

SCIENTIFIC MANAGEMENT REVIEW BOARD

MEETING SUMMARY—MAY 7, 2014

Porter Seminar Room, Ground Floor, Porter Building (35); Bethesda, Maryland

Board Members Present:

Norman R. Augustine, Chairman
Nancy C. Andrews, M.D., Ph.D.
Lee E. Babiss, Ph.D.
Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Josephine P. Briggs, M.D.
Gary H. Gibbons, M.D.
Stephen I. Katz, M.D., Ph.D. (via teleconference)
Scott Koenig, M.D., Ph.D.

Michael A. Marletta, Ph.D. (via teleconference)
Gilbert S. Omenn, M.D., Ph.D. (via teleconference)
Roderic I. Pettigrew, M.D., Ph.D.
Griffin P. Rodgers, M.D.
Larry J. Shapiro, M.D.
Martha J. Somerman, D.D.S., Ph.D.
Clyde W. Yancy, M.D.

Ex-Officio Members Present:

Francis S. Collins, M.D., Ph.D.
Lawrence A. Tabak, D.D.S., Ph.D.

Designated Federal Official:

Amy Patterson, M.D., Executive Secretary

Opening Remarks

Mr. Norman Augustine welcomed Board members, invited guests, and members of the public to this meeting of the Scientific Management Review Board (SMRB), the 21st meeting of the full Board. Briefly, Mr. Augustine reviewed the agenda for today's meeting, which included three presentations related to a new charge to the SMRB on the NIH grant review, award, and management process. The SMRB will also discuss the progress of the Pre-College Engagement in Biomedical Science (PEBS) Working Group.

Mr. Augustine welcomed new members of the SMRB and allowed time for introductions. He noted that the summaries from SMRB meetings held on September 18, 2013; October 24 and 25, 2013; December 18, 2013; and March 25, 2014, have been completed and reviewed. The SMRB voted unanimously to accept the minutes from these previous meetings. Lastly, Mr. Augustine noted that the final report of recommendations for the Assessment of Value of Biomedical Research has been printed and copies were provided to each SMRB member.

Mr. Augustine reminded attendees that today's meeting will include an opportunity for public comment and that written statements may be submitted to the SMRB at any time via smrb@mail.nih.gov.

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

NIH REVIEW AND AWARD PROCESS

SMRB Charge on the NIH Grant Review, Award, and Management Process

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director, NIH

Dr. Lawrence Tabak began his presentation by noting that he would address both what this charge is intended to accomplish and what it is not intended to accomplish. The grant review, award, and management process is very broad, and many reform efforts are already ongoing in this area. Dr. Tabak said that he hopes to delineate the area of focus for the SMRB charge. Two other members of NIH leadership, Dr. Sally Rockey and Dr. Richard Nakamura, will present the background material and inform the SMRB of other efforts related to this charge. Dr. Tabak will continue to inform the SMRB of activities in this space as it crafts and deliberates recommendations for this charge.

Dr. Tabak acknowledged that many aspects of this process are bound by statutes, laws, and regulations, which limit possibilities for sweeping reform. He said that the challenge for NIH is to optimize grant-making in a way that streamlines the process while maintaining accountability and high performance standards. Reducing the time and effort needed to comply with grant-related administrative requirements will allow researchers to spend more time on research. He noted that nuances of laboratory structure have changed; the size of many laboratories has increased from six researchers to 60, and NIH must carefully weigh the administrative burden of all requirements.

Dr. Tabak reviewed the scope of NIH peer review. Each year, NIH issues more than 1,000 funding opportunity announcements, reviews 70,000 to 80,000 grant applications, recruits more than 22,500 reviewers, and schedules and holds approximately 2,500 meetings. He noted that this scale is unlike that of any other institute in the world. Since 1998, the number of applications submitted to NIH has been steadily increasing, with a spike in applications associated with the 2009 American Recovery and Reinvestment Act.

Next, Dr. Tabak discussed the origins of NIH peer review. The Public Health Service Act (sec. 492 [289a]) requires the technical and scientific peer review of applications for grants and contracts. Under this act, NIH is required to provide a written description of the research under review, an advisory council to consider this description, and the results of the review. In addition, federal regulation 42 CFR Part 52h focuses on "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects." This regulation invokes the Federal Advisory Committee Act, defines the membership of review groups and expertise, defines conflicts of interest for reviewers, and outlines review criteria for research projects. Dr. Tabak noted that these rules must be followed and considered appropriately when any changes are deliberated.

Dr. Tabak defined the core values of NIH peer review: expert assessment, transparency, impartiality, fairness, confidentiality, integrity, efficiency, and continuous review of the peer review process. Review of the process, established when Dr. Zerhouni was NIH Director, has been performed through a series of

reports, including “Enhancing Peer Review Survey Results Report,” published in May 2013. Dr. Tabak noted that the overall length of applications was reduced for most applicants (with some exceptions, such as clinical trials). NIH also has changed the format of review information transmitted to applicants to avoid the use of bullet points. Dr. Tabak noted that the report monitors applicant satisfaction with these changes through a number of specific perspectives to enable an objective view of the process. In addition to review of the peer review process, the Advisory Council to the Director (ACD) Working Group on Diversity in the Biomedical Research Workforce recommended that NIH establish an ACD working group comprising experts in behavioral and social sciences and in studies of diversity with a special focus on determining and combating real or perceived biases in the NIH peer review system. The group also recommended that NIH pilot different forms of validated implicit bias/diversity awareness training for NIH scientific review officers and program officers to determine the most efficient approaches. After identifying the best approach, the ACD Working Group recommended piloting these programs with members of study sections to ascertain if their value is sustainable. Dr. Collins accepted these recommendations.

Dr. Tabak next reviewed ongoing efforts to improve the NIH grant review, award, and management process, including developing new approaches for ensuring that NIH peer review is a dynamic process responsive to important and emerging scientific trends and opportunities. In January 2013, the NIH Director convened a team of NIH experts to develop methods for identifying emergent, highly active areas of science, along with areas that have stagnated, and to recommend approaches for coupling the “state” of scientific fields with study section organization to yield a dynamic system responsive to scientific trends. Dr. Tabak specified that this effort is not part of the charge to the SMRB.

Lastly, Dr. Tabak discussed the new charge to the SMRB. He reiterated that this charge will be distinct from and complementary to ongoing efforts. He emphasized that he will keep all groups involved in this area apprised of the actions and activities of the others. NIH is asking the SMRB to craft recommendations on ways to streamline and shorten the review process while maintaining high review standards.

Dr. Tabak said there are challenges and opportunities in this space. In the current fiscal climate, researchers face declining application success rates, and devote more time and effort to preparing and submitting applications. By contrast, technological advances may help improve overall efficiency and effectiveness in the grant-making process. Dr. Tabak believed that the range of backgrounds and perspectives represented on the SMRB presents NIH with the opportunity to seek high-level advice regarding the grant-making process as a whole.

Dr. Tabak reviewed the formal charge to the SMRB: “NIH requests that the SMRB recommend ways to further optimize the process of reviewing, awarding, and managing grants in a way that maximizes the time researchers can devote to research while still maintaining proper oversight. In addressing this charge, the SMRB should consider: (1) how NIH could streamline the grant-making process and shorten the time from application to allocation of funds, and (2) how administrative requirements of applicants and their institutions, scientific reviewers, Council members, and NIH staff could be reduced while maintaining a high-quality review and management process.”

Dr. Tabak ended his presentation by reminding the SMRB that the allocation of funds is not always under NIH control. This year, a Congressionally-allocated budget for NIH is in place, but that is not always the case. In many years, NIH has operated under a continuing resolution, which results in

uncertainty and ambiguity as to the allocation of funds, leading NIH to move decisions to later in the fiscal year. This is something for the SMRB to consider as it deliberates its charge.

Discussion

Dr. Nancy Andrews asked whether the evaluation of the peer review process includes other outcomes in addition to satisfaction. Dr. Tabak stressed that one cannot determine which project will have the greatest future impact in real time; the benefit of a scientific discovery comes years after it was made. For basic research, it can take 20 to 30 years, and no one wants to wait that long. NIH is considering surrogate outcomes that may help determine success, but that process will take time to develop. There is an untoward effect when leadership places an emphasis on impact. For example, using translation as an outcome can be interpreted to mean that a finding must be immediately translatable to be impactful, which could have a negative consequence for fundamental inquiry. Dr. Nakamura added that NIH has wrestled with this question since its inception. He noted that problems can arise when the promising applications are divided among study sections; this division may not always occur evenly. Additionally, scores may be flawed when inappropriate measures are considered. Dr. Tabak noted that these are important questions that SMRB can consider, but they are not part of the strictly-stated SMRB charge.

Dr. Scott Koenig asked whether SMRB might consider either minor changes to the current system or larger, more disruptive questions. Is the charge is to improve the current system or devise a new process that could be tested and, if successful, implemented. Dr. Tabak reminded the SMRB that many laws restrict how the current system operates. The SMRB might consider ideas that would require legal changes, but it should appreciate the current framework. He stressed that he did not want to dissuade creative solutions, but there should be no false expectation that the framework can be changed. Dr. Sally Rockey offered to assist the SMRB in understanding policy and regulatory constraints and some of the flexibility that exists in the system.

Dr. Gibbons observed that NIH appears willing, within specific boundaries, to continue experimentation in the grant review process. He asked for clarification of the metrics to measure the success of efforts to improve the process. Shortening the length of the process is a reasonable outcome. Dr. Tabak agreed, adding that keeping the SMRB informed about the efforts of other groups will be important to determine whether metrics to enhance efficiency may affect other metrics. Comments from extramural researchers about the increased burden of excessive grant writing indicate that improvements to the system are imperative. Dr. Clyde Yancy added that reducing the length of time from submission to funding would provide an incentive to investigators. Rolling submission and review would be challenging, but should be an option to consider. Dr. Lee Babiss cautioned against offering solutions too early and recommended acquiring more information before deliberations begin. Dr. Josephine Briggs reminded the SMRB that improved time to award was central to the recommendations the SMRB put forth related to NIH Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) programs; similar considerations could be made for this charge.

Dr. Gilbert Omenn noted that considering the time that elapses between the initial scientific review and final award will be helpful. Investigators and their institutions must gather a significant amount of information during this time, which results in a significant administrative burden.

Dr. Andrews asked whether NIH has considered a grant program that involves funding smaller grants but with a faster turnaround, such that it might bridge a potential funding gap. Dr. Rockey said that the R03

essentially fills that purpose. Dr. Tabak said similar mechanisms could be an avenue of discussion but noted that he would not want to provide investigators with just enough money to allow them to fail. His experience at NIH has led him to believe that smaller awards are not very successful. The R23 was not successful, but the SMRB could consider similar funding schemes and determine whether they might be helpful. Dr. Tabak clarified that the charge will include the period involving post-award administrative requirements and aspects of the review process itself.

Mr. Augustine thanked Dr. Tabak for his presentation and said that researchers often tell him that grant writing takes time away from research; this is true both for NIH and the National Science Foundation (NSF). He believed that the review process is central to U.S. success but acknowledged that nothing is perfect.

From Input to Output: Center for Scientific Review's View of Biomedical Research Support

Richard K. Nakamura, Ph.D.

Director, Center for Scientific Review (CSR), NIH

Dr. Richard Nakamura began his presentation by citing the NIH mission: “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 illness and disability.” He noted that NIH achieves its mission through awarding research grants based upon the peer review of applications from extramural scientists. In this way, NIH considers the development of knowledge as well as its application. CSR’s mission is: “to see that NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research.”

Dr. Nakamura reviewed grant success rates from 1978 to 2013. These rates have recently undergone a downward trend that has resulted in funding of fewer than 20 percent of applications. Research investigators’ dissatisfaction is growing as a result of a decade-long science recession. This recession affects almost every aspect of science and has a significant effect on peer review. The funding for extramural research, when adjusted for inflation, has been stagnant or slowly decreasing since 2003; whereas the number of applications has been rising. In 2013, more than 80,000 grant applications were submitted to NIH. The government-wide application system grants.gov has added to problems in the application process.

Dr. Nakamura showed the group a schematic of the NIH extramural grant process. Peer review can take place either through a specific Institute or Center (IC) or through CSR. Advisory councils then consider the results of the review process for final approval. The process of assigning grants to study sections assumes that fundable applications are evenly distributed across study sections, which may not be a fair assumption. Next, he reviewed the statistics and trends documented by CSR. In 2013, NIH received 83,753 applications, of which 54,056 were reviewed by CSR. The funded proportion of CSR applications was 58 percent, and the proportion funded through IC review was 42 percent. 26,853 CSR reviewers were enlisted to attend 1,471 study section meetings in 2013. Dr. Nakamura noted that CSR makes a significant effort to ensure that reviewers are NIH-funded experts in the appropriate field, but noted that it was not feasible to have all be recognized by, e.g., membership in the National Academy of Sciences (NAS) or Institute of Medicine (IOM).

Dr. Nakamura stressed that CSR must be efficient and effective, and that today’s presentation will emphasize efficiency. He noted that efforts within CSR are part of a larger NIH process that affects

funding timelines. CSR oversees receipt and peer review of many applications, which are then forwarded to specific ICs' councils for award decisions. Many ICs have their own separate review systems, which review approximately 27 percent of NIH grant applications. Dr. Nakamura noted that often, when efficiency within the process is discussed, there is a focus on peer review through CSR.

Next, Dr. Nakamura reviewed the time frames for submission to award for R01 grants. Currently, there are three grant cycles per year. The schematic depicting this process can be found [online](#). It explains the stages of the review process ongoing through the calendar year for each review cycle. The process of assigning reviewers is fairly long, and funding of cycle 1 grants is often deferred due to budget uncertainties. Ideally, those awards should be granted in September, but the beginning of the fiscal calendar is October 1, which often causes delay, sometimes as far as January or February of the following calendar year.

Dr. Nakamura reviewed the kinetics of CSR review through a number of graphs depicting the days from receipt of an application compared to the cumulative application percentage. These graphs differentiated most R01 applications from AIDS applications, which have an expedited review process. Delays occur primarily during the period when study section meetings are held. The median number of days from receipt to award for a non-AIDS application is 284; for an AIDS grant, it is 217. The median number of days to release of the summary statement is 129 and 87 for non-AIDS and AIDS applications respectively. More time is taken to make the award decision than for the review process; the number of days to award 90 percent of AIDS grants is 363, and 414 for non-AIDS applications. Review time varies between CSR and the ICs, which themselves have a great deal of variation.

Both Dr. Nakamura and Dr. Rockey stated that changing award dates to avoid the fiscal uncertainty of fall, similar to SBIR applications, could improve the overall review process. Dr. Nakamura believed that it would not speed the time to review all grants to the level of the AIDS grants, but significant improvement could be made. In response to questioning, Dr. Nakamura explained that the AIDS grants are reviewed through their own process as a result of legislative mandate. There are only 800 AIDS grant applications and they require a smaller field of expertise for review, which allows for increased efficiency. Scaling that system for all NIH grants would be very expensive. Dr. Rockey noted that NIH is working on automated smart computer software that could enable use of key words to make study section assignments; this could speed the process for approximately 70 percent of grant submissions.

Briefly, Dr. Nakamura reviewed the workload calculations for reviewers per round of funding. This varies across ICs depending on the number of applications that require review. Dr. Nakamura also reviewed the current cost estimates for different review platforms, including face-to-face meetings, Internet-assisted meetings, video-assisted meetings, teleconference-assisted meetings, and combinations thereof. The cost for face-to-face meetings per application is estimated to be \$518, other platforms cost less. He suggested improvements in the following areas: improvement in grants.gov, avoiding fiscal year uncertainties, speeding the award process, and including positive reinforcement for reviewers. He noted that governmental rules, such as those that restrict providing food and drink, reduce efficiency. Another problem is the necessity of a 1099 form for every expense for which reviewers are compensated, which creates work and removes incentive for reviewers to contribute to the peer review process.

Lastly, Dr. Nakamura noted that he had included slides on considering quality of review for the SMRB members' consideration. He provided his email address for additional inquiry: CSRDIRECTOR@csr.nih.gov.

Discussion

Mr. Augustine noted that the pace of business is much faster than it used to be and that every day matters. The CEO of Intel once told him that 90 percent of the revenue on the last day of the year was from products that did not exist on the first day of the same year. Dr. Rockey acknowledged that 60 percent of awards are given in the last three months of the year. The ICs do take some risks, but they need a budget to make funding decisions. Dr. Nakamura was asked whether he could estimate the cost to make all grant reviews as efficient as the AIDS grant review process; Dr. Nakamura responded that he could create a spreadsheet to estimate the cost. Dr. Rockey also recommended consideration of the SBIR review plan.

Dr. Griffin Rodgers asked how NIH might be able to improve the process when the fiscal year is tied to congressional decisions. Dr. Rockey noted that one option would be to allow NIH to be funded for more than one year at a time, similar to some other agencies. She noted that money not spent by September 30 of a given year is lost, so NIH must plan carefully. Dr. Story Landis said that comparing funding approaches across ICs may be instructive to learn best practices. She noted that some ICs fund awards prior to the council meeting of final approval, and some have managed to fund September grants and avoid depletion of funds. She acknowledged that setting the pay line early is risky but that in her experience, it was problematic in only one out of 10 years. Dr. Gibbons noted that the types of grants awarded across ICs vary a great deal and that larger studies and clinical trials will always be more complicated and require detailed review.

In response to questioning, Dr. Nakamura explained that CSR generally reviews basic applications and R01 grants, whereas the more complicated applications are handled by the ICs. In some instances, CSR might review training grants. Dr. Koenig suggested that rolling submission might shorten the time for review. Dr. Rockey noted that NIH already accepts rolling submissions, but the applications are sorted into three review cycles. Dr. Koenig suggested considering standing committees to review grants as they are submitted. Dr. Babiss stated that Cold Spring Harbor Laboratory used that approach, but on a much smaller scale. Dr. Linda Birnbaum suggested editorial reviews for rolling submissions to decrease meeting time. Dr. Nakamura replied that CSR is considering a number of alternative review platforms and just instituted a survey to receive feedback from reviewers.

Dr. Andrews acknowledged that these are challenging fiscal times, but ideas in grants awaiting award—sometimes waiting 10 to 14 months—run the risk of getting stale or being outstripped by competitors. Dr. Nakamura agreed, noting that there are many sound reasons to make the system more efficient.

Dr. Koenig expressed concern for reviewers' preferences for face-to-face meetings. Their preference may not be relevant if other formats improve outcomes. Despite limitations in opportunities to change the system, technology has made us more mobile and workers must adapt to real-time solutions. Dr. Nakamura agreed, noting that CSR is considering how other research systems (e.g., Canada) conduct the review process. CSR also is investigating how researchers prefer to have their own grants reviewed. The importance of face-to-face meetings is an ongoing consideration. Dr. Gibbons asked whether there are outcome measures to compare costs and efficiencies of face-to-face meetings and other methods. Dr. Nakamura responded that he could return to the SMRB to speak about experiments designed to understand bias and the development of different measures to improve the validity of ranking applications. Dr. Rockey suggested The SMRB could consider the outcomes of efforts NIH took after the

government shutdown in 2013, trying conducting the review process using numerous different methods to ensure that grant funding was not delayed.

Dr. Martha Somerman suggested that new, young principal investigators could be prioritized within the process. Dr. Rockey stated that they already are. She also noted that summary statements are provided to these investigators immediately to allow them to consider the comments before the next review cycle. Dr. Nakamura added that the grants from new investigators are reviewed separately.

Dr. Pettigrew asked Dr. Nakamura and Dr. Rockey to comment on changes under consideration to advisory council review. Dr. Rockey responded that there is an opportunity to use electronic concurrence. She offered her assistance in determining where dead time might occur in the review process, noting that there are several councils, which adds to the complexity of the issue.

Streamlining the NIH Grant Review and Award Process

Sally J. Rockey, Ph.D.

Deputy Director for Extramural Research, NIH

Dr. Rockey began her presentation by providing an overview of the grants process, which includes planning, writing, and submitting; receipt and referral; peer review; award; and post-award management. She noted that reporting requirements produce a lot of burden. Dr. Rockey believed the burden on research institutions was equal to or greater than the burden on individual researchers at those institutions. Dr. Rockey noted that there have been many calls to reduce administrative burden, including through presidential memorandums. She informed the SMRB members that she provided information on reporting requirements for their consideration, including:

- The National Science Board Report “Reducing Investigators’ Administrative Workload for Federally Funded Research”
- The Federal Demonstration Partnership (FDP) 2012 Faculty Workload Survey Research Report
- The list of public policy and administrative requirements maintained by the Office of Extramural Research
- A Request for Information: Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions, Summary of Public Comment, November 29, 2011

Dr. Rockey stressed that there should be a balance between reducing administrative burden and maintaining or increasing accountability via regulatory and policy requirements. Examples of requirements and their sources include federal-wide, Department of Health and Human Services (HHS), and NIH-specific policies and obligations. She noted that differences in the requirements from each entity add burden and that efforts have been made to reduce burden by harmonizing these requirements.

Dr. Rockey provided an example of reporting requirements in a legislative mandate in effect for fiscal year 2014. The statutory provisions include 12 legislative mandates, including reporting on topics such as gun control, salary limitation, anti-lobbying, restriction on pornography on computer networks, and restriction on abortions. The Digital Accountability and Transparency Act, which is about to be signed, places an enormous burden on agencies to properly report data to the government. Another example that is specific to governing science is the draft legislation on sex differences research.

Next, Dr. Rockey reviewed federal and NIH efforts to reduce administrative burden. Public Law 106-107 is the Federal Financial Assistance Management Improvement Act, which was signed into law in 1999. This act focused on pre-award, post-award, and audit considerations for streamlining the grant process. It resulted in the Web site grants.gov, which is a central place for all federal grants that use all of the same forms. Dr. Rockey acknowledged that some challenges arise as a result of this system. Another federal effort is the Paperwork Reduction Act of 1980, but Dr. Rockey noted that often in this effort the administrative burden is shifted to the federal agency.

Dr. Rockey reviewed FDP, which was formed in 1986 as a cooperative initiative organized by the National Academies through the Government-University-Industry Research Roundtable. Its purpose is to advance scientific discovery and increase transparency and accountability by reducing the administrative burdens associated with research grants and contracts. Dr. Rockey provided examples of ongoing projects, including the demonstration and testing of a federal-wide researcher profile system, the Science Experts Network (SciENCv). FDP conducted a faculty burden survey that indicated that 42 percent of principal researchers' time is dedicated to something other than research. FDP also is attempting to identify common policies for awards to streamline processes. Lastly, FDP revised a circular from the Office of Management and Budget to incorporate expanded authorities as a standard option. Dr. Rockey provided the Web site for the FDP: <http://sites.nationalacademies.org/pga/fdp/index.htm>.

Next, Dr. Rockey reviewed the Research Business Models Working Group (RBM), an interagency working group that she co-chairs with Clifford Gabriel at NSF. The RBM's purpose is to facilitate coordinated efforts across federal agencies to address important policy implications arising from the changing nature of scientific research and to examine the effect of those changes on business models associated with the conduct of federal research. Dr. Rockey provided examples of ongoing RBM projects, including effort reporting and a pilot to reduce its burden. Meeting audit requirements is a concern. Many offices can now use payroll systems to perform effort reporting instead of assigning it to an individual member of a laboratory; this change can result in a significant reduction in effort, but it must be able to withstand an audit. Another successful change was to allow researchers to directly charge administrative costs as opposed to charging them as indirect costs; this helps managing human subject and animal care and use requirements.

Dr. Rockey informed the SMRB about Uniform Guidance, which incorporates many of the products of previous federal-wide streamlining efforts from groups like FDP. It promotes consistency across the federal government, including promoting standard definitions and forms, consolidating administrative requirements, and performing work related to effort reporting. NIH also has streamlining initiatives, including expanded authorities such as application of initial no-cost extension and a Streamlined, Non-Competing Award Process (SNAP), which is being replaced by Research Performance Progress Reporting (RPPR). SNAP includes automation to reduce burden and allows more structured data analysis. NIH also has introduced modular grants that eliminate the itemized budget, and Just-In-Time, a process that allows submission of certain application elements later in the review process. NIH Commons and the Application System & Interface for Submission Tracking (ASSIST) are parts of RPPR. Advantages of ASSIST include Web-based assembly of grant applications that can store work in progress (as opposed to the downloadable forms from grants.gov). Information can be transmitted across ICs to pre-populate information. NIH also has made efforts to reduce burden to NIH staff with increased automation and validation for forms, including progress reports, financial reports, conflict of interest forms, and special reporting requirements. Numerous other examples of reducing NIH burden through automation are available. Dr. Rockey noted that efforts are still ongoing and include addressing requirements for animal

studies and addressing possible increases in reporting on topics such as data sharing, sex differences in research, clinical trial requirements, and monitoring of required training. Dr. Rockey stressed that it is important to reach out to the community about requirements in order to avoid unintended consequences. Dr. Rockey has a blog titled “Rock Talk” that reviews changes and updates related to grants submitted to NIH.

Dr. Rockey noted that one of the documents the National Science Board provided to the SMRB was a survey of faculty and institutes about burden that applies to many NIH concerns as well. Writing grants is a burden, and the treadmill for continued funding increases angst among researchers. The NIH Office of the Director is considering longer, larger grants to reduce burden and promote the best science. She suggested that SMRB consideration of the peer review process focus on time to award, including the period around council review.

Public Comments

There were no public comments.

Discussion

SMRB Members

Dr. Babiss asked how well the efforts Dr. Rockey detailed have been communicated, noting that some of the information was new to him. Dr. Rockey replied that communication with the biomedical community is a high priority for her, which is why she has an NIH blog. The NIH guide is another helpful resource. She believed that communication at NIH has improved and that NIH Director Dr. Francis Collins has done an impressive job of communicating with the extramural community. She also noted that FDP is composed of faculty members and federal agencies and they actively communicate its efforts. It was noted that social media can overwhelm communication and make identifying important messages more difficult. That said, people need to understand the reasons for the decisions being made and have the opportunity to provide input.

Dr. Yancy noted that, unfortunately, the unethical actions of a few have a significant impact on the many. Emphasis on disclosure of methodology could slow progress. He believed the grant award process is clean but could be streamlined. Dr. Rockey responded that NIH is dedicated to the greater good and preservation of the scientific knowledge base. Significant amounts of information can be omitted from research applications to keep the process streamlined and avoid undue burden. She believed striking a balance is important. If NIH or the government request data, then it should be clear how the data will be used. She believed that collecting data on science can be meaningful, but the approach should be clear and not present an undue burden on researchers.

Dr. Stephen Katz noted that communication is challenging because people are inundated with information. Many grant processes are fairly transparent, but funding awards can be a challenge because the government budget process does not allow NIH staff to draw a pay line. Dr. Katz considered this process a serious problem. Dr. Omenn added that Dr. Landis’ comments were instructive and he believed it would be helpful to hear the opinion of other IC Directors. Dr. Michael Marletta stated that Dr. Rockey’s blog is very informative and an effective way of communicating change.

Mr. Augustine acknowledged the low percentage of grants funded each cycle and noted that it is difficult to satisfy people under those conditions. He questioned whether a faster filter could weed out grants that would not be funded and suggested that some decisions may merit a meeting in person, whereas others may not. Perhaps ICs could project the lowest conceivable budget and make decisions based on that with relatively low risk. Dr. Nakamura stressed that, according to regulatory language, all applications must be provided a full review for validation. Mr. Augustine replied that perhaps this Board could recommend that that be changed. Dr. Rockey suggested that perhaps some grants could be given a full review but not be provided a discussion synopsis.

NIH UPDATE

Reflections from the NIH Director

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

Director, NIH

Dr. Collins thanked the SMRB members for their continued efforts and acknowledged the challenge of improving efficiency in the grants award process. He reviewed recent Congressional hearings relevant to NIH on topics including Alzheimer's disease, the future of biomedical research, the budget, innovation and the government's role, and a roundtable on 21st century cures. The roundtable participants understood the need for cures in a bipartisan way, but words must be translated into action. The mission of this roundtable was clearly stated, and the number-one priority was improving resources to address lost purchasing power. The draft legislation resulting from this roundtable is slated for consideration in 2015. Dr. Collins noted that Rep. Fred Upton, Chairman of the House Energy and Commerce Committee and co-leader of the 21st Century Cures Initiative, is term-limited and wants to make this legislation part of his legacy.

Dr. Collins noted that Sylvia Burwell was recently named the nominee for HHS Secretary. Ms. Burwell has been the head of the Office of Management and Budget and worked for the Gates Foundation.

Next, Dr. Collins updated the SMRB on the BRAIN Initiative, which President Obama called "the next great American project." The BRAIN Working Group, co-chaired by Dr. Cornelia Bargmann and Dr. William Newsome, has created a list of specific NIH goals, including generating a census of brain cell types, creating structural maps of the brain, and linking neuronal activity to behavior. Six requests for applications (RFAs) have been established as a result of the goals articulated by the Working Group; the first awards should be announced soon. In June, the Working Group will provide a detailed plan for the next five years in brain research with ambitious but achievable milestones.

Dr. Collins addressed another issue of recent interest: late-stage failures related to insufficient target validation. Follow-up studies find promising targets to be not as relevant as was first thought, and are found to lack efficacy. Dr. Collins noted that this trend appears to be getting worse, and NIH is considering systematic ways to address the issue. NIH is partnering with the private sector to create the Accelerating Medicines Partnership, which is a unique endeavor wherein participating groups share costs for pilot projects in areas such as Alzheimer's disease, type 2 diabetes, and autoimmune disorders. Dr. Collins noted that the partnership is still in the early stages, but it may be a model for finding effective targets or biomarkers.

Next, Dr. Collins acknowledged the growing problem of antimicrobial resistance, which has been particularly troublesome in the hospital setting. The problem is nationwide. NIH is encouraging basic research for this problem as well as the development of a network that will identify people with infections for clinical trials. The Obama administration has a council (the President's Council of Advisors on Science and Technology) developing recommendations for presidential-level actions and is leading a trans-U.S. government agency initiative called the Interagency Policy Committee on Combating Antibiotic Resistant Bacteria to unite all federal departments and agencies to develop a blueprint for tackling this major public health issue. This includes creating a national database. The NIH–Food and Drug Administration (FDA) Joint Leadership Council also is addressing antimicrobial resistance through a workshop in July 2014 that is intended to develop a template for a common clinical protocol and promote the use of common control groups.

Dr. Collins ended his presentation by noting that many other interesting efforts are ongoing, and this is just a snapshot of NIH today.

Discussion

SMRB Members

Dr. Koenig applauded the effort to form big initiatives for antimicrobial resistance and said that studying the microbiome will aid in this effort. Dr. Collins agreed. Dr. Koenig also mentioned the failure rate of late-stage clinical trials, noting that the complexity of disease and systems biology is a challenge for target validation. NIH's efforts to work with large pharmaceutical companies are laudable, but smaller entities should also be encouraged to contribute. Dr. Collins agreed, noting that RFAs are available for small biotechnology companies through NIH or the Foundation for NIH. Dr. Babiss added that scientists are still taking a single-drug approach to polygenic diseases, and they do a poor job of testing drugs in parallel. He encouraged running more complex studies based on genetic signatures that do not stratify by origin. Dr. Collins hoped that would be possible as well, noting that oncology would be an ideal space because it is unlikely that there will be a single successful agent. The complexity causes barriers for proper study design, and getting drug companies to work together will likely be challenging. Dr. Babiss noted that it was successful for drugs for hepatitis C virus, although the studies were performed in Europe. Dr. Collins stated that the NIH relationship with the FDA provides an opportunity to have these types of conversations. He believed that the FDA is open to more creative project designs but that these efforts take time.

Dr. Yancy asked whether the 21st Century Cures Initiative was embedded within NIH. Dr. Collins explained that it is led by the Federal Energy and Commerce Committee. Dr. Collins believed that a focus for the committee should be changes to support and enable what is already being done. He noted that resources require further discussion. Rep. Upton is requesting specific examples of how researchers are impeded by regulations. Dr. Collins pointed to oversight of scientific travel and meeting requirements, which wastes money and time. The time he personally spends time signing off on conference budgets is not the best use of his time. Paperwork requirements for primary investigators are another example. Thousands of reports are required for each government agency, and it is not clear that they are all being read or used. For generating cures, shortening time tables would be advantageous; this concept focused on changes within the FDA.

Mr. Augustine thanked Dr. Collins for taking time to address the SMRB.

Working Group on Pre-College Engagement in Biomedical Science (PEBS)

Clyde W. Yancy, M.D.

Chair, PEBS Working Group

Dr. Yancy reviewed the roster of SMRB members participating in the PEBS Working Group and reviewed their charge: “recommending ways to optimize NIH’s pre-college programs and initiatives that both align with the NIH mission and ensure a continued pipeline of biomedical science students and professionals.” Considerations for this charge include:

- Examining the evidence base for successful approaches for pre-college biomedical science programs aimed at strengthening the biomedical workforce pipeline;
- Identifying the attributes, activities, and components of effective pre-college biomedical science programs, including the role and relative importance of teacher training programs;
- Identifying the points in the pre-college biomedical workforce pipeline where NIH’s efforts could be applied most effectively, given finite resources; and
- Defining ways for NIH to improve the evidence base for effective pre-college biomedical science programs.

Dr. Yancy stated that the group was beginning with a broad landscape, understanding that the charge is not meant to address general scientific literacy. Briefly, he reviewed the goals of the PEBS Working Group, including determining where there are problems with the biomedical pipeline; understanding the factors that influence pre-college educational achievement; improving student engagement; identifying characteristics of effective, scalable pre-college programs; reviewing the evidence base for analyzing pre-college engagement and achievement; and developing short-, medium-, and long-term steps NIH can take to improve pre-college engagement in biomedical science. NIH’s role in student engagement, the audience that is being targeted, and what resources and options are available must be understood. NIH should consider partnering with groups like the National Education Association.

In the United States, principal investigators (PIs), clinician scientists, and postdoctoral researchers undergo pre-college education, post-secondary education, graduate education and professional development, and continuing education. It is important to define the biomedical workforce, including the jobs available and the education required to complete those jobs. NSF has compiled a list of jobs that constitute the biomedical workforce that includes varied fields and talents. Problems that have been attributed to stages of workforce development include long training periods and lack of diversity for PIs and clinician scientists; uncertain promotion and compensation in academic settings for staff scientists, X-ray technicians, and statisticians; an oversupply of postdoctoral researchers; and insufficient training and high rates of turnover for science teachers. Additionally, many legitimate scientific professions are not considered successful outcomes compared to becoming a traditional academic researcher, including science policy analyst, pharmaceutical manufacturer, regulatory official, and grants manager.

Dr. Yancy noted that in asking about problems within the biomedical workforce, the SMRB members must consider whether the quality and quantity of individuals entering the pipeline are sufficient. They must also consider that some groups are underrepresented in the biomedical workforce and in positions of leadership. Then the SMRB must consider whether the problems identified within the workforce can be addressed at the level of pre-college engagement in biomedical science.

Dr. Yancy next reviewed factors that affect pre-college engagement and achievement, including socioeconomic status, curriculum, teachers, personal interest, and peers. For teachers, training and skill level are significant issues, particularly at the elementary-school level. Specific professional development is lacking for the higher grades, and science teacher turnover rates are high. Some programs have effective ways to raise teacher skill level, but they are too costly to scale up. Dr. Yancy noted that improving teachers' preparedness could be a good avenue for NIH to influence pre-college education.

Another important factor for PEBS to consider is curriculum, and whether an emphasis on general thinking skills should be prioritized over topic-specific information. Current curricula do not allow much time for science-specific teaching prior to high school, and some schools do not offer advanced science courses.

At the last SMRB meeting, the Board learned about the Next Generation Science Standards (NGSS) developed by the National Research Council. To the extent that they can be developed and implemented, the NGSS may be a viable long-term solution to pre-college engagement. Eleven states have adopted the NGSS, and 26 other states are considering their adoption. Implementing the NGSS involves challenges, and the SMRB must consider what NIH can do to support the NGSS. Much of science education takes place outside of the classroom and that it is helpful to expose students to positive science environments. The SMRB should also consider NIH's role in this endeavor.

Dr. Yancy provided a list of PEBS literature, including Web sites and PDF links, to the SMRB members. Dr. Yancy noted that he has been struck by the interest of the scientific community at large, and he was encouraged that NIH could make a difference with reasonable application of current resources. He added that diversity of people in the biomedical pipeline should reflect the current population to further improve NIH's reputation within the community at large.

Discussion

SMRB Members

Dr. Koenig brought to the group's attention a recent article in *The New York Times* on the National Math and Science Initiative, supported by major companies and organizations like Lockheed Martin, the Gates Foundation, and Exxon, to support science training for tutors and teachers. The initiative was found to improve test scores, and programs like this could have a positive impact on the biomedical pipeline. Dr. Yancy responded that the PEBS Working Group is developing a list of initiatives that could serve as candidates for PEBS pilots for consideration by the SMRB.

Panel Presentations on the Definition and Health of the Biomedical Workforce Pipeline and Successful Approaches to Engaging Pre-College Students in Biomedical Science

Hannah A. Valantine, M.D.

Chief Officer for Scientific Workforce Diversity, NIH

Kevin Finneran, Ph.D.

Director, Committee on Science, Engineering, and Public Policy, National Academy of Sciences

Presentation 1

Hannah A. Valantine, M.D.

Chief Officer for Scientific Workforce Diversity, NIH

Dr. Valantine thanked the SMRB for the opportunity to speak on engaging pre-college students in biomedical science, noting that she has worked a great deal in this field but not specifically in K–12 area. She believed it is important that NIH influence building the next generation of scientists to ensure the scientific enterprise is robust. Human health and disease are complex and require innovative solutions.

Dr. Valantine stated that addressing the diversity of the workforce is important; at every stage in the educational process, representation of specific groups is lost, leading to their underrepresentation in biomedical science.

Dr. Valantine next informed the SMRB of a study performed in 1999 asking children at various levels of grade school to draw a scientist. The majority of children draw a white male, a majority that increases as children age (75 percent, compared to 58 percent of younger children). When people do not see people who look like them in a particular profession, they tend to believe that they are not cut out for this field.

Dr. Valantine reviewed data on medical students' race/ethnicity in 2010 and 2011. More than half of the students were white, 20 percent were Asian, and only 8.2 percent and 6.3 percent were Hispanic and African American, respectively. This is in stark contrast to the general population. Next, Dr. Valantine reviewed the numbers of students from underrepresented groups (including African Americans, Hispanics, Native Americans, Native Hawaiians, and Pacific Islanders) by stage along the academic career path. Twenty-one percent were medical students, 12 percent were graduate students, 11 percent were residents or fellows, 3 percent were postdoctoral fellows, and 6 percent were faculty. At NIH, the Office of Intramural Training and Education is dedicated to rectifying this situation; a trans-NIH effort run by Sharon Milgram is focused on helping trainees develop scientific and professional skills. The Web site for this office is www.training.nih.gov. The office works to raise awareness and recruit to improve diversity at NIH and to retain and advance trainees through career development resources and support for affinity groups that improve cultural competency. Areas of trans-NIH intramural training opportunities span the educational spectrum (from high school to postdoctoral training), including the Summer Internship Program (SIP) for high school students. SIP is highly competitive: more than 6,000 students apply each year for a limited number of openings. SIP offers an important opportunity to increase diversity and reach out to underserved schools in the DC area. Another training effort is the Community College Summer Enrichment Program (CCSEP); community college students make up 40 percent of all college students, and community colleges educate a large number of African American and Hispanic students. Additional pre-college efforts include middle and high school science fairs. The NIH Office of Intramural Training and Education also hosts Community College Day and Native American Student Visit Week to increase diversity at NIH. Dr. Valantine noted that infrastructure, cost, and scale are challenges for all of these endeavors.

Dr. Valantine provided additional information about the NIH SIP. SIP includes more than eight weeks of research experience at all educational levels at all NIH campuses. Participants may be paid or volunteers. The experience includes attendance at workshops, journal clubs, and a science skills boot camp. All attendees also participate in an end-of-summer poster session. CCSEP, wherein participants are placed in laboratories in Bethesda, Baltimore, and Frederick, Maryland helps community college students develop science and professional skills through a weeklong orientation and weekly programs. Students give both oral and poster presentations, and they attend workshops on laboratory culture, laboratory math, reading scientific papers, writing, public speaking, team skills, self-awareness, and career

planning. Students have two mentors outside of their assigned laboratory and meet periodically with program staff. This program has been ongoing since 2010. Seventy-four students have participated in the program, 40 percent of whom were from underrepresented groups.

Dr. Valentine reviewed data on SIP and CCSEP from 2013. She noted that African American participation in SIP was 7 percent and could be improved; African American participation in CCEP was 27 percent.

Next, Dr. Valentine highlighted a successful pre-college engagement effort called the Stanford Medical Youth Science Program (SMYSP). In 2011, its founder received the Presidential Award for creating a science program for low-income high school students, many of whom come from ethnic groups underrepresented in the biomedical sciences. SMYSP began in 1987 as a student-directed program with a complementary set of university- and school-based programs in biomedical sciences, academic enrichment, college guidance, and long-term mentoring. Dr. Valentine believed this program serves as a national model for programs that seek to enrich and diversify the scientific and health professions, train future leaders who reflect America's increasingly diverse communities, and address the health needs of medically underserved populations.

SMYSP consists of a five-week residential program on campus for very low-income high school students; all ethnic groups are welcome. The program gives priority to students who are not on track for college and potential first-generation college students. Each year, SMYSP selects 24 students from northern California from approximately 300 applicants; the program is led by a staff of 10 Stanford undergraduate students, often from similar backgrounds. Beyond gaining exposure to biomedical research, students attend faculty lectures, receive SAT preparation and assistance with college admissions, attend field trips, and receive long-term support. SMYSP students also receive exposure to medicine via hospital internships in a variety of fields. Mentorship with health and medical professionals, as well as medical and graduate students, is available through SMYSP. Participants either live with or spend one evening of each week with a Stanford student, building a relationship that may provide long-term support. A directory of contacts is available for all participants, as well as one-on-one advising for college, graduate, and medical school; letters of recommendation; and online information about college and health careers.

Dr. Valentine reviewed the ethnic makeup of SMYSP: 22 percent African American, 27 percent Southeast and East Asian, 34 percent Latino, 4 percent Native American, and 7 percent Caucasian. SMYSP has been ongoing for 26 years and is able to report long-term outcomes for its participants. As of 2012, 571 students had participated in the program, with 99 percent follow-up for up to 26 years. All of the participants came from low-income families, many with poor academic preparation. Since the program's inception, 99 percent of college-aged participants were admitted to college, and 90 percent graduated from four-year colleges. Of these, 47 percent attend or have graduated from medical or graduate school. The graduation rates of SMYSP participants are significantly higher than the average U.S. graduation rates for students in the same low-income racial/ethnic groups (e.g., 78 percent of SMYSP African American students compared to 15 percent of all low-income African American students). The majority of SMYSP students attend public colleges; 12 percent attend community college, and 10 percent attend Ivy League colleges. The founder of SMYSP, Marilyn Winkleby, co-wrote a book about the program titled *Healing Journeys: Teaching Medicine, Nurturing Hope* and was featured in a 30-minute documentary about the program. Quotes shared from SMYSP participants highlighted the powerful positive impact of the program.

Dr. Valantine discussed the relevance for SMYSP success for NIH efforts. NIH has interrelated approaches like NIH Building Infrastructure Leading to Diversity (BUILD), the National Research Mentoring Network, and the Coordination and Evaluation Center. NIH also has increased efforts to ensure fairness in the peer review process. Lastly, engagement by all NIH leadership has increased, as evidenced by the establishment of the NIH Steering Committee Working Group on Diversity and the appointment of Dr. Valantine as the Chief Officer for Scientific Workforce Diversity. Dr. Valantine's medical background is in cardiology, which is strongly based in evidence, and she hopes to apply similar rigor to NIH training and diversity efforts. Accordingly, she has brought in experts in sociological and psychological theory to provide input on the design and execution of important programs.

Discussion

SMRB Members

Dr. Koenig noted that the number of women attending medical and veterinary school has increased, and he asked Dr. Valantine about the percentages of women at Stanford University. Dr. Valantine replied that participation of women has increased slightly, but there has not been a rapid change, and that stereotypes about scientists are still deeply rooted. Moreover, percentages have not changed significantly within biomedical leadership. The perception that males predominate in science is so deeply rooted that even adults who recognize the problem of diversity in the scientific workforce have been shown to associate scientists with white men, as recently seen when a Stanford Executive Committee was posed the question of what a scientist looks like.

Dr. Koenig next asked Dr. Valantine if SMYSP is scalable. She replied that she believed it could be scaled in a step-wise fashion. Incentives would be a good place to start. Dr. Babiss asked if other universities are trying similar programs; Dr. Valantine answered that Duke University has a similar program and she believes that other universities will follow. Currently, all programs are being created independent of one another. Dr. Babiss suggested packaging and franchising the program for wide dissemination.

Dr. Tabak noted that 42 percent of SMYSP graduates went on to medical school and graduate school but asked for the breakdown between the two groups. His own observation was that the majority of these students go to medical school, and although that is good and necessary, there is an underlying challenge of encouraging underrepresented groups to participate in biomedical research. Dr. Valantine agreed that the majority do tend to attend medical school, but noted that this is true for the majority of students, not just minority students. The length of the career ahead of a student interested in biomedical career, comparing medicine with research, complicates the choice of a research career. This is an overarching theme for all students expected to succeed; the path toward medical school feels clearer for most students. Dr. Yancy added that SMYSP, the NIH SIP, and others serve as individual models but the platforms remain the same. He suggested using the curriculum to define the outputs. Dr. Tabak asked whether a change in emphasis in the curriculum could tip the balance to encourage more students to enter the biomedical pipeline. Dr. Andrews observed that these students are savvy at looking forward—they require clear milestones and seek secure jobs and good income. Exposure to graduate school reveals that it is open ended and that obtaining and retaining jobs is difficult. She suggested an alternative route would be to recruit medical students into science. Dr. Yancy added NIH could move even further upstream and portray science as a global endeavor. Dr. Valantine stressed that the success of SMYSP was due not only to its curricula but also to the mentoring and long-term support. Dr. Birnbaum stated that she was comfortable with a large percentage of students in programs like SMYSP pursuing a professional career and encouraged focusing on improving the pool of people in

science She then cited a recent editorial in the *Proceedings of the National Academy of Sciences* by Dr. Harold Varmus and others entitled “Rescuing US biomedical research from its systemic flaws.” Dr. Rodgers agreed with Dr. Birnbaum, noting that there is the pipeline for students interested in health research is leaky, and it is a challenge to maintain their interest in investigative inquiry. He said there has been a long history of creating programs to target minorities, and that more is needed beyond short-term summer enrichment (including mentorship and the ability to return to the laboratory). NIH has the added challenge of the difficulty in tracking participants long-term. Dr. Andrews mentioned that mentors with similar identities are particularly helpful to students.

Dr. Birnbaum stated that reaching high school students must be a local endeavor. The National Institute of Environmental Health Sciences has a program that runs workshops on Saturday mornings and links the students to summer research programs at historically black universities. She acknowledged that the program was too young to effectively evaluate, but believed there is promise in a bottom-up approach to encourage young students to pursue science. Dr. Koenig stated that although many programs focus only on high school students, a focus on younger students would have a bigger impact because elementary and middle school students are more impressionable. If NIH focused only on high school, influence on another generation could be lost. Dr. Koenig suggested an alternative: a community-based science fair sponsored by NIH. NIH mentors could be paired with low-income schools and communities. He believed it could be scaled similar to programs that have brought robotics and engineering into lower school grades. Mr. Augustine agreed, noting that he used to believe that eighth grade was a pivotal year due to the introduction of algebra, but he now is considering that the ideal grade may be fourth grade or even earlier. He also noted that the recent USA Science and Engineering Festival held in the District of Columbia appears to have been well attended by minority groups.

Presentation 2

Kevin Finneran, Ph.D.

Director, Committee on Science, Engineering, and Public Policy, National Academy of Sciences

Dr. Finneran acknowledged Mr. Augustine’s 2005 report “Rise Above the Gathering Storm” and its relevance to today’s discussion. NAS performs rigorous, thorough studies, but they are not always what policy makers need. Recently, NAS has been creating action memos on topics in current debate. Instead of convening a large panel, NAS does the research and presents recommendations that are pertinent to the question. When Dr. C. Daniel Mote was asked to recommend a topic for these reports, he suggested “talent.” Although the topic of talent is not the same as the number of science, technology, engineering, and mathematics (STEM) graduates or students with a college degree in science; it includes a need for a mix of training, ability, creativity, and imagination. These skills are needed across the economic span within science. NAS is still working on this action report, but the thought process may be similar to the SMRB’s current charge. Dr. Finneran noted that he began with the “Gathering Storm” report but noted that training is not sufficient to identify talent; resources are also needed. A report on diversity in STEM that followed “Rise Above the Gathering Storm,” written by Dr. Hal Salzman, concluded that there were too many STEM graduates. Yet many take an opposing view. Economists also disagree on biomedical investment; Mr. James Dimon considers it a drag on the economy, whereas Dr. Paul Krugman believes biotechnology needs investment and more jobs. Dr. Michael Teitelbaum argued that if there were truly a shortage of workers, salaries would go up, which is not the case. Mr. Robert Atkinson countered that it depends on who to define as a STEM worker; different analyses showed that some workers are paid a premium. A study performed by the Massachusetts Institute of Technology found that manufacturing companies could find skilled workers but struggled to find employees capable of reading instructions;

none of these companies sought education beyond two years at a community college. Meanwhile, the Department of Education considered the fate of graduates with specific degrees and found that graduates with an associate's degree in a technology field were paid twice as much as those with a bachelor's degree in biology. Dr. Finneran believes that this indicates that there are good, available jobs for which certificates are sufficient. He believed Americans tend to be elitist about the four-year degree, but with increasing debt and diminished opportunities, it is important to think differently. The importance of a wide field of view for STEM workers is especially important for the discussion of underrepresented minorities, who often have higher levels of student debt. Dr. Finneran said he often feels a little guilty encouraging people to go into science when he considers the current challenges facing postdoctoral scientists; it is difficult to tell a young group of students about the future of science. The French economist Dr. Thomas Piketty wrote a book entitled *Capital in the Twenty-First Century* that discusses how the current understanding of the balance between labor and capital is askew. He states that today's period of inequality is typical for the United States, except for unusual events such as the Great Depression, which leveled wealth across groups. Today, there is increasing inequity and little reward for many. So one must ask, what type of talent and training will be most important in the future? Dr. Finneran believed there is cognitive dissonance in the thoughts of current analysts. He stressed the need for increased emphasis on professional master's degrees rather than doctoral degrees. Last year, Dr. Robert D. Atkinson argued that there are too many STEM graduates and that STEM should not be pressed on students in younger grades, risking boring those who may be most interested. Dr. Paul Osterman noted that the skills for STEM are not demanding and that a four-year degree provides other benefits, such as better health outcomes and more civic involvement.

To understand why so many people see the current situation so differently, one must understand the definition of STEM workforce and the skills required. The skills needed are not always directly related to the education received. Dr. Finneran said that he attempted to moderate a panel of these economists and that they were unable to agree on a definition; STEM is too broad to discuss clearly.

It is important to understand what STEM knowledge is. He noted that half of those in the information technology industry in New York State do not have college degrees, and Google hires after freshman year and offers people money not to return to school. Employers that require a four-year degree care less about attaining specific skills, and more about use of a college degree as a social filtering system for potential employees.

Another relevant concern is the difficulty in knowing how the world will change within the next 10 years. One survey assigned a range of numerical categories to jobs based on skill sets and estimated which positions would be performed by machines in 10 years' time. Eighty percent of jobs were estimated to be automated. This prediction is dire, but it is similar to what happened in agriculture. Understanding how best to nurture and prepare students for the future economic landscape is a challenge.

Dr. Finneran believed that NAS has not done a good enough job addressing these challenges. Several studies at NIH have at least considered skill/work projections. Dr. Finneran acknowledged the challenge facing the SMRB and said that he looks forward to reading its recommendations.

Panel Discussion

Key Questions:

- What jobs should be included in a definition of the biomedical workforce?
- Are there problems with the biomedical workforce?

Can any of these problems be addressed at the pre-college level?

What is the point and nature of effective interventions to engage students in biomedical science and attract them to the biomedical workforce?

Dr. Yancy noted that the concept of talent should be considered very carefully among K-12 students, taking into account challenges and biases in assessment including in standardized testing. Dr. Gibbons agreed and noted that Dr. Finneran's presentation proved the old adage that you can ask 10 economists one question and get 12 separate answers. The concept of talent is best considered, in his opinion, taking into account the untapped resources of underrepresented populations that will soon be part of the majority in this country. Dr. Gibbons expressed concern that a large portion of the students in the United States are not meeting their potential, and that that failure carries negative ramifications for NIH. He believed that NIH's efforts within PEBS should at least attempt to address this point. The success of SMYSP as described by Dr. Valentine came not from money or curricula but from human connections and mentoring to advance a child's potential.

Dr. Yancy asked Dr. Valentine how SMYSP was funded and the estimated costs. Dr. Valentine said she did not have specific information, but noted that there was significant "in kind" support. During the program, the students lived on campus and were provided food. She said that the program is now being rolled into the infrastructure at Stanford.

Dr. Augustine related an experience from last year when he was co-chair of a committee charged with addressing the need for scientists and engineers for the Department of Defense. One senior scientist believed there was no problem finding talent and that decreasing budgets meant avoiding hiring new people who would have to be laid off later. He noted that if there were truly shortages, wages would rise, and although wages are competitive, they are not increasing. One reason that there is no shortage of skilled workers is because the supply is now global.

Dr. Koenig noted that if people limit their perceptions of talent, the scope is narrowed. The biotechnology industry needs skills at multiple levels of talent and education. Moreover, industry is more likely to pay well compared to academia, and success should not be narrowly confined to the academic research path.

Dr. Birnbaum expressed uncertainty about increasing PEBS without also addressing science literacy in the general population. Dr. Tabak replied that the need to curtail the scope is practical. Approximately \$20 million of NIH funds will be allocated to this topic, and one cannot assume that the NIH budget will expand in the near future. Dr. Tabak acknowledged that science literacy is a wonderful and noble thing, but it could also pose a bottomless need for resource allocation and is not a good investment for the funds available. It is within the rights of the SMRB to consider the matter differently, but Dr. Tabak believed it is important to advocate for the best value for the modest NIH budget. Every IC is involved in some aspects of science literacy when dealing with patients and providers.

Dr. Andrews suggested incentives for science teachers to increase their professional training; she believed this could be a modest investment that could have a positive impact. She stressed considering actions that are economically viable and scalable. Dr. Birnbaum noted that NIH already has a summer training program for teachers and agreed that some small actions can have far-reaching positive outcomes. She believed increasing diversity could have this effect.

Dr. Finneran reminded the SMRB that some believed interventions should happen as early as fourth grade, and he questioned whether perhaps it should be earlier. Additionally, there is no clear consensus that teachers generally need continued education, and further that smaller class sizes and increased resources have not made a significant difference. In some studies, increasing one-on-one interaction and using test scores to adjust teaching methods made a positive impact on math scores in low-income schools, but did not impact reading scores.

Dr. Rodgers noted that the end of Dr. Finneran's presentation stressed finding candidates and encouraging mentoring to excite creativity. He mentioned a 2012 *Wall Street Journal* article stating that the top 10 jobs of that year did not exist in 2005; training must allow for growth in ways that do not yet exist. Thus, lifelong learning is critical. Dr. Finneran agreed that it is important to provide scientific skills that include transferable knowledge, and the National Research Council is considering this knowledge in curriculum.

Dr. Babiss agreed with the group about the importance of early engagement. In coaching his daughter's basketball team, he noticed a significant transition in fourth grade. It became clear who had talent, who worked hard, and who wanted to be there. He believed the team members each required a different kind of nurturing and that you cannot apply one solution to every child. Dr. Yancy said that identification of talent is proactive and that it is difficult to do in certain cultural environments. He stressed that not all children are given the same opportunities. Dr. Koenig agreed, noting that NIH need not target the economically advantaged.

Dr. Valentine noted that this discussion reminded her of theories to "unlock latent talent" and that current systems do not allow for easy access to biomedical science. She believed access is a significant hurdle to overcome, and that engagement of social scientists would aid in understanding how to address this point. Dr. Yancy noted that unlocking latent talent could influence the biomedical pipeline.

Dr. Briggs admitted that she was struggling with the disparate voices on one side saying that there are enough trainees in science and on the other stressing the need to recruit more scientists. Dr. Yancy said that, in his opinion, the problem is not the overall number of people with STEM education, but rather a focus on diversity. NIH is a \$30 billion enterprise that can leverage and build incentives to engage the strengths in local communities. He suggested that NIH resources might be better leveraged to high school students compared to fourth graders.

Dr. Gibbons referred to points made by Dr. Briggs and Dr. Birnbaum about leveraging existing NIH resources; bolstering some existing programs could have a significant positive impact. He noted that the primary investment in SMYSP was not money, it was leveraging resources. He suggested that perhaps community engagement could be folded into the Clinical and Translational Science Award sites with grantees as mentors. Dr. Tabak reminded the SMRB of the morning's discussion about the stresses already placed on NIH researchers to obtain and retain funding, and expressed caution about adding more required activities for R01-level investigators. Dr. Briggs noted that participation need not be a mandate; it could involve an added incentive or prize.

Dr. Yancy asked for clarification on continuation of initiatives to consolidate specific aspects of funding requirements. Dr. Tabak explained that the White House announced plans to consolidate across agencies in some areas, such as aspects of the Science Education Partnership Award (SEPA) program. Congress did not permit NIH to perform any of those actions. Many NIH SEPA grantees are concerned;

NIH has expressed their commitment within the bounds of the law. NIH is on record offering to assist any federal agency interested in the space of biomedical research-type K through 12 STEM activities.

Dr. Koenig said he understood the daunting challenge and issues of burden for institutions and PIs. But he also noted that the SMRB members were asked to think creatively, and he urged consideration of actions for younger children. In closing, he noted that scientists at retirement age are a valuable, untapped resource.

Mr. Augustine thanked the panel members for their participation.

Public Comments

There were no public comments.

Discussion and Wrap-Up

SMRB Members

Mr. Augustine offered SMRB members an opportunity to make a final comment. Dr. Birnbaum requested that materials for future meetings be sent earlier, if possible. Dr. Rodgers reminded the group that SMRB recommendations are viewed by Congress, and that the SMRB has the opportunity to have a unique impact on the peer-review process. Dr. Yancy informed the SMRB that the first review of BUILD awards takes place in July 2014 for established institutions. He believed that today's meeting has provided information to inform those deliberations. Dr. Tabak thanked Mr. Augustine for his able leadership and noted his personal interest in science education. He looked forward to continued discussion with the SMRB.

Closing Remarks and Adjournment

Norman R. Augustine

Chair, Scientific Management Review Board

Mr. Augustine emphasized that he has always felt that the statement "we have too many scientists and engineers in America" should be followed by the phrase "for what we care to invest." Mr. Augustine informed the SMRB members that their next in-person meeting will take place on July 7 and July 8, 2014.

Mr. Augustine thanked the staff for their efforts. The meeting was adjourned at 2:55 p.m.