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

> February 11, 2021 12:00–1:00 p.m. EST Virtual Meeting

SUMMARY

Subcommittee Members	Other Participants
Dr. Anna D. Barker, Chair	Dr. Francis Ali-Osman, NCAB
Dr. Peter Adamson	Dr. James Doroshow, National Cancer Institute
Dr. Deborah Bruner	(NCI)
Dr. Yuan Chang	Dr. Howard J. Fingert, NCAB
Dr. Andrea Hayes-Jordan	Dr. Paulette S. Gray, NCI
Dr. Scott W. Hiebert	Ms. Anne Lubenow, NCI
Dr. Nikan Khatibi	Ms. Thu Nguyen, NCI
Dr. Timothy J. Ley	Dr. Electra D. Paskett, NCAB
Mr. Patrick McGarey, Executive Secretary	Mr. Ricardo W. Rawle, NCI
Dr. Margaret R. Spitz	Dr. Norman E. Sharpless, NCI
	Dr. Peter Wirth, NCI
	Ms. Joy Wiszneauckas, NCI
	Dr. Amanda Cenname, The Scientific

Consulting Group, Inc., Rapporteur

Budgets—Transition—Uncertainty—Timing

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 12:01 p.m. EST. In her opening remarks, Dr. Barker asked the Subcommittee to consider ways that the NCI can address the impact of the coronavirus disease 2019 (COVID-19) pandemic on research; many groups are advocating increased support of the NCI.

The National Institutes of Health (NIH) and NCI budgets for fiscal year (FY) 2022 are consistent with increases in previous years; the NIH budget is \$42.93 billion (B) (i.e., an increase of \$1.25 B from the previous year), and the NCI budget is \$6.56 B (i.e., an increase of \$119.5 million [M]). Cancer MoonshotSM funding will be continued, and the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act of 2017 will be funded fully. Dr. Barker encouraged the Subcommittee to consider other funding sources that could provide additional support for investigators.

Many federal resources have been allocated for COVID-19 research (e.g., the U.S. Food and Drug Administration, Biomedical Advanced Research and Development Authority, Centers for Disease Control and Prevention). Dr. Barker emphasized that ultimately, these areas of support also benefit the cancer research community. President Biden has expressed his support of the NIH and NCI; further support for a Cancer MoonshotSM 2.0 and 21st Century Cures Act is in discussion. Dr. Barker noted, however, that a COVID-19 relief package for 2021 has not yet been finalized. Additionally, the Secretary of Health and Human Services nominee has not been confirmed.

Dr. Norman E. Sharpless, Director, NCI, commented that the NCI requires additional funds to address the impact of COVID-19-related closures on other research activities. The COVID-19 pandemic has resulted in significant research-related disruptions, and no additional funds have been appropriated to the NCI to address the associated costs of these disruptions. Dr. Sharpless said he anticipates that investigators will approach the NIH to request additional support. He emphasized that the impacts of COVID-19 on research (e.g., clinical trials, laboratory closures, personnel changes) must be conveyed broadly.

Budget Overview: Focus on Budget Trends

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

Mr. Patrick McGarey, Associate Director for Finance and Legislation, NCI, presented an overview of the NCI's budget and highlighted current budget trends. He asked the Subcommittee to consider the dynamic external influences that can have significant effects on the NCI budget.

The FY 2021 budget contains the same basic components as FY 2020. Cancer MoonshotSM is a 7-year, \$1.8 B initiative that will end in 2023. The FY 2021 Moonshot funding level for NCI is \$195 M. After FY 2023, the stream of Moonshot funding will end.

The Childhood Cancer Data Initiative is in the second year of a 10-year planned initiative, with \$50 M per year. The NCI received \$306 M in FY 2020 for the NCI Serological Sciences Network for COVID-19.

Congressional appropriators set an FY 2021 target of 1.5 percent as a minimum increase for all NIH institutes and centers; the increase varies across NIH Institutes and Centers (ICs). The new Administration has not yet announced proposed budget levels for FY 2022.

Mr. McGarey highlighted trends in the difference between the requested (i.e., from the president) and approved (i.e., by Congress) budgets from FY 2014–2021. During President Obama's administration (FY 2014–2017), the requested and approved budgets largely were consistent with each other each year, and fluctuation was minimal. During President Trump's administration (FY 2018–2021), however, these figures were markedly more variable.

Sequestration (automatic cuts to budgets of federal agencies) can play a role in the budget planning process. The Budget Control Act of 2011 imposed strict caps on domestic and defense spending. The budget caps have been raised every 2 years since 2014. Consequently, Mr. McGarey explained, the potential for budget growth is greater during even-numbered years than odd-numbered years. Because the debt ceiling will expire this year, however, opponents of federal spending may advocate a new round of budget caps.

In response to a question from Dr. Barker, Mr. McGarey cautioned that future caps and trends are difficult to predict; the COVID-19 pandemic and current economic situation might influence limits to federal spending. He added that the initial spending caps were implemented shortly prior to the sequestration; the 2-year cycles have allowed the budget trend to rise at a greater rate than the budget caps originally allowed. Mr. McGarey noted that the sequestration initially was a 10-year plan.

Round Robin: Subcommittee Members' Thoughts on the Future Budget Needs

Subcommittee Members

In response to a question from Dr. Margaret R. Spitz regarding how new needs for cost extensions will affect the NCI's paylines, Dr. Sharpless explained that paylines have been set for 2021; NCI reached the 11th percentile. He stated that the NCI committed to funding more new awards than last year but cautioned that future requests—and the NCI's ability to meet those requests—are difficult to predict.

Additionally, Dr. Sharpless noted that the NCI has released a Notice of Special Interest for training grants; investigators are encouraged to submit no-cost extensions as needed.

Dr. Barker asked whether the loss of productivity resulting from the COVID-19 pandemic has been studied to the point of estimating the financial impact. Dr. Sharpless replied that the NIH has conducted extramural surveys to assess the impact of the COVID-19 pandemic on research. The results of the survey are being analyzed now. The effects of the disruptions are dynamic and complex, particularly for clinical trials. Mr. McGarey added that for some types of research, the effects likely will become apparent toward the end of grant cycles. Dr. Barker expressed concern that early-career and underrepresented (e.g., minority) investigators are likely to experience the greatest impact of COVID-19-related disruptions. Dr. Sharpless suggested discussing the survey results at a later date. He added that many early-career investigators rely on funding from foundations; presently, fundraising opportunities for foundations are more limited.

Dr. Scott W. Hiebert stated that trainees have expressed concern that COVID-19-related disruptions to research will inhibit their ability to apply for funding in the future. He suggested widening the application window for career development awards. Dr. Sharpless affirmed that the NCI will strive to allow flexibility on training grant deadlines. He added that the barrier for no-cost extensions is low, but additional funding is challenging to provide. Dr. Timothy Ley emphasized the importance of clear guidance from the NIH and NCI on this issue.

In response to a question from Dr. Barker, Mr. McGarey anticipated that the Biden administration's budget trends are likely to be consistent with those of the Obama administration, but the exact numbers cannot be anticipated. President Biden has consistently voiced support for the NCI and cancer research. Mr. McGarey also reflected that, currently, there also are many other pressing domestic priorities.

Dr. Barker asked about the NCI's discretion in funding caps for well-funded investigators. Dr. Sharpless explained that the NIH ICs employ different approaches to control the distribution of funds across investigators. The NCI's recent approach has been to employ a semi-cap and restriction of percent effort on awards. Dr. Sharpless noted that the outcomes of this new approach still need to be assessed, and he emphasized that this issue requires further consideration. Dr. Barker reflected that, initially, the research community voiced resistance to funding caps for well-funded investigators; in the current funding environment, however, opinions may have shifted.

Replying to a question from Dr. Barker about future extensions of the Cancer MoonshotSM initiative, Dr. Sharpless stated that the initiative has provided a significant value to the cancer research community, but its transition has been challenging for several reasons (e.g., the COVID-19 pandemic). He reiterated that the Biden administration has expressed strong support for cancer research and emphasized that the NCI is prepared to assist in the development of a new or continued program. The Cancer MoonshotSM initiative was found to be highly successful. Dr. Sharpless emphasized that cancer represents many distinct diseases, and a flexible framework is needed to tackle different programs and topics with different solutions. The Cancer MoonshotSM initiative helped facilitate a more comprehensive approach to cancer research.

Actions/Recommendations—Future Meeting Topics

Dr. Anna D. Barker and Subcommittee Members

• Dr. Barker noted that the passage of the Clinical Treatment Act was implemented into policy this year; state Medicaid programs will be required to cover routine patients costs that are provided as part of a qualifying clinical trial for cancer and other life-threatening disease. This is a significant

change for Medicaid which should significantly impact the cost of clinical trials for these patients.

• Dr. Hiebert suggested that the NCAB draft a resolution to commend NCI Leadership for the "Nothing Will Stop Us" initiative commemorating the 50th anniversary of the National Cancer Act of 1971.

Adjournment

Dr. Barker thanked the attendees and adjourned the Subcommittee meeting at 12:59 p.m. EST.

Dr. Anna D. Barker Chair Date

Mr. Patrick McGarey Executive Secretary Date