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WebEx Q&A Session

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

Dr. James Anderson

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Q&A SESSION (3/16/2020)

DR. JAMES ANDERSON: With that, I'm going to go to my colleagues and ask if they can start reading your questions.

DR. SARAH RHODES: Hello, Dr. Anderson. So, we have a few questions that have come in for you already. The first question I'm going to read actually came in at the end of the last webinar as it finished. How does funding international organizations for research benefit Americans, and how does it fit into the NIH-Wide Strategic Plan?

DR. JAMES ANDERSON: Okay, that's a very good question. The NIH does fund investigators in other countries and research that's conducted in other countries. It's a small part of our entire investment, and we do it when there is a capability that we can't locate in the American workforce or it's a topic that's not readily researched or is important to the American...the health of Americans. Examples would be clinical studies of active TB or active AIDS or things that might have a higher frequency in some parts of the world. So, it's important to examine public health across the globe, but our general approach is to support research in other countries that is difficult to do here but is important to our overall portfolio. Thanks, Sarah. Did you have a second question?

DR. SARAH RHODES: We do, and this also a two-parter. Where do ethics fit into the currently proposed cross-cutting themes? Would NIH consider adding an ethics cross-cutting theme?

DR. JAMES ANDERSON: That is a good question. I would say that that is something that's included all across the spectrum of the work that we do—from the very basic rigor and reproducibility—is in a way an ethics issue. Certainly, working with animals, there are processes there, and very specifically, human studies all are covered by ethical standards. So, I think we can consider that. I think that's woven throughout.

DR. SARAH RHODES: Okay. You have another one. Will you publish webinar questions and RFI responses to keep a public record of the input provided for the strategic planning process?

DR. JAMES ANDERSON: As I said, this webinar is being recorded and will be available, I have to say...I have to refer to my colleagues. I'm not sure if we're going to summarize responses to the RFI or

list them individually. It's more typical to summarize categories of comments. Can I hand that to you, Marina or Sarah?

DR. SARAH RHODES: I can quickly jump in here. I think the current plan is that we are going to provide some sort of summary of RFI responses, and we're also going to post a transcript of the webinars online.

DR. JAMES ANDERSON: Okay, thank you. I think we're ready for another one.

DR. SARAH RHODES: Does the Plan address the development of new models for translational and clinical sciences?

DR. JAMES ANDERSON: Absolutely. That translational work is very important in two of the pillars, both promotion of development of cures, as well as disease prevention. There is a very explicitly and translational component to both of those intentions. It's really done throughout NIH. I also point out that we have an Institute that's about 8 years old—NCATS—which was established specifically to address the bottlenecks that occur in translation, but this is a theme that's throughout all of our Institutes.

DR. SARAH RHODES: Next question. Will the Strategic Plan lead to a directional change to NIH or reprioritization?

DR. JAMES ANDERSON: I think it's unlikely that you'll see any major shifts. I think what this document does is explain in detail where we intend to go and how we intend to get there and conduct the research. Priority setting is really done on a continuous basis with opportunities that arise that we need to address, and with the input from Congress—that they occasionally have areas that they expect us to work on—or for example, in response to emerging needs, such as the coronavirus, where I suspect that for some period of time there will be more requests for activity and work that are relevant to emerging infectious diseases. But you're not going to see a major shift in the portfolio or radically new directions or topics.

DR. SARAH RHODES: Why has NIH only planned two short webinars instead of holding public meetings in the form of workshops or councils like individual Institutes often do?

DR. JAMES ANDERSON: No, that's a very fair question. This is the second NIH-wide plan. The first one had very, very, very extensive public input because it was the first plan where we intended to describe how NIH as a whole intends to work. This is just a minor change that we see from the previous, where our intention is to keep the format very similar and keep it at a high level, so we're looking for...your input from the RFI would be the principal one. I think that will be a useful way to get your input. Again, this is not a major revision of the last Plan, which we've heard people thought was very successful.

DR. SARAH RHODES: Okay, we have another one. How will this Strategic Plan strengthen and advance the biomedical research enterprise?

DR. JAMES ANDERSON: Well, we have to go back. Why do we have strategic plans? It's not only to demonstrate how we do the work, but it's to hold ourselves accountable—it's a roadmap for what we plan to do and how we're going to do it and how we're going to hold ourselves accountable. So, it's really a foundational document that describes and guides how we do the work, and each of our Institutes has one. I would say the work is very driven by accountability, and that's what a plan's all about.

DR. SARAH RHODES: What role does Congress play in setting the NIH priorities outlined in this Plan?

DR. JAMES ANDERSON: Well, in several ways. I think NIH has always enjoyed significant bipartisan support and largely has been allowed identify its own directions and processes for doing research. Occasionally, Congress will step in and ask that specific things be addressed with more emphasis, such as examples recently with the Alzheimer's, and they did ask that a number of things be put in this Strategic Plan that we will pay close attention to as we do the work going forward. But I would say that Congress is...I think it's fair to say they're generally hands-off with the processes that we use here.

DR. SARAH RHODES: What is the best way to stay updated on NIH's progress towards these goals?

DR. JAMES ANDERSON: Oh, that's quite a good challenge. We're not going to publicly list the

progress on all of these in a continuous way. We have discussed having sort of a mid-term review to acknowledge where we are, and we will consider that. Some description of the accomplishments of the last period will be included in this new Plan, so there'll be an update when this Plan is renewed again. But what's the best way to stay up on NIH's progress? I think the Institutes and Centers themselves are very active in reporting the work that they do on their websites. The NIH overall website is very rich with information about what's going on. As one small example, I'm responsible for the NIH Common Fund. If you go to the NIH Common Fund website, you will find detailed information on what our investigators are doing, examples of recent publications, a description of the overall goals of projects, and where they are. So, a very rich source of information is our Internet sites.

DR. SARAH RHODES: Next question. What is the relationship between this Plan and the strategic plans of individual Institutes and Centers across NIH?

DR. JAMES ANDERSON: Okay, that's a very good question. Each individual Institute, Center, and Offices have their own mission. They have their own assignment, whether it's infectious disease or cancer or asthma, and that would be described in the individual plans of the Institutes and Centers. The overall Plan...it describes at a higher level how we intend to do work across NIH, what everyone does and why, so that's why...it focuses on things. What are we all doing to address women's health and minority health overall? How do we maintain the highest level of stewardship overall? What are the processes for that? So, I would say the NIH-wide Plan is not a list of specific outcomes. It's more a description of how and why we do the work and what's our intention. It also informs, as is requested by Congress, that the themes or objectives of our overall plan guide how the Institutes write their Plan. So, in the future, you'll see each Institute, Center, and Office plan follow a common template and also, obviously, make reference to the NIH-wide goals as they address their very specific categorical goals. So, very different levels in the Agency.

DR. SARAH RHODES: Okay, next question. Objective 3 addresses monitoring progress. How does NIH monitor progress, and is there public feedback involved in that process?

DR. JAMES ANDERSON: Well, a whole of variety of ways. Some of it is internal, where we are

constantly evaluating the success or results of individual programs. This is in terms of some...a whole range of metrics. Are there publications from these investments? Are they important publications? Did they have an impact? How many people applied for a particular training activity? So, our own staff is constantly monitoring the impact or effect of our investments and redirecting as necessary. In terms of public input, I think a major one is our advisory councils. Each of our Institutes has a public council that advises them. For example, those councils do things such as clear the intention to fund particular areas—so whether we put out a funding opportunity announcement or not—and what it looks like is informed and approved by public councils. Also, the doors are always open. People contact me frequently with ideas. They contact the Institute directors frequently, and I know they often contact Francis Collins.

DR. SARAH RHODES: How will you ensure that money invested in research going forward realizes its promise? In other words, how does NIH envision a kind of cost-benefit analysis regarding specific approaches to diseases or interventions?

DR. JAMES ANDERSON: Well, funding decisions are made at several levels. First of all, it would be the intent to fund funding opportunity announcements if we have them in their specific core area where we need research done. That would be an informed decision, but that's where we want research done. A large part of the portfolio is investigator-initiated, and we trust our community to be informed about what's the best opportunities, where can we make progress now, what it is that communities think is important to work on. The next step would be peer review—our peers review applications by the criteria you're all familiar with in deciding who's scientifically meritorious. And then, finally, our Institutes make programmatic decisions about what to fund, which is not necessarily a reflection of the scores from the study section, but they impose another layer of decision making based on the priorities of that Institute. So, I think that answered the question.

DR. SARAH RHODES: Okay, so next question. It's been in the news that the White House is considering changing current policy on publications by reducing the publication embargo to 0 months. How will NIH support grantees to be compliant with this new policy?

DR. JAMES ANDERSON: Well, first of all, it's not been established yet, so I'm not in a position

to describe how we would implement it. So, I think I'll leave it at that, except to say that data sharing is extremely important for the advancement of science, so generally, it's very supportive of making data available soon. How that would happen? I can't speak to that yet.

DR. SARAH RHODES: The next question is similar to a previous one. How do you plan to strategically align efforts across all NIH Institutes, Centers, and Offices?

DR. JAMES ANDERSON: I've lost...we're all on WebEx here. I lost the first part of your sentence.

DR. SARAH RHODES: Sorry. How do you plan to strategically align efforts across all NIH Institutes, Centers, and Offices?

DR. JAMES ANDERSON: That's a very, very good question, because we do have 27 Institutes and Centers. I will say, though, that there's a significant level of information flowing in the Agency at all levels across the Institutes at the program level, at the leadership level. There are multiple programs that are conducted across Institutes. Big examples would be the BRAIN Initiative, projects in regenerative medicine, projects...there are many things. One very clear and recurring way is, again, with the NIH Common Fund, which is about \$640 million a year that's used specifically for projects that must by law include multiple Institutes and Centers. So, there are multiple channels for sharing information across. And there's also the NIH Director, who also takes the liberty of directing the activities and pulling in several Institutes for particular projects.

DR. SARAH RHODES: You indicated that all plans must follow a single template. Can you make that template available for public view?

DR. JAMES ANDERSON: Let me ask you: Have we made that public?

DR. SARAH RHODES: It's not currently public. No.

DR. JAMES ANDERSON: Oh, I think the outline...we can do that. We will...we'll put something on the DPCPSI website that addresses what the common template is all about and then put it out at some level that will make sense to folks. In other words, it shouldn't be a mystery how we're organizing or also what the intent of certain parts of the document are, so we'll do something on the

DPCPSI website for that.

DR. SARAH RHODES: Next question. What opportunities will exist for further commenting on the Plan during its development?

DR. JAMES ANDERSON: Well, I think the most important way to get input that can still guide us at the highest...highest level is to respond to that RFI. We're also going to be taking it to the Council of Councils for their approval, and I've offered to go any of the Institutes' and Centers' advisory councils and get their input if asked by Institute directors.

DR. SARAH RHODES: Will there be a possible extension for the Request for Information deadline due to the fact that the workforce, as many organizations, is affected by the coronavirus and because many staff are now working from home.

DR. JAMES ANDERSON: We will look into the feasibility of that. Marina, please remind me again. Has it been a 60-day period this time?

DR. SARAH RHODES: It's a 6-week period at the moment, closing on the 25th of March.

DR. JAMES ANDERSON: Yes. What we'll do is we'll look at the volume of responses that we have now. If there's a sense that it's falling off because of other events, we can consider extending.

[pause]

DR. SARAH RHODES: And I think that is the end of the questions that we have at the moment.

[WEBEX ENDED AT APPROXIMATELY 11:00 A.M.]