The Nature Institute

Unintended Effects of Genetic Manipulation
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Novelty, Complexity, and Number of Future Biotech Products May Overwhelm U.S. Regulators, Major Report Suggests

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Over the next five to ten years, a profusion of new genetically engineered products is likely to emerge, including an increasing number featuring such complex interactions and novel traits that U.S. regulatory agencies may be overwhelmed, in terms of trying to provide timely product review and to protect human health and the larger environment from unintended effects. So suggests a major recent report by a committee of the prestigious U.S. National Academies of Sciences, Engineering, and Medicine.

The March 2017 report, "Preparing for Future Products of Biotechnology," concludes that the federal agencies that either fund research on biotechnology or that regulate biotechnology products should increase their spending and their focus on advancing the science that regulators need to be able to adequately conduct ecological and other risk analyses before new kinds of such products are approved for release. That includes trying to find answers to many outstanding questions about the range of potential effects of the advanced new engineering techniques known as "synthetic biology," but also research on the science and practice of risk analysis itself. Federal agencies should also "invest in new methods of understanding the ethical, legal, and social implications associated with future biotechnology products." The report suggested the need for better systems for monitoring such products after they are actually on the market, to track any negative impacts.

Regulatory agencies, the report added, also should "increase scientific capabilities, tools, expertise, and horizon-scanning in key areas of expected growth in biotechnology." It highlighted the following as priority areas for them to focus on: new products for which there are no non-biotechnology products to compare them; "off-target gene effects, and phenotypic characterization; genetic fitness, genetic stability, and horizontal gene transfer; impacts on nontarget organisms; control of organismal traits; modeling (including risk-analysis approaches for coping with uncertainty) and life-cycle analyses; monitoring and surveillance; and [evaluating] the economic and social costs and benefits." The committee listed the kinds of new products that are being designed for deliberate release in an open environment, with low — or no — management after their release, and indicated they require special attention.

It avoided recommending specific changes in laws and regulations, stating that that was outside the scope of its charge. But it did predict that some new products "will likely challenge federal agencies to protect the public's health, welfare, safety, and environment using the legal tools they already have." In terms of all the issues it covered, it added:

> "Existing statutes offer promising pathways to meet these challenges, although there may be cases when a novel product falls outside the jurisdiction of FDA, EPA, or USDA and is either in a jurisdictional gap (where no regulator has authority to address potential safety concerns) or under the jurisdiction of another agency, such as the Consumer Product Safety Commission, that has fewer statutory authorities and

> capabilities to conduct rigorous and timely risk analysis. For this reason, FDA, EPA, and USDA may at times need to make use of the flexibility available under their statutes to minimize gaps in jurisdiction and to position novel products under the statutory framework most suited to each product's characteristics and level of risk."

The committee added that for some new lines of products "consumer safety regulatory agencies have little or no authority to restrict the receipt, use, sale, or distribution of products to address risks that otherwise-safe products may pose in the hands of unqualified or malicious users." And it expressed concern about whether the Occupational Safety and Health Administration has sufficient legal authority and resources to protect workers from hazards that might arise from novel biotechnology products used in industrial applications.

"Almost all of the [U.S.] statutes," the 214-page report added, "lack adequate legal authority for post-marketing surveillance, monitoring, and continuous learning approaches. Thus, although the products of future biotechnology are often likely to be within the jurisdiction of existing regulators, they may struggle to regulate these products effectively and to respond nimbly to the products that will be coming."

Chaired by Richard M. Murray, a bioengineering professor at the California Institute of Technology and founder of a biotechnology startup company, the committee also endorsed the idea that government oversight should "balance innovation and safety." The committee's report was written in response to a request from three U.S agencies — the Environmental Protection Agency, the Department of Agriculture, and the Food and Drug Administration — that share various regulatory authorities related to particular biotechnology applications.

NOTE: The membership of the committee that wrote this report — the Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System — has been a matter of public controversy.

Last summer, about 40 scientists and representatives of non-profit organizations, including The Nature Institute, sent a letter to a leading official at the National Academies, expressing concern that the committee lacked "balance, perspective, and independence." They noted that many members were working to develop biotechnology tools and products that, to be commercialized, may be subject to federal regulation. This, they added, presented obvious conflicts of interest, favoring the biotechnology industry. The panel included no obvious proponents of the precautionary approach to regulation or critics of industry products and practices, to help provide balance, they said.

In December, 2016, *The New York Times* cited that letter and reported that by its own count, seven of the 13 members initially appointed appeared to have potential financial conflicts. (The seven includes one member who later resigned, citing scheduling problems.) The academies, in announcing the committee, had itself noted the financial conflicts of two of the members, one of whom, Steven L. Evans, is a fellow at Dow AgroSciences, a major biotechnology company, and co-chairs the synthetic biology subteam of the Industrial and Environmental Section of the Biotechnology Innovation Organization (BIO). BIO describes itself as the world's largest biotechnology trade association. The exploration of the committee's potential financial conflicts was part of a broader *Times* story on concerns about conflicts of interest on committees appointed by the National Academies to provide advice on biotechnology and other issues.

Sources

National Academies of Sciences, Engineering, and Medicine (2017). *Preparing for Future Products of Biotechnology*. Washington, DC: The National Academies Press. http://dx.doi.org/10.17226/2460

Stephanie Strom (Dec. 27, 2016). “National Biotechnology Panel Faces New Conflict of Interest Questions,” *The New York Times*. Available at: https://www.nytimes.com/2016/12/27/business/national-academies-biotechnology-conflicts.html?_r=0