NIH SCIENTIFIC MANAGEMENT REVIEW BOARD

July 11, 2012

MEETING SUMMARY

Board Members Present:

Norman R. Augustine, Chairman
Josephine P. Briggs, M.D.
William R. Brody, M.D., Ph.D.
Gail H. Cassell, Ph.D.
The Honorable Daniel S. Goldin
Richard J. Hodes, M.D.
Stephen I. Katz, M.D., Ph.D.
Garry A. Neil, M.D.
(via teleconference)
Gilbert S. Omenn, M.D., Ph.D. *(via teleconference)*
Griffin P. Rodgers, M.D., M.A.C.P.
William L. Roper, M.D., M.P.H.
Susan B. Shurin, M.D.
Solomon H. Snyder, M.D.
Clyde W. Yancy, M.D.
(via teleconference)

Ex-Officio Members Present:

Francis S. Collins, M.D., Ph.D.

Designated Federal Official:

Amy Patterson, M.D., Executive Secretary

Opening Remarks

Mr. Augustine welcomed current and new Board members, panelists, and guests and reviewed the meeting agenda. He also announced that Dr. Gilbert Omenn, Dr. Clyde Yancy, Mr. G. Steven Burrill, and Dr. Garry Neil have joined the SMRB as ad hoc members and are awaiting final approval for full member status. Mr. Burrill was unable to participate in today's meeting. Brief member introductions were made.

Dr. Collins thanked the SMRB members for their continued efforts. He stated that science is experiencing a paradoxical time: current scientific advances are exhilarating, and yet there is a deep anxiousness about the future of science. He acknowledged that government sequesters could cause significant budget restrictions—up to 8 percent of the NIH budget in 2013—which means that a strategy is required to maximize resources. Dr. Collins believed that partnerships will be a critical part of this strategy and that today's discussion about the NIH Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs is therefore timely and important. He reiterated his gratitude to the SMRB members for their

recommendations on a number of NIH issues and expressed interest in the meeting agenda. He thanked Mr. Augustine for his able leadership.

Mr. Augustine thanked Dr. Collins and reminded all participants that there will an opportunity for public statements during today's meeting and that written statements may be submitted to the SMRB at any time. The minutes from the teleconference held on May 29, 2012, were approved as written.

Dr. Patterson reviewed the NIH conflict of interest policy, and members reported no conflicts.

Overview of SMRB SBIR/STTR Working Group Process
Solomon H. Snyder, M.D.
Chair, SMRB SBIR/STTR Working Group

Dr. Snyder provided an overview of the progress of the SMRB SBIR/STTR Working Group as an interim report to the SMRB. He explained that the Working Group has been considering its charge for a number of months, and the bulk of the overview addresses how SBIR/STTR programs are managed at a sample of Institutes within NIH as well as other government agencies. He noted that the Working Group has been in discussions with these groups to better understand current procedures before making recommendations.

Dr. Snyder reviewed the charge to the SMRB: "To recommend strategies for how NIH can optimize its utilization of the SBIR/STTR programs in keeping with the NIH mission." With a total budget of $32 billion, NIH funds one of the largest SBIR/STTR programs. He reviewed the mission of NIH: to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. He noted that this mission creates a unique challenge for the SBIR/STTR programs because it is not focused on developing products and technologies for use by NIH and because identifying projects with potential "commercial value" that align with the mission can be challenging and complex. Dr. Snyder believed that the impetus for the SMRB charge is apparent in the recent reauthorization of these programs, which requires increasing the set-aside percentages over the course of the next six years despite the projection for stagnant budgets. He explained that the fiscal set-aside percentage for SBIR is 2.6 percent in 2012, and it will increase to 3.2 percent by 2017. STTR's set-aside percentage will increase from 0.35 percent to 0.45 percent during that period.

Dr. Snyder listed several considerations with respect to the SMRB charge: NIH should encourage the SBIR/STTR programs to foster innovation within small businesses that aligns with the priorities of the NIH Institutes and Centers (ICs), fund quality proposals yielding the greatest potential for successful commercialization, and leverage existing resources and expertise to enable the success of its grantees. He noted that currently, the ICs use different approaches to address these points. Dr. Snyder also reviewed the membership of the Working Group.

Dr. Snyder briefly reviewed the process that the SBIR/STTR Working Group has undertaken in considering its charge. He referred to the framework established by the SMRB, outlined in its report *Deliberating Organizational Change and Effectiveness.* He also acknowledged previous

reviews of the SBIR/STTR programs by NIH (2009), the National Research Council (NRC; 2009), and the Government Accountability Office (GAO; 2006, 2011). Dr. Snyder then discussed the lifecycle of a grant in the NIH SBIR/STTR program, outlining each step in the SBIR/STTR process: program outreach to prospective applicants, concept development and proposal submission, scientific peer review, Institute/Center funding decision, discovery and development, commercialization, and outcome evaluation. He noted that SBIR/STTR proposals could either be submitted under targeted requests for applications, wherein the Institute identifies a specific area of priority, and under an omnibus solicitation, which utilizes broad categories of interest. He reminded the SMRB that the strategy used is determined by the ICs.

Dr. Snyder stated that, in general, the Working Group was very impressed with the activities of the SBIR/STTR program at NIH, and stated that any recommendations would try to take this program from "good to great." The Working Group believed that the programs have been quite useful and are meeting all statutory requirements. Dr. Snyder stated that a considerable strength of this program was the flexibility afforded each institute/center (IC) to establish its own approach because the ICs vary in size of programs and budgets, degree of program management, implementation of pilot initiatives, assessment of success, and number of grants. Along these lines, Dr. Snyder explained that in 2009, the NRC provided recommendations "designed to improve an already effective SBIR program at NIH," which included establishing reliable metrics and outcomes, strengthening the application process, enhancing scientific peer review, and defining and tracking success. He noted that the guidelines for distribution of money for phase I and phase II grants are not requirements, and some programs alter their distribution allocations to fund promising applications. Dr. Snyder also acknowledged that the establishment of metrics is important to assess the success of all discoveries and that commercialization provides its own challenges, particularly in light of the NIH mission to find causes and cures for disease. He stated that education is needed to help companies not accustomed to the NIH funding system understand the grant application process. Lastly, Dr. Snyder remarked that the peer review system is challenging for the SBIR/STTR programs because they are designed to fund development of a product and require a unique set of assessment criteria.

Dr. Snyder explained that the majority of the meeting would comprise panel presentations from members of NIH involved in SBIR/STTR, presenters from SBIR/STTR programs within other federal agencies, and experts discussing and defining metrics and outcomes of success for SBIR/STTR-funded applicants. He noted that an SMRB meeting in October will allow additional input from stakeholders.

SBIR/STTR Re-authorization Update
Matthew E. Portnoy, Ph.D.
Manager, NIH SBIR/STTR Programs

Dr. Portnoy informed the SMRB that the SBIR/STTR reauthorization was signed into law on December 31, 2011, reauthorizing the programs until fiscal year 2017. Dr. Portnoy explained that the reauthorization includes the most substantial changes to SBIR/STTR in 20 to 30 years. For example, as a result of the reauthorization, the Small Business Administration (SBA) has 120 days to issue draft revised eligibility regulations, called Size Rules, and 180 days to issue draft revised Policy Directive, which include the program rules, phasing, and guidelines. The deadline

for public comment on the Draft Size Rules is July 16. 2012; the Policy Directives, which address all rules and regulations of the programs beyond eligibility, are expected to be released for public comment in the near future. Dr. Portnoy informed the Board that federal officials may provide comments as private citizens during non-work hours. He stated that NIH as an agency had the opportunity to comment prior to the open public comment period.

Dr. Portnoy noted that one change to the Size Rules allows more leniencies in the inclusion of companies with venture capital backing, but this change will not be effective until the Size Rules are formalized after the public comment period. The Policy Directives, however, will go into effect at the time they become available for public comment.

Dr. Portnoy reviewed the changes that will take place as a result of the reauthorization. As Dr. Snyder noted, the SBIR/STTR set-aside percentages will increase yearly throughout the six years for which the programs have been reauthorized. Dr. Portnoy informed the SMRB that the guidelines for the size of awards have changed slightly: SBIR will remain at $150,000 for phase I and $1 million for phase II, and STTR will be adjusted upward to match the SBIR guideline. A new provision creates hard limits on award size to 50 percent over the guideline. Agencies will have the option to request a waiver from the Small Business Administration (SBA) for specific topics. As noted previously, venture capital participation has been expanded to 25 percent for NIH, the Department of Energy (DoE), and the National Science Foundation (NSF). It is 15 percent for other agencies. Two technical assistance programs for SBIR, a niche assessment program for phase I and a commercialization assistance program for phase II, have been expanded to STTR, and the reauthorization allows a funding increase to $5,000 per award per year for both phase I and phase II grants.

Dr. Portnoy also stated that the reauthorization requires all agencies to continue to work with the National Academies on continued study of the programs and initiate a new study on the STTR program. A new pilot program will allow agencies to use 3 percent of the set-aside budget for administrative funds, to cover administrative costs, outreach, management of the program, and compliance. A business may be able to receive phase II funding from a different agency than its phase I funding, and one with phase I funding from SBIR or STTR may receive funding from the other program for phase II, which was previously not allowed. Dr. Portnoy acknowledged that the metrics and tracking for an application that switched programs could be complicated. In addition to these changes, the requirements for phase II submissions allowed only through invitation will be eliminated. NIH, the Department of Defense (DoD), and the Department of Education may award a direct phase II award if the company can provide the necessary phase I data (previously, grants were only available to those with a SBIR/STTR phase I or fast-track award).

Dr. Portnoy informed the SMRB that the reauthorization allows agencies to allocate up to 10 percent of SBIR funds for a commercial readiness pilot program. He noted that the time frame for award decisions is a consideration and noted that NSF and NIH are given one year from receipt of the application to inform the applicant of their intent to fund. He added that external peer review contributes to the overall amount of time it takes to award funds.

Dr. Portnoy explained that the reauthorization sets new benchmarks for commercialization, for which agencies must develop phase I to phase II conversion rates. The reauthorization also increases outreach to women-owned small businesses, small disadvantaged businesses, and states with historically low application and award rates. It also addresses fraud, waste, and abuse policies to be coordinated with the Inspector General's office. A new Interagency Policy Committee will be instituted through the Office of Science and Technology Policy. New SBA databases will be built to allow more rigorous reporting, which will cover registration, application, award, solicitation, and commercialization; all agencies must comply with these new reporting requirements. The reauthorization includes additional reporting, such as reporting to SBA and Congress on pilots, venture capital, phase flexibility, coordination, and other issues.

Dr. Portnoy informed the SMRB that NIH will begin to phase in implementation of the changes from the reauthorization as SBA issues new rules. The final eligibility rules have yet to be formalized, so implementation will likely begin in 2013 at the earliest. Coordination will have to take place with the ICs, SBA, and other agencies.

Discussion

Dr. Cassell requested clarification on several issues, including a requirement than any SBIR awardee have a university partner. Dr. Portnoy responded that he was not familiar with that provision and believed that, previously, partners only had to be from nonprofit institutions. Dr. Cassell then asked whether any rules preclude agencies from pooling money to fund a particular initiative. Dr. Portnoy explained that, within the Department of Health and Human Services, all SBIR programs coordinate. Joint solicitations are also drafted between agencies; for example, one robotics initiative involves NIH and five other federal agencies. Lastly, Dr. Cassell asked whether SBIR/STTR collaborates with similar programs in other countries. Dr. Portnoy answered that these programs are for domestic U.S. businesses, but companies may collaborate with foreign partners.

Hon. Goldin expressed concern that $5,000 in technology support is exceedingly low given the cost of facilities and equipment. Dr. Portnoy explained that the technical assistance funds are not given to the awardee, but rather are allocated to IC programs or contractors to provide bulk services, such as business training programs. Capital equipment upgrades could be provided in phase I, but not phase II. He noted that other funding options are available at NIH to procure equipment.

Dr. Collins asked Dr. Portnoy to elaborate on the commercial readiness pilot program. Dr. Portnoy stated that it allows agencies to spend 10 percent of SBIR funds, or roughly $63 million at the NIH, for awards to small businesses for commercialization. These awards can be up to three times the guideline amount without requiring a waiver. Dr. Portnoy informed the Board that NIH is considering the commercial readiness pilot program as an option to fund phase IIb programs. Dr. Neil asked whether large corporate venture capital companies qualify; Dr. Portnoy replied that companies with venture capital funding from a variety of sources could qualify based on specific eligibility criteria.

PANEL PRESENTATIONS
Innovation within the SBIR/STTR Programs
Panel Presentation I—Pilot Initiatives across NIH
Moderators
Josephine P. Briggs, M.D., *SMRB Member*
Solomon H. Snyder, M.D., *SMRB Member*
Panelists
Jodi B. Black, Ph.D., M.M.Sc., *National Heart, Lung, and Blood Institute (NHLBI)*
Elena Koustova, Ph.D., M.B.A., *National Institute on Drug Abuse (NIDA)*
Michael Weingarten, M.A., *National Cancer Institute (NCI)*
Jerome Wujek, Ph.D., *National Eye Institute (NEI)*

Catalyzing the Next Generation of Cancer Technologies
Michael Weingarten, M.A.
Director, NCI SBIR Development Center

Mr. Weingarten briefly reviewed NCI's major initiatives for enhancing its SBIR program, including the SBIR Development Center, targeting solicitations, the SBIR Phase II Bridge Award, and the SBIR Investor Forum. He explained NCI's $115 million SBIR program is the primary resource for enabling commercialization of high-impact technologies that can benefit patients, including small molecules and biologics, cancer diagnostics, cancer imaging, and electronic health and education tools.

Mr. Weingarten explained that the SBIR Development Center has changed its management model. Under the old model, 40–50 NCI program directors each spent 5–10 percent of their time on SBIR. Few of the program directors had significant commercialization expertise. In the new management model, a 10-member management team focuses exclusively on the SBIR/STTR portfolio. The Development Center is staffed by program directors with industry experience and a broad range of scientific expertise who collaborate with staff from other NCI divisions to integrate the small business initiatives with NCI's scientific priorities. Currently, the Center is developing a range of new initiatives to help small businesses. Mr. Weingarten briefly showed the SMRB the current make-up of the SBIR Development Center staff.

Mr. Weingarten reported that SBIR Development Center staff conduct regular outreach events to recruit more focused, commercially minded SBIR applicants. They also coach applicants on how to develop stronger applications, oversee and manage projects, mentor and guide companies throughout the award period, and facilitate match-making with third-party vendors.

Mr. Weingarten next discussed the use of targeted solicitations within the NCI SBIR program. Previously, 95 percent of NCI's SBIR-funded grants were investigator initiated. He noted that a targeted strategy encourages the small business community to perform critically needed research and development in emerging areas with strong commercial interest, such as companion diagnostics and novel cancer imaging agents. Another benefit of targeted solicitation is that reviews are conducted in-house rather than via CSR, which allows NCI to tailor review panels that can evaluate the specific scientific and commercial merits of each proposal. The SBIR Development Center convenes an ad hoc Technology Advisory Group to evaluate NCI priorities

and select topics for solicitation; this group identifies topics that are both priorities for NCI and areas of interest to the commercial sector based on market opportunity. NCI uses the contracts mechanism wherein awards are milestone-based with defined activities and deliverables.

Mr. Weingarten next explained the NCI SBIR Phase II Bridge Award, which was designed to help investigators cross the "valley of death" between research development and commercialization. He referred to a February 2012 article that detailed the "truly staggering cost" of inventing new drugs—between $4 and $11 billion—and explained that the Bridge Award helps create partnerships and attract investors to defray those costs for promising new drugs. These awards provide up to $1 million per year for up to three years to extend selected projects, and they involve a peer-review cycle separate from previous applications to evaluate progress and future plans. NCI gives competitive preference and funding priority to applicants who can raise substantial third-party funds (at least a one-to-one match).

Mr. Weingarten stated that the partnership benefits for the Bridge Award include the opportunity to leverage millions of dollars in external resources and valuable input from third-party vendors, including rigorous commercialization due diligence prior to the award, guidance for commercialization during the award, and additional financing beyond the award period. Benefits for third-party investors include the ability to partner with small businesses to develop and commercialize technologies that have been vetted by NIH peer review and projects for which a substantial proof of concept already exists.

Projects eligible for the Bridge Award include current phase II awards, those that ended within the last two years, and cancer-related phase II projects initially funded by other ICs. Mr. Weingarten stated that the review process must be tailored to the objectives of projects at this stage of development; the technical and commercial merits of a project are considered by a panel comprising reviewers from academia, clinicians, industry professionals, and venture capitalists. They emphasize important considerations for commercialization, including intellectual property and strategies for gaining U.S. Food and Drug Administration (FDA) approval. Preferred types of funds from third-party investors include cash, liquid assets, and convertible debt. Funding could come from another company, venture capital firm, individual "angel" investor, foundation, university, or state or local government.

Mr. Weingarten informed the Board that since 2009, NCI has awarded 12 Bridge Awards: three in therapeutics, six in imaging technologies, and three in molecular diagnostics. Awardees have been able to leverage approximately $72 million in third-party investments to supplement approximately $31 million in NCI award (a two-to-one ratio). Third-party investments from venture capital, strategic partners, and individuals or other investors are roughly equal. Mr. Weingarten noted that NCI is creating the opportunity, but companies are finding different ways to raise additional capital.

Mr. Weingarten next discussed the NCI SBIR Investor Forum, which took place in April 2012 in the San Francisco Bay area. The top 18 SBIR-funded companies were present, as were more than 200 life science investors and leaders. The forum resulted in more than 150 one-on-one meetings with potential investors. At a 2010 SBIR Investor Forum, six of 14 companies were able to attract more than $230 million in contracts and investments. Mr. Weingarten highlighted the

example of Zacharon, a company that focuses on developing therapeutics for rare diseases and cancer. Zacharon finalized a major partnership with Pfizer worth up to $200 million. Lpath, MagArray, and ImaginAb also raised significant investments.

Mr. Weingarten suggested several issues for the SMRB to consider. First, tailoring the peer-review process to the needs of small businesses is critical to ensure the review criteria are suited to small business applicants, increase participation by industry professionals in study sections, and shorten the time between application and selection. Second, NIH might establish a comprehensive program for metrics collection and analysis to track the progress of companies for 5–10 years post-award, standardize sets of metrics-oriented questions, and allow ICs to access and analyze the raw data on awardees across NIH. Lastly, Mr. Weingarten emphasized the need to maintain program flexibility on award sizes, noting that proposed caps would severely constrain NIH's ability to assist technology progression to key inflection points. Currently, more than 50 percent of NCI awards exceed the proposed caps.

Discussion

Hon. Goldin noted that other ICs have struggled with potential conflicts of interest when including private industry representatives on their review panels and that it is a topic of consideration for the SMRB. Mr. Weingarten replied that in cases where there may be a conflict of interest, individuals leave the room for the votes. He stated that academic representatives also have conflicts of interest and that industry representatives should not be excluded on this basis.

In response to questioning, Mr. Weingarten clarified that the matching funds stipulated by the Bridge Award may come from foreign or domestic investors.

The SMRB briefly discussed the amount of time from request for applications to receipt of the award and observed that a year is a long time in the business cycle. Mr. Weingarten acknowledged the concern, noting that solicitations for the Bridge Award are typically faster (six- to seven-month turnaround). He also noted that targeted solicitations are typically smoother because the number of applications is smaller and the review panels are simpler to arrange.

Mr. Weingarten cautioned that the Bridge Award would be jeopardized by the new limits for funding in the recent reauthorization unless NCI receives a waiver. He added that he believes the Bridge Award is one of the strongest aspects of NCI's programs, and the Institute hopes to work closely with SBA to ensure that it can continue this funding mechanism. Dr. Neil added that promising programs may be jeopardized by missteps in management and that quality standards from industry and regulations are not always helpful. Some of these elements may require enhancement to ensure that the right management team is in place for each project. Mr. Weingarten agreed, noting that the NCI NExT program provides resources and assistance with preclinical development to prepare drugs for clinical trials.

National Eye Institute SBIR/STTR Program Initiatives and Issues: A Program Officer's Prospective

Jerome Wujek, Ph.D.
Research Resources Officer, National Eye Institute

NEI is smaller than NCI, and Dr. Wujek is the only employee dedicated to the NEI SBIR/STTR program. He reviewed NEI's mission, which is to "conduct and support research for new treatment and cures and training relating to blinding eye diseases and visual disorders, including research and training in the special health problems and requirements of the blind and in the basic and clinical sciences relating to the mechanism of the visual function and preservation of sight." He explained that, based on this mission, NEI is a clinically oriented Institute that is committed to investigator-initiated research with a cross-cutting management organization. NEI conducts and supports research into vision and blinding eye diseases, mechanisms of vision and pathophysiology of eye diseases, diagnosis and prevention, and rehabilitation and assistive mechanisms for people living with blindness and low vision.

Dr. Wujek informed the SMRB that the NEI SBIR/STTR program was run originally by several program officers, each with a small subset of the portfolio with which they had research expertise. These individuals had many other obligations within their job descriptions and had little industry experience. Now, one program officer, who has a focus on small business, increased knowledge about SBIR/STTR regulations and policies, and experience in small business, manages all NEI SBIR/STTR awards. The management of the program mirrors that of the Institute at large.

Dr. Wujek observed that research and discovery related to the eye and aiding vision is unique in that it lends itself to commercialization. Challenges remain, however, such as difficulties with long-term tracking of projects to determine whether they ultimately achieve commercial success. He noted that NEI receives many high-quality applications but is unable to fund all worthy applicants due to current funding constraints. Peer review was also cited as an area that should be addressed, both in the need for commercialization expertise on the review panels and challenges with resubmission of applications. Lastly, Dr. Wujek noted that grantees need access to product development resources, including guidance related to pharmacokinetics, toxicology, formulation, and FDA regulatory expertise. To meet this need, NEI implemented the Regulatory Assistance Program as a pilot to help applicants navigate the federal regulatory pathway through a competitive application process. Successful applicants will use a single regulatory consultant company to help develop a comprehensive strategy for navigating the regulatory process and provide follow-up and progress review.

Enhancing the National Heart, Lung, and Blood Institute (NHLBI) SBIR/STTR Program to Navigate the Transition from Discovery to Marketplace
Jodi B. Black, Ph.D., M.M.Sc.
Deputy Director, Division of Extramural Research Activity
National Heart, Lung, and Blood Institute

Dr. Black reported that NHLBI has re-engineered its SBIR/STTR program with the following points in mind: the set-aside is nearly 10 percent of NHLBI's competing grant fund, the Institute used an omnibus solicitation, specialized policies and processes were confusing, the path from discovery to market is challenging, and scientists are not trained to be entrepreneurs. Dr. Black noted that in addition to funding, mentors are needed to remedy a lack of knowledge about how biomedical technologies are brought to market; sufficient technology development and commercialization expertise is also required for early-stage product development. For example,

grantees need to understand intellectual property protection, appropriate valuation of technologies, and company formation. The NHLBI Office of Translational Alliances and Coordination (OTAC) coordinates the SBIR/STTR programs, encourages business development, provides regulatory assistance, enhances outreach and partnership, and assists in the commercialization of NHLBI discoveries.

NHLBI created an internal group called the Accelerated Innovations Program Working Group to develop strategic planning, map out the process from discovery to commercialization, define the scope of work and typical funding mechanisms, and identify gaps. Dr. Black explained that this group comprised stakeholders, academics, venture capitalists, and regulatory representatives. Funding gaps identified included validation, preclinical development, and the transition from phase II clinical trials to commercialization. Dr. Black noted that in addition to the funding gap, there was a gap in innovators' knowledge of how to bring technologies to market. Innovators also lacked access to sufficient technology development and commercialization expertise.

The primary recommendation from the working group was the creation of a program called the NIH Centers for Accelerated Innovations. Dr. Black explained that, to increase NHLBI staff engagement, the Institute established the Topic Review Advisory Committee. She informed the SMRB that NHLBI is increasing outreach at meetings, such as BIO, and intends to establish investor forums. It also has incorporated a Bridge Award similar to NCI's. In addition, NHLBI has developed the SBIR/TT Award, or Translational Technology Award, which provides funding to assist collaborations of intramural programs and small extramural businesses.

Dr. Black briefly reviewed the process for encouraging technology development through the Centers for Accelerated Innovations program. The program will have agreements with research-performing institutions to solicit technologies and review them for medical, scientific, and business merit. This process will include project management, product and business development, and assistance with regulatory and intellectual property issues with the goal of acquiring additional funding. During the development process, the institutions can leverage other NHLBI development resources.

Early involvement of several government agencies has been incorporated into the program. For example, the FDA will be able to view technologies in progress and provide early guidance for the approval process. The Centers for Medicare & Medicaid Services will provide the payer perspective. The intent is to help researchers produce more robust applications to ensure success. Those awarded funding will receive additional funding to conduct non–hypothesis-driven scientific feasibility studies to define their products. The goal is to develop technologies to a point where they can attract the next level of independent financing and exit the program either through licensing by an existing organization or by starting a new company.

Dr. Black stated that she believes that the Centers for Accelerated Innovations program has the potential to benefit public health by identifying, accelerating, and increasing the number of highly innovative scientific discoveries that are translated into marketable products. The program was developed to address critical bottlenecks and gaps, decrease the time from discovery to product, increase products' chance of success, encourage public-private partnerships with an

integrated environment of resources, and foster a culture conducive to sustained technology development.

Historically, SBIR/STTR funds could not be used to support proof-of-concept activities, but the reauthorization permits NIH to use $5 million of STTR funding for such efforts. In fact, the goals delineated in the reauthorization are nearly identical to those for NHLBI's Centers for the Accelerated Innovations program. If the $5 million is used for these types of activities, the Centers for Accelerated Innovations could become a trans-NIH program. This change would have numerous benefits. A trans-NIH program could promote participation of other ICs at reduced costs; increase efficiency and economies of scale; increase the number and geographic diversity of Center locations; enhance outcomes and provide a broader basis for effective program evaluation; provide other ICs with ready access to NHLBI infrastructure in place for Centers program management (OTAC); create a vibrant trans-NIH network to share experiences, develop best practices, and enhance culture change; provide opportunities to conduct technology development process research across a broader scope of technologies; and provide opportunities to conduct regulatory science research.

Dr. Black briefly reviewed the issues and challenges facing NHLBI with respect to SBIR/STTR, noting that they are similar to those expressed by other speakers at the meeting. Funding flexibility is critical, and budget caps could negatively impact the NHBLI SBIR/STTR program; compliance with the FDA requires both time and money. She stressed that waivers to the funding cap should be simple and broad. She added that there are issues with restrictions on administrative funding, the inability to evaluate commercial outcomes, and challenges related to peer review.

Building an SBIR Program for a Niche Market
Elena Koustova, Ph.D., M.B.A.
SBIR/STTR Coordinator, National Institute on Drug Abuse

Dr. Koustova stated that a "one size fits all" approach to SBIR/STTR program management is not appropriate within NIH because of the differences in the size and focuses of the ICs. The National Institute on Drug Abuse (NIDA) SBIR program currently has $25.3 million in funding. It has no dedicated program officers but instead is managed by several program officers who represent all of NIDA's centers and divisions and provide policy assistance to NIDA staff.

Dr. Koustova briefly reviewed the findings of the National Research Center (NRC) review of the NIH SBIR/STTR research programs. As a result of this assessment, NIDA addressed concerns about modest management and leadership engagement. The Institute created an SBIR Web page on its Web site, allocated time for regular presentations at its senior staff meetings, established a "Tea with NIDA Director" celebratory ceremony for the winners of the best SBIR contract topics contest, instituted separate and transparent funding meetings, established a NIDA SBIR Idea Board, and increased visibility of the program. Dr. Koustova explained that NIDA promoted the program through a "yellow T-shirt campaign," which increased Web traffic by 500 percent; e-mail lists; and other mechanisms to improve relative scores and number of applications to its SBIR/STTR programs. The Institute also collaborated with the Library of Congress to perform targeted outreach by searching 17 databases to identify public and private companies that might

be interested in NIDA programs. Dr. Koustova noted that, following those activities, the number and quality of applications improved significantly. NIDA also is interested in targeted topics for applications.

Dr. Koustova informed the SMRB that NIDA currently has 14 study sections reviewing grants and that there have been complaints about the lack of cohesion among sections and the lack of specific expertise within them. She expressed the belief that one study section with the appropriate knowledge would serve NIDA well. In addition, it is important to decrease the burden on NIDA staff because of the Institute's small size. Educating staff on issues related to commercialization is also important.

Dr. Koustova briefly reviewed an internal concept for rating requests for proposals (RFPs) and requests for applications (RFAs) on 10 factors: market size, urgency, uniqueness, speed to market, cost of value delivery, pricing potential, cost of customer acquisition, up-front investment, up-sell potential, and evergreen potential.

Lastly, Dr. Koustova reviewed issues and challenges for the NIDA STTR/SBIR program. NIDA is striving to find a balance in the level of staff engagement, considering modification in peer review, and working on ways to improve the number of high-quality grant applications.

Panel Discussion

Dr. Cassell expressed interest in the NHLBI Centers for Accelerated Innovations program discussed by Dr. Black and asked whether the participants would be external centers awarded on a competitive basis. Dr. Black affirmed that they would be external and would be created through cooperative agreements. In response to additional questioning, Dr. Black explained that centers would receive assistance with strategies to handle regulatory standards. Based on these partnerships, the centers may be able to perform regulatory science research similar to what is already done at NIH. Dr. Black clarified that the specifics have not been worked out, but the ability to perform regulatory research should be considered a part of these centers going forward.

Mr. Weingarten was asked whether the SBIR investor forums NCI holds are ever targeted to academia, and he responded that NCI holds forums at primary sources of new technology. NCI does, however, perform outreach at biotechnology companies and universities as an important part of acquiring new applications. Mr. Weingarten added that the idea for Centers for Accelerated Innovations is valuable as well.

Mr. Augustine asked whether the panel could elaborate on issues related to intellectual property with the NHLBI Centers. Dr. Black responded that NHLBI requires that agreements clearly specify concerns related to this issue. Dr. Black also noted that finding ways to fund regulatory guidance is difficult. The strategy employed by the Centers for Accelerated Innovations program is to provide matching funds when a center uses alternative money sources to acquire regulatory guidance. Dr. Cassell suggested that private sector entities with regulatory expertise might be willing to offer their expertise in an advisory panel. Dr. Black stated that FDA is open to the concept of Centers for Accelerated Innovations, and NHLBI is currently deliberating whether the main program staff will have regulatory expertise. Dr. Neil suggested initiating conversations with Foundation for NIH. Dr. Black explained that NHLBI has reached out to other NIH ICs

about the concept for the Centers for Accelerated Innovations, and although many are excited by the concept, they also are wary of current budgetary concerns. The use of $5 million from the set-aside could allow many ICs to join the program. Dr. Black clarified that the funding opportunity announcement for the new Centers was released in May 2012.

Panel Presentation II—SBIR/STTR Programs within Other Federal Agencies
Moderators
Hon. Daniel S. Goldin, *SMRB Member*
Gail H. Cassell, Ph.D., *SMRB Member*
Panelists
Michael Mutty, *Defense Advanced Research Projects Agency (DARPA)*
Manny Oliver, Ph.D., *Department of Energy (DOE)*
Grace J. Wang, Ph.D., *National Science Foundation (NSF)*

SBIR at DARPA
Michael Mutty
Contracting Officer, Defense Advanced Research Projects Agency

Mr. Mutty is a contracting officer at DARPA with more than 20 years of experience with the Naval Air Systems Command and several years at DARPA. He noted that the SBIR program at DARPA typically develops a topic for targeted applications. The DARPA standard operating procedure, like that of Department of Defense (DoD), is simple and uniform, with only three source-selection criteria for SBIR awards: technical merit, ability to commercialize, and expected benefit. Awards are typically granted within a couple of months, and oversight is minimal.

Mr. Mutty gave an example of a recent solicitation. Topic selection took six months, solicitations were accepted during months 6–8, source selection with no peer review took place during months 8–10, and awards were given in months 10–12. He emphasized that a contracting officer at DARPA can be the sole reviewer for SBIR awardee selection. Grant awards can be performed in as few as 10 days depending on the application.

Mr. Mutty briefly discussed how success is defined. DARPA generally seeks out innovative ideas that can transition to other funding sources once established. The metric for success, then, is to transition to other funding sources through other agencies or private companies. DARPA attempts to monitor success of its applicants after SBIR involvement, but no hard metrics are used for this monitoring. Mr. Mutty acknowledged that it was worth considering the use of metrics in the future. He ended his presentation by suggesting that NIH consider simplifying its processes in the areas of definitions and source selection and consider program officer review for a subset of applications.

Discussion
Dr. Cassell expressed approval for the speed of operations at DARPA. She asked whether DARPA tracks the number of awards that transition to other funding sources and whether other agencies track outcomes. Mr. Mutty responded that the peer review process is not used at DARPA, even for standard solicitations. He also noted that the philosophy at DARPA is unique

in that failure is considered part of the process when pushing the expansion of technology. As a result, DARPA does not place an emphasis on success as a metric. He noted that sometimes promising technologies are not transferred or advanced simply because the military is not ready to adopt the technology. Dr. Cassell expressed an interest in any data available on the number of awards that transition to other funding and the success of those that are continued. She also remarked that DARPA and NIH's approaches to SBIR funding differ in that DARPA funds based on needs, whereas NIH funds based on its mission. Mr. Mutty conceded that DARPA is different, noting that its mission is to maintain the technological superiority of the U.S. military and prevent technological surprises from harming our national security. Hon. Goldin noted that DARPA is the customer for the discoveries it funds, whereas NIH is focused on encouraging research with an end goal of acquiring private financing. NIH also has less room for risk and failure and faces regulatory hurdles that DARPA does not.

Mr. Mutty asked whether any portion of the NIH portfolio might be fit for program officer review. Dr. Cassell stated that the extramural community might consider a lack of peer review unfair and that lack of transparency might be an issue. Hon. Goldin suggested that perhaps some tools or instruments, particularly those that do not require regulatory oversight, might be eligible for program officer review. Dr. Collins added that NIH is adopting the DARPA approach for collaboration on a preclinical toxicity approach to assess safety, and he expressed an interest in creative thinking about how the timeline might be shortened. He acknowledged that less review would likely be less rigorous but believed that it is important to speed up the process, noting that NIH is missing important applications because the process is too protracted.

Hon. Goldin noted that NASA too has removed peer review from its processes for select applications; at NIH, the contracting officer could serve in the role of primary reviewer. Dr. Shurin suggested that if the RFPs are focused on a specific goal and criteria are established upfront, the peer review process might be curtailed or removed. Dr. Portnoy informed the SMRB that 5 percent of NIH's portfolio is awarded through a contract mechanism and that contracts require peer review. Hon. Goldin noted that cooperative agreements are a potential funding mechanism that would award money based on achieving milestones. Dr. Collins informed the SMRB that NIH has used that strategy on a limited basis with the National Center for Advancing Translational Sciences and the Cures Acceleration Network. Dr. Kathy Hudson noted that some grants do not require transaction authority, suggesting that there could be a specific award designed as a fast-funding mechanism. Mr. Mutty agreed, noting that DARPA still has competitive rules and source selection for its awards.

Mr. Weingarten explained that 25–30 percent of the NCI's SBIR/STTR budget is dedicated to contracts. Generally, the number of grant proposals received is more manageable when delineated by topic, allowing for quicker review. Some strategies could be explored to speed up review, but there are budget limitations. He suggested exploring new methods through pilot awards.

Mr. Augustine stated that the peer-review system championed by NIH has resulted in the high quality of American science today, although he acknowledged that recently it has resulted in more conservative outcomes. He noted that DARPA's goals for RFPs are exceedingly rigorous

and that DARPA has successfully tackled some of the issues raised by the panel. He questioned, however, whether NIH was willing to sacrifice fairness and rigor for expediency.

Lastly, in response to questioning, Mr. Mutty clarified that the majority of DARPA's ideas for proposal are internal and approximately 5–10 percent are solicited through a broad agency announcement.

Improving the DOE SBIR/STTR Programs
Manny Oliver, Ph.D.
Director, SBIR/STTR Program Office
Department of Energy

Dr. Oliver informed the SMRB that his past experience was in the private sector. He reviewed the work chart for DOE, noting that the DOE's SBIR/STTR budget in FY2012 was $174 million and that 12 DOE programs, each with a unique mission, contribute to the SBIR program. DOE has one grants office and 12 program offices that identify reviewers and select topics. A single administrative office handles applicants to SBIR/STTR programs, and funding is managed in a central office.

Dr. Oliver then reviewed the SBIR/STTR application statistics for 2011. Of 2,190 applications, 223 phase I awards were issued; each grant provides $150,000 for nine months. Out of 290 applications, 138 phase II awards were awarded, each providing $1 million for two years. Dr. Oliver then reviewed the timeline for reviewing applications in 2011, from topic selection to release of funds. For phase I awards, the time from application due dates to award notification averaged 5.5 months; eight months in total passed between application due date and release of funds. Phase II award notification took place on average three months after the application due date, with funding release slightly less than six months later. Dr. Oliver noted that investigators do not typically begin work upon award notification and instead wait for the release of funds.

Dr. Oliver reviewed ways to improve the funding cycle at DOE. These include providing additional time to generate breakthrough ideas and prepare applications, improving communications to ensure that applicants understand technical topics, reducing the award selection time, and reducing the award negotiation time. Topics are announced four weeks before the official FOA to improve the fit of applications received. This practice also allows direct interaction of applicants with DOE program managers and provides additional time for researchers to develop ideas. DOE also has implemented a topic-based Webinar wherein topic managers briefly discuss their topics and answer questions; this effort has garnered positive feedback from applicants.

Dr. Oliver informed the SMRB that DOE's SBIR/STTR program used to have only one phase I solicitation per year. Transitioning to three solicitations throughout the year has improved the program's efficiency by splitting up topics and allows more flexibility for small businesses. He noted that general solicitations receive an overwhelming number of applications, so DOE prefers to use targeted solicitations. In addition to the topics Webinar, DOE implemented an FOA Webinar to discuss changes in the application process.

The DOE SBIR/STTR program also recently introduced both a letter of intent and a pre-application. Dr. Oliver explained that the primary purpose of the letter of intent, a short technical abstract, is to begin reviewer identification prior to receipt of full applications to reduce the award selection time. In addition, it allows program officers to inform applicants when their applications do not fit the criteria for the FOA; 80 percent of applicants that are not considered appropriate choose not to apply. Pre-applications require a project description more detailed than an abstract, and only applicants who receive letters of encouragement may submit a full application. This change allowed DOE to shorten the phase I grant cycle by three months from the time of the application deadline to the release of funds. Dr. Oliver hopes to remove another three weeks from the process for the 2013 grant cycle.

Dr. Oliver discussed other ways to improve outcomes. In 2012, DOE modified the application and selection process to increase emphasis on commercialization potential and changed its Commercialization Assistance Program. In the near future, the Department plans to establish performance metrics and an annual evaluation process. It also hopes to improve its topic selection process. Changes to the 2012 process included introducing a mandatory commercialization plan as part of phase I applications. Applications with likely commercialization issues are flagged in the selection process; typical issues include poor commercialization history, low revenue forecast, or low commercial potential review score based on a phase II commercialization plan. Dr. Oliver explained that DOE has attempted to improve its Commercialization Assistance Program, which provides phase I awardees a commercialization readiness assessment and mentoring to support development of phase II commercialization plans. Phase II awardees are given access to a broad menu of options to meet company-specific needs in the areas of market research, business planning, and marketing communications. Each awardee is allowed to select one vendor to provide these services.

Dr. Oliver addressed the measurement of outcomes in the SBIR/STTR programs. In 2012, DOE reviewed data from available surveys through 2007 and reviewed commercialization histories provided with applications. Seventy percent of phase II awardees proceeded to commercialization, but it was not clear how long it took. Dr. Oliver noted that commercialization should be clearly and thoughtfully defined. For example, 38 percent of awards showed a profit, but the profit may be less than the amount of the initial SBIR/STTR award.

Dr. Oliver stated that DOE hopes to define metrics for measuring outcomes in 2013, including commercialization success, mission impact, and other economic benefits. He noted that the impact can be complicated when it is broad and can be challenging to quantify. DOE also hopes to improve topic selection in 2013 by learning from historical outcomes and gathering input from the private sector. Dr. Oliver said DOE also intends to leverage technology transfer opportunities within the topics selected and ultimately expand this initiative to include universities.

Dr. Oliver concluded by stating that improving operations will lead to greater transparency, better communications, and significantly reduced award selection and negotiation times. DOE will improve outcomes by increasing emphasis on commercialization in the application and review process, improving utility and flexibility of the Commercialization Assistance Program, and defining appropriate performance metrics.

NSF SBIR and STTR Programs
Grace J. Wang, Ph.D.
Division Director, Industrial Innovation and Partnerships Division
National Science Foundation

Dr. Wang informed the SMRB that the NSF SBIR/STTR budget for 2012 was $190 million. She reviewed the NSF SBIR/STTR Innovation Model, which funds research in phases I, II, and III, including matching of NSF funds by a third-party investor in phase I and II support. For phase I awards, third-party investors match NSF funds 1:2 for up to $30,000. In phase II, they match NSF funds 1:2 up to $500,000. Dr. Wang stated that attracting private sector funding and encouraging companies to raise funds are critical, and providing matching funds stimulates this process. Phase III, which is not eligible for SBIR/STTR funding, is supported through the private sector or by NSF's non-SBIR programs.

Dr. Wang explained that NSF awards funds entirely through grants and, like NIH, NSF is not the final customer for SBIR/STTR-funded discoveries. The SBIR/STTR programs at NSF have a strong focus on technology commercialization, which is part of the NSF mission.

Review criteria for NSF SBIR/STTR applications include intellectual merit and commercial impact. Dr. Wang explained that the applications must have a sound technical plan, innovative concept, and well-qualified technical and business team, and they must ultimately lead to market-viable products, processes, or services with significant market potential. Dr. Wang informed the SMRB that NSF has a highly detailed, high-level review process for these criteria and offered to provide additional detail to those who are interested.

Dr. Wang explained that all applicants must provide a phase II commercialization plan. This plan addresses four main aspects: market opportunity, the company/team structure, the product or technology and competition, and the financing and revenue model. Additionally, NSF has criteria for funding. High-risk, high-payback innovations are considered, but high commercialization potential is essential. Dr. Wang added that SBIR funding should help develop applicants as entrepreneurs so they can move forward to secure private funding and ultimately become profitable.

Dr. Wang next reviewed the five-step process by which NSF makes award decisions. In step one, program directors group proposals into panels based on technical areas and select both technical and commercial reviewers as panelists. In step two, panelists provide individual reviews prior to the panel meeting, which occurs in step three. For phase II applications, panels consist of three technical reviewers and three business reviewers and place equal emphasis on technical and business merits. Step four involves the program directors' due diligence, in which they ask investigators to respond to reviewers' concerns and request more information as needed. The application process for phase I awards is complete after step four. The process for phase II awards requires an additional step to evaluate financial viability. This step can take up to two months and ensures that an audit is performed before funding is approved. The entire process takes approximately five months to award notification for phase I applications and approximately nine months for phase II applications.

Dr. Wang briefly described NSF's seven program officers, who have diverse backgrounds in startups, research, fundraising, and investment and also have experience working in large corporations. Dr. Wang briefly reviewed the responsibilities of each program director, including approval of all interim reports to allow continuation of funding. NSF program directors actively engage the technology-based small business community, including university spin-offs and other technology-based startups, through conferences, workshops, trade shows, and networking.

Dr. Wang informed the SMRB that NSF program directors also provide assistance in proposal preparation throughout the application process. Applicants are encouraged to provide a one-page executive summary to the program director so they can provide instructions for the application process, budget instruction, and transparent criteria and review. Phase II application approval is commercially driven and includes phase IIB funding to incentivize fundraising from the private sector, technology enhancement for commercial partnerships to incentivize collaboration with strategic customers, and entrepreneurial training. Finally, NSF performs an outcome evaluation that includes both external evaluation through the National Academy of Sciences and internal evaluation with an expert who evaluates grantees at three, five, and eight years post-award.

Panel II Discussion

In response to questioning, Dr. Oliver explained that each program at DOE runs its own review process for applications. Typically, applications are mailed to three technical reviewers, who are given three weeks to assess the applications. Each reviewer is given one to six applications for review, and the reviewers do not interact. Program officers handle any discrepancies between reviews. Dr. Oliver was asked what happens when program officers are approached with a great idea that does not fit the current topic selection criteria; he explained that they generally talk with program managers to design a new topic suitable for inclusion of the new idea.

Dr. Katz noted that NSF follows its awardees' success and asked whether Dr. Wang could comment on NSF's return on investment. Dr. Wang responded that NSF defines success as a company three to five years post-award that can generate $500,000 annually and that continues to work on the technology. She noted that significant long-term commercial potential is difficult to evaluate because a project can have both visible and invisible value.

Dr. Cassell asked Dr. Oliver to discuss financial audits. He responded that audits are performed by the contracts office to assess financial viability. Dr. Collins noted that audits can cause delays and suggested the SMRB consider ways to shorten the time needed. Mr. Mutty said that DARPA's viability assessment does not typically significantly add to its timetable. Dr. Portnoy added that NIH does not typically perform an audit but does perform an extensive financial check, and companies are required to conduct internal audits. Hon. Goldin mentioned that some entities select a contractor for audits, but this can sometimes result in delays at the level of the grants office. He suggested that adequate work upfront could remove one to two months from the timeline by allowing NIH to perform financial assessment only on those it intends to fund. He also acknowledged that many researchers with new companies lack experience in running a business and that work done upfront could reduce the amount of time to award. Dr. Briggs suggested that NIH reconsider the separation of program and review.

Dr. Roper stated that there is a lack of understanding of outcomes for many programs because it is difficult to measure success in terms of research.

SBIR: Defining Metrics and Outcomes of Success
Sally J. Rockey, Ph.D.
Deputy Director for Extramural Research, National Institutes of Health

Dr. Rockey informed the SMRB that defining metrics for the SBIR programs has been challenging but that NIH has some in place. She noted that the new appropriation of funds by the reauthorization will provide the resources to help hone NIH's ability to define metrics. She posited that SBIR should support high-risk, high-reward projects but noted that those types of projects can be difficult for small companies, and NIH must weigh the risks with survival outcomes.

Dr. Rockey reviewed some caveats regarding metrics for SBIR. A number of studies through NIH and the NRC provide information about SBIR awardees, but those studies are a "snapshot in time" and cover only a subset of phase II awardees. They also depend on survey responses. The reauthorization dictates that the NRC continue to review SBIR every four years. Information is also collected through the Commercial Assistance Program (CAP), wherein participants are tracked for 18 months. A database is available with this information, but it does not track other participants. Dr. Rockey noted that because not all participants are tracked, most outcome numbers available for the SBIR program are underestimated, but she noted that invention reporting is required as a term and condition of award and must be updated post-award.

Dr. Rockey briefly reviewed evaluations of SBIR by NIH and the NRC. In 2003, NIH surveyed companies that received phase II awards between 1992 and 2001 and found that 73 percent reported commercializing new or improved products over a 10-year period. A 2009 NIH survey of companies that received awards between 2002 and 2006 indicated that 61 percent of these companies reported commercializing core technologies supported by their award. An NRC evaluation of the SBIR program considered whether the program was meeting program and legislative goals, supporting the NIH mission, and supporting small businesses. In it, the NRC found that NIH is achieving significant commercialization: 40 percent of phase II awardees had products reach the marketplace, 3–4 percent of projects generated more than $5 million in revenue, and 58 percent of survey respondents reported attracting additional investment.

Dr. Rockey next reviewed NIH Commercialization Assistance Program (CAP). Established in 2004, this program provides specialized technical assistance for phase II SBIR awardees. It is funded by NIH and managed by the Larta Institute. Grantees from the previous five years are eligible to participate each year. In 2009 and 2010, companies were split into two tracks: an advanced commercialization training track and a commercialization training track. The 10-month program includes personalized one-on-one mentoring and assistance with developing industry connections. To date, 690 companies have used CAP.

CAP uses an online portal to track companies' performance for 18 months after the program assistance ends. Metrics include investment funds raised, grants or loans received, new jobs created, partnerships, new products, product sales, financial indicators, and qualitative

assessment. Dr. Rockey provided some CAP tracking results from 2004 to 2010, including the number of confidential disclosure agreements signed, initial proposal and term sheets, and deals signed. Dr. Rockey observed that the information CAP collects can be used to determine outcomes. The amount of non-government funding raised could also be determined; from 2004 to 2010, more than $500 million was raised. Dr. Rockey noted a significant dip in funds from 2007 to 2008, which was not surprising given the economic climate. Increases were apparent in 2009 and 2010. Over the same time period, 51 percent of CAP companies reported increases in employment, with 1,581 new jobs created by 355 companies.

Dr. Rockey next discussed the Performance Outcomes and Data Systems (PODS) used to track CAP participants. PODS is an integrated, flexible tool for program managers that is currently available to NIH users only. It allows users to save reports and share them with others. All data are primarily linked to a project number. PODS enhances the NIH SBIR/STTR programs' reporting ability on commercialization outcomes. Dr. Rockey informed the SMRB that the office of extramural research hopes to invest additional administrative funds into this system for better tracking of SBIR and STTR. Once the system is more established, NIH may consider allowing public access to a portion of this database. It also may allow the federal government to use this information.

Dr. Rockey explained that the information in PODS currently includes SBIR/STTR awardee data; legacy data from the 2002 and 2008 National Survey of Programs; CAP outcomes and information on SBIR companies; success stories; publicly available data, including patents and publications; and a Google search link to each company. PODS also has support features, including query, save, share, and export of data.

Dr. Rockey ended her presentation with a series of next steps related to tracking SBIR programs. She explained that NIH's goal is to institute routine tracking of all awardees using multiple metrics, including long-term commercialization outcomes. This requires additional funding, which may be made available through the 3 percent administrative funds allowed through the SBIR reauthorization, pending Office of Management and Budget (OMB) approval to track awardees after the award ends. This process would allow NIH to rely less on the NIH and NRC studies of its program. Dr. Rockey noted that NIH has the same challenge as other programs: tracking after an award has been completed is difficult. The reauthorization requires companies to provide updates on the commercialization outcomes of previous, current, and future awards. Expanding PODS to capture this information for both SBIR and STTR would assist in this requirement. Lastly, another step in this improvement process is a revised, enhanced NIH SBIR/STTR final report form undergoing clearance. This form is designed to capture structured commercialization data at the end of an award and could be used for additional tracking.

Perspectives from SBA
Sean Greene
Associate Administrator, Small Business Administration Office of Technology
Small Business Administration

Mr. Greene informed the SMRB that his background includes working in the private sector and being an entrepreneur. His work at SBA includes oversight of the SBIR, Small Business

Investment Company, and Startup America programs. Mr. Greene said he considers these programs particularly important in the current era; data show that net new growth is coming from new businesses and that a subset of these businesses create jobs. Since the economic decline starting in 2007, there has been a concomitant decline of 25 percent in new startup companies per year, which some estimate could cost the U.S. approximately 2 million jobs. Company death rate has also accelerated. Mr. Greene noted that it is important to consider the new criteria of the SBIR reauthorization and make changes to improve commercialization of discoveries from the laboratory. In addition, NIH and others should consider the broader initiatives of streamlining to make programs more effective.

Mr. Greene acknowledged that he is not an expert in health or the life sciences, but for Startup America, he worked with companies to define barriers, the most prominent of which was quick access to funding dollars. He noted that SBIR funds can have a significant impact on the funding of small companies: SBIR contributes approximately $2.5 billion in cash annually, whereas the entire venture capital industry contributes approximately $1.6 billion.

Mr. Greene stated that the SBIR program is sound in concept and effective in practice. Across all federal agencies, approximately 50 percent of SBIR-funded businesses get a product to market; of *R&D Magazine*'s top 100 most innovative technologies, 25 percent are funded by SBIR. Although this is impressive, Mr. Greene stressed that targeting opportunities can improve the program.

SBA's role in SBIR is very specific, Mr. Greene explained. SBA sets the policy, oversees all reporting and performance, conducts broad outreach, and facilitates work among agencies to identify best practices and foster collaborations. The current Administration is focused on bolstering the economy and supporting small businesses; SBIR is fundamentally well suited to this mandate. Partnering entrepreneurs and scientists is one way to assist small biotechnology companies.

Mr. Greene reminded the SMRB that the SBIR/STTR programs received 14 successive temporary extensions. There was disagreement about what types of changes should be in the reauthorization; discussion was not a bipartisan debate. Since the president signed the reauthorization into law, SBA has been busy trying to implement mandated changes. Mr. Greene explained that the reauthorization addresses size standards, broadens criteria for the inclusion of venture capital, and a timetable. These rules are currently open for public comment, after which revisions will take place, and the formal rules will be issued by the end of 2012. A second portion of the reauthorization is the internal policy directive, which will be released soon and will provide guidance and rules for how the programs and funds will be administered. Mr. Greene noted that a long-term commitment of six years has been made to SBIR/STTR, and the set-aside percentage will increase every year. He acknowledged that, going forward, it will be critical to track and measure SBIR/STTR grantees' performance with a targeted set of initiatives and guidelines for improving performance. Improvement areas include overall simplification, faster turnaround times, more support for commercialization, and greater efforts to reduce fraud, waste, and abuse. Administrative funding for these goals is provided as part of a a three-year pilot program, which puts pressure on all programs to establish metrics, collect and interpret data, and improve overall timelines.

Mr. Greene observed that the timing of the SMRB's efforts to consider improvement of SBIR/STTR at NIH is ideal. Adaptation to the reauthorization will involve many changes, and guidance at NIH on how to improve procedures will be useful. He noted that input on prioritizing changes will be particularly helpful and that the SMRB members, as new observers, may be able to provide unique perspectives and solutions.

Mr. Greene offered examples of specific challenges that the SMRB could help address. A common theme, for NIH and government-wide, is that cycle times are too prolonged. He explained that the majority of agencies must make their award decisions within 90 days of the close of solicitation. NIH, on the other hand, has one year. There may be ways to speed up the process, and the SMRB's perspective could be beneficial. He said the SMRB could consider whether it is acceptable for SBIR/STTR to have different processes than other research and development programs or to have distinct processes for phase I and phase II. Ideas like evergreen invitations or rolling solicitations could be considered but would require program redesign.

Another issue Mr. Greene considered important was commercialization: matching programs are already in place in some ICs, but perhaps there are alternative methods for more aggressive partnerships with third parties. Accelerators and proof-of-concept centers should be considered and that this could potentially include mentoring as post-award support. Mr. Greene gave the example of the Deshpande Center at Massachusetts Institute of Technology (MIT), which identifies promising research in the labs at MIT, runs a competitive process, and evaluates the commercialization potential of those ideas. He also suggested that the process should be simplified to reduce or eliminate the need for third-party grant writers in order to encourage more solicitations. Mr. Greene also recommended that NIH consider using the STTR program as a pilot program. Because STTR is smaller than SBIR, it could be used to test unique approaches and mechanisms that, if successful, could be scaled up for SBIR. Mr. Greene was added that it is important to consider measuring performance across the entire program with a database that could include information beyond that gathered through surveys, with standardized baseline metrics further customized by each agency.

Mr. Greene ended his presentation by encouraging the SMRB to talk other groups to get a broad perspective of the SBIR/STTR programs. For example, the SMRB could consider talking with promising companies to understand why they might not be applying to SBIR/STTR. Discussions with awardees about their experiences, angel investors, and the National Advisory Council on Innovation and Entrepreneurship (NACIE) within the Department of Commerce could also provide insight and ideas for how to improve SBIR/STTR.

Discussion

In response to questioning, Mr. Greene clarified that NACIE was founded approximately 1.5 years ago by Steve Case, founder of AOL; Desh Deshpande, founder of Sycamore Networks; and Mary Sue Coleman. The council focuses primarily on improving access to capital and improving federally funded research to attain a higher level of innovation and entrepreneurship. Mr. Greene noted that the recent American Jobs Act focused on rules from the Securities and Exchange Commission, such as those related to early-stage processes like the opening of an initial public offering. NACIE approved of these changes.

Hon. Goldin acknowledged the current weakness in metrics, noting that if one cannot accurately measure, one cannot effectively manage. It will be important to work across government and the venture capital enterprise to create realistic metrics. Mr. Greene agreed, noting that SBA has struggled with appropriate definitions. He cautioned, however, that the perfect should not be the enemy of the good. He also said that data should be collected as a starting point for creating definitions; new administrative funding through the reauthorization should assist this effort, and it is a priority for SBA.

Dr. Collins mentioned the new cap on award dollars and the negative effect it could have, particularly on phase II awards. He asked how SBA will handle waiver requests. Mr. Greene responded that venture capital participation will be critical for many NIH SBIR awardees. Congress instituted spending caps, and although SBA has the option to give targeted waivers, it would like to avoid micromanagement. Agencies can circumvent the funding cap through subsequent awards or matching dollars. He also mentioned an interagency policy committee that is considering flexibility on award sizes, with a potential option to establish the importance of larger or more flexible awards. Dr. Rockey noted that NIH-funded companies with venture capital backing, approximately 15 percent of awardees, were not receiving funds near the maximum amount.

Dr. Cassell asked whether approval from OMB was required for metrics. Mr. Greene referred to the Paperwork Reduction Act, noting that data collection must be approved by OMB. Given the statutory mandate for collection of information, Mr. Greene was fairly confident that SBA will be able to obtain approval to collect the necessary data. SBA is attempting to obtain approval for all agency SBIR/STTR programs. Dr. Rockey added that it will be important to specify the information collected, to which Mr. Greene replied that the system should be built while the approval process is under way. Dr. Cassell suggested that it will be important to collect information on the types of jobs created and their duration. Mr. Augustine countered that an invention can be successful in the absence of job creation—for instance, if it leads to the prevention of a serious disease. Dr. Rockey added that scale is important: Addition of one job to a company of 15 people is significant. Dr. Neil postulated that it would be helpful to track dollars and asked whether SBA is thinking about ways to lower the cost of capital. Mr. Greene responded that generally SBA focuses on the amount of funding required for research and development projects before a private-sector company is willing to support them. Dr. Neil stated that this practice lowers the cost of capital for these companies by reducing the risk of investment.

Panel III Discussion: Metrics
Moderators
William R. Brody, M.D., Ph.D., *SMRB Member*
Susan Shurin, M.D., *SMRB Member*
Panelists
Sean Greene, *Small Business Administration*
Manny Oliver, Ph.D., *Department of Energy*
Matthew E. Portnoy, Ph.D., *National Institutes of Health*
Sally J. Rockey, Ph.D., *National Institutes of Health*
Grace J. Wang, Ph.D., *National Science Foundation*

The group next discussed metrics for assessing outcomes of SBIR/STTR awardees. Dr. Shurin briefly discussed the need to measure NIH's return on investment, noting that this issue is not unique to SBIR/STTR. She reviewed a graph from a 1997 book by Donald Stokes titled *Pasteur's Quadrant: Basic Science and Technological Innovation,* which delineates two main innovative drivers: the quest for knowledge and the quest for application. She noted that it is difficult to measure pure discovery compared to technologies that have well-defined outcomes. She asked whether commercialization is an adequate metric for NIH discoveries and what the time course is for determining success.

Mr. Greene responded that the standard SBA definition of commercialization is whether a product has reached the marketplace. He noted that DoD has different definitions, so flexibility is required. FDA approval could be a metric for NIH-funded discoveries. Investment could be an intra-milestone and is a critical metric for NIH. Dr. Portnoy agreed with all of the comments made and stated that standard metrics such as sales, licenses, and revenue could be tracked. He added that NIH could consider how well a discovery fit its mission. This metric is less tangible but still valuable.

Dr. Oliver explained that the DOE philosophy holds that commercial potential is essential but not necessarily sufficient. Defining success is important and challenging; additional investment is not necessarily success, and he echoed the statements of others that it is important to try to capture return on investment. Capturing that data, and secured access to it, could be challenging. Project timelines would also vary based on the project technologies.

Dr. Wang noted that it is important to move discoveries into product development. She agreed that it is challenging to measure the long-term impact of awardee discoveries and cautioned that SBIR program managers not be driven solely by that outcome. The goal is to assist high-risk innovations and NIH should not be driven solely by revenue. Dr. Rockey agreed, adding that the status of small businesses fluctuates rapidly, making it more challenging to follow technologies long term. NIH should consider methods to track innovations, and the OMB and FDA may be helpful in this effort.

Mr. Greene noted that defining metrics can be daunting, so it is very important to continue cataloging success stories. Dr. Shurin asked whether failures should be tracked as well. It was noted that many failures come back in the form of modified proposals. Dr. Oliver observed that

defining common themes of failures could be helpful. Dr. Snyder stated that NIH should accumulate honest, rigorous data that could show Congress how NIH is fulfilling its mission.

Dr. Collins raised the issue of SBIR mills, companies that submit continually for SBIR funding without ever achieving commercialization. Dr. Rockey responded that the reauthorization of SBIR requires applicants to reveal their SBIR funding history. Agencies also will be able to track how many awards transition from phase I to phase II. During phase II funding, efforts to commercialize discoveries are a priority. Mr. Greene agreed that the requirement to disclose SBIR funding history is a key element of the reauthorization. He noted that each agency may set its own benchmarks for phase I and II awards.

Hon. Goldin, who has interacted with NIH staff during the course of his research into SBIR/STTR at NIH, complimented the seriousness with which staff members considered these challenges.

Dr. Wang informed the SMRB that NSF tracks commercialization history, including a company's phase II record, phase II awards from other agencies, and licensing revenue. NSF uses this information to reject solid proposals that are not likely to advance to commercialization. Dr. Wang and Dr. Oliver agreed that changes within the reauthorization will provide more authority to weed out companies with less successful commercialization records.

Public Comments
There were no public comments.

Hearing no additional comments, Mr. Augustine thanked the panel for its thoughtful contributions and introduced NIH Director Dr. Collins as the next speaker.

Issuance of New Charge to the SMRB: Value of Biomedical Research
Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

Dr. Collins expressed his thanks to the SMRB members for their continuing hard work. He asked the Board to consider a new topic: What is the value of biomedical research? This should be considered in a careful, rigorous, defensible way, not just in terms of dollars but including the impact on human health. Dr. Collins admitted that he had not realized how much time and effort he would spend on the economics of NIH as its director. Identifying the value NIH provides is critical to fortify its future.

Dr. Collins noted that benefits of NIH-supported biomedical research include improving public health, stimulating economic gains, advancing scientific knowledge, and strengthening the biomedical workforce. He then provided examples of the positive impact of NIH within the last 25 years. A baby born today can look forward to an average lifespan of approximately 79 years, nearly three decades longer than an infant born in 1900. In addition, the five-year survival rate for breast cancer has increased from 75 percent in the mid-1970s to 90 percent today. Tremendous progress has also been made in the treatment and prevention of AIDS. Lastly, the

survival rate for children with the most common childhood leukemia (acute lymphocytic leukemia) is now 90 percent.

Dr. Collins said is it important to consider NIH's part in the economic engine, and he cited several resources that address NIH's contribution. In 2012, United for Medical Research (UMR) Published "NIH's Role in Sustaining the U.S. Economy: A 2011 Update Authored by Dr. Everett Ehrlich." Dr. Collins noted that the NIH Web site features a page titled "Impact of NIH Research," which notes that NIH research funding directly supports hundreds of thousands of American jobs and serves as a foundation for the medical innovation sector, which employs 1 million U.S. citizens. Dr. Collins acknowledged a recent report from the Information Technology Innovation Foundation and UMR called "Leadership in Decline," which described an alarming decline in the U.S. contribution to health-related innovations and technology compared to other countries. This concern must be addressed; describing the value of NIH's contribution goes beyond addressing how the agency handles taxpayer dollars. Guidance from the SMRB will help NIH to identify parameters and approaches to assess the value of biomedical research.

Dr. Collins formally issued this new charge to the SMRB, asking that the SMRB identify appropriate parameters and approaches for assessing and communicating the value of biomedical research (VOBR) supported by NIH. Specifically, the SMRB is asked to analyze current strategies for assessing VOBR, examining both national and international methodologies; evaluate the strengths and weaknesses of both extant and potential approaches for evaluating VOBR; and identify fundamental principles that should guide any comprehensive and rigorous approach for assessing VOBR. Dr. Collins stressed that the SMRB should focus on the fundamental principles, not conduct the actual analysis. Dr. Collins encouraged the SMRB to seek outside expertise for this charge. He ended this request by noting that it will be useful to making the case for the economic value of NIH efforts.

Discussion and Next Steps
Norman R. Augustine
Chair, Scientific Management Review Board

Dr. Cassell acknowledged the importance of this task and asked whether the current process of translating new findings into practice should also be considered. She noted that adopting new guidelines, for example, can take years, and efforts should be made to improve the process of implementation. Dr. Collins acknowledged that it is an important problem, but implementation of practice guidelines affects the entire health care system, and he expressed concern that the current charge could not address a problem of that magnitude. Dr. Cassell asked whose role it might be, and Dr. Roper responded that no federal agency is responsible for implementing changes in medical practice and that this is an important but separate issue.

Dr. Katz asked whether VOBR is to be considered beyond economic terms. Dr. Collins reviewed examples in the slide presentation and noted that any included information should be rigorous and defensible but should include concepts beyond economics. Dr. Rodgers postulated that perhaps research not only changed the rate of change of scientific advances, but accelerated the rate of the change; NIH's mission to acquire knowledge has allowed exponential expansion. He suggested the acquisition of knowledge and its positive impact on health should be considered.

Dr. Brody recommended bringing in advisors with financial expertise to help with an economic analysis, although he acknowledged that the Board must consider the impact of NIH beyond economic benefit. He noted that some knowledge pays off years after the initial discovery. Dr. Shurin stated that the SMRB must determine all of the factors to be included in the equation to assess value. She gave an example of the positive impact of the successful treatment of hemophilia: People with this disease went from 90–15 percent unemployment with treatment, allowing them to be productive members of society. She also provided the examples of improved treatment of heart attack and stroke, which have decreased health care costs and increased longevity. Dr. Hodes noted that some economists might consider longer survival a net loss of dollars, so some points must be addressed with care. Dr. Cassell suggested attempting to place a value on NIH's education, outreach, and ability to provide information to the public.

Mr. Augustine recommended preparing a list of topics for potential inclusion in the value assessment, agreeing that although the Board members must consider aspects beyond pure economy, they also must attempt to assign a value in order to make a strong statement about NIH's worth. He emphasized that Dr. Collins is not asking the SMRB to perform the analysis, but rather to determine what factors should be considered. He hoped that recommendations from the SMRB on this topic will help lend credibility to the overall endeavor. Mr. Augustine suggested an exercise to consider what life would be like if NIH had not existed in the last 25 years. What would be the impact on people's lifestyle or life expectancy? Value could be defined as the amount it costs per day to receive specific benefits for each individual.

Dr. Omenn noted that the Lasker Foundation performed a study in 2002 titled "Exceptional Economic Returns on Investments in Medical Research" by Dr. Leon Rosenberg. The results were a startling and credible assessment of the benefit of biomedical research. He remarked that the strategy of identifying gains in health status is credible. He also noted that not all medical advances have been thoroughly implemented and that it might be possible to include implementation in the SMRB's analysis through a cost-effective approach and potentially make recommendations about how to leverage NIH resources for specific improvements. In addition, the Institute of Medicine released a report in March titled *Evolution of Translational Omics: Lessons Learned and the Path Forward* that considered the improvement of medical diagnosis. Dr. Ohmenn recommended considering cost-effectiveness and how it might be enhanced. He also mentioned that some papers in leading biomedical journals have not been reproducible and that NIH should revisit responsible conduct of research across all fields. Dr. Collins agreed that irreproducible results are disturbingly common and informed the SMRB that a meeting will take place in September 2012 to consider this concern.

Mr. Augustine noted that the charge to consider how to assess VOBR may require ad hoc members with specific expertise; he stated that anyone interested in working on this charge or providing name recommendations for specific expertise should contact him and Dr. Patterson.

Closing Remarks and Adjournment
Norman R. Augustine
Chair, Scientific Management Review Board

Mr. Augustine informed the SMRB that the next meeting will take place on October 3, 2012, on the NIH campus. He and Dr. Snyder thanked Dr. Patterson and her staff for coordinating logistics for the SMRB.

Dr. Collins informed the SMRB that when he testified before the House Energy and Commerce Committee's Subcommittee on Health, the subcommittee members were interested in the NIH Reform Act and the SMRB. Dr. Collins was pleased to report the value provided by this Board. He expressed his gratitude for its high-level advice.

Mr. Augustine thanked the SMRB members for their time and efforts and adjourned the meeting at 3:11 p.m. Eastern Standard Time.