates. I remember thinking at the time, "That is so simple! Somebody must have thought of that." There were some papers, but they reported on small numbers of people. We analyzed a large number of patients and found out that – lo and behold – recovery heart rate was a very strong predictor of mortality. Our report was published in the *New England Journal of Medicine* in 1999 (and has been cited over 1200 times). This was huge. Every clinical scientist dreams of getting a *New England Journal* paper, but at the same time, I was terrified for two reasons. One was that somebody was going to tell me that they had discovered this 50 years ago and there was nothing new, and that almost happened. There was an army scientist who contacted me and said, "You know, we thought about this, and we actually noticed that our recruits who had high pulse rates during recovery after exercise did not look all that good, but we never pursued it." Second, I was worried that the results would not be replicated. You might say that the second most thrilling thing was that about three or four years later researchers at Stanford published a

paper replicating our findings. Then, there was another replication study from Paris (which was published in the *New England Journal)*, and since then there have been others. The replications were an enormous relief. So yes, it is a real discovery, and it is kind of cool to be able to be part of that.

Barr: One of my other questions is what interests you in looking at whole patient populations risk assessment? You have been a part of a variety of research studies from heparin covered stents to when to give aspirin, so it is interesting to see such a variety. And it is also interesting that it is not individual patients. You are very interested in whole populations. Can you talk a little bit about that?

Lauer: That is the magic of epidemiology. You can learn a tremendous amount by looking at large groups of people. Classic epidemiology is population based: the Framingham Heart Study or the population studies that showed that cigarette smoking leads to lung cancer. Another kind of epidemiology is what we call clinical epidemiology, where the populations that you study are patient populations. They are people that doctors and nurses actually see. A place like Cleveland Clinic offered an enormous patient population with a robust electronic infrastructure. We had massive amounts of data. We had leaders like Eric Topol and Gene Blackstone who encouraged the work and said, "You know, we should take advantage of this. This is a gold mine that we have, and we can make insights and make discoveries that others are not able to do." I started computer coding when I was in eighth grade (in the 1970s). I love doing computer coding. I still do computer coding, although my coding is nowhere near as good as it used to be. I get a visceral thrill working with, analyzing, and visualizing data. In my current work, we are working with grant data, but the underlying philosophy is the same as with clinical epidemiology. We are not looking at people or patients, we are looking at grants, but it is the same idea. We have massive amounts of data here at NIH. It is in a robust, rich electronic format, and so it enables us to make some interesting insights.

Barr: While at the Cleveland Clinic, a medical malpractice suit was brought against you for allegedly failing to diagnose myocardial sarcoid in a patient who died. Ultimately, you were not found to be negligent, but how did this experience impact how you think about expertise, particularly expertise in legal settings in clinical trials? You said it had a major effect on you.

Lauer: Yes. That was an awful experience. Ironically, what was really awful was that this was a young man who came in with a complete heart block, and I was the first cardiologist to see him, and I actually thought of sarcoid. I wrote it in my admission note and ordered the appropriate test for the time. The test that we had at the time (it is much better now) came back unrevealing. Anyway, he wound up getting a pacemaker, and then, many years later, he unfortunately died. He died suddenly, and on autopsy, he turned out to have sarcoid. Part of what was so painful about this was that I did not do anything wrong. There were no mistakes. Unfortunately, we did not make the diagnosis, but it was not that we had not thought about it. The lawsuit took up massive amounts of time and was personally painful. The trial lasted a week, and I had to sit there in court for the entire week. There was an expert witness who had no clue what he was talking about. He was being paid; he was a professional expert witness. This guy did hundreds of these cases, and he would be paid massive amounts of money to basically say whatever the attorneys wanted him to say. He had no clue what he was talking about, and fortunately, he did not make a good impression on the jury. I remember in the summation my lawyer said, "Who would you rather have as your cardiologist? Would you rather have that guy, or would you rather have of Dr. Lauer? What's your thinking about that?" The trial made me very cynical. I am still cynical when it comes to medical malpractice litigation. I think that the system stinks. I came close to quitting medicine at the time. It was that awful. At one point, one night, my phone rings, and it is my

Rabbi, and he said, “I hear that you might do something stupid. Do not do anything stupid, please. Do not do anything until you talk to me,” and I said, “Okay.”

Barr: That is a good thing.

Lauer: That is a formative story.

Barr: That is a formative story. We are now going to turn to your years at NIH starting with your time NHLBI. What enticed you to leave the Cleveland Clinic to become the Director of the Division of Prevention and Population Science at NHLBI?

Lauer: I was recruited by Betsy Nabel, who at that time was the Director of NHLBI. I was not looking for a new job, but I was asked to apply for the position. I knew Betsy Nabel, and I had enormous amounts of respect for her. She was one of my role models, and the idea of being able to work for Betsy Nabel was just [unbelievable]. Her recruitment style was not subtle. That is why I came to NHLBI. I came to NHLBI to have the opportunity to work for Betsy Nabel. The other reason that I came to NHLBI was I was ready to do something different.

Barr: What was it like to go from applying for grants for all those years to being part of creating, distributing, and overseeing them, and what insights do you feel like you brought to that from being on the other side of the process?

Lauer: I think it is important that I was on the other side of the process. I have actually been there. I wrote grant applications: some that were pretty good, others that were lousy. I wrote some that did well on peer review, and I also wrote some that did poorly. I had run-ins at various points with the NIH system. For example, there was an NIH official who told me that she did not think I was doing patient-oriented research. I just found that stunning. It is like, “Excuse me, I am doing research here on the Cleveland Clinic on patients in the Cleveland Clinic. I cannot think of anything more patient-oriented than that. I spend my day surrounded by patients and I work on patient data,” and to me that made no sense. I think it is important that I have been “on the other side.” In some respects, it made my start at NHLBI easier as many people tried to explain to me the grant process, and I said, “You know I actually do know something about the grant process. I do not know what exactly happens on this side of making the sausage, but I have been on the other side.” The work that I get to do at NIH is absolutely fascinating. I get to think about things on a completely different level than as an individual researcher. You do not get the glory of publishing papers in top-notch journals about whatever your latest research discovery is, but you do have the opportunity to be at the table addressing some of the most interesting issues that we have had to deal with in biomedical science over the last 15 years.

Barr: In 2009, you became the Director of the Division of Cardiovascular Sciences at NHLBI. Will you speak about your contributions to developing NHLBI’s priorities and strategic plans?

Lauer: When I arrived there were two heart divisions: there was the Division of Prevention and Population Science and there was the Division of Cardiovascular Diseases. Betsy Nabel decided that she was going to merge the two. I got called to her office one day, and she said, “I am going to merge these two divisions together and you are going to be the head of the entire division. It is going to all start in in a few weeks, so go ahead and put together a plan.” To a large extent, many of the priorities were articulated by the IC [Institutes and Centers] director because that is their prerogative, and then a big part of my role is to help frame the questions, help the IC director in thinking through what is

reasonable and what is not, and then, of course, also working with staff and working with the community to make those make those priorities actually happen.

Barr: Will you speak about how genomics, proteomics, tissue engineering, nanotechnology, and informatics influence the direction of NHLBI grants, and how NHLBI has sought to balance these new areas of science with sort of the long-term clinical trials? What are some of the new kinds of initiatives that got funded?

Lauer: If you think about those areas of science, like the various omics and genomics, now we are talking about big data.

Barr: Yeah.

Lauer: At Cleveland Clinic, I thought I was dealing with big data, but this was big, big data on a whole new scale. This was something that Betsy Nabel was extremely interested in. My former colleagues at the Framingham Heart Study became extremely interested in genomics. NHLBI has been one of the leading institutes at NIH in in taking big data to a new level. I mean, big is just an unfair term. Maybe I will speak the way my younger son uses the term ginormous. [Lauer makes a motion spreading out his arms emphasizing the size] That is what we are talking about. This, to a large extent, drove many of the other various types of projects that we were working on. Epidemiology projects, clinical trial projects, and so forth, were taking advantage of these mega, mega data opportunities.

Barr: For what kinds of questions, do you think, some of these non-traditional approaches are appropriate and even ideal?

Lauer: Well, when you are looking at, for example, complex interactions in complex biological systems, it is not one thing. Cigarette smoking causes lung cancer—that is fairly straightforward. There are complex mechanisms underlying that link, but it is pretty easy to connect the dots from A to B. Most biological processes are not that simple. Genes are interacting, different environmental factors are interacting, and they are interacting in ways that are hard to analyze. We need to work with large samples or large amounts of data, because only in that way can one actually start to tease out patterns. The same is true with clinical trials, and this is one area where I think cardiology was way ahead of everybody else. Most treatments in medicine have fairly modest effects. Therefore you need large samples, large populations, large trials, many centers in order to be able to answer a question in a reasonable and robust way. This was as idea that NHLBI promoted as a top priority. We wanted to spend our money funding large definitive trials that would yield important, robust, and interesting answers.

Barr: During your tenure at NHLBI, cardiovascular disease was recognized to be a global health issue, not just that of developing countries. How did NHLBI respond in terms of its funding and programming?

Lauer: For Betsy Nabel, this was a top priority. She was interested in chronic diseases in developing countries. She took trips (and I remember she would share these experiences that she had). She visited people in sub-Saharan Africa, and in other developing countries to learn about their chronic health conditions. We used to think that in developing countries the major causes of death were infectious diseases. That is not true anymore. Now the major causes of death are heart disease, high blood pressure, stroke, emphysema, and so forth, to a large extent, similar to what we have here. They have different kinds of problems than we do. She made it very clear to us that this was going to be a top priority for us, and this was something that we put a lot of effort into.

Barr: You were chosen to be the co-chair of NIH's Precision Medicine Initiative. What was involved in this endeavor, and what were what were the goals?

Lauer: Francis Collins had this dream that he was going to set up a gigantic cohort: not a few thousand people, not 10,000 people, but more like one million people. He was going to set up this kind of enormous cohort in order to be able to tease out patterns that would be highly specific for certain groups of people. I had been working with Francis already, on a variety of different projects related to comparative effectiveness research and PCORI [Patient-Centered Outcomes Research Institute]. He knew of course, the kinds of things that I was interested in, and he had been pushing this idea for a while. Eventually, President Obama got interested. Now, once President Obama gets interested in something things start to happen. So then, we started working on putting this "Precision Medicine Initiative" together. Now it is called the All of Us Program. I had an opportunity to be involved in some of the early planning. I was one of many people who worked on it, and it is wonderful to see the progress that they have made. It is incredible. They have now enrolled I think half a million people, and they are doing fantastic work.

Barr: What were some of the challenges that you encountered while you were at NHLBI doing your work as well as some of the things that you are most proud of?

Lauer: Well, one very interesting challenge was – remember I mentioned that we had two heart divisions and Betsy Nabel decided she was going to merge them to have one heart division? Here we were, two different divisions. We were both at NIH, we were both in the Heart, Lung, and Blood Institute, and we were both in the same building, yet the cultures were vastly different. This was fascinating actually.

Barr: Why they were so different?

Lauer: Well, I have come to appreciate this a lot more, but in large organizations, this happens. You have different groups of people, and they develop their own ways of doing things. These two divisions thought about the world in different ways, even though we were part of the same agency, and to large extent doing similar work. It was hard, and actually, I became interested in corporate mergers, where different organizations come together. Some corporate mergers are successful, and others are unmitigated disasters. I wanted to make sure that we were not going to be an unmitigated disaster. We had a few hard years, and we did get some help along the way. One of my most proud moments was that many years later, one of the most skeptical leaders within the division said, "I cannot believe this, but we are actually now functioning as one division of cardiovascular sciences." I was, in a way, stunned, but at the same time, yes, he was right; we had arrived. Right now, my successor, David Goff, who is a lovely, lovely man, took over that division and as best as I can tell, that division is one of the most highly functional units at NIH. They are doing amazing work.

Barr: That is really wonderful. Now, we are going to turn to your time with the Office of the Director. So, in 2015, you became a Deputy Director for Extramural Research. What responsibilities does this position entail and what was the transition like from focusing on one specialty and institute to becoming familiar with the needs and practices of all the institutes and centers?

Lauer: I was asked to apply for this position, and I already knew that this was something I was quite interested in. I remember when Francis Collins interviewed me and said, "Really? You really want to do

this? Would you not rather be doing more scientifically oriented work as opposed to administrative work?" I said, "Francis, take a look at the papers I have been publishing lately. I have been publishing about peer review. I have been publishing about grant metrics and research outcomes. This is the kind of stuff that I am now finding interesting." The kind of things that we are dealing with, is very different than when I was at NHLBI. We have a gigantic IT infrastructure, and we are making sure that our IT infrastructure is working. There are a whole set of fascinating problems there. Another interesting area that I personally find quite interesting is integrity and compliance. When I was at Cleveland Clinic, I was the Vice Chair of the Institutional Review Board which oversaw human subjects' protection in research. We were a high-volume operation and had to deal with a lot of difficult ethical issues. Unfortunately, I saw various ethical breaches and developed some expertise. This is a big part of what we are doing here. In our current unit, the theme is accountability and stewardship, and dealing with integrity breaches, compliance breaches, financial irregularities, and in some cases, actual crimes. We have dealt with some scientists who have committed crimes, so it is a very different kind of work.

Barr: Yes.

Lauer: Another part of our work is analyzing our grants portfolio, because we have massive amounts of grant data. It is a different kind of work, but at the same time it is kind of similar to what I was doing before.

Barr: Can you talk a little bit more about some of the policies and other issues that you have been part of negotiating? You have looked at harassment, duplicative funding, clinical trials and how to make them broader, early career scientists, and those from under-represented groups and women performing peer review. Can you talk about some of those sorts of issues?

Lauer: Perhaps one of the most interesting ones has been harassment. My very first day on the job at NIH, in the Office of the Director, I was asked about my thoughts on sexual harassment. I knew nothing about sexual harassment. Absolutely nothing at all, but it was rapidly brought to my attention that this was a problem and that NIH appeared to be completely ignoring it. We were not doing much. As time went on, Francis Collins became more interested, and started asking difficult questions, "What are you doing about sexual harassment?" Not much. "Why not?" I did not have a good answer. We felt that our authority only went so far, but he did not like that answer. He put together a working group. We then started exploring what we could do, and it turned out that we had some levers. To make a long story short, we have taken an active stance. Since 2018, we have dealt with over 500 cases of alleged harassment or discrimination. Out of those 500 cases, maybe about 25 to 30 percent turn out to be real (meaning that allegations are substantiated). Many are employee disputes and misunderstandings, but even so, we are talking about a large number of substantiated cases of harassment or discrimination. We have taken an activist stance, and one of the ways I know that is that I get nasty letters from lawyers.

One direct effect is that Congress passed a law that requires institutions to inform NIH of harassment cases which previously they were not required to report. We wanted this to happen. It has now ratcheted up the bar, raising the level of accountability that we are now expecting from universities and medical schools. I think that there is a higher level of awareness, and I think that we have had some positive effects. The universities are realizing that if their faculty are misbehaving or worse, we are not just going to sit and twiddle our thumbs. We are going to take it seriously, and we will push our authority as far as we possibly can to hold people appropriately accountable. I have to give Francis an enormous amount of credit, and I also want to give Carrie Wolinetz credit. She helped lead the working

group, but in OER [Office of Extramural Research], the way we think about it is that we not only help to develop policies, we implement them. We get “dirty” and into the weeds. Our whole Integrity and Compliance Unit is now working at a much higher level. We used to deal every year with about 60 or 70 new allegations of different kinds of misconduct. We are now handling over 500 new misconduct allegations every year. We have more staff, highly skilled people. We work closely with the Inspector General, with the Department of Justice, and with the Office of Civil Rights. It is hard work. Some of it is unpleasant, and many of these cases are messy. I think that one of the key messages is that we are expecting the scientific enterprise to work at the highest ethical level.

Barr: Definitely. This is in the cases of harassment, but would NIH require other sorts of things to be parts of grants? Obviously, it is not as pressing, but maybe sustainability of their lab practices, and other ethical issues like discrimination. That is not quite harassment, but it is still an issue.

Lauer: We are dealing with discrimination. Discrimination is often harder to demonstrate than harassment. We are dealing with hostile work environments, and we are dealing with other kinds of compliance problems such as financial irregularities. We have dealt with places that basically have no accounting system and the money just flows wherever it flows. They have no idea what is going on, and almost certainly, some of the money is being misspent. We have held institutions accountable for unallowable charges, and for charging us inappropriate indirect-cost rates. We have dealt with a variety of kinds of misconduct.

Another kind of misconduct that is getting quite interesting involves peer review. Peer review is done by humans, and therefore it is not perfect. On one hand, one of the strengths of peer review is that it is done by humans, and we get lots of people together to share diverse perspectives. One of the key points that we make is that there are a set of rules governing peer review. This is no different than the set of rules governing baseball or basketball. These are the rules, and if you break the rules, and depending upon how serious it is, you will be held accountable. You may be ejected. Our most critical rules (it’s actually a fairly easy one) is everything is confidential. Peer review involves sensitive confidential discussions about people's nascent ideas, and we expect that reviewers will handle these in an objective, unbiased, and confidential way. Unfortunately, we have had cases where confidentialities have been breached, and it looked like people were attempting to tamper with the system. We have taken on a much more activist stance. I have to give particular credit to Sally Amero, one of my former colleagues, for helping to push this. We are taking peer review integrity up to a higher level. I also want to credit Noni Byrnes, who is the director at CSR [Center for Scientific Review], who takes peer review integrity in general, and peer review integrity in particular, seriously. This is another area where we are much more active now than we were seven years ago.

Barr: How do you balance data sharing requirements with data security concerns?

Lauer: I think that it is a false dichotomy. Data sharing is a major advance; we are taking this to a higher level. Congress made it clear that this was required as part of the 21st Century Cures Act, sharing data is good for science. When I was a junior researcher at Cleveland Clinic, I used shared data. NHLBI, my future employer, interestingly enough, was sharing data. There were certain rules, but we got some of the data and we used it. We published some papers that I think were decent. Sharing data is a critical part of success in science. There are rules and one of the key rules is that we protect people's privacy. An individual, a human being, who participates in a research study – their privacy should be protected. That does not mean that their data cannot be shared, but their privacy should be protected, and their wishes should be honored. And we can do that. I do not see that as a problem.

Barr: Before we end this session because you have a call at four, how do you handle those in the extramural community who are frustrated with NIH and the grants-based system at large? I know there are ways that you have been trying to be more transparent about the whole process, through your Open Mic lectures and your blog. Can you talk a little bit about that?

Lauer: Well, I think that one of the biggest problems we have, and it is almost unsolvable, is that we have a hyper-competitive system. It is much more hyper-competitive than when I was applying for grants. I was applying for grants in the late 1990s and early 2000s, and at that time, the success rate was running around 30 to 35 percent. You had about a one out of three chance of getting a grant funded. Now that is competition, but it is not ridiculous. Unfortunately, for a whole variety of reasons, we are now in a different world. A number of years ago, we were down to success rates of about 15 percent. Only 15 percent of grants were getting funded. Now we are running around 19 percent. It is inherently a frustrating system because the vast majority of people are going to lose. When you submit a grant application, you have a greater than 80 percent likelihood of failure. It is a massive amount of work to put a grant application together. You have to write lots of grant applications, and then, even for scientists who get funded, most of our funded scientists have only one grant to their name at any given time, which means that they are only one grant away from losing all their financial support, or losing a big part of their financial support. That creates a great deal of anxiety. We should make our system as transparent and user-friendly as possible, and we do that, but hyper-competition is a fundamental reality of the world that we live in today. We have no magic bullets.

Barr: Now we are going to speak a little bit about your experiences with the COVID-19 pandemic which has been the past two and a half years. Quite an experience. When and how did you begin preparing for COVID-19? What were your thoughts when you first heard of SARS-CoV-2?

Lauer: My wife is an infectious disease physician. She was at Cleveland Clinic, and now she is at Johns Hopkins. She has cared for countless COVID patients literally from the beginning, back in March of 2020. Needless to say, I was already hearing about COVID-19 from her probably as early as December of 2019 and January 2020, when it was coming out that there was something very wrong in China. Then, in one of our internal meetings, Tony Fauci started ringing the alarm bell. This was in January of 2020 when for many of us COVID-19 was a curiosity. We were reading about in newspapers, but Tony said something like, “This is really bad. This is a serious infection, and it is only a matter of time before it comes here to the United States, and we are going to find ourselves with a serious problem.” I will also mention that one of our leaders in OER, Pat Brown, the Director of the Office of Laboratory Animal Welfare and a veterinarian with a background in public health, warned us as early as February 2020 that, “This one is going to go on for a long time. It will be a long pandemic.”

Barr: How did she know that?

Lauer: She had a background in public health. We all looked at her and said, “You are kidding, right? You do not really mean that.” And she said, “Yes, this one is going to be a long one.” Tony was certainly sounding the alarm bells early on, and I was hearing it here at home and also within our Office of Extramural Research. We already appreciated by January/February of 2020 that something bad was coming down the pike.

Barr: How did you contribute to conversations around NIH’s broader COVID-19 agenda as well as to specific COVID initiatives like ACTIV [Accelerating COVID-19 Therapeutic Interventions and Vaccines],

RADx [Rapid Acceleration of Diagnostics], caring for children with COVID-19, and RECOVER [Researching Covid to Enhance Recovery], in terms of the extramural grants components of all these different efforts?

Lauer: We had several things we had to think about. First, our staff. Like everybody else, we were threatened by a dangerous virus for which we had no treatment, no vaccine, and no immunity. We set up a group that we called the NIH Coronavirus Response Team that met every morning at 7:30 a.m., seven days a week. We talked about telework, IT infrastructure, and work environment. Other conversations focused on supplements from Congress and rapidly establishing a meaningful private-public partnership – something for which I give Francis an enormous amount of credit. We got a bolus of money from Congress to deal with diagnostic testing; those monies supported the RADx initiative, and we had to set up some rather unusual extramural funding structures in order to get things up and running. We got that going within days. It was like running an emergency room where we had a multi-vehicle trauma all happening at once. Clear everything out, we are going to take in all the casualties, and we are going to go full court press in every possible direction, to get things moving.

Barr: You talked about it, but what was it like to disperse so much money, for such an urgent situation, in such a short amount of time, and what were some of the considerations made in how to go about this issue, because this is not the way that NIH extramural grants usually operate?

Lauer: Right. From our end we had to think about multiple things. We needed to help our colleagues get money out the door. In OER, we are not the scientific experts, but we are the administrative experts. We needed to make sure that we could do everything we possibly can so that they could help get the money out and get it going to where it needed to be. We worked with our colleagues at the Department of Health and Human Services, and also through them, with the Office of Management and Budget, to work on grant flexibility. There are many rules that govern grants and contracts, and what was clear was that at this moment some of those rules had to be relaxed. We had to relax them in order that we could get the COVID work done, but we also had a whole slew of researchers who did not do COVID research and were seeing their world falling apart. They were being told, like many of us, to stay home. They could not do their work. They were seeing their animal colonies go away, and they could not do their clinical trials. They were seeing a different kind of disaster, and somehow, we had to work with our colleagues downtown to do everything we could to try to reassure researchers that we knew what they were going through, that we felt their pain, and that we were going to do everything that was legally possible to keep them afloat. We had a mega communication operation going on as well. We were working with every medium we could possibly think of and every key stakeholder that we could get in touch with to let them know that we are aware of the issues, we are aware of the concerns, and we were doing everything we could to be on top of them.

Another concern was oversight and audit, because whenever Congress allocates a large amount of money to an agency, the biggest fear is that it is all going to get lost, that it is going to be abused or wasted. The agency is responsible for getting the money out quickly, but at that same time we had to track every penny and make sure that we could say that we were protecting the taxpayers' monies properly. I think we did a decent job of keeping track of what happened, so that we could withstand the audits that inevitably come on down the line.

Barr: To date, is there any idea how many COVID-19 grants have been awarded by NIH, and what is that precent in the overall number of grants NIH has distributed in this period?

Lauer: According to our RePORTER web site, we have issued over 3700 competing and non-competing awards between FY2020 and FY2023. But counting grants is that it only tells a relatively small part of the story. Some of the monies supporting vaccine and treatment work came from the Department. Other funds went through existing contracts and cooperative agreements which were rapidly pivoted towards COVID-19 work. That's how we were able to get robust projects going so quickly. We actually had definitive trials going on COVID treatments before COVID was a thing. We were all sent home in the middle of March. Well, by the middle of March, there had already been a definitive COVID trial, an NIH funded COVID trial, going on for a month at that point in time, and that trial finished about a month later and yielded a treatment that actually works. That treatment is still being used today.

Barr: Is that the ACTT [Adaptive COVID-19 Treatment Trial] trials with Remdesivir?

Lauer: Yes, that is Remdesivir. My wife tells me she uses Remdesivir as part of her standard protocol. The vaccine trials started almost immediately, and the amazing thing is that they moved all the way through phase one, phase two, and then definitive phase three trials in a matter of months. At the beginning, when this was all starting, the vaccine experts said a year and a half, two years, two and a half years, three years, to get a vaccine. Some of us were thinking that, well, that is crazy. We are going to isolate ourselves at home for three years? I think it is one of the greatest triumphs of modern medicine, that we have effective vaccines. They are not perfect, they have their problems, but nonetheless, remarkably effective vaccines within 11 months of when the virus was first discovered. That has never happened before in medical history, and I think, that is something that we should be proud of.

Barr: Definitely. Have some of the funding mechanisms worked better than others in funding COVID-19 research, and if so, how? You were talking about all these different kinds of grants and contracts.

Lauer: Yes. One mechanism is called Other Transaction. This is a typical government term, right? If you hear it, you have no clue what we are talking about. Other Transaction Authority was given to us by Congress in a limited degree many years ago, and then a couple of years ago, in the setting of the opioid epidemic, Congress expanded our Other Transaction Authority. Other Transaction is not a grant and is not a contract. It is not bound by grant laws and regulations, and it is not bound by contract laws. However, it is not completely lawless or chaotic. There are rules, but nonetheless, it is much more flexible. We are now spending about one and a half billion dollars a year (it's a big part of our budget) on Other Transactions. ACTIV was set up by Other Transaction. The so-called CEAL initiative [Community Engagement Alliance], a large community-based initiative for COVID research, was set up by Other Transaction. The RECOVER program, which is this mega program on long COVID was set up by Other Transaction. Other Transaction turned out to be a remarkably powerful mechanism by which we can get things done quickly, and we can also be a lot more flexible. Stopping a grant is hard and stopping a contract is hard. With Other Transaction, we could literally say from one day to the next that we do not feel like doing this anymore, and just shut the whole thing off. You know we would not do that, but the point is that we do have that degree of flexibility, and perhaps, more realistically, what we can do is that if we see that a particular line of work is going nowhere, or not going well, we can rapidly say, "You know what? Let's stop that, and let's move this way instead, and move the money."

Barr: Did that happen with the convalescent plasma work that happened at some point in the pandemic and was kind of sidelined to some degree?

Lauer: Convalescent plasma was one of our disappointments. We were not able to get high-quality large-scale trials going for a long time. Unfortunately, tens of thousands of people, maybe even more received convalescent plasma and it either did not work or it worked but only to a limited degree. During one of our Building 1 senior leadership meetings Francis said something like, "I am unhappy about convalescent plasma. It is just not going well. We are going to be having a conference call at 11, and so Mike, can you be on it?" I looked at my schedule and I had something else really important scheduled at the time, and Francis looked at me as if to say, "No is not an acceptable answer," so, I said, "Sure, I will be on it." At that point, I really had little insight into what was going on. He said, "I want you to be on it and then I want you to tell me what you think". So I am on this call, and afterwards, I guess Francis and I are chatting, and I said, "Well, it looks like it is a disaster. It does not look like things are going well," and he said, "That is right, things are not going well so we need to work on this." So I had the opportunity to work with FDA on some of the data that they had on convalescent plasma. I could be an epidemiologist all over again. It brought back memories of good times, and I got to work with outstanding statisticians at FDA and at NIAID. I also used the opportunity to develop new programming skills that I did not have before. Why not? I always look for opportunities to learn how to do new things.

Barr: What did you learn? What language did you learn?

Lauer: In the old days, I used to do most of my statistical programming in SAS, but about 25 years ago I shifted to R because that is what my colleagues using. There is a form of R which is called R Markdown that enables you to put together sophisticated reports in which you combine text, statistical analyses, tables, and graphics. I remember one of my fellows, a long time ago, showing it to me, and I remember thinking, "I will, at some point, learn how to do this". It never happened. So the folks at FDA were using R Markdown, and I said, "Okay, this is the excuse I need. I am going to learn how to use this." It took me a few weeks. Now we are using R markdown routinely in OER for our statistical reports.

Barr: With all the grants work?

Lauer: We now are using R Markdown to give reports to NIH leadership and also for some of the public reporting that we have done. It is a powerful package. I have the convalescent plasma experience to thank for giving me the impetus to learn it and to encourage my OER colleagues to use it more often.

Barr: Due to the speed that the grants needed to be dispersed, many allocations initially were dispensed in the form of supplements which has drawn some criticism about not allowing as many early career scientists and those from less funded institutions not being able to take part in COVID research. As the pandemic lingers have there been thoughts given on how to tackle this situation?

Lauer: If you think about it, let us use the middle-of-the-night emergency room analogy and say you have a mass casualty event. You know who you bring to the front lines. You bring in your experts. This is not the time to be bring in medical students. They can observe but not come and do any of the actual work. So, that was kind of what was happening back then in 2020. The idea was to take advantage of the robust already-existing scientific infrastructure and cohort of experienced investigators and pivot them to COVID. We have a separate Next Generation researchers initiative going on for a while. We started that back in 2017, and it has been quite successful. We are funding more early-stage investigators than we ever have in the history of the agency. Every year, we are funding larger numbers than we had the year before. I think this year we are going to start to stabilize, but in any case, our commitment to funding early career investigators has been firm and real, and that continued through the pandemic. Even as the pandemic happened, each year, we were funding more early career investigators than we

were before. My guess is that most of them were not working on COVID. Most of them were working on other areas of science that are interesting and important but not COVID.

Barr: Which discussions have there been about the length of time of COVID grants? Biomedical research is criticized often for being really slow, but then there is discussion about the speed of COVID projects in terms of their rigor. Some of them have seen that they are being put out too fast. How do you strike that happy medium?

Lauer: For standard grants, it takes a long time. It takes three months to get reviewed, which actually is not bad. Then, the length of time from when a grant comes in and the time that it gets funded can be nine months to a year. It can be a long time. When grants do not get funded and the investigators will submit a revision, they go through this whole process all over again, so it could very well be nine months to two years from the time that they initially submit an application until it actually gets funded, if it actually gets funded at all. That is a fairly lengthy process.

All of us would love to speed it up, but you are dealing with a very high-volume system. We get 80,000 applications a year, and we give out about 16,000 new awards per year. Since most awards last four or five years at any given time, we have 60,000 active awards. We are by far the largest agency in terms of the number of grants that we are funding. Somehow, we have to make sure that at the end of the fiscal year, we are down to the last penny. I should also point out that in addition to individual grants, we fund larger-scale research networks, some funded by contracts, others by cooperative agreements. This illustrates the genius of Tony Fauci. Tony Fauci was setting up research networks years ago, and his thinking, his vision was that in running an infectious diseases funding agency, we are going to have to deal with new infectious diseases. We do not know what they are going to be: HIV was a new infectious disease, SARS was a new infectious disease, MERS, Ebola, Zika, and you can go on, and on. We have these new emerging infectious diseases, and standard grant or contract mechanisms do not really work. Well-established networks make it possible to pivot to new problems, like COVID-19, in a rapid and robust way.

Barr: How has COVID-19 affected peer review?

Lauer: What has happened with peer review – this is fascinating – is that we went overnight from about 10% virtual to a 100% virtual. In some respects, it has dramatically changed the dynamic of peer review, and in other respects it has had no effect whatsoever. Let me explain. We already knew from some data that had been obtained pre-pandemic that virtual meetings worked. Grants got essentially the same kind of evaluation in a virtual meeting as it would get in an in-person meeting. It was about 10% of the business, but all of a sudden, one day we were all told that we have to go home and cannot come to work, not only here at NIH but every university was sending everybody home. Nobody was traveling, and what were we supposed to do? So, literally within days we went to 100% virtual. Fortunately, our IT system was such that it went fine. I will not say there were not problems, but it went fine, and peer review continued. We actually received more grant applications than we had in times past. I think part of the reason why we got more grants is that scientists are being sent home, they were not allowed to work in the lab, so what were they going to do? They were writing grants.

Barr: Do you think that it is something that may continue after the pandemic, that peer review would be conducted virtually?

Lauer: That is a great question. So, what did we discover? Well, one thing we discovered was that it worked. We could actually do it. The second was that it did not really affect the review outcomes. The review outcomes were essentially identical. The third was that it saved money because we were not traveling people. We were not paying for people to fly in airplanes and stay in hotels. We also probably had an easier time recruiting reviewers, because think about it – if you are a reviewer and you have got family responsibilities, you do not like to travel. We are not totally sure what we are going to do. I think, at this point, what we are looking at is a 2:1 arrangement: two virtual meetings a year and one in person meeting a year. We are going to experiment with that and see how that works. We are not doing hybrid meetings just yet because hybrid meetings are difficult and challenging in their own right. It is hard enough to run a 100% virtual meeting, or a 100% in-person meeting, but doing a hybrid meeting presents a whole new set of challenges. We are concerned that we may lose reviewers. Reviewers may say, "Yeah, I really like not traveling. Especially if I am living out on the West Coast. I really like not traveling, so if you are going to make me travel, I am sorry, I can't do peer review. On the other hand, if you are willing to make this 100% virtual, send me the materials and I will work on it."

Barr: Interesting things to think about. With the increasing number of grants, have there been an uptick of extramural research staff to help guide researchers and process these grants and all the other things that go along with it behind the scenes?

Lauer: Yes. We have been hiring within our own office. Within the Office of Extramural Research, we increased our staff by about 25% over the last few years. We have also been hiring more review officers to decrease the workload on individual review officers and that appears to be working reasonably well. There has also been hiring of additional program staff. We are, of course, pleased with recent NIH budget increases, but increased appropriations necessitates more staff to oversee the additional work.

Barr: You mentioned it earlier, but obviously, the pandemic affected researchers in a lot of different ways: people caring for families, travel restrictions, not being able to work, early career scientists, and training. Can you talk a little bit about the surveys that OER put out over the course of the pandemic as well as how you worked with the extramural community in terms of allotting more time or adjusting the scope of these projects so that these grants could be a success?

Lauer: We did implement a number of flexibilities which were allowed us by OMB [Office of Management and Budget], and I think that offered some sense of relief to external researchers. I have to give an enormous amount of credit to the Office of Scientific Workforce Diversity, for helping design that survey. We conducted the survey in October/November of 2020. The results were not surprising, but they were still interesting. The groups that were most concerned about how the pandemic would affect their careers were early career investigators, laboratory-based investigators, and Asian Americans. Another finding, again not surprising, but nonetheless important, was that women with children under the age of five were the ones who saw their productivity suffer the most. There were worries at the beginning, and there are still worries now, that the pandemic would have a disproportionate effect on women scientists, and particularly women scientists who are early on in their career. Robin and I (Robin is my wife), we were actually thinking, "Well, we could not have timed this better. Our children are grown up, they are out of the house, they are married, they have their own families, and we are here by ourselves, and we do not have to deal with childcare." Robin was spending her days taking care of COVID patients, so she was plenty busy, and then I was dealing with COVID at NIH, so I was plenty busy. So we were in the "ideal circumstance," but around us we saw people earlier in their careers, and earlier in their family lives, for whom it seemed the whole world was falling apart, with their dreams were just blowing up in smoke. It was a scary time.

Barr: How was the pandemic positive in advancing scientific research funding?

Lauer: I think it has been positive in a number of respects. Information was made publicly available much more quickly. There was greater use of preprints and journals were publishing results much more quickly. It created new collaborations that previously did not exist. The ACTIV collaboration, the public-private active collaboration, that worked out remarkably well. I think, there was a real sense among scientists across the country, and not only scientists but scientists and community leaders, that they had to get together. They had to work with each other, and there was just no way around this. Convalescent plasma was one of the exceptions, where that kind of camaraderie did not quite happen, but in many of the other areas, it really did, and we have results to show for it.

Barr: What cracks in the scientific infrastructure do you think that the pandemic has exposed and how has that been dealt with through the lines of the pandemic?

Lauer: I am sorry Gabrielle. I did not get the beginning of it.

Barr: What cracks in the scientific infrastructure do you think that the pandemic has exposed?

Lauer: Well, one of the biggest cracks is that we have a fragmented health care system with silos of health IT. I saw there was a commentary in the New England Journal this week talking about how it is difficult to know how well vaccines work in this country because we do not have an integrated data system. I remember Tony used to say something like, "Well, if we really want to know what is going to happen with COVID, we just look at Israel because in Israel they have their act together. They have a robust, highly integrated health care system and their IT infrastructure is cutting edge." The result is that they knew exactly what was happening. They knew how well the vaccines were working, and they were able to make rapid research and policy decisions based on super high-quality data. We cannot do that here in the United States. Another good example is the United Kingdom. In the UK, they are able to run large-scale clinical trials at low cost because they can leverage their integrated health IT platforms. So if I give a patient a certain drug and I want to know what happens to them – do they get hospitalized or do they survive – it is all one big system. It is actually multiple systems, but they all talk to each other. This way you can run a trial much more efficiently and at much lower cost than we can here in the United States. Another problem: we wanted to do studies on home testing of COVID tests. That turned out to be remarkably difficult because the CDC is not an overarching public health structure. What we have instead is a patchwork state and local public health systems that are fiercely autonomous and underfunded.

Barr: It is unfortunately. How have or do you think the opinions of the public and current events like the exposed racial tensions in the U.S. in 2020 affect the grant processes? The public, for the first time, became very much aware of biomedical research and has very strong opinions on it for the first time. Has that impacted you at all on how you thought or talked about your work?

Lauer: Oh, yeah. It has impacted us a lot. Francis would often say that one of his biggest disappointments is that we went to all this trouble to develop an effective vaccine, and a third of Americans are just not going to take it. They are not going to take it just because they are not going to take it. That is just part and parcel of lots of other things. They won't allow themselves to be treated. They won't wear masks. They won't get themselves tested, and they won't isolate themselves if they get sick. They believed the conspiracy theories. They do not trust – there had been a great deal of mistrust

of elitists [Lauer uses air quotes around elitists] and experts for a long time. Sometimes, I have to remind the people who are leaders at universities, "You know, there are many Americans (maybe even most Americans) who do not think highly of you. They see universities, medical centers, and medical schools as a negative. They think that you are making things worse, and we've got to address that." The Black community has distrusted biomedical research for a long time, and for good reason. That has really deep effects on the community. I took care of quite a few Black patients when I was at Cleveland Clinic, and for the most part I got along with them well, and I think I helped them, but I do remember some of the black patients saying to me, "I will not be a guinea pig." I get that sentiment comes from. With the Tuskegee study and a whole variety of other very bad experiences that the black community has had and with the depth of the racism that we have had in this country, I completely get why many of them simply do not trust us. The NIH did attempt to address with the RADx studies and the CEAL studies. This is one of the biggest problems I think we have in science. There is a deep, deep distrust, including among some very highly educated people in this country. There is deep distrust of science, of the scientific approach, of the academic community, of the government, of so-called experts, and this distrust is causing enormous amount of damage. People have died. This is not just a political or academic debate.

Barr: What do you feel you have learned from this situation and would apply to other scenarios, and similarly, how do you think the pandemic has impacted policies, practices, and approaches associated with extramural research in the long term?

Lauer: One thing I have learned is that, for the most part, the government works and actually works quite well. This is one of the greatest blessings that I have ever had. I get to work with amazing people in my immediate sphere as well as the rest of NIH. Our extramural staff – these are amazing people. They are dedicated, mission driven, and want to do high quality work. They are highly educated and well-trained. It is popular in the newspapers and the press to talk about how government does not work, and of course, politicians like to talk about how government does not work. Of course, like all organizations, we do have our failings and problems. When a government agency messes something up, that becomes a big event. When a company messes something up, they move on. We have also learned more specifically that the extramural research enterprise is resilient. The world did not fall apart. This is not at all to minimize the extraordinary stresses that people are feeling. Researchers are back at work. Their laboratories are humming again, and clinical trials are enrolling again. Despite all the threats – and it was incredibly gloomy particularly during the first say four to six months – the system has withstood that stress and has shown resilience. I think we have learned to develop a more open, creative, and flexible approach towards supporting extramural research, while at the same time being careful to assure the highest levels of accountability and stewardship.

Barr: Can you talk a bit about some of your creative and flexible approaches?

Lauer: I think that you know one of them, as I mentioned before, is OTs (Other Transactions). Within our office, we are right in the middle of Other Transactions. All Other Transaction proposals have to come through our office. You do not have to follow the grant and contract rules, but it also means that the opportunity for mess up is much greater because you do not have those guard rails. When we look at all Other Transaction proposals, we look at two things. Number one: is there a strong justification about why you need to use Other Transaction as opposed to a grant or contract mechanism? The second: what guardrails do you have in place so that we can feel comfortable that things will move along? This is now one and a half billion dollars of the portfolio. This is not some little peripheral experimental program; this is a very big part now of what we do in OER. We have also learned to be flexible with late grants. Grant comes in a few days after the deadline; we are not as strict about that as we were before, and we

do allow late grants to come in. Another flexibility that we have implemented is to allow scientists to submit more preliminary data after they submit their grant, but before the grant undergoes peer review. At the time, we thought that was a really big deal, but it turned out to be a remarkably manageable. That is another example, and that is something that was well received by the by the community. They like being able to do it, and also it shows that the agency understands their stresses.

Barr: In addition to being a scientist and an administrator at NIH, you have also been a person who has been living through the pandemic, so what have been some personal opportunities and challenges that COVID-19 has presented for you and how have you coped with the increased stress and morale for both yourself and those that work with you?

Lauer: I have to say that the first few months were hard, and there was a time that I was skeptical about what was going on. Of course, I was going along with it, but I was not really sure that we were doing the right thing. There were times I was angry. Not at work, I was quite careful about that, but I was not happy. I have close friends, and we would confide with each other about how unhappy we were with what people were doing although we could not come up with better ideas. That was part of it. I think another important part is – thank God my wife and I are very close and continue to be. We have been married now for 32 years, and we were both dealing with COVID and the COVID stress, so we could relate to each other. Even though the kind of work she does and the kind of work I do are different, we had a lot to talk about over the dinner table. The other thing is that we had some major family events which occurred during this time. Our younger son was supposed to get married on Memorial Day of 2020. When the pandemic first started, they were nervous, and we said, "Oh, don't worry. By Memorial Day this whole thing is going to be over. This is just going to be a few weeks," although as I told you, Pat Brown told us this was going to last a long time, but I did not want to believe it. Well, we had to push the wedding off, and we wound up doing the wedding in August of 2020. It was amazing. We had 120 people come. We held it in a huge hall, so we had social distancing. Everybody was seated six feet apart, only one family per table. We gave people ropes so they would not hold hands while they were dancing. We had 100 people in a room that was designed to hold a thousand, so there was plenty of space. Then what we also did was that we zoomed it. We probably had about 400-500 people who attended the wedding by Zoom, and we had 120 who were there in person. The bride and the groom, our son and his bride, were careful. We gave everybody hand wash, face shields, extra masks, and gloves. We had Plexiglass everywhere. For the smorgasbord there was plexiglass. We took every safety precaution you could possibly think of, and thank God, nobody got it. I mean, it was amazing. Nobody got it. The first two weeks after the wedding, we were sitting there like this [Lauer makes a gesture off-screen]. Nobody got it. The bride and the groom wore their masks throughout the event, so they modeled for everybody else. People wore their masks essentially the entire time, and that was probably the most important thing. So, we had that major event. Thank God, it went fine, and then, last December, we had our first grandchild.

Barr: Oh, that is great!

Lauer: This is our older son. They got married back in 2018, so they had a more conventional wedding. So that happened. We had some nice family events.

Barr: Have you gotten to see your new grandchild?

Lauer: Oh, yes. Our granddaughter, absolutely. In fact, next weekend we are going up. She is cute! I think these have been also very helpful. Another interesting thing – we had an event in OER, a social

event. They would randomly assign us to meet with people whom we may or may not know, and then they gave us questions. One of the questions that was asked was, "What have you started doing new during the pandemic? What are you doing now that you did not do before?" For me, this gets back to your question about music. For me, I started getting into shows. I did watch some shows before. My wife and I saw *Phantom of the Opera*, and we saw *Cats*. We had seen some shows but few. It was not a big part of my life. It turns out that there are shows on video. *Hamilton* came out on video in July of 2020, and it was amazing to watch. It was like, wow! It turns out there are shows on video, including some of the shows I did as a viola player in pit bands. I am now spending a good part of my time watching shows or watching musicals that were movie musicals, and it is a lot of fun. Next week actually, my wife and I are going to go see *Hamilton* at the Kennedy Center. We are going to see the real thing.

Barr: That will be wonderful. Do you have a favorite one that you have seen?

Lauer: *Hamilton* has definitely got to be up there, and I recently saw a West-End production of *Gypsy*. I do not know if you have heard of it, but it is one of the great classics. Another fun show is *Newsies*. I do not know if you have heard of that one. To watch the dancing in *Newsies* is like watching Olympic level or higher gymnastics for two straight hours along with fabulous music and song. "Really, human beings can do this?" Those are some of the fun ones.

Barr: Is there anything else that you would like to share about your COVID-19 experiences or comments about your time at NIH?

Lauer: I feel blessed. I think working at NIH has been one of the greatest blessings I have had. I feel blessed that I got to work with Francis Collins. Francis Collins has got to be one of the most amazing human beings that that I have ever known. As I told you, Betsy Nabel was the person who recruited me, and I had the opportunity to work for her for a few years. It is an amazing agency. We have problems, of course, and we spend our days dealing with problems. I told you, at RPI our motto was solving problems. It is amazing what we actually do. We process 80,000 grants a year. We give out 60,000 awards a year. We run an enormously effective research program; all that seemingly just happens. Despite the stresses of the pandemic, it all continued. We continued. There was no interruption. Peer review continued, and the grants continued to come in, and they continued to be handled, and there were no major mess-ups. I think that is amazing. It is something which every so often, we have to step back and remind ourselves when we are having a lousy day and everyone is screaming and yelling, but for the most part, our system is working well. This is not to diminish the problems, but it is working well.

I also think that our leaders, Francis, Larry, Carrie Wolinetz, and others, are deeply visionary people who are never happy with the status quo, always think that we can do better, and are not afraid to deal with difficult problems. Harassment was a difficult problem. Racial discrimination is a difficult problem, and by the way, that is another thing I have been working on. I have been reading a lot about racial discrimination. I grew up with racial discrimination because I was heard about it often from my parents. They grew up in Nazi Germany, so they were subject to legal racial discrimination, racial discrimination that was openly sanctioned by the government. The last time I spoke with my mother, she talked about Kristallnacht. This was one of the most impressive experiences of her life. Thank God I never had to go through anything like that. Francis and other NIH leaders are not afraid to deal with this. I think that for all the challenges and problems that we have, we have a lot to be incredibly proud of, and it has been a great blessing for me to be part of it.

Barr: Did you guys get a lot of pressure with the grants that went to EcoHealth Alliance? There have been a lot of situations about that grant, and so did you have to deal with some of that fallout?

Lauer: Oh, yes. There was a press conference where the president said, "That grant will be canceled" The grant was canceled, and my signature was on the letter that canceled it. Actually, when we were talking about who was going to actually do it – who was going to actually cancel the grant – I said to my supervisor, Larry Tabak, "I am the director of extramural research. It is coming from me, so I am taking this, and I am going to take the heat that is going to go along with it." Let me just point out here, that this was a team effort. There is an old line in management that 20% of the of the items take up 80% of your time, and I would just modify that, I would say a 0.1% of the items take up 99% of your time. This one grant has taken up a massive amount of time. I feel bad for Tony Fauci and all the ridiculous stuff that he had to put up with: the threats and the false narratives. I mean, there were problems with the grant, but the false narrative is that the grant created COVID. That it was because NIH funded that grant what led to an accident that happened in a Chinese lab that caused COVID. Well, that is not even close to the truth. There is absolutely no way that that happened. It does not mean that there were not problems with the grant, but unfortunately, this has been an incredible time sink. By the way, I am still spending a huge amount of time dealing with that grant. There has been stuff that has been written up. You may have seen that there was an article that was written somewhere that I started referring to the grant as a "gift" – I started calling it the gift. There was a reporter who described a scenario by which he figured out, or he claimed to figure out, why I was calling it the gift. Well, it had nothing to do with that. It was it was an internal discussion one day, and we just said, "Oh, yes, the EcoHealth Grant. The gift that keeps on giving." So, we started calling it the gift.

Barr: Yeah because there is criticism first that NIH ended the grant too soon, and then there is criticism about the grant, like you said, that it had a lot of issues and caused COVID. It feels like there has been every possible thing said about this.

Lauer: There have been dramatic conspiracy theories. If you think about it, NIAID is a $4 or $5 billion a year enterprise. This was a grant of about $500,000 a year, so compared to the NIAID budget, it is one tiny little thing. Then the amount that was going to the Chinese lab was about $130,000 a year, so that is even less. It was a tiny amount of money that was going to that Chinese grants' budget. Nonetheless, this is an ongoing story.

Barr: To be continued. Thank you very much for all your service during COVID and also throughout your career. I wish you and your family all the best.

Lauer: Thanks, Gabrielle and the same to you. Take care.