U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES

WebEx Presentation

Developing the NIH-Wide Strategic Plan for Fiscal Years 2021-2025 Dr. James Anderson

March 9, 2020

PROCEEDINGS

[CALL STARTED AT 1:30 PM]

WELCOME

DR. JAMES ANDERSON: Welcome to our WebEx, folks. Hi. This is Jim Anderson from NIH. We're going to wait another minute and get started. Please hold on with us. [pause for attendees to be online] Hello and welcome. I am Jim Anderson, the NIH Deputy Director for Program Coordination, Planning and Strategic Initiatives. Our plan today is to present an overview of the process for developing the NIH-Wide Strategic Plan for fiscal years 2021 through 2025, to hear your comments, and hopefully answer your questions. Today will be the first of two public webinars. For anyone you know who could not attend today, March 9th, there will be another on March 16th. I'd first like to introduce three members of our Office of Evaluation, Performance, and Reporting. They are Drs. Marina Volkov, Sarah Rhodes, and Kelly Singel, and they will be reading questions or comments that you submit; and if I cannot answer them, hopefully, they can. They all play key roles in developing the plan, along with many staff from across NIH, and input from stakeholders outside of NIH-namely, the folks on our call today. We'll start with a presentation on the strategic plan development process, the proposed framework for the plan, followed by time for questions and answers from you folks. And we expect this will take about up to an hour. You can submit questions via the WebEx chat function, which I think you can see on the right side, as well as the email address, which is at the bottom of this email nihquestions@scgcorp.com, and you can do that at any time during my presentation or our question-and-answer session. So, it is time to update the NIH-wide Strategic Plan. The last plan, which was the first NIH-wide plan, covered fiscal years 2016 to 2020 and was released in December of 2015. All of the NIH Institutes, Centers, and Offices have had regularly updated strategic plans for many years. Congress directed NIH in the 21st Century Cures Act that we develop a plan for the entire agency—an agency-wide perspective. The Act was signed into law on December 13th of 2016. Congress provided a list of requirements for the plan, not all of which had been addressed in the first plan, and these include such things as there is a mandate for NIH to produce a plan no less frequently than every 6 years. Since our Institutes', Centers', and Offices' plans are typically

5 years, we decided to follow that precedent for the NIH plan, which will repeat every 5 years from now on. Congress also outlined a list of things that must be addressed in the plan, and I'm going to refer you to the statute, which is listed at the top of this slide, if you'd like to see the full list of requirements, but this includes things like they have asked us to address multi-Institute priorities and coordination efforts across the Agency, to address biomedical workforce training activities and plans, to describe collaborations with other agencies and departments, and to address how NIH will address health disparities and research to improve women's health, and a list of other items that they felt were important to be included in the Plan. Congress also required that the NIH Institutes' and Centers' strategic plans be informed by the objectives of the NIH-wide plan—we'll go through those—and to use a common template for preparing their documents; and NIH has been using this template for new and revised plans since January of 2019. So, what are the goals that we have set for ourselves in preparing the Plan? Well, at a high level, these are some major guidance we've set for ourselves. First of all, what will the Plan be? It's going to clearly articulate the highest priority for NIH overall, not specific issues that would be covered by categorical plans within each of our Institutes. It's going to describe how NIH will achieve the highest priorities—in other words, what coordination activities, what funding mechanisms, what programs. And it's going to represent an update from the last Plan, including accomplishments that were achieved under the last Plan and new initiatives across NIH that have been established or will be. What will it not do? Again, I'm going to repeat. It's not going to describe the many important issues that NIH does and will do in the future. It's not a catalog; it's a higher-level document—it's prepared for the public. It will also present priorities. It will not present priorities for the individual Institutes, Centers, and Offices since each of these has their own more specific plan. And again, it will not be a complete overhaul of the last Plan; it will be relatively familiar to those of you who know that document. Okay. What's the process and timeline for developing the new Plan? During the first phase of development, which was the last third of calendar year 2019, we developed a draft framework with the working group of the NIH subject-matter experts and leadership. In the next phase, which was from December through May of this year, we're gathering public input to further develop the framework and actually draft the Strategic Plan document.

For example, on December 13th, an outline of the plan was presented publicly to the Advisory Committee for the Director of NIH, and they provided input at that time. Also, that framework was available to the public beginning then, and now we're seeking more public input from two formats—one of the webinars today and the 16th of March—and the major format is a Request for Information (RFI), which you can find on the Web. It's open for 6 weeks from February 12 through March 25, and this asks questions and can take any written comments on our plans. I do want to repeat that the framework is still under development, so public input is quite welcome, and please respond in writing to the RFI. In the final phase of preparation, we will clear the Plan through the NIH Council of Councils—NIH leadership across the Agency, and we aim to release the plan finally and publicly in December of 2020. Okay. Next, I'm going to provide an overview of the Strategic Plan framework. For reference, this is a very high-level outline of the first currently active plan. It starts with an overview section that includes items such as the NIH mission and goals, the organization of NIH structurally, the research landscape being faced, and division and challenges that we have. Then there are currently four objectives—and these include, basically, the work that we do. Objective 1: Advance Opportunities in Biomedical Research. And as is typically done, it covers fundamental or basic science, the activities that are conducted in research to provide a treatment or a cure for a condition or a disease, and then the very important goal of preventing—doing research to promote disease prevention. So, that's how we do the research or the research that we do. The second objective is Fostering Innovation by Setting Priorities. How do we determine what's funded, what's a priority, which programs will be created and others not? The third, Enhance Scientific Stewardship. This would be issues like the efforts for transparency, research rigor, and reproducibility. And the fourth objective currently active is Excel as a Federal Science Agency by Managing for the Results—or the processes we use to conduct our work. And then, we ended at kind of a fun issue for us: to develop a set of 14 bold predictions for America's future. In contrast to the very highlevel general perspective of the rest of the document, these were specific goals, like to develop X cure for something or fix new something for X or Y. So, we had some fun with that, and we hopefully will do that again. Okay, so that was the previous plan. The current plan outline is only slightly modified and outlined

here. We propose keeping the same basic structure of the Plan that we used last time, with a few tweaks that are based on our experience with the last plan and discussion with NIH leadership and the planning working group. It was the goal of the last plan to produce a document that was relatively short, well illustrated, and very approachable by a wide audience. And we think we've heard feedback that that was the case, and that's what we're aiming for again. So, in order to do that, we're going to actually move some items to the appendix to maintain the flow of reading, and these are things such as the organizational structure of NIH. The NIH strategy will now be presented in three objectives, noting our observation that the previous four were somewhat overlapping and could be streamlined. For example, the issue of priority setting is an example of stewardship, and there was overlap among 2, 3, and 4, so they've been combined into just three. So they are, once again, in number one is the science that we propose to pursue—this is Advancing Biomedical and Behavioral Sciences; the second—Developing, Maintaining, and Renewing Scientific Research Capacity. This is things like—I'll get to this in a little more detail infrastructure and workforce and other; and number three—Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science. And then again, it hasn't been determined what they would be at this point, but we are likely to include another set of bold predictions and hold ourselves accountable for those. Okay, so in terms of Objective 1, I'm going to break it down a little bit more. The detail would go even further, but I'm staying at a high level for today. Advancing Biomedical and Behavioral Sciences, and this will be divided at a high level into three areas. One, driving foundational science. This is our basic research—the foundation that we do—agnostic to particular diseases that we can dip into that knowledge when we need it to apply. Under this, there's also population and epidemiology that's at a rather basic level. And then, on to the very important goal of preventing disease and promoting health, and this runs the typical span from translational work, the clinical studies, to getting it out there and being used in terms of implementation/dissemination research, and again, some population science and epidemiology is pursued to promote health. And the third major category is developing treatments and interventions. So, once individuals have an affliction or a disease, or condition, what can we do to provide a treatment,

intervention, and a cure for that? And that runs the same spectrum of the types of research from translational, clinical, to getting it used, implementation, dissemination, and population science and epidemiology. So, that's a breakdown at a very high level of the first objective. The second is developing, maintaining, and renewing scientific research capacity. So, this is providing the structure that allows the work to be done, and that falls into two major categories. The first is cultivating the biomedical research workforce. No one trains the NIH workforce. We do it ourselves. It's very specialized work, and our investments go from graduate students up through clinical trainees and beyond. So, what are the overarching goals of our training and career development programs? Why do we have them? What are we trying to achieve? And then, we'll provide examples in specific areas, such as: What types of funding mechanisms are used and why, our special attention to diversity of training our workforce, and then special areas like clinician-scientist training, veterinary training, dental and research trainers. The second major area, then, is the infrastructure or the physical capacity and resources to do the work. And again, what are the overarching goals of our investments in these resources and infrastructure? And then, a list of specific examples. Here on the slide are things like our Comprehensive Cancer Centers' infrastructure organized to do a broad range of research from basic to clinical on cancer, and then our major investments now in data sharing and platforms. This also includes other areas, like instruments, renovation grants, and just the material and infrastructure that we need to invest in to allow the work to be done. And then, the third is Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science. This is divided, really, into four major areas—they overlap to some extent. The first—Fostering a Culture of Good Scientific Stewardship. How do we set priorities here? What input do we take? How do we compare one thing against another, and what do we take into account when making funding decisions? That's the categories of things. How do we monitor our progress and hold ourselves accountable? And then, other areas that deal with stewardship. Leveraging Partnerships. This, again...we do this. We would have presented it, but it's something that Congress specifically ask that we note the partnerships that we have with our funded universities and research institutions and how valuable that is to conduct the work; what forms of public engagement we

use to inform the work that we do—so, who we work with. And this can be other agencies, too. The third area—Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences. This whole area is the ethical and equitable conduct of research, enhancing the workforce that's diverse and can conduct research across the broad spectrum of our portfolio, and other areas in accountability. The final area or major heading would be Optimizing Operations. This is, to some extent, more of an internal operations issue about increasing efficiency and effectiveness of the work that we do and the management of science and the planning of science that we do and improving NIH operations, business processes, and coordination. So, those together are the way that we'll present the work we intend to do. Now, interesting here, there are some major themes that we'll cut across that will be presented both in the introduction to the document and then woven throughout all the sections, and I present here the five major crosscutting themes that we will use. The first is an intention to increase and enhance and support diversity, and this is diversity in our workforce. The second is specifically, again, something which we do anyway, but Congress wanted a specific accounting for, is improving women's health and minority health, and reducing health disparities. The third very important area, which is emerging very rapidly, is optimizing data science and the development of technology and tools. First of all, the data science, I would note that we have recently developed a strategic plan—NIH-wide strategic plan—for data science, which you can find on the NIH website, acknowledging the very...the explosion of data—digital data—that we work with and how to improve the access, use, reuse, and sharing of data. But that is a major theme NIH will be involved in for years. And the next is the technology and tool development. Many, many scientific advances are based on the development of a tool and technology, and yes, we actually specifically focus on developing those that will enable wide ranges of research. The next theme, which will be woven throughout the document, will be promoting collaborative science and then addressing public health challenges across the lifespan, acknowledging that our research must cover all ages of the folks that we serve. Okay. So, that is a high level—on a very high level—is where we are. Details of the strategic plan are still being formulated with input from experts here at NIH and from public input, and I want to remind you again that there's two major ways that you can provide input. One is today through your comments

and questions that we'll take in a minute, and the second—a little more formal and detailed—is you can provide written responses to the Request for Information (RFI). That, again, is open 6 weeks, and it will end on March 25th. So next, I would like to move on to take your questions. Since time is limited, we may not have an opportunity to respond to everyone's questions, so I encourage you again to submit feedback via the RFI. Remember that the major goals of the Strategic Plan are to articulate the highest priorities of NIH overall and how NIH will achieve them, and this Plan will not describe all the important efforts NIH undertakes nor the very specific goals and priorities that are set by each of our Institutes and Centers. Specifically, we'd like your input on such things as the five crosscutting themes. Are there additional themes to be considered? How would you prioritize the ones we've developed? What are NIH priorities across the three objectives we've outlined? Do you see potential benefits or drawbacks or challenges in specific areas? And then, future opportunities for emerging trends NIH needs. This was not...I didn't specifically address that. And again, we ask you to think broadly about the priorities for NIH as a whole, not for a specific Institute. We know as researchers, patient advocates, and other stakeholders, we all have specific interests in the priorities, but our goal today is to discuss how best NIH overall can achieve a broad, wide-reaching impact on the future of biomedical research. And so, with that, I'm going to ask my colleagues here who are taking your questions, we'll just begin, read questions, and I will attempt to answer and ask for their help if I can.

[WEBEX (BOTH PRESENTATION AND SUBSEQUENT Q&A) ENDED AT APPROXIMATELY 2:13 P.M.]