Viewpoint: Eric Lander is the first geneticist to direct US science policy. Here's how he can harness the biotechnology revolution

Eric Lander—geneticist, mathematician, president and founding director of the Broad Institute—took the helm on June 2 as director of the Office of Science and Technology Policy (OSTP). He is the first biologist to serve as presidential science advisor and takes a seat in the cabinet. Inasmuch as the 21st century is on course to flower as the Age of Biology, this is a welcome, if overdue development.

The OSTP director always faces demands to do many more things than any mortal could accomplish. In our view, the top priorities that would ensure a successful tenure for Lander include at least these three:

1. Launching and ensuring the success of ARPA-H/HARPA;
2. Galvanizing the wide application of mRNA technology in vaccines and therapeutics; and
3. Unleashing the innovative potential of cutting-edge techniques like gene editing in broader applications.

Let's take a closer look at each of these.

Two of the most important qualities in successful OSTP directors have been understanding how bureaucracies function (or fail) and using the levers of power effectively. Brilliant individuals too often have failed these tests, and based on his embrace of locating HARPA (Biden's proposed Health Advanced Research Project Administration) within NIH, Lander may be off to a rocky start.

President Biden has proposed to fix one of the most frustrating shortcomings of the U.S. biomedical establishment by setting up a new body called ARPA-H, or HARPA, the acronym standing for Advanced Research Projects Agency–Health, modeled after the Pentagon's DARPA. NIH is world-leading in delivering cutting-edge breakthroughs in fundamental understanding of biology, but translating these into diagnostic tools, treatments, and cures for diseases has not kept pace.

Lander has been aggressively forward-leaning in his determination to focus a wide variety of tools on new approaches to some of the most fundamental challenges in biology, and in recent remarks has given every sign of bringing this attitude to the highest levels of the Biden administration. And creating a new vehicle like DARPA-H/HARPA to focus on advancing translational platforms is not at all a bad idea. But the purpose of this new vehicle calls for a particular kind of innovative culture different from the basic research fostering *weltanschauung* of NIH.

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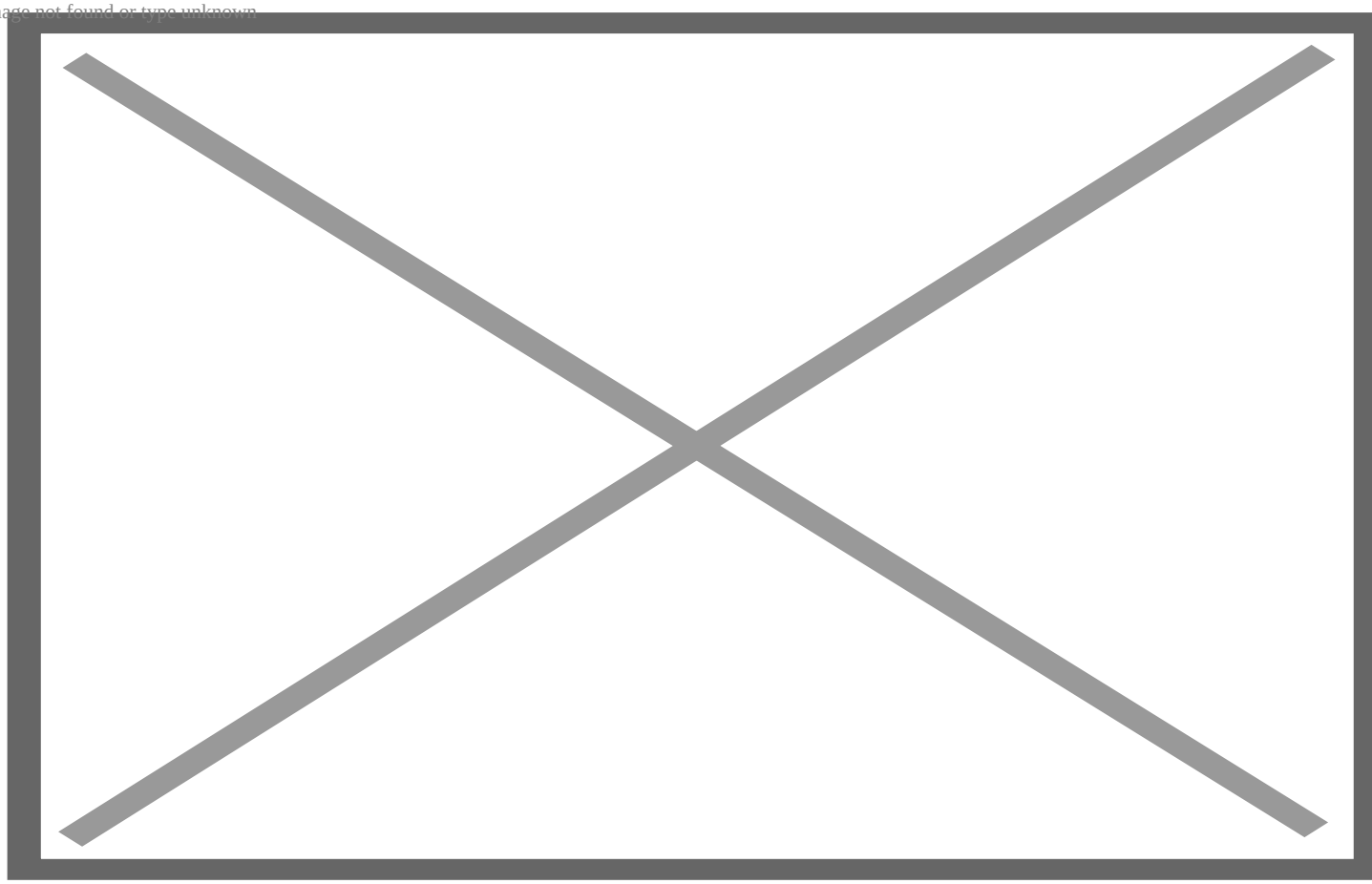

Eric Lander and President Biden. Credit: Matt Slocum/AP

The history of bureaucratic evolution suggests that grafting a new organization with a different mindset and purpose onto the entrenched bureaucratic behemoth in Bethesda is likely to reduce the potential for it to succeed. NIH has long had the ability to do some of the things that have been key to the successes of DARPA and its simulacra (like ARPA-E), like relying not on grants but contracts linked to milestones, and the fact that NIH has not taken advantage of them does not bode well for ARPA-H, but time will tell.

There remain nevertheless reasons to be hopeful for Lander's tenure at OSTP. He has proposed, for example, that the dramatic and unprecedented success mRNA vaccines have delivered against COVID-19 be translated into a generic platform that can deliver new vaccines against emerging viruses within a hundred days to help quash future pandemics. Judged against the history of vaccine development, this would be astounding progress; but measured against the potential of mRNA vaccine design and manufacturing capabilities, and what we've learned in recent years about potential pandemic viruses in the wild our aim should be higher.

Two of the mRNA COVID-19 vaccines have been far more successful than we had any reason to expect, delivering protection levels of 95 percent or higher, imparting strong, long-lasting safety even against emergent variants, and rapidly adaptable to generate new, variant specific upgrades. But the ease with

which the technology can now be applied, and the achievable economies of scale and speed in production, mean it is now entirely plausible that, as Matt Ridley has proposed, for a relatively small investment we could develop and hold in reserve vaccines for every known coronavirus, and many other potential breakout viruses, dramatically reducing if not banishing the specter of pandemic that has stalked humankind for millennia, not to mention the potential applications to other diseases. These are ambitious goals, but now within our grasp and well worth pursuing.

Our third priority may hold the greatest potential, but it's also perhaps the least sexy: regulatory reform. It might just be the easiest to achieve, however.

Modern molecular biology—CRISPR along with its many adjacent platforms—enables humanity to adapt plants, animals, and microbes to serve and solve problems with a power that has been underestimated by all but a few science fiction writers. First-generation genetic engineering has already delivered enormous environmental and economic benefits in agriculture, with benefits in the diagnosis and treatment of human disease close behind. Adding gene-editing techniques to the toolbox promises to accelerate the advance of human welfare in many ways and on multiple fronts. The single biggest obstacle on this path to progress comes from regulatory burdens imposed in the name of safety.

The United States since 1986 has had a strong, science-based policy on how to manage and mitigate risks from crops and foods produced with genetic engineering. This policy stipulates that these products should be regulated on the basis of science-based risk assessments and evaluated according to their characteristics and traits rather than how they were derived. This rational approach to risk assessment and management played no small role in the explosion of new crop varieties which have transformed modern agriculture into a far more productive, efficient, and environmentally beneficial sector than it could otherwise have become. Yet today regulations and policies are in place at the responsible U.S. agencies that depart from this policy and instead treat such products as if they were intrinsically more hazardous than others when all the data and experience demonstrate the opposite. The additional scrutiny and data requirements add years and millions of dollars to the development of new crop varieties and other innovations in agriculture and medicine while doing little or nothing to improve safety or productivity. This makes no sense.

We have proposed science-based approaches that could be taken by FDA, EPA, and USDA, within their existing authorities, that would dramatically reduce the time and cost of gaining regulatory approvals for new products developed with gene editing or genetic engineering. If these approaches were adopted consumer and environmental safety would be in fact enhanced, as the newer products have been shown generally to be as safe or safer than those they would supplant. At the same time, the innovative potential of these powerful new techniques would be unshackled at a time when our need has never been greater. The major reason these regulatory course corrections have not been accomplished to date is a lack of leadership. Lander can fix that, and if he does, he will leave a powerful legacy for which future generations will be grateful.

In summary, then, we think the top three priorities for Dr. Lander in his new role should be:

- Launching HARPA in a configuration that delivers success;
- Galvanizing the development and deployment of mRNA vaccines as a successful platform for new vaccines and therapeutics, including a stockpile of vaccines pre-developed and held against potential breakout pandemic viruses; and
- Driving regulatory reform within U.S. agencies to bring them into alignment with longstanding U.S. policy that will unleash broad innovation and economic growth.

Lander's tenure will be a success if he delivers any of these items. We need them all.

Val Giddings is a senior fellow at the Information Technology and Innovation Foundation (ITIF). Giddings received his Ph.D. in genetics and evolutionary biology from the University of Hawaii in 1980. Val can be found on Twitter @prometheusgreen

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