Written Testimony by Jonathan S. Lewin, MD, FACR,
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Driving Innovation from Federal Investments
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Thank you for providing the Academy of Radiology Research with the opportunity to submit testimony on the important topic of driving innovation from federal research and development (R&D), particularly as they pertain to the National Institutes of Health (NIH).

As a long-time NIH investigator and a senior administrator at one of the country's largest research institutions, biomedical research is near and dear to my heart. I currently have the honor of serving as the Senior Vice President of Integrated Healthcare Delivery for Johns Hopkins Medicine, as well as the Chair of the Department of Radiology and Radiological Science. Like my colleagues at other institutions, I get to see first-hand the incredible work that NIH-funded scientists are doing to save lives, improve the health care delivery model and contribute to Maryland's economy.

While the central mission of the NIH is to improve human health, NIH is often looked to as an engine for innovation-based economic growth. Overall, this investment from Congress into university-based R&D has been shown, through a number of broad economic assessments, to be a productive use of taxpayer dollars. However, I would encourage members of this committee to begin to utilize specific metrics to assess the exact economic impact of federally funded R&D to guide policy decisions and assess the impact of Congressional budget allocations.

While there are challenges in quantifying the economic value of innovation, several metrics do exist and are widely accepted in the private sector – specifically, an assessment of the quality and quantity of a company's intellectual property as indicated through patents. In general, companies that have a track record developing new patents through their own R&D generate greater investor confidence and a higher market value. Investors tend to have greater confidence that these companies will continue to be innovative leaders in a particular field or sector. Not surprisingly, many of the most innovative companies invest heavily in in-house R&D – including Apple, Google, GE, and others – and are rewarded through a strong investor base that keeps the company well capitalized and moving forward.

However, producing a patent does not always mean that a technology will be developed and translated to the commercial sector. Often, a company can generate new patents for business strategy reasons, not to generate new innovations. To help weed out these patents, looking at the number of *forward citations* for a patent has become a common approach for assessing the economic impact and value of patents. Forward citations are references to a particular patent by later patent filings, and help identify if the original patent was integral to downstream technological development in a field. The more forward citations, the more new patents were "spawned" from the original patent, and the greater the likelihood that the original patent was economically valuable and truly transformative. In patent infringement cases, courts often take forward citations into account as a proxy for economic value when assessing monetary damages and awards to plaintiffs. This can be a significant metric for policymakers if applied to federal R&D programs, forward citations from federally-driven patents represent millions of dollars of additional and successful private sector R&D.

It is worth noting that patent output does not paint a complete picture of the value of research; many basic research discoveries do not lend themselves to patenting, but often form the knowledge foundation that make future discoveries possible. These fundamental contributions to the research enterprise are essential and more difficult to measure – and should be recognized as vital to the long-term goal of NIH to better human health. However, in the short term, the success of patent metrics in the private sector may present policymakers with a proven methodology for identifying areas of federal R&D that are most likely to contribute to future development and economic activity, as patents have been found to be highly correlated with higher levels of downstream R&D, new innovations, start up activity and jobs (Brookings, 2013).

The Academy of Radiology Research recently completed an analysis using this methodology to look at the history of patent production (2003-2012) from a number of federal agencies, including across the NIH by Institute, to identify those areas of science that may be producing a disproportionate amount of intellectual property. This analysis is currently in-press with a prominent scientific journal and will be published in June. However, we appreciate the opportunity to offer generalized comments on the results, as the economic impact of the NIH in particular was found to be quite significant.

As a whole, the NIH average for forward citations was found to be nearly five times higher than the average number of forward citations for biotechnology patents in the private sector. This is an strong indication of the economic power of NIH research, as each patent generated led to the downstream creation of approximately 8 additional patents, compared to 1.7 future patents from similar private sector R&D. In order to make a general economic estimation, we will assume all of the future patent development work is done in the private sector, at the industry average of $3.4m per patent (Brookings, 2013). If this is the case, NIH on average helps spur $26.8m in private sector R&D for every patent that it generates (7.9 future patents x $3.4m in R&D for each patent), compared to just $5.8m in downstream R&D as a result of private sector patenting (1.7 future patents x $3.4m in R&D for each patent).

This differential between public and private sector patenting is economically significant: a high number of forward citations from NIH not only indicates higher levels of downstream private sector R&D, but <u>successful</u> R&D since it resulted in additional unique patents being granted by the U.S. Patent and Trade Office (USPTO). In fact, this figure is likely deflated, since it fails to capture "unsuccessful" downstream R&D. While it is easy to discount "unsuccessful" R&D considering its failure to produce a new patent, it still engenders the positive economic impact of supporting the employment and economic activity that policymakers are likely interested in assessing.

We also found that NIH produces 2.5 patents for every $100m spent on all activities, however this figure is also likely deflated due to underreporting of investigators when filing a patent. This figure also takes into account all of the training mechanisms that NIH supports, which are not considered R&D and would not be expected to result in new intellectual property. Despite these caveats, it can be conservatively estimated that NIH research creates an estimated $67m in private sector R&D for every $100m in research activity (2.5 patents per $100m x $26.8m in total downstream R&D).

However, taking underreporting and training mechanisms into consideration, the downstream economic impact of NIH research is likely closer to $81.1m in downstream R&D for every $100m in actual R&D activity – meaning NIH research activities generate nearly as much R&D in the private sector as the original investment by Congress, largely due to the quality of NIH's patent portfolio. So while the private sector tends to produce patents at a higher rate than the NIH, private sector patents have significantly less impact throughout the economy. Without NIH patents, the innovation economy and R&D employment base that the U.S. relies on would be significantly smaller.

Looking within NIH, we find a number of patent hubs, specifically the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the National Institute for General Medical Sciences (NIGMS), the National Eye Institute (NEI) and the National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The patent performance of NIBIB was striking, as it produced both higher numbers and higher quality patents than other prominent federal R&D programs, such as Defense Advanced Research Programs Agency (DARPA), National Science Foundation (NSF), and the Department of Energy (DOE). Given the high levels of basic science conducted by the top performers (NIBIB and NIGMS) in terms of patent output, this analysis suggests that basic research conducted through NIH is a powerful catalyst for the generation of new intellectual property. A greater focus on basic research throughout the Institutes might also spur higher levels of patent output.

In looking at quality, patents from NIBIB averaged 13 forward citations, for a total $54.4m of future R&D in the private sector for each patent created (13 forward citations x $3.4m in downstream R&D per patent). Since NIBIB produces an astonishingly high 16 patents per every $100m of research funding, **they generate an astounding $707.2m in private sector R&D for every $100m in research activity over time.** Using the same methodology, DARPA spurs $203.3m in private sector R&D, while NSF spurs $185.6m - making NIBIB an unbelievable jobs-engine that Congress should be proud to have within the NIH.

At Hopkins, we currently have an exciting project that demonstrates the public health and economic impact of NIBIB funding, and is aimed at tackling one of our country's most threatening public health concerns: obesity. This particular grant uses the image-guided injection of microbeads to embolize the small artery in the stomach that supports a key hunger hormone called ghrelin. By finding exactly the right artery, and thus the supply of nutrients and oxygen, the interventional radiologist can inject microbeads that impede the blood supply and down-regulate the amount of ghrelin that is produced – resulting in less desire to eat and sustainable long-term weight loss. This minimally-invasive procedure has the potential to replace more expensive and risky bariatric surgery, as well as create a whole new manufacturing facility around Hopkins for the novel microbeads that make the technique possible. I am proud to report that the application for this project received a priority score of 1 from the NIH (the best possible reviewer score), making it an incredibly exciting project from both the NIH's and Hopkins' perspectives.

Conclusion

Like the most innovative private sector companies, NIH seems to have a strong "investor base" that would like to see the agency well-capitalized and moving forward, especially when looking at the recent public opinion polling by the organization Research!America. Their findings clearly indicate that a majority of Americans believe that basic medical research is a wise and productive use of public dollars. The patent evidence presented here indicates that they are indeed correct: that investments in NIH not only lead to better health, but significant amounts of downstream private sector R&D and a level of economic impact that patent data shows cannot be replicated by the private sector. While NIH's mission should always remain to improve human health, Congress should recognize the economic output from NIH and NIBIB as one of the best among its federal peers, and consider support for NIH as a critical component of our innovation economy.

References

J. Rothwell, et al. "Patenting Prosperity: Invention and Economic Performance in the United State and its Metropolitan Areas," Brooking Institution, February 2013.