FACT SHEET. This document contains all the information you'll need to answer the question below. We provide this information so that you can focus your time on thinking and writing – please try and use this information rather than spending time researching further.

QUESTION: Should greater regulatory control be exerted over genetic biohacking?

Vox

Biohacker Josiah Zayner has had health problems for years, and some of his biohacking pursuits have been explicit attempts to cure himself. But he's also motivated in large part by frustration. Like some other biohackers with an anti-establishment streak, he's irritated by federal officials' purported sluggishness in greenlighting all sorts of medical treatments. In the US, it can take 10 years for a new drug to be developed and approved; for people with serious health conditions, that wait time can feel cruelly long. Zayner claims that's part of why he wants to democratize science and empower people to experiment on themselves.

Scientific American

While intending to break new ground in underserved health domains, new forms of participatory health research suffer from a lack of legitimacy. Regulators tend to question the quality and scientific validity of experiments that occur outside of certified clinical trials.

MIT Technology Review

Citing the tremendous cost of new drugs, an international group of biohackers say they are creating a knockoff of a million-dollar gene therapy. The drug being copied is Glybera, a gene therapy that was the world's most expensive drug when it came on the market in Europe in 2015 with a price tag of $1 million per treatment. Glybera was the first gene therapy ever approved to treat an inherited disease. Now a band of independent and amateur biologists say they have engineered a prototype of a simpler, low-cost version of Glybera.

***Science* journal**

The US Food and Drug Administration (FDA) has chosen not to formally wield its enforcement power over biohacking, but the agency still has a role in community engagement—education, warning, and standard-setting for activities that pose public health risks. Through its longstanding role in assessing drugs and biological products, FDA is the government regulatory agency equipped with the expertise to assess the safety and effectiveness of genetic biohacking. FDA involvement, therefore, may help to realize the promise of genetic biohacking through guiding biohacking efforts toward interventions that live up to the communities' hopes.

***Science* journal**

Just as the popularization of computers in the late 1970s and early 1980s gave rise to computer hacking, the recent accessibility and affordability of relatively easy (and widely hyped) genome-editing technologies and resources has spurred interest in genetic "biohacking"—molecular genetics experiments performed outside institutional laboratories by individuals who may have little formal scientific training.

MIT Technology Review

"Biotechnology, more than any other domain, has great potential for human good, but also has the possibility to be misused," says Daniel Gerstein, a senior policy analyst at RAND and a former under secretary at the US Department of Homeland Defense. "We are worried about people developing some sort of pathogen with robust capabilities, but we are also concerned about the chance of

misutilization. We could have an accident occur with gene editing that is catastrophic, since the genome is the very essence of life."

Scientific American

A professor of computer engineering, Matt Might, worked with many physicians for multiple years to find even a preliminary diagnosis for his son, who has a rare genetic disease. Matt hunted the genetic mechanisms responsible for Bertrand's disease with the hope of finding targets for experimental therapies. His subsequent work in building a community of families whose children possessed similar symptoms ultimately aided researchers and physicians in the discovery of a more concrete diagnosis for the rare neurological disorder.

US Food and Drug Administration (FDA)

FDA is aware that gene therapy products intended for self-administration and 'do it yourself' kits to produce gene therapies for self-administration are being made available to the public. The sale of these products is against the law. FDA is concerned about the safety risks involved.

***Science* journal**

Apart from legal mechanisms, some biohacking communities have adopted their own ethics restrictions, which, even if not intended to do so, might indirectly avoid harms to public health caused by genetic biohacking. Given that many biohackers who conduct work at home are also members of community labs, their safety policies have the potential to go a long way in promoting safety in genetic biohacking.

The Brookings Institute

Biohacking group DIYbio has provoked outrage among environmental groups. In March 2015, the UN Convention on Biological Diversity released a report discussing the implications of synthetic biology on biodiversity and small-scale agriculture. Earlier this year, the FDA proposed regulations that would require any genetically-engineered organism to go through strict and lengthy regulatory trials to be approved.

***Science* journal**

Experiments to modify genetic expression that once required specialized training and substantial investments in equipment and reagents can now be conducted for a few hundred dollars and with a basic instruction manual. The rise of direct-to-consumer genetic testing has also resulted in individual access to raw genetic data, fueling a variety of health, wellness, ancestry, and relative identification services that offer to interpret those data.

Royal Society of Biology

In 2009, amid concerns that biohackers could create dangerous pathogens, the FBI began sending agents to biohacking conferences and even sponsoring workshops in an attempt to better understand the burgeoning amateur movement. Cooperation with law-enforcement agencies was welcomed by many biohackers, and it was generally concluded that the development of material that could be used in bioterrorism was extremely unlikely.

***Science* journal**

Like government regulation, private governance is important and laudable but not a perfect or comprehensive solution. Private actors may not be inclined to regulate conduct that poses few risks to them, even if safety risks to others are numerous, obvious, and serious. In other cases, the social stigma of violating community norms may simply be an ineffective deterrent.