



THE
SMALL BIOTECHNOLOGY
BUSINESS COALITION

**Proposed *Innovation for Healthier Americans* provisions to create
*NIH Commercialization Advisory Councils***

***Recommendation of
The Small Biotechnology Business Coalition***

Recommended is a new legislative initiative to more rapidly accelerate the translation of biomedical research into products that will simultaneously improve patient outcomes and create sustainable job growth. Importantly, this initiative would not necessarily require any increased appropriations.

Each year the NIH awards about \$27 billion dollars in grants to external researchers. The overwhelming majority of this funding goes to hypothesis driven basic research by academic researchers. (The sole exception is the 2.8% of SBIR funding that is mandated by statute to go to small businesses.) The end goal of academic research is almost always a publication in a peer-reviewed scientific journal. However, the research required to obtain these publications is substantially less rigorous, burdensome, and expensive than that required to develop a product for use in a clinical or commercial setting.

In order to translate the results of published studies into working drugs, devices, or diagnostics the results must first be replicated in studies with substantially larger numbers of tests and/or subjects (*in vitro*, animal, or human) under meticulous evaluation conditions. This tends to be the highest risk stage in the biomedical R&D pipeline which neither large companies nor venture capitalists are willing to fund. Unfortunately virtually no NIH support is provided for this stage of research. That is because all of the NIH funding decisions are made by representatives of the academic community who direct funding to projects at which their institutions excel. The funding priorities of academics do not necessarily match those of patients, physicians, or biomedical entrepreneurs.

The most recent SBIR reauthorization expressly stipulated that the SBIR allocation (about 3%) is a minimum threshold (floor) rather than a mandated level (ceiling). Yet no NIH institute goes beyond this minimum even if the public health needs warrant such an increase.

Typically NIH funding priorities are set by institute level Councils made up almost entirely by leaders of the academic research community.

In order to give other stakeholders a say in recommending NIH funding priorities it is proposed that each of the six largest NIH institutes create Commercialization Advisory Councils (CACs). These Councils would each comprise 12 representatives from the following stakeholder organizations:

- 3 physicians who specialize in treating diseases that is the focus of the Institute. (These physicians would not be NIH grant recipients)
- 3 representatives from patient advocacy organizations
- 3 representatives from academia

- 3 representatives from companies developing innovative drugs or devices for diseases that is the focus of the Institute. (Two of whom represent small businesses)

The CACs would make the following annual recommendations to the Institute Director, based on current medical needs, new biomedical innovations and developments, and review of projects funded by the institute in the past three years:

- 1) The SBIR allocation, to the extent that it should exceed the statutory minimums,
- 2) Targets for allocation of funding between basic, applied, and translational research,
- 3) Priorities for disease interventions,
- 4) Grant review and management policies and practices,
- 5) The distribution of funding mechanisms (contract, cooperative agreement, grant, etc.).

The CACs would issue a non-binding set of recommendations to Congress and the NIH Institute Director at the end of each calendar year. Within 30 days of receipt of the report the Institute Director would advise Congress on whether or not the report recommendations would be implemented by the Institute in the upcoming fiscal year and the basis for any recommendations not being adopted.

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