National Cancer Advisory Board (NCAB)
Subcommittee on Planning and Budget

June 14, 2021
11:00 a.m.–12:00 p.m. EDT
Virtual Meeting

SUMMARY

Subcommittee Members
Dr. Anna D. Barker, Chair
Dr. Peter Adamson
Dr. Deborah Bruner
Dr. Yuan Chang
Dr. Andrea Hayes-Jordan
Dr. Scott W. Hiebert
Dr. Nikan Khatibi (absent)
Dr. Timothy J. Ley
Mr. Patrick McGarey, Executive Secretary
Dr. Margaret R. Spitz

Other Participants
Dr. Francis Ali-Osman, NCAB
Dr. Otis W. Brawley, BSA
Dr. Paulette S. Gray, NCI
Ms. Anne Lubenow, NCI
Ms. Thu Nguyen, NCI
Dr. Electra D. Paskett, NCAB
Mr. Ricardo Rawle, NCI
Dr. Norman E. Sharpless, NCI
Dr. Dinah S. Singer, NCI
Dr. Peter Wirth, NCI
Dr. Eileen P. White, BSA
Ms. Joy Wiszneauckas, NCI
Ms. Kathryn Brown-Huamani,
The Scientific Consulting Group, Inc.,
Rapporteur

Call to Order and Introduction

Dr. Anna D. Barker, Chief Strategy Officer, Lawrence J. Ellison Institute for Transformative Medicine, University of Southern California

Dr. Anna D. Barker, Subcommittee Chair, called the meeting to order at 11:00 a.m. EDT. In her opening remarks, Dr. Barker remarked that the NIH budget has increased by $12.85 billion since 2016, which represents a 42.7 percent increase. She added that Congress is highly supportive of the NIH and NCI. She outlined the topics to be discussed during the Subcommittee meeting and remarked that during NIH Congressional testimonies, members of Congress expressed concern about NIH paylines. Paylines, therefore, will be one topic of discussion.

The other topic for the Subcommittee meeting is President Joseph Biden's proposal for a new agency that would seek to hasten the development of medical treatments by funding risky, innovative projects. The proposed Advanced Research Projects Agency for Health (ARPA-H) would be modeled on the Defense Advanced Research Projects Agency (DARPA) but housed at the NIH. Although the original ARPA-H proposal focused on cancer, it has now expanded to include other diseases. President Biden has proposed a large budget for ARPA-H.

Budget Updates
Mr. Patrick McGarey, Associate Director for Finance and Legislation, NCI

In his opening remarks, Mr. Patrick McGarey, Subcommittee Executive Secretary, echoed Dr. Barker's comment regarding Congress' strong support for the NIH and NCI. He delivered a presentation on fiscal year (FY) 2021 and 2022 budgets.

Mr. McGarey began his presentation by reviewing NCI appropriations since 2015. Since that year, the NCI budget has increased annually and now stands at $5.65 billion for FY 2021. If Congress adopts the budget proposed on May 28, 2021, by the Biden Administration, NCI's budget will rise to $6.7 billion, which would represent a 36 percent increase since FY 2015. Mr. McGarey added, however, that increases have been variable. For example, NCI received a 9.1 percent budget increase in FY 2017 compared to an increase of 1.9 percent in FY 2021. The largest percentage increase was 4.5 times greater than the smallest increase over this time period. The high increase in FY 2017 was largely due to the Cancer Moonshot initiative being implemented that year, resulting in a $300 million increase in NCI's budget. Cancer Moonshot funding began to decrease in FY 2020, and FY 2023 will be the last year that the NCI will receive this funding. The Childhood Cancer Data Initiative (CCDI) boosted NCI's budget beginning in FY 2020. Mr. McGarey highlighted the NCI's FY 2022 Professional Judgment Budget. This budget is aspirational and based on what the NCI Director determines is needed to conduct a robust national cancer research program.

Mr. McGarey provided a brief update on FY 2021 funding. In FY 2021, the NCI received a $120 million increase from Congress, which represented a smaller percent increase than NIH's overall 2.5 percent increase. Funding amounts for Cancer Moonshot and the CCDI remained the same as in FY 2020. Congress targeted one third of the NCI budget increase in FY 2021 to fund competing and continuing grants. These targeted funds allowed the NCI to raise paylines for R01 and Early Stage Investigator (ESI) grants by one percentile each. In FY 2021, the NCI will pay at the 11th percentile for R01s and the 16th percentile for ESIs, with continuing awards paid at 100 percent.

For FY 2022, the President's budget submitted to Congress proposes a $174 million (2.7%) increase for the NCI. The FY 2022 NCI budget proposal represents the first time in 5 years that a budget proposing an increase was submitted to Congress. The proposed FY 2022 NCI budget increase keeps CCDI funding at the same level as in FY 2021 and decreases Cancer Moonshot funding by only $1 million. The Biden Administration also has proposed a $9 billion (21%) budget increase for the NIH. About 70% of this increase ($6.5 billion) is for ARPA-H.

According to Mr. McGarey, the four most prominent drivers of NCI's cost profile for FY 2022 are noncompeting grants, taps and assessments, federal pay raises, and cybersecurity investments. The NCI expects the number of noncompeting grants to increase by 80 awards in FY 2022. FY 2021 competing awards add to the FY 2022 noncompeting costs. Mr. McGarey estimated that NCI's total noncompeting award costs will increase by approximately $100 million in FY 2022. He estimated an increase of $40 million for NCI's share of taps and assessments, which involves the costs of operating the advanced infrastructure on the NIH campus. The NCI estimated a $23 million increase for pay costs. The Biden Administration is

increasing total federal investment in cybersecurity by 14 percent in FY 2022, representing a $16 million increase for NCI cybersecurity costs in the same fiscal year. The estimated cost increases for the NCI in these four areas (which do not represent all cost increases) exceed the budget increase for the NCI in FY 2022. Although the NCI plans to invest more in grants in FY 2022 compared to FY 2021, the paylines for R01s and ESIs will need to be reduced by 1 percentile each to 10 and 15 percent, respectively. The NCI expects to pay noncompeting grants at 96 percent in FY 2022.

Mr. McGarey delivered an overview of ARPA-H. The model for ARPA-H, DARPA, focused on research investments to advance breakthrough technologies for the military. Goals of ARPA-H would be to drive transformational innovation in health research and accelerate the application and implementation of health breakthroughs. The ARPA-H proposal appears to be in the early stages of development, but likely will require a series of flexible research authorities to accomplish ARPA-H objectives. NIH and Congressional Appropriations Subcommittee leadership have made statements suggesting similar visions for ARPA-H; some members of the Congressional Appropriations Subcommittee, however, emphasized the importance of striking a balance between the ARPA-H approach and basic research funding.

Discussion

Dr. Barker thanked Mr. McGarey for his presentation. She remarked that the proposed budget increase coming from ARPA-H is substantial, but the proposal has not yet become legislation. She asked participants about any concerns that ARPA-H might lead to a reduction in funding for the usual NCI activities of supporting new and continuing grants. Mr. McGarey responded that leadership of the Congressional Appropriations Subcommittees responsible for NIH funding demonstrated consistent support for NIH and NCI work, as well as for ARPA-H. Even if the amount of the proposed budget is reduced, it is still likely to be large.

Dr. Barker asked NCI Director Dr. Norman E. Sharpless to comment. To provide context, Dr. Sharpless remarked that his first NCI budget was cut by more than 25 percent and that a $9 billion budget increase for NIH would be remarkable and stated that ARPA-H would be useful for the cancer research enterprise. He acknowledged that limits on paylines present a challenge for the NCI: The NCI has set a goal of increasing paylines to at least the 15th percentile, which would require robust support from Congress.

Dr. Barker commented that a reduction of the current 11th percentile R01 payline will need to be explained to the cancer research community. If ARPA-H legislation is enacted, researchers might expect more substantial research funds to be available through the usual NIH mechanisms, which would not necessarily be the case.

Dr. Sharpless remarked that he believes that key members of Congress still understand the need for basic biological research, as well as the need for higher paylines. ARPA-H will not support paylines; its purpose is not to support basic, investigator-initiated research.

Dr. Deborah Bruner expressed uncertainty about the value added with ARPA-H. She argued that the NIH is capable of implementing rapid, crosscutting research as demonstrated by such initiatives as Rapid Acceleration of Diagnostics (RADx). ARPA-H could create another bureaucracy that would siphon much needed money for paylines. Dr. Bruner asked why ARPA-H goals could not be accomplished within the current NIH infrastructure.

Dr. Sharpless recommended that participants listen to NIH Director Dr. Francis Collin's prepared remarks at the House Appropriations Subcommittee hearing regarding ARPA-H and responses from members of Congress. Dr. Sharpless summarized some of the comments made during the hearing. The NIH and NCI, specifically, are adept at supporting basic science and clinical trials. The Cancer Center program is an example of an activity that the NCI performs well. Other areas that involve more translational research are more challenging for the NIH, primarily because of the amount of time involved in implementing an initiative (e.g., a new Request for Applications often takes 18 months to issue). This approach might work well for basic science, but mechanisms are needed to facilitate translational research that is faster.

In addition, the NIH faces several restrictions on collaborations with industry. Collaborations between industry and the scientific research community are important for rapidly advancing certain types of science. For example, ARPA-H might offer a useful mechanism for conducting large clinical trials to test cancer early-detection approaches in healthy adults. The NCI could undertake this type of effort, but it likely would take a long period of time and strain the Institute's budget. ARPA-H would be managed by project managers, involve rapid disbursement of funds, and allow broader interaction with industry.

Mr. McGarey added that Congress sees the ARPA-H as an opportunity to support both basic research and other types of research in a more flexible way.

Dr. Barker described how the U.S. Department of Defense (DoD) established a program to fund breast cancer research in 1994. That program had some similarities to ARPA-H in that the DoD program also targeted translational research and scientific breakthroughs. The DoD program created a new infrastructure, including a new peer review infrastructure. She explained that the DoD breast cancer program and similar programs have succeeded in generating scientific breakthroughs. The NCI also has considered a translational science initiative with program managers as a central component. In addition, NCI's early drug development work followed a model similar to that proposed for ARPA-H. Dr. Barker added that NCI's Frederick National Laboratory for Cancer Research (FNLCR) might be a logical place to launch an ARPA-H cancer research effort.

Dr. Sharpless agreed that the FNLCR could be valuable for conducting ARPA-H supported research. Its special capabilities have been especially useful during the COVID-19 pandemic, and the federal government as a whole is now more aware of the capabilities of this facility for conducting nimble, government-directed research using novel authorities. Dr. Eric Lander, Science Advisor to the President and a principal architect of ARPA-H, is aware of the capabilities of the FNLCR. Dr. Sharpless explained that ARPA-H would not be constrained to a specific mechanism and could use whatever authority was most effective.

Mr. McGarey remarked that ARPA-H goals are well aligned with FNLCR capabilities. He mentioned that the collaboration between the FNLCR and Department of Energy demonstrates how two federal entities can collaborate to solve challenging biomedical research problems.

Dr. Barker added that the FNLCR has a nimbler approach to funding contracts and much of ARPA-H research likely will be supported through contracts. She remarked that the research community is at an inflection point with regard to cancer, with data coming from many sources. The new challenge is to create vehicles for testing new technologies in the types of rapid trials described by Dr. Sharpless. There also is a need to combine technologies and work across different areas of science to advance various fields of oncology, including areas not well supported by the NCI at present. Dr. Barker asked if participants had any further comments or advice.

Dr. Margaret Spitz asked about the level of investment that would be required to build the infrastructure for ARPA-H and what percentage of allocated funds would go to building ARPA-H infrastructure, rather than research. Mr. McGarey responded that DARPA has a budget of $3.6 billion but only 200 employees. Because DARPA is a model for ARPA-H, these figures suggest that investment in infrastructure would be fairly low. ARPA-H would need a relatively small number of staff with appropriate knowledge and talent to form critical partnerships that would advance new technologies.

Dr. Barker observed that 100 program managers might be sufficient to manage ARPA-H. Finding program managers with the requisite expertise would be a challenge, however, since their employment with ARPA-H might end after 3 years. Dr. Barker also asked whether cancer would be prioritized by ARPA-H in terms of funding applications.

Dr. Sharpless responded that cancer, diabetes, and Alzheimer's disease appear to be the priorities for ARPA-H, but some members of Congress want to support more crosscutting efforts that focus on conditions that affect many diseases, such as obesity. Dr. Lander indicated that President Biden wants to continue to prioritize progress in cancer research. Advancements in cancer research likely will be an important metric for ARPA-H.

Dr. Barker asked if a model for ARPA-H exists within the NIH. Dr. Sharpless responded that the model was DARPA. ARPA-H likely will not replace the rapid work performed by biotechnology and pharmaceutical companies. Other areas of research, however, could take advantage of the flexible funding vehicles offered by ARPA-H.

Dr. Barker remarked that many NCI-funded cancer centers have developed strong discovery and translational capabilities in terms advancing treatments to clinical trials. She noted that ARPA-H is one of the most potentially transformative proposals she has seen in cancer research for some time and asked Subcommittee members to comment on whether the NCAB should support the ARPA-H proposal.

Dr. Scott Hiebert indicated that it is not clear how ARPA-H would work at this point. He also was concerned about decreased paylines and the possible need to reduce noncompeting renewals in FY 2022, with or without ARPA-H. Dr. Barker agreed and added that reduced paylines might be counterproductive in promoting ARPA-H. The basic research funded by the NCI drives the discoveries that would be translated by ARPA-H.

Dr. Timothy Ley concurred that the combination of additional money from ARPA-H paylines frozen below the 15th percentile could send a negative message to the research community. Dr. Barker reiterated that the R01 payline currently stands at the 11th percentile. Dr. Sharpless indicated that Dr. Ley was referring to the ESI payline, which currently stands at the 15th percentile, which still is low.

Dr. Sharpless discussed the early days of the Cancer Moonshot initiative, when little funding from that initiative went to the RPG pool, but the number of applications increased. As a result, paylines dropped to the 8th percentile. ARPA-H could lead to an increase in applications of 10 percent or more followed by frustration within the research community when funds for that initiative are not available to support their applications.

Dr. Barker added that some universities built new infrastructure in response to the doubling of the NIH Budget initiative (1994-1998) because they expected increased interest in biomedical research, which did not occur. She asked how the more recent Cancer Moonshot currently is perceived within the cancer research community.

Dr. Sharpless referred participants to a review of the Cancer Moonshot recently published in *Cancer Cell*. He remarked that the Cancer Moonshot was productive and led to team- and network-driven collaborative and translational science, which helped to move new technologies into clinical use. The research generated by the Cancer Moonshot were different from the type of research funded through research-based grants. Dr. Sharpless asked Dr. Singer for her input on the Cancer Moonshot.

Dr. Singer agreed that the Cancer Moonshot resulted in substantial progress in every area prioritized by the Blue Ribbon Panel. The Cancer Moonshot demonstrated how quickly the NCI and the research community can work together to implement new research and serves as a good example of how to move research forward quickly. A challenge will be sustaining and continuing the momentum of the Cancer Moonshot efforts beyond 2023.

Dr. Barker remarked that the DARPA model is good, as are a number of other recent models. She explained that Dr. Lander is setting up a committee to gather community input and commented that it would be helpful for members of this subcommittee to participate.

Dr. Barker added that investigators will need to adjust to the ARPA-H model for supporting research. She asked Dr. Sharpless what the scientific community can communicate to Congressional leaders regarding paylines. Dr. Sharpless responded that Congress has been interested in payline crises in FY 2020 and 2021 and is interested in hearing community concerns. In particular, Congress tends to listen to communications from patients, cancer center directors, the NCAB, and patient advocacy organizations.

Adjournment

Dr. Barker adjourned the meeting at 11:56 a.m. EDT.

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Dr. Anna D. Barker Chair	Date	Mr. Patrick McGarey Executive Secretary	Date