THE MERIT REVIEW PROCESS: ENSURING LIMITED FEDERAL RESOURCES ARE INVESTED IN THE BEST SCIENCE

Statement of

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Before the

Subcommittee on Research and Science Education Committee on Science and Technology U.S. House of Representatives

July 26, 2011

Good morning, Chairman Brooks, Ranking Member Lipinski and Members of the Subcommittee. Thank you for the invitation to present a statement before you today. I am Keith R. Yamamoto, Vice Chancellor for Research, Executive Vice Dean of the School of Medicine and Professor of Cellular and Molecular Pharmacology at the University of California, San Francisco. I received a Bachelor of Science from Iowa State University and a PhD from Princeton University before migrating to San Francisco, where I have been on the faculty for 35 years. My molecular biology lab has been studying the detailed mechanisms by which small molecules made in our bodies, hormones, control important physiological processes such as metabolism, stress responses and immunity; in the course of that work, I have had primary responsibility for training approximately 100 graduate students and postdoctoral scholars. Our research has been funded throughout by grants from the NIH and NSF.

For the past 30 years, I have also been active in matters of science and public policy, leading or serving on dozens of committees focused on a broad range of issues, challenges and opportunities. One of the major areas of emphasis for those activities has been federal merit review system for evaluation of biomedical and biological research grant applications, especially those overseen by the National Institutes of Health (NIH) and the National Science Foundation (NSF). For example, I co-chaired the NIH effort to assess and enhance its peer review process, and served on the National Science Board/NSF task force on transformative research. These extensive experiences have provided me with a rather deep perspective on the merit review process and its relationship to the U.S. life science research enterprise.

In my testimony today, I shall: (1) describe the key operational and organizational features of the merit review process for biomedical and biological research; (2) assess how well that process works; (3) consider the impact of a particular change to the process that is currently being considered; and (4) enumerate some potential modifications that might further improve the process.

Every application for NIH and NSF life sciences research support (NIH, for example, receives some 80,000 applications per year) undergoes rigorous review and prioritization of scientific merit by committees of peers, typically by scientists who themselves hold grants from the same agency, and whose research is in the same area of research as the proposed study. The details of the review process differ among the different federal agencies, but evaluation by peers is the crucial common feature.

To populate the federally chartered merit review committees, agencies enlist volunteer service from expert scientists in each area of research, who agree to set aside time from their own scientific research at academic and research institutions around the country, typically several times a year, to carefully evaluate written proposals for scientific investigation. The reviewers exercise their individual and collective scientific judgments free of other biases, prioritizing the scientific merit of the applications.

To help prevent nonscientific biases, the formats of both the applications and the reviews are tightly delineated, whereas the applicants have broad flexibility in choosing the scientific

subject matter of the applications. In the NIH process, for example, a standardized set of five criteria (significance, approach, innovation, investigator and environment) is mandated as the basis for rating every application. Assessment of the investigator is focused solely on past performance and qualification for carrying out the proposed study. Importantly, merit review committees are charged to judge only scientific merit. In particular, they do not assess relevance of the applications to the portfolio of the funding agency, nor do they not make funding decisions. This singular focus on merit (together with peer-driven review) is the second key feature of the merit review process.

Thus, it is important that decisions of scientific merit are insulated and separated from decisions of funding. In addition, of course, the merit review process has no control over the level of funding allocated to support meritorious applications. When funding levels fall far below the capacity to support some of the very best applications (as is presently the case), the merit review process appears to fail, *i.e.*, outstanding science goes unfunded. This apparent failure instead reflects a misalignment between the number of highly meritorious applications and the number of dollars available to fund those applications.

Any merit review process that depends upon peers to carry out evaluations must acknowledge and address at least two intrinsic and related conflicts of interest: reviewers might unfairly support applications from their friends to create an "old boys" network, or they might unfairly disadvantage applications from competitors or from those outside of some perceived "inner circle". In general, these intrinsic conflicts have been addressed successfully by well-crafted

regulations, and more importantly, by a universal "culture of respect" from the participating scientists who serve as reviewers.

While peer-driven merit review plays a crucial role in identifying excellence among proposed ideas and research plans, it is also the case that an element of conservatism is intrinsic to peer review, which complicates recognition and prioritization of "transformative" ideas and approaches. This is because the majority of scientists, and therefore the majority of peer reviewers, embrace and extend prevailing scientific paradigms, whereas transformative research disrupts or destroys accepted paradigms and creates new ones. Because both types of research are essential, approaches to address intrinsic conservatism are important. One strategy is to adopt special funding mechanisms, and perhaps some special elements of the review process, designed to identify ideas.

The current merit review processes, which have been in place in the U.S. for over 65 years, recognize that only scientific peers have the knowledge and perspective required to assess the relevance, innovation and impact of proposed research projects. Indeed, the current system of peer-driven merit review is widely held to be not the "*best* good system" for evaluation and prioritization of merit, but "the *only* good system".

By any measure (*e.g.*, quality of scientific publications resulting from support of meritorious applications, honors and prizes given in recognition of the highly meritorious research, products and services that are developed from the results of supported research, creation of an

outstanding scientific workforce resulting from training of students and fellows supported), peer-driven merit review has been spectacularly successful at identifying and prioritizing the most interesting, innovative and significant scientific research projects. Hence, the merit review process enhances profoundly the *strength* of the research funded by the federal government. In contrast, the merit review process is not intended to influence the *breadth* or *type* of research that is funded. Rather, breadth and type are strongly influenced by funding mechanisms, and by the range and diversity of disciplinary foci that are chosen by the funding agencies.

Are there specific changes that might further strengthen the merit review process to ensure support of the best science? Let me mention first a change currently under consideration that would in my view damage the process, and then end with a brief enumeration of some potential changes that might enhance it.

The National Science Board (NSB) Task Force on Merit Review is currently reviewing the NSF's merit review criteria, and has proposed a revision of both the "Intellectual Merit" and the "Broader Impacts" requirements, with the goal of clarifying their intent and the ways that they would be used in the merit review process. The purpose of the Broader Impacts criterion "is to ensure the consideration of how the proposed project advances a national goal(s)." This criterion, as stated, would in my view adversely affect the merit review process because it departs from the singular focus on scientific merit that is essential to the process, and because it obligates peer reviewers to judge grant applications by metrics outside of their expertise.

This being said, I concur fully that broader national goals are essential, and as stated in the NSB Merit Review Principles, "collectively, NSF projects should help to advance a broad set of national goals." It is important, however, to remain mindful of the language of the NSF Act of 1950, which directs the Foundation "to initiate and support *basic* scientific research and programs to strengthen scientific research potential and science education at all levels." Indeed, NSF itself originated from "Science the Endless Frontier", the redoubtable 1945 policy initiative of Vannevar Bush, which called out untargeted basic research as "the pacemaker of technological progress" in which "new products and new processes ... are founded on new principles and new conceptions, which in turn are painstakingly developed by research in the purest realms of science".

This implies that broad national goals should be advanced by the *composite* federally funded scientific research endeavor, and in particular should not be mandated for individual NSF research grant applications. In general, such goals should be addressed by development of funding mechanisms and by defining agency priorities, and not as a part of the merit review process. Moreover, it seems that broad national goals might specifically be mandates for mission-driven agencies that seek to support research relevant to health, environment, energy, food and agriculture, or national security, rather than for the National Science Foundation.

While the current merit review process has great strength, there are conceptual and operational aspects that might improve it further. Some examples for consideration across a wide spectrum:

- Reconfigure the grant application conceptually to be viewed less as a "contract", and more as demonstrations of an investigator's capacity to identify an important scientific problem and devise tests that could advance knowledge and understanding, and thereby impact the field. Thus, the grant application is not intended as a "roadmap of experiments" projected 3-5 years into the future. Grant application formats and merit review criteria should place greater focus on the merits of the proposed idea and of the investigator, whole reducing the current focus on proposed experimental details and feasibility.
- Motivate top scientists to maintain active participation in the merit review process, in part by developing mechanisms that more effectively encourage applicants to submit bold scientific ideas.
- Establish and formalize two separate investigator-initiated funding mechanisms, innovative and transformative, which invite, identify and support research that, respectively, advances and deepens our understanding of current paradigms, or disrupts and destroys prevailing paradigms, and forces creation of new ones. Consider unique aspects of merit review process for transformative applications.
- The topical/disciplinary focus of review committees has been eroded by the demands of reviewing a rapidly increasing proportion of grant applications that include a remarkable diversity of experimental approaches. To recover the conceptual focus of merit review committees, institute a "focused external review" process in which *ad hoc* reviewers are requested to contribute electronically brief comments that address solely

those technologies or approaches for which specific expertise is lacking on the chartered committee. Such external reviewers would not be asked to assess the overall scientific merit of the application; that responsibility would reside solely with the chartered committee.

The merit review process used for review of federal grant applications for support of biological and biomedical research is indisputably the best system for managing this important responsibility. Its primary features of peer-driven review and singular focus on merit have been critical in identifying grant applications that describe the best science by the best scientists. Once unique in the world, the process is being widely emulated.

This concludes my testimony. I would be pleased to answer your questions or address your comments. Thank you again for the opportunity to discuss this important matter with you.