ENDOCRINE SOCIETY
Hormone Science to Health

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Accelerating the American Scientific Enterprise

The Endocrine Society appreciates the opportunity to provide comment for the Request for Information on Accelerating the American Scientific Enterprise. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. Our membership of over 18,000 includes researchers who are making significant contributions to our understanding of endocrine diseases such as diabetes, obesity, cancer, and others.

Biomedical researchers play an important role in the science and technology ecosystem by making discoveries that accelerate the development of novel medicines and technologies to improve health. Our members have focused our comments on several specific questions within the RFI.

(ii) How can the federal government better support the translation of scientific discoveries from academia, national laboratories, and other research institutions into practical applications? Specifically, what changes to technology transfer policies, translational programs, or commercial incentives would accelerate the path from laboratory to market?

Steady, sustainable investment from the federal government in science and technology is essential for translating scientific discoveries into practical, real-world applications. Uncertainty and instability hinders scientific research through the inability to plan for long-term projects and hire personnel accordingly. Congress should dedicate funding streams to long-term projects that achieve scientific and public health objectives with safeguards to prevent rapid funding shifts due to changing political priorities.

We also note that existing programs to support high-impact research exist and could be reformed and/or better supported. One area of financial investment the federal government has traditionally invested in is through the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs, which help

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researchers and entrepreneurs at academic institutions turn their discoveries and technologies into products for commercialization. Authorization for the SBIR/STTR program expired at the end of Fiscal Year 2025 and has not yet been renewed. Even with a renewed SBIR/STTR program, a more streamlined process to accelerate commercialization following intellection property (IP) that is developed at academic institutions is needed. Clear guidelines are needed to protect the IP of all participating entities while simultaneously preventing gatekeeping that can hinder emerging competitors. The development of these start-up companies takes time and detracts from laboratory research; new ways to support the development of startup companies or reduce the time and effort it takes to start a new company would accelerate the commercialization process. Our members suggest that artificial intelligence applications could be developed to help researchers more efficiently advance the patent process or other aspects of commercialization that they are not trained to navigate.

Additionally, the National Institutes of Health (NIH) offers grant programs such as the R21 and DP2, aimed at giving investigators flexibility to pursue high-risk, high-reward projects that could prove transformative. While we support the intention of this program, grant review panels often fail to evaluate applications consistent with the goals and objectives of the program. Our members report that such applications are often evaluated similarly to and alongside traditional research grants that require preliminary data and established techniques instead of being evaluated more broadly for potential impact in biomedical research and application. NIH leadership should train reviewers to better evaluate high-risk, high-reward proposals, e.g., by reducing bias for projects with preliminary data or prioritizing research with the potential to address an unmet commercial need and by creating separate study sections for these mechanisms.

The federal government should also support shared national facilities and infrastructure in partnership with research institutions. For example, academic medical centers are uniquely positioned to access and collect biospecimens from patients and have the equipment and expertise needed for 'bench to bedside' translation. Investment in infrastructure to support these repositories can help bridge the gap between discovery and clinical development of therapies and technologies for commercialization. Investment in shared national facilities, such as research laboratories, biomanufacturing facilities, and good manufacturing practice (GMP)

facilities, can lower the barrier to translating research to technologies by reducing research costs, enabling scaling of projects, and by promoting collaborations between academia, national labs, industry, and the federal government. In addition to the infrastructure, the knowledge required to translate preclinical research to the clinic is siloed. The federal government could support the Food and Drug Administration (FDA) with additional staff to share and explain guidances as they pertain to preclinical research that are earlier in the translational pipeline to more efficiently correct or adjust materials or techniques for implementation. This sharing of knowledge could bridge the gap between the bench research testing or manufacturing and products that are ready to test in the clinic.

Finally, we note that market conditions are often a barrier to commercialization of promising discoveries. For example, rare disease research is supported by the federal government, but the market for commercial products to treat these diseases is small and may not align with business strategies. Incentives are needed to align market needs and business objectives with research goals to ensure investment throughout the pipeline for all aspects of human health.

(vi) What reforms will enable the American scientific enterprise to pursue more high-risk, high-reward research that could transform our scientific understanding and unlock new technologies, while sustaining the incremental science essential for cumulative production of knowledge?

The tenure process across U.S. institutions often disincentivizes early career investigators from pursuing high-risk, high-reward research projects. Tenure and promotion often rely on publication volume and receipt of traditional NIH - R01 awards which may incentivize showing productivity through low-risk, incremental advancements and applying for grants that require significant preliminary data and minimal risk. Institutions should design tenure and promotion processes to incentivize a variety of research outputs, including commercial applications and patents. Researchers who have achieved tenure should also be given protected time and resources to pursue new lines of investigation that may be considered high-risk. Additionally, the federal government through the NIH could increase the number of high-risk funding mechanisms to a sustained and predictable level. This would enable tenure-track faculty to demonstrate success while also taking risks and potentially

advancing science with greater leaps while sustaining incremental, foundational research.

(ix) What specific federal statuses, regulations, or policies create unnecessary barriers to scientific research or the deployment of research outcomes? Please describe the barrier, its impact on scientific progress, and potential remedies that would preserve legitimate policy objectives while enabling innovation.

Open Access:
We appreciate the intention of policies to improve access to scientific publications that have been supported by tax dollars, an unintended consequence of such policies is a significant rise in publication costs. This limits researchers' ability to publish their work in the most appropriate journal, prevents disseminating findings in a timely manner, and draws funding away from necessary research supplies and personnel.

Regulatory burden:
Long grant applications and extensive regulatory requirements, such as progress reports, are a significant regulatory burden for scientists. The time spent completing these forms could instead be spent on accelerating scientific progress by guiding trainees, conducting experiments, and pursuing translational collaborations. Grant applications, for instance, can consist of over 150 pages of text, much of which is not relevant to the research project itself. Meanwhile, grant progress reports often have redundant fields that still require direct input and modified text. Finding ways to utilize AI to complete redundant administrative tasks for applications and progress reports will allow researchers to focus their responsibilities on work that has the potential to transform research into marketplace products. Additionally, many regulatory documents, such as institutional review board (IRB) and institutional animal care and use committee (IACUC) protocols, plans or drafts, are required to be submitted as part of a grant application in a different format than the one approved by the institution. These could be streamlined and presented as approval letters at a later stage in the application or grant funding approval process to reduce the administrative burden from the applicant, the institution, the scientific review committees, etc.