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Public Health Service
National Institutes of Health
National Cancer Institute

3rd Virtual Meeting
Frederick National Laboratory Advisory Committee

Summary of Meeting
May 21, 2020

National Cancer Institute
National Institutes of Health
Bethesda, Maryland

National Cancer Institute
3rd Virtual Meeting of the Frederick National Laboratory Advisory Committee
21 May 2020

Summary Minutes

The Frederick National Laboratory Advisory Committee (FNLAC) convened for its 3rd Virtual meeting on 21 May 2020. The meeting was open to the public on 21 May 2020, from 1:00 p.m. to 2:51 p.m. The FNLAC Chairperson, Dr. Lawrence J. Marnett, Dean of Basic Sciences, University Professor, Mary Geddes Stahlman Professor of Cancer Research, and Professor of Biochemistry, Chemistry, and Pharmacology, Vanderbilt University School of Medicine, presided.

FNLAC Members
Dr. Lawrence J. Marnett (Chair)
Dr. Catherine M. Bollard
Dr. Andrea Califano* (absent)
Dr. Timothy A. Chan*
Dr. Lisa M. Coussens
Dr. Kevin J. Cullen
Dr. Raymond N. DuBois
Dr. Angela M. Gronenborn
Dr. Robert L. Grossman
Dr. Klaus M. Hahn
Dr. David I. Hirsh
Dr. Elizabeth M. Jaffee (absent)
Dr. Candice S. Johnson*
Dr. Patrick Nana-Sinkam
Dr. Nilsa C. Ramirez-Milan
Dr. Lincoln D. Stein
Dr. Cheryl L. Willman (absent)

*Pending Appointment

***Ex Officio* Members**
Dr. Stephen J. Chanock (absent)
Dr. James H. Doroshow
Dr. Paulette S. Gray
Dr. Sara Hook
Dr. Anthony Kerlavage
Dr. Douglas R. Lowy
Dr. Tom Misteli
Ms. Donna Siegle (absent)
Dr. Dinah S. Singer

Executive Secretary
Dr. Caron A. Lyman

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I. OPENING REMARKS—DR. LAWRENCE J. MARNETT

Dr. Lawrence J. Marnett, Chair, called to order the 3rd Virtual meeting of the Frederick National Laboratory Advisory Committee (FNLAC) and welcomed the Committee members, National Cancer Institute (NCI) staff, and guests. Dr. Marnett reminded members of the conflict-of-interest guidelines and confidentiality requirements. Members of the public were welcomed and invited to submit to Dr. Caron A. Lyman, Executive Secretary, in writing and within 10 days, any comments regarding items discussed during the meeting.

Motion. A motion to approve the minutes of the 24 October 2019 FNLAC meeting was approved unanimously.

Dr. Marnett called Committee members' attention to the confirmed future meeting dates listed on the agenda. He noted that the next FNLAC meeting will be 13 July 2020.

II. REPORT FROM THE NCI DIRECTOR—DR. NORMAN E. SHARPLESS

Dr. Norman E. Sharpless, Director, NCI, also welcomed the FNLAC members and attendees to the meeting. He provided updates on the operating status of the NCI and Frederick National Laboratory for Cancer Research (FNLCR), the NCI's ongoing activities, the NCI COVID-19 response, and progress in cancer research.

Dr. Sharpless introduced new FNLAC members: Dr. Timothy A. Chan, Director, Center for Immunotherapy and Precision Immuno-Oncology, Co-Director, National Center for Regenerative Medicine, Cleveland Clinic, and Dr. Candice S. Johnson, President and CEO, Director, Wallace Family Chair in Translational Research, Chair, Department of Pharmacology and Therapeutics, Roswell Park Cancer Institute.

NCI and FNLCR Operating Status. Dr. Sharpless reported that aligning with the Maryland stay-at-home order, the NCI's on-campus activities are limited while the majority of workers are able to telework. On 15 May 2020, the National Institutes of Health (NIH) extended telework for all staff until further notice. A small number of staff are working within the NCI and FNLCR campuses supporting coronavirus-related research and certain mission-critical activities. The COVID-19 serological efforts at the FNLCR, which will be discussed later on the agenda, are considered essential. He explained that the NIH is actively planning when and how staff may safely return to the workplace. Dr. Francis S. Collins, Director, NIH, in his 21 May 2020 virtual Town Hall meeting addressed questions concerning a phased-in return to the physical workplaces, including the FNLCR. Dr. Collins also announced a graded plan—NIH Framework for Return to Physical Workspaces—involving five phases spanning from the current state (baseline) to a full return to work. The first group that will return (early June 2020) will be staff conducting work that cannot be completed remotely, which includes COVID-19 researchers, staff performing clinical care, and wet-bench scientists. Safety is a high priority for the NCI; the Centers for Disease Control and Prevention (CDC) guidelines for social distancing and wearing a mask will continue to be enforced. Dr. Sharpless noted that a message he conveys in communications across the NCI and the extramural community is that the NCI's primary focus—cancer research and care provided to patients by the NCI-Designated Cancer Centers (Cancer Centers)—remains unchanged.

NCI COVID-19 Response. Dr. Sharpless outlined three reasons that the NCI is important for responding to a pandemic such as COVID-19. First, people with cancer and who have survived cancer are disproportionately affected and are vulnerable to poor outcomes from the SARS-CoV-2 (the novel coronavirus that causes COVID-19) infection. Second, the history of research expertise and capacity

across the NCI and FNLCR is reflected in the NCI's decades of leadership in virology, intramural and extramural research infrastructure, and collaborations and convening power. Third, the NCI has a duty to contribute to addressing a global public health crisis. He further elaborated that the interruptions in cancer care delivery as a result of the pandemic are clearly affecting American patients with cancer. The reports from leaders in the extramural community at various academic medical centers about the deferred care have been unsettling. Cancer registry data from previous years concerning delaying diagnosis and therapy plainly demonstrate that such delays lead to worse outcomes for patients with cancer. These data indicate that the approaches to prevent, diagnose, and treat cancer work and cannot be delayed indefinitely. The United States has made progress in cancer diagnosis, treatment, and care resulting in a 2 percent decrease in mortality for the past two decades. This progress is predicted to be significantly affected if cancer care (e.g., surgeries, chemotherapy, screening) is further delayed and likely will be reflected in the coming years. Dr. Sharpless emphasized that the NCI focuses on improving outcomes for cancer patients and is considering many options to mitigate any negative impact of COVID-19.

The FNLAC members were updated on the FNLCR serology efforts in support of COVID-19 research. Dr. Sharpless first called attention to the 4 May 2020 U.S. Food and Drug Administration (FDA) revision to the policy concerning antibody tests for commercial manufacturers related to the Emergency Use Authorization (EUA) and providing clinical performance expectations for these tests. With this revision, manufacturers of serological tests and devices currently in the market without an EUA will have 10 business days to provide the FDA with the EUA submission and likely will be forced to remove their products. This stricter approach, he emphasized, reflects the FDA's confidence that specific manufacturers are making these tests available and are doing so in large supply. EUAs have been granted for several commercial devices from manufacturers meeting the quality standard. On behalf of the government, the NCI is leveraging the expertise of the FNLCR in serological testing and validations. In collaboration with the CDC, the Biomedical Advanced Research and Development Authority, and academic partners on a validation project, the FNLCR investigators have conducted performance testing for the FDA and provided high-quality, unbiased evidence that serology testing works, particularly for high-quality assays available to the American consumer. The FDA has posted the NCI FNLCR validation results to its website, and further details are posted on the NCI Cancer Currents blog.

Dr. Sharpless noted that Congress appreciates the NCI's capabilities at the FNLCR, its world-class expertise in virology, and extensive clinical research networks. Collectively, these attributes reveal that the NCI is well positioned to lead a much-needed serology research effort. In that regard, the fourth aid package—the Paycheck Protection Program and Health Care Enhancement Act—to address COVID-19 to support small businesses and the economy and preserve such critical operations as health care was signed into law on 24 April 2020. The bill includes a $306 million (M) appropriation for the NCI to develop, validate, improve, and implement serological testing and associated technologies. The NCI is working closely with the National Institute of Allergy and Infectious Diseases (NIAID) to decide on the research areas best suited to use these funds for public benefit. He explained that the legislation is not specific to cancer and that the COVID-19 funding, which is separate from the NCI's regular appropriations, does not shift the NCI's priority from cancer. The NCI envisions three areas of spending for the COVID-19 appropriation: serology and immunology capacity building, clinical serological sciences, and foundational serological sciences. Further details about the COVID-19 spending will be provided later on the agenda.

NCI Ongoing Activities. Dr. Sharpless informed the FNLAC members that Congress has been focused on the supplemental funding related to the COVID-19 pandemic, and the work on the fiscal year (FY) 2021 budget has been delayed. After the fifth emergency appropriations bill is completed, the appropriators likely will resume work on the regular FY 2021 appropriations bill.

Regarding normal NCI business, Dr. Sharpless announced that Dr. Philip E. Castle is now Director, Division of Cancer Prevention (DCP). He reminded the FNLAC members that the Childhood

Cancer Data Initiative (CCDI) announced at the 5 February 2019 State of the Union Address includes a $10 M annual appropriation to the NCI for 10 years. Dr. Jamie Guidry Auvil, Director, Office of Data Sharing, Center for Biomedical Informatics and Information Technology, and Executive Secretary, convened the Board of Scientific Advisors *ad hoc* Working Group in Support of the CCDI on 27 March 2020. At that meeting Dr. Guidry Auvil discussed the CCDI and its relationship to ongoing NCI pediatric cancer activities. The Working Group will present its report at the 15 June 2020 virtual joint meeting of the Board of Scientific Advisors (BSA) and National Cancer Advisory Board (NCAB). Dr. Sharpless explained that the NCI is using the FY 2020 CCDI appropriation to support the foundational aspects of childhood cancer research and data sharing.

Progress in Cancer Research. Dr. Sharpless reported that the FNLCR chimeric antigen receptor (CAR) T-cell facility within the Biopharmaceutical Development Program is operational. He announced that the vector-production facility component soon will open and evaluate potential viral production projects proposed by the extramural community. The NCI will be accepting applications for development and clinical proposals this summer.

Dr. Sharpless highlighted three Intramural Research Program (IRP) efforts, noting that research advances are too numerous to report as this one meeting. NCI Center for Cancer Research (CCR) investigator Dr. Nirali Shah, in collaboration with Children's Hospital of Philadelphia investigator Dr. Richard Aplenc, is co-leading the cluster of differentiation (CD) 33 CAR T-cell clinical trial investigating the anti-CD33 CAR-expressing T-cells in children and young adults with relapsed/refractory acute myeloid leukemia (AML), and the trial has enrolled its first patient. The CAR T-cells used for this first-in-human CAR T trial for AML were manufactured in the FNLCR CAR T-cell facility. Dr. Sharpless expressed appreciation to Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research, Director, Division of Cancer Treatment and Diagnosis (DCTD), and FNLCR and DCTD researchers for their efforts in enabling CAR T-cell manufacturing at the NCI-Frederick.

On 14 May 2020, the FDA approved and expanded the indication for pomalidomide (Celgene Corporation) to include treating adult patients with AIDS-related Kaposi sarcoma after unsuccessful highly active antiretroviral treatment. CCR investigator and Director, Office of HIV and AIDS Malignancies, Dr. Robert Yarchoan, in collaboration with Accredo and Celgene, coordinated the Phase I/II clinical trial at the NIH Clinical Center leading up to this approval.

Two resources expanded and validated in the RAS Initiative—disulfide tethering high-throughput screening (HTS) (e.g., covalent bonding of adjacent cysteine residues) and a disulfide tethering library—are being used to support COVID-19 research. Two SARS-CoV-2 protease targets involved in the viral lifecycle—3-chymotrypsin-like protease and papain-like protease—are being evaluated using FNLCR's HTS assay. In an iterative drug discovery design, the U.S. Department of Energy's Argonne National Laboratory will use artificial intelligence approaches to identify therapeutic targets to inform the FNLCR HTS, which The University of Chicago will refine and optimize using medicinal chemistry methods.

In the discussion, the following point was made:

- Dr. Sharpless confirmed that a portion of the COVID-19 funding will include research-related serology, which drives policy and provides immediate benefit to coronavirus patients.

III. COVID-19 SEROLOGY AND IMMUNOLOGY CAPACITY BUILDING—DR. DOUGLAS R. LOWY

Dr. Douglas R. Lowy, Principal Deputy Director, NCI, reported on serology and immunology capacity building at the FNLCR. He reminded the FNLAC that the NIAID has made extensive use of the

FNLCR in responding rapidly to emerging infectious disease epidemics: SARS in 2003, Ebola in 2013, and Zika virus in 2015. In January 2020, the NIAID—supported by the FNLCR—opened the Adaptive COVID-19 Treatment Trial (ACTT), a multicenter international trial evaluating remdesivir (Gilead Sciences) in hospitalized COVID-19 patients. Remdesivir, a known treatment for Ebola and Marburg viruses because of its function as an RNA chain terminator, also inhibits replication of other RNA viruses, including coronaviruses. As of mid-April 2020, more than 1,000 patients worldwide have been enrolled in the ACTT, the majority of whom are in the United States. On 29 April 2020, Dr. Anthony Fauci, Director, NIAID, in a White House briefing from the Oval Office, disclosed that preliminary results from the ACTT were positive. In fact, hospitalized COVID-19 patients treated with remdesivir (i.e., remdesivir group) were discharged from the hospital 31 percent sooner than patients not receiving the drug (i.e., placebo group). The 14-day mortality rate was lower in the remdesivir group compared with the placebo group, but the results were not statistically significant at the time of this report. These data continue to be evaluated, and the ACTT investigators are collecting data on the 28-day mortality rate.

Dr. Lowy informed the FNLAC members that in a collaborative effort primarily with the NIAID, CDC, FDA, and Mount Sinai Hospital, the FNLCR human papillomavirus (HPV) Serology Laboratory within the Vaccine, Immunity, and Cancer (VIC) Program has successfully converted to SARS-CoV-2 serology. Dr. Lowy noted that at the 24 October 2019 FNLAC meeting, FNLCR VIC Program lead, Dr. Ligia A. Pinto, reported on the capabilities of that program. Activities of the multifaceted HPV Serology Laboratory include supporting NCI vaccine trials (e.g., NCI Costa Rica Vaccine Trial) and leading the HPV Serology Standardization Initiative jointly supported with the Bill and Melinda Gates Foundation launched in 2017. Recent data from the VIC Program showed that the GlaxoSmithKline PLC bivalent vaccine Cervarix® induces durable antibody and long-term immunity to the extent that women receiving one dose remain seropositive and HPV-16 negative in the 11-year follow-up. Although not sufficient at this phase of the studies to change the standard of care, these data have informed a broader HPV vaccine trial in Costa Rica and provided the basis for converting part of the HPV Serology Laboratory to perform SARS-CoV-2 serology.

The main aims of the HPV serology standardization are to enable comparisons of data between different vaccines and studies and to accelerate implementation of new vaccines and new vaccine indications. The short-term goals are to characterize different serologic assays and correlate the data with existing neutralization assays to better understand the possible cross-reactivity interactions from prior exposures to other coronaviruses and to validate serology assays that have been submitted to the FDA for approval. The long-term goals are to improve understanding of the implications of being seropositive in terms of resistance and duration and to participate in the cohort-oriented COVID-19 project described previously.

Dr. Lowy emphasized that because of the increased interest from commercial laboratories in developing antibody tests for SARS-CoV-2, on 16 March 2020, the FDA permitted the sale of commercial laboratory-based and rapid lateral flow SARS-CoV-2 serology devices without an FDA performance assessment. The FDA clarified that only devices that measure viral RNA or viral protein are used to diagnose current SARS-CoV-2 infection and not these point-of-care serology devices. Dr. Lowy echoed Dr. Sharpless on the EUA granted to several commercial devices and the recent FDA requirement that all other manufacturers with devices on the market must provide an EUA submission within 10 business days, noting that the submission period closed on 18 May 2020.

Dr. Lowy summarized the initial results of the 20 commercial serology devices evaluated by the HPV Serology Laboratory. The devices were assessed using Immunoglobulin G (IgG)-based antibody tests, which appear more stable than IgM-based tests. Of the 20 devices tested, the sensitivity, a detection of true positives, varied from 30 to 100 percent. The specificity, which does not detect false-positives, also varied across devices and was within 87 to 100 percent. The results have been sent to the FDA to help

determine devices suitable for an EUA. Dr. Lowy projected that only devices with high sensitivity and high specificity will be available in the United States. He noted the importance of maintaining specificity at low rates of seroprevalence similar to that seen in most of the American population and summarized key questions concerning seropositivity that should be used in assessing future devices.

In the discussion, the following points were made:

- The readout of the rapid lateral flow SARS-CoV-2 serology devices is qualitative (i.e., yes or no), whereas the ELISA assays provide quantitative antibody titers.

- Although the preliminary results from the ACTT did not include genotype information on COVID-19 patients or SARS-CoV-2, the NCI anticipates these data being reported in future updates.

- Dr. Lowy noted that making any determinations on immunoprotection or immunodominance in the serology testing or validations is beyond the scope of the HPV Serology Laboratory in its intended role of supporting the FDA.

IV. CLINICAL SEROLOGICAL SCIENCES—DR. JAMES H. DOROSHOW

Dr. Doroshow provided an update on the work of the NCI Clinical Trial Network (NCTN) during the COVID-19 pandemic and described the efforts in clinical serological science. He explained that recent large-scale studies show that 70 percent of cancer patients diagnosed with COVID-19 are male, and the overall death rate is between 8 to 10 percent. The predictors of hospitalization reveal that patients over 65 years of age, patients with hematological malignancies, and patients being treated with immune checkpoint inhibitors are disproportionately affected. In addition, patients with advanced disease—such as lung, gastrointestinal, and metastatic cancers—are at high risk for COVID-19, and their mortality also is increased. He expressed appreciation to health care professionals worldwide for their efforts in maintaining the standard of care for cancer patients (inpatient and outpatient settings) with COVID-19.

In the NCTN trials, the accrual rates decreased more than 40 percent beginning mid-March 2020 for all trials (interventional and screening) and across all cooperative groups. Dr. Doroshow attributes this decrease to the fact that many Cancer Centers have temporarily closed accruals to most of their studies because of the increased patient workload for health care professionals caring for COVID-19 patients and the level of care these patients require. Despite these challenges, some institutions, including the Clinical Center have continued enrolling patients in trials, particularly for studies that offer curative therapies.

Dr. Doroshow detailed the NCI's three areas of response to COVID-19 in the NCTN. The NCI is adapting to COVID-19 with modifications to the NCI clinical trial processes in discussions with the NCI central institutional review board (CIRB) and in collaboration with the FDA. The Cancer Therapy Evaluation Program (CTEP) issued guidance that patient care can be transferred to different participating study sites. Local health care providers can provide study activities to deliver continuity of care, with oversight by the responsible investigator. The NCI can ship oral investigational new drug (IND) agents directly to patients, but injectable CTEP IND agents must be administered at an FDA-registered site. Alternative procedures that do not compromise safety or the integrity of the study will be considered minor deviations. Major deviations may be unavoidable but must be reported to the CIRB. On-site auditing visits are being rescheduled; remote auditing has been adopted by NCTN groups. The CIRB supports remote informed consent (e.g., by phone) in conjunction with the patient's signature on written documents.

In the tocilizumab (Genentech, Inc.) compassionate use (i.e., treatment referral) clinical trial, the NCI will use its treatment referral mechanism to distribute this interleukin (IL)-6 agent to hospitalized

cancer patients testing positive for SARS-CoV-2 or displaying severe complications of COVID-19. Dr. Doroshow emphasized that the protocol was developed within a 4-day period by CTEP's Dr. Richard F. Little and IRP investigator Dr. Shah and was subsequently approved by Genentech. The eligibility criteria are broad to include patients (older than 2 years of age) with severe respiratory compromise from either presumed or proven SARS-CoV-2 infection and intensive care unit patients with or without worsening lung function. The goal is to decrease the amount of time spent in the intensive care unit, on a ventilator, and in the hospital. Investigators will collect limited clinical data and blood samples for biomarker evaluation. The protocol will be reviewed by the CIRB in the coming week and then activated across the NCTN. The NCI anticipates activating the protocol nationwide as the trial progresses.

The NCI is sponsoring a natural history study—NCI COVID-19 in Cancer Patients Study (NCCAPS)—to build a U.S. national COVID-19 longitudinal cohort of 2,000 patients. The NCCAPS goals are to develop a cohort of cancer patients with SARS-CoV-2 infection/COVID-19 symptoms across all age groups and follow a subset of patients for more than l year to assess survivorship and quality of life. Efforts also will focus on collecting patient blood samples at study entry and at selected intervals to estimate antibody response and genetic susceptibility and for biomarker development and also on collecting blood samples from family members. The outcome will be development of a public database of COVID-19 biospecimens. Data will be stored in the NCTN Biobank and The Cancer Imaging Atlas (TIGA). The aim is to launch the study at more than 1,000 sites across the NCTN, Early Therapeutic Clinical Trials Network, NCI Community Oncology Research Program (NCORP), and Cancer Centers in high-, moderate-, and low-prevalence regions. The NCI will fully support per-case reimbursements, ensure that patients from the NCORP Minority/Underserved Community Sites are enrolled, and leverage existing resources (e.g., NCI CIRB) for the study. The critical milestones are to initiate patient accrual on or before 26 May 2020, enroll the first 500 patients during a 3-month period after the trial starts, complete the 2,000 patient accruals by 1 December 2020, and complete follow-up and survivorship evaluations by the end of 2021.

Dr. Doroshow highlighted other COVID-19 and cancer clinical trials. More than 12 Cancer Centers have developed COVID-19 therapeutic trials for cancer patients. Vanderbilt-Ingram Cancer Center established the COVID-19 and Cancer Consortium with the goal of using a de-identified information, open-access internet database to rapidly share information to the scientific community. The American Society of Clinical Oncology and American Society of Hematology have started similar initiatives. In addition, large pharmaceutical companies have sponsored several Phase III trials evaluating IL-6 antibodies and antivirals in both cancer and non-cancer patients with COVID-19.

In the discussion, the following point was made:

- Given that much is unknown about which cells are actually being infected in patients who develop COVID-19, use of circulating demethylated DNA analyses could help to determine which tissues and organs are being infected by SARS-CoV-2 at the various stages.

V. FOUNDATIONAL SEROLOGICAL SCIENCES—DR. DINAH SINGER

Dr. Dinah Singer, Deputy Director, Scientific Strategy and Development, NCI, presented the NCI plans to integrate and expand the various COVID-19 efforts into the broader NCI community. She echoed Dr. Sharpless on the aim of the NCI supplemental funding of $306 million to support serology testing, noting that the NCI has moved quickly to respond to the legislation. The NCI is establishing a Serological Sciences Network for COVID-19 to support expanding the serological testing capacity and research characterizing the immune response of SARS-CoV-2 infection. The network is designed to enhance

collaborative efforts to rapidly expand testing capacity in diverse geographical areas, develop novel serological assays, and enhance understanding of the innate and adaptive immune response to SARS-CoV-2 infection.

Dr. Singer detailed the five components of the proposed network. The FNLCR HPV Serology Laboratory, as the core, will implement and validate SARS-CoV-2 serology assays, build validation proficiency panels for assay development using SARS-CoV-2 patient samples, and produce assay standards. Implementing standards, evaluating determinants, and establishing partnerships with regulatory bodies and assay developers for serology validation and testing platforms also are key roles for the core laboratory.

The Serological Capacity Building Centers (CBCs) will be geographically located across the country to develop, validate, and deploy serology tests in the local community. The CBCs also will acquire convalescent sera from recovered seropositive COVID-19 patients, conduct surveillance clinical trials in those patients, and pursue focused serological science on the acquired sera. The centers will be supported through four to eight contracts to academic and private-sector organizations with a total annual budget up to $3 M per year for 5 years.

The goals of the Serological Sciences Centers of Excellence are threefold: (1) understand the mechanisms involved in the serological, humoral, and cellular immune responses to SARS-CoV-2 infection to inform development of novel serological tests; (2) determine the serological correlates with disease pathogenesis and protection against future infection; And (3) improve population-based models of outbreak and susceptibility through serology-focused studies. The centers will be supported thorough four to eight Cooperative Agreement (U54) awards with a total annual budget of $2 M per year for 5 years and a 10 percent budget set-aside for post-award collaborative projects. Preference will be given to applications that include a cancer-relevant component. Each center will conduct two to three projects and include an administrative core and possibly a technical one as well.

The Serological Sciences Research Projects share the goals of the Serological Sciences Centers of Excellence but will be supported by five to 10 Research Project Cooperative Agreement (U01) awards with a total budget up to $0.5 M per year for up to 5 years, as well as a 10 percent budget set-aside for post-award collaborative projects.

The Network Coordinating Center operations will be housed at the FNLCR and will provide program management across the network, coordinate data sharing and results, coordinate partnerships with national and international associates (e.g., CDC, FDA, World Health Organization, National Institute for Biological Standards and Control), and work closely with the NCI staff. The coordinating center will be supported through a FNLCR task order with a total annual budget of $0.75 M.

Dr. Singer informed the FNLAC members that on 15 May 2020, the NCI issued a Notice of Intent to publish a funding opportunity announcement (FOA) for the Serological Sciences Centers of Excellence, which describes the goals, funding mechanisms, and scope. The final FOA is expected to be published 10 June 2020 with an anticipated due date of 20 July 2020. In addition, the NCI plans to publish a request for information (RFI) on research strategies for COVID-19 serology testing to incorporate feedback from the research community. The RFI will remain open to responses for 10 days; the responses will be reviewed and incorporated into the network design.

Dr. Singer reiterated that the NCI, in conjunction with the NIAID, is planning to establish an integrated network of cores and centers that will collaborate to advance the national capacity for serological testing and improve understanding of the immune response to SARS-CoV-2. On 12 May 2020, the BSA approved establishing the NCI COVID-19 Serological Research Initiative. Today, the NCI is

requesting the FNLAC's concurrence on the proposed Serological Sciences Network for COVID-19 and related activities. She expressed appreciation to NCI leadership, NCI staff, and NIAID colleagues for assisting in planning the network concept.

In the discussion, the following points were made:

- FNLAC members concurred with the proposed Serological Sciences Network for COVID-19 and its related activities.

- FNLAC members lauded the NCI's rapid response to the COVID-19 pandemic and new legislation for serology testing, both in leveraging the unique capabilities and demonstrating the flexibility of the FNLCR.

- The COVID-19 appropriation for the NCI focuses on serology testing, not diagnostics. The NIH launched the Rapid Acceleration of Diagnostics (RADx) initiative to focus on technology development for diagnostic testing. Separate legislation provides funding to the NIH and National Institute of Biomedical Imaging and Bioengineering to addresses nucleic acid and viral antigen testing approaches.

- Given the speed and governing authorities at which these data are being collected, the NCI should ensure that data sharing and integration across projects from the multiple sources (internal and external) remain at the forefront of NCI FNLCR COVID-19 funding opportunities and agreements.

- The opportunity exists to revisit establishing a universal patient identifier to assist in linking the COVID-19 data sets, which also will address any data privacy issues in the long-term.

VI. CLOSING REMARKS—DR. NORMAN E. SHARPLESS

Dr. Sharpless confirmed that the FNLAC concurs that the FNLCR is on course in its COVID-19 response and other activities. He expressed appreciation to the FNLAC members for their wisdom, guidance, and assistance with the important mission of the FNLCR. Members wishing to express any new concerns or additional thoughts can send them to Drs. Lowy, Singer, Doroshow, or Sharpless.

VII. ADJOURNMENT—DR. LAWRENCE J. MARNETT

Dr. Marnett thanked the Committee members and other participants for attending. Members were reminded to send potential agenda topics for future FNLAC meetings to Dr. Lyman. There being no further business, the 3rd Virtual Meeting of the FNLAC was adjourned at 2:51 p.m. on Thursday, 21 May 2020.

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Date Lawrence J. Marnett, Ph.D., Chair

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Date Caron A. Lyman, Ph.D., Executive Secretary