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WebEx Q&A Session

Developing the NIH-Wide Strategic Plan for Fiscal Years 2021-2025

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Q&A SESSION (3/9/2020)

DR. SARAH RHODES: Okay. So, we have one question here from the audience. How will this Strategic Plan be used to coordinate across NIH Institutes and Centers?

DR. JAMES ANDERSON: That's a very good question. As I said, this is broad guidance, direction, and priorities for the entire Agency, so it would be, as we pointed out, issues like workforce development. We have some common approaches to workforce development that all of the Institutes and Centers use, such as specific funding mechanisms for specific categories of trainees. Those are available and used by all Institutes. In contrast, there might be a very specific one. We have a little unit that's responsible for veterinary training, and they have training opportunities just for vets as opposed to things that are cut across. So, all of the things we talk about in the NIH-Wide Strategic Plan are tools or approaches that are used by all of the Institutes. That's how it's used.

DR. SARAH RHODES: Second question. How will this development process ensure that the NIH-Wide Strategic Plan will align with the research priorities of other federal agencies—specifically, other federal research agencies?

DR. JAMES ANDERSON: Okay, that's a very good question. We are...so, each Agency has its own authorities and mission from Congress, so we attempt not to overlap but to complement with what others do. We do that by working groups, other opportunities to know what they're doing, what they intend to do so that what we do complements, and sometimes it's part of a pipeline of development with what we do over the government-wide...but the short answer is, we intend not to overlap but to synergize with the others and use a variety of ways to know what they're up to and for them to know what we do.

DR. SARAH RHODES: There's another question for you. How will the current fiscal climate impact NIH's ability to achieve the goals in the Strategic Plan?

DR. JAMES ANDERSON: Well, two answers to that. This document provides how we do work, why, and the intention, and that's scalable. You know, if you had half the budget, we'd still use the same Strategic Plan. But fortunately, NIH has had very strong bipartisan support for years now, and our budget has continued to grow. So, again, we will do the best we can with the funds that are provided.

DR. SARAH RHODES: How does NIH envision addressing precision or personalized medicine in this Strategic Plan?

DR. JAMES ANDERSON: Right. The theme of making treatments appropriate for the individual based on everything about them—from genetics to social environment—is a very strong theme across NIH and all of the programs that we have. It's also being addressed by several specific programs that continue to grow and will be a real foci for trans-NIH research in the future, and the strongest example of that is the *All of Us*SM Program, which continues to grow in size and support from Congress. The number of participants continues to skyrocket, and we expect that will be a platform for finding participants and providing a set of basic research data about them as we go forward. So, I know that many of the Institutes are planning to use that platform in the future.

DR. SARAH RHODES: Given the events of the past weeks, how will the NIH integrate emerging infectious diseases globally in the new Plan?

DR. JAMES ANDERSON: Well, this has always been a capacity that NIH has built. I want to give you an example that I find really quite striking. In the past, the ability to produce antigens and develop a vaccine took years. You find from MERS to SARS, and now to the recent coronavirus, that the timeline from quickly responding to starting with vaccines has now been down to 2 months, versus perhaps a decade, several decades ago. I think our capacity to do that has ramped up, and we are in a good position to provide the research base for responding. There are also many drugs that were shown some effect in previous corona-like viruses. These have already been in human clinical trials for some time, as well as in laboratory studies. I think a really striking, fascinating example is our investments in—you wouldn't have thought this, perhaps, 10 years ago—cryoEM has become really a foundational structural biology approach that has rapidly emerged and was one of our bold predictions, actually. And you've all seen in the newspaper—and you can also go to the NIH website—that a week and a half ago, the cryoEM structure of the surface proteins of the new coronavirus were published. Those structures are now known, and they're being used to inform antigen production and vaccine development. It's all of those general capacities that weren't for a specific cause. That's the intention of the current Plan is to just have the

processes for science ready and optimized.

DR. SARAH RHODES: How does NIH take advantage of the latest technology developments?

DR. JAMES ANDERSON: Well, that's an interesting question, because most of the work that happens is through competitive funding applications, so much of what we do is guided by the insights and intention of investigators like many of those on the phone, I'm sure. So, we're responsive to the communities' insights into what's important to do, including technology development, and Institutes such as NIBIB and NIGMS have programs for technology development. Again, an insight that often the ability to do something new like CRISPR or PCR is what creates entirely new fields and capabilities. So, another aspect of that is we also invest in small business grants, which can take the technologies out and commercialize them. [pause] Okay, we've got another?

DR. SARAH RHODES: Are there programs of quick and short research, such as those that could address the immediate coronavirus issues?

DR. JAMES ANDERSON: I'm not sure I understood the question. Marina, do you want to interpret it?

DR. MARINA VOLKOV: I think that the question gets to how does NIH provide rapid response funding for emerging public health emergencies, such as coronavirus? Or the opposite: How do we have quick and fast ways of responding to scientific opportunities?

DR. JAMES ANDERSON: See, well, if you want to keep it just in the current response, NIH maintains an infrastructure that's capable of responding, whether it's a resource—again, the cryoEM facilities are there ready to work on a new virus protein—or if an animal model is required, such as our primate centers for particular issues—Zika and Ebola was an issue—they are ready and able to accept funds, often through supplements to existing awards, or just additions to the infrastructure that we've developed. Also, within NIH, for example, is the Vaccine Research Center, which for decades has been at the forefront of being able to respond quickly. And this, I think, is in the category of what we call fundamental governmental responsibility, is to have the infrastructure in place here within the government to quickly pivot and address a new issue, such as has been done with corona.

DR. SARAH RHODES: Okay. We have another one. How will the NIH-Wide Strategic Plan manifest scientific workforce diversity across the Institutes and Centers?

DR. JAMES ANDERSON: Well, one of the cross-cutting themes of our current Plan—and actually quite an active part of much of what we do—is to recognize the importance of diversity in the workforce. There are quite a number of programs that are devoted to that. There's investigations of funding differences and what the origins of those are and how we might address them. The NIH Common Fund, which is a pot of money that we use for projects that are participated in by multiple Institutes—we have several diversity-enhancing programs there that are really at the undergraduate and slightly above level. We have a new program that will be starting very, very shortly that's more addressed at the early faculty diversity pipeline. So, I'm not sure how to reassure folks. This is a major issue for all of us at NIH, and we address it in quite a number of ways.

DR. SARAH RHODES: Are the bold predictions in the current Plan being evaluated, and how did we do?

DR. JAMES ANDERSON: Yes. Well, I can give you an overview of just at a baseball level. There were 14, and we had home runs on four, and the other were about half strikes and half fouls. So, we have a ways to go, but, I have the pleasure of working with Francis Collins, who's a visionary in science and also a bit of an ambitious provocateur at times, and he put the Agency up to these bold predictions with the expectation that they weren't bold if they all came true. So, we'll be setting another set like that for this one. [pause]

DR. SARAH RHODES: How does NIH infrastructure support different scientific research areas using different research models?

DR. JAMES ANDERSON: Okay. If I understand the question, these would be investments not just in people but in physical things and places and processes. So, this is anything from, let's say, clinical trial networks that are set up to accept and work on new trials...they don't have to start them de novo. They are things like zebrafish facilities, where it's quite expensive. No one would ever de novo set up a facility to work with zebrafish just for one project. The things like the Cancer Centers and the CTSAs. I

think there's a recognition that we just have to have a platform in place that can accept a wide range of research that we hadn't all anticipated. So, this is a significant part of the NIH investment, as is the funds that we use to train our workforce. So, all of that is not a specific scientific question. It's developing the capacity to address any questions. That's why it's very relevant for the NIH-wide Plan, as opposed to an Institute-specific disease-focused goal, but thank you for the question. [pause] Okay. [pause] I guess I'm going to toss out a few here and see how you respond and how fast people can type. We're interested in whether you used our previous Plan and whether it informed how your institutions' work or how you think about the future of science. So, if that's something that would be helpful. If you tell us you never read it, that would make us feel bad. [laughs] If you said this was very useful and important for us but other parts not, that's very helpful. And we're also curious what your thoughts are on the five cross-cutting themes that we outlined and if there are additional themes you think are important. And again, I'm challenging you to type quickly, but these are also things that can be addressed in the RFI. Oh, actually, a quick question. If you have worked with our previous one, what did you think of the length? We tried to keep it short but provide enough information so it's very clear how we think about the issues at the Agency but not to make it a catalog and unreadable. So, that's...we're curious about that. So, we'll give you a few minutes if anyone wants to respond. Otherwise... [pause]. Okay. We've something?

DR. SARAH RHODES: Can I ask the question?

DR. JAMES ANDERSON: Thank you. Let's roll with those.

DR. SARAH RHODES: How will NIH use all of the input it receives from industry?

DR. JAMES ANDERSON: That's a good question. You know, we have numerous programs with industry—[the Accelerating Medicines Partnership]. As an example, before we start new programs—certainly Common Fund programs and other programs where there's already industry involvement—we will typically bring in representatives—research vice presidents, groups from pharma, biotech—and ask questions like: What are the obstacles? What are you...what could NIH do, not to help your company specifically, but to help the field that you're working in? So, we often...I don't think most people see this, but we engage industry as a source of insight into what are important things to work on, and we have

programs with industry specifically. The AMP program you can find on the website. AMP is a very good example of that. It's precompetitive, so they have to share data with each other, and there's no conflict of interest—we're not helping a particular company—but industry is quite willing to share and work in that precompetitive area, and they're good partners for us.

DR. SARAH RHODES: There's another one. This is quite long. How does NIH view the new and/or increased allocation of funding to historically underfunded disease research areas? Does NIH use metrics—I assume for this—for example, disease prevalence, available treatment options, or treatment burden?

DR. JAMES ANDERSON: Yes, that's a very good question because it gets at how we set priorities, and we do take into account the disease burden of things like cancer. Certainly, there's a higher investment than the common cold or hepatitis A, but these are not the only inputs. Certainly, the opportunity to make progress in an area is a determinant. If there's an area where there's just evidently no insights recently or progress, we might stimulate ways to think about a problem, but it's not necessarily the time to invest if the progress is slow. Another would be whether there's appropriate people to do the work. Part of our grant review criteria is both the environment and the personnel. Are these the people to do the work, and is this the place? So, we take a range of inputs in setting the programmatic priorities for what we fund. In addition, I'll say the very, very strong focus, which will continue, is on early stage investigators and assuring that there's a good flow of new investigators into the workforce. [pause] I'll just address, that Congress also has interests, and they occasionally direct funds, although this is certainly not the most prevalent way that NIH guides its funding. Most of this done through investigator-initiated insights and almost an intellectual dialog between the NIH and the community of what the priorities should be. [pause] We're going to wait for one more. I'll just add another priority setting. It's been a long-standing priority at NIH to fund research on rare diseases for several reasons. We have the Office of Rare Diseases Research that's focused on this. There's a responsibility to take care people with rare and unusual conditions and not neglect them, and another is just the biologic insight that often understanding a rare disease provides a great deal of insight into just common human biology. So, we'll go on if there's

another or so? Alright, then with that, I want to thank folks for your attendance, and I want to encourage you to respond to the RFI if you wish, and thanks for your time today. That concludes the webinar. Oh? We have one more. [pause]

DR. SARAH RHODES: Along the lines of funding early-stage investigators, isn't there a chicken and egg problem where researchers tend to devote their time to well-funded areas? How does NIH view changing that cycle?

DR. JAMES ANDERSON: Oh, that's a fascinating question. So, we don't like investigators to work on the same old thing [chuckles], and we're quite aware of that. And there are ways to encourage people not to do that. We have a whole set of grant mechanisms, for example, that are based on the Common Fund Pioneer and New Innovator awards that don't require preliminary data, for example. That's the approach that can make people ultra-focused and risk averse, so processes like that—new grant mechanisms that require investigators to take a new direction that they or no one else has taken in the past—these are our Pioneer awards. And then, there's a growing set of awards not just through the Office of the Director but in the Institutes that don't require preliminary data, and the expectations that people take a risk. There's also the NIGMS MIRA awards, fairly new and a few years old, and these are intended to fund a laboratory, not necessarily specific projects. So, it's the funding to the collection of people and the PI to do whatever work they think is most appropriate. So, this is an excellent question, and we are...we recognize the concerns about taking risk and have undertaken a number of ways to mitigate the risk, so encourage people to try new things. [pause] Okay. So, I think I'm just going to thank you for your feedback and encourage your review of the RFI online and submit your comments, and for those colleagues who you run into who might be interested, please let them know about the March 16th 10 a.m. webinar. And with that, we will conclude. Thank you.

[WEBEX ENDED AT APPROXIMATELY 2:13 PM]