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GAIN-OF-FUNCTION RESEARCH

By Awa Jasseh

INTRODUCTION

The onset of the Covid-19 pandemic sparked widespread public concern over the safety and effectiveness of studying virology, and more specifically, the risks associated with **gain-of-function (GOF) research** — experiments in which biological organisms, such as viral **pathogens**, are mutated to produce a new gene product. The rapid spread of Covid-19 raised questions about the origins of viral pathogens, especially because of the highly transmissible and mutagenetic nature of the coronavirus. The original explanation for the virus' origin, which is still widely accepted today, involved animal-to-human transmission at a meat market in Wuhan, China. But civilians and government officials alike raised the possibility that the virus was synthesized as part gain-of-function research being conducted at the Wuhan Institute of Virology and escaped — or "leaked" — out of the laboratory. These suspicions amplified an ongoing debate over gain-of-function research in the United States about the risk of creating viruses that are particularly severe or transmissible.

Gain-of-function (GOF) research – *experiments that introduce or modify a genetic product for scientific purposes.*

Pathogen – *biological organisms that can cause disease, such as viruses*

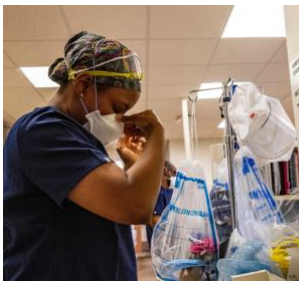
A large proportion of studies related to vaccine development, disease prevention, and epidemiological studies fall under the category of GOF research. Scientists have continued to weigh the associated risks and benefits of gain-of-function research, as its applications are vital to vaccine development, but its unintended uses could have expansive negative effects, such as the possible creation of biological weapons.

In 2014, following alarming studies of H5N1 Avian Influenza that involved increasing the virus' transmissibility in a lab (Bagherpour, 2013), the United States government instituted a voluntary moratorium on GOF research, and ceased all federal funding for GOF research that "'may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have

enhanced pathogenicity and/or transmissibility in mammals via the respiratory route" (Kaiser & Malakoff 2014). This period was designated to allow US officials and public health organizations with the opportunity to reassess the risks that gain-of-function research pose to the general public as well as the entire field of virology.

EXPLANATION OF THE ISSUE

Historical Development



Because COVID-19 is highly transmissable, hospitals became overwhelmed with the number of infected patients, especially before the development of a vaccine

Joseph Prezioso Getty Images

Despite the recent increase in public interest in regulating gain-of-function research following the COVID-19 pandemic, concerns about GOF experimentation are not entirely new. The term gain-of-function gained its name following a series of experiments that were previously conducted by researchers who aimed at combatting the Highly Pathogenic Avian Influenza (HPAI) H5N1 virus, which scientists at the time believed posed a serious threat to global public health (Bagherpour, 2013). Similar to other related GOF research endeavors, these studies' findings were a part of efforts to improve the effectiveness of vaccine development and antiviral medication production (Bagherpour, 2013). Despite the recognized scientific benefits of conducting GOF research into the H5N1 virus, it was ceased in 2012 after scientists at the University of Wisconsin and the Dutch Erasmus Medical Center in Rotterdam, Netherlands created a form of the virus that could be transmitted through airborne particles between ferrets, a mammal that is often used to represent humans in experimental models. These findings raised alarms about the effects of mutant strains of viruses being created in labs, and especially about the risks that would accompany the "nefarious" applications that could come with the publishing of this research (Bagherpour, 2013).

2014 Gain-of-Function Moratorium

Moratorium *– a temporary or indefinite pause on an activity*

In 2014 the White House announced that the United States government would temporarily halt federal funding for "so-called gain-of-function (GOF) studies that alter a pathogen to make it more transmissible or deadly so that experts can work out a U.S. government-wide policy for weighing the risks" (Kaiser & Malakoff 2014). In addition to halting federal funding for GOF research, the federal government also imposed a voluntary **moratorium** that asked researchers who were conducting GOF related studies to pause their work over concerns related to the risks they pose to the public (Kaiser & Malakoff 2014). This moratorium extended to "any new studies … that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the

respiratory route" (Kaiser & Malakoff 2014). The funding pause was lifted in 2017 (National Institutes of Health 2017).

Scope of the Problem

This section will detail the various policy issues surrounding the topic of gain-of-function research as well as the considerations to be made when drafting related policy. As you read, weigh the scientific benefits of GOF research with the public health risks, and imagine how you would strike a balance between productive scientific research and public safety.

Scientific Benefits

Despite the suspected drawbacks and risks associated with gain-of-function research, its applications have been pivotal to the development of the field of virology. From the perspective of virologist Paula Traktman, Ph.D., a former president of the American Society of Virology, the goal is not plainly to increase the transmissibility or virulence of a pathogen, but rather to better understand how pathogens are evolving (Adams, 2023). Dr. Traktman said that virological studies founded in GOF research has led to medical triumphs including the development of drugs to fight HIV and Hepatitis C (Adams, 2023). Traktman suggests that these breakthroughs "came from day after day after day working in the lab to say, 'OK, what does this enzyme do if we swap that with another virus?' 'Does it have a bigger error rate or a lower error rate that led to drugs that are really dramatic?'" (Adams, 2023).

Hazmat protected officials disposiving chickens believed to be carrying avian influenza
NEWS medical & life sciences

Bioterrorism *–The deliberate use of biological agents to inflict harm on a population.*

GOF Research & Bioterrorism

However, despite the significance of GOF research in virology, its potential misuse has raised congressional eyebrows. One of the main fears held by Congress is that gain-of-function findings could be used to facilitate biological warfare. **Bioterrorism** is the deliberate use of pathogens to negatively impact human, animal, or crop populations (OSHA). Since gain-of-function research often results in a disease product that is more transmissible or resistant to treatment than wildtype strains, experts fear that the publication of GOF findings may result in the use of viral diseases as a weapon against human populations.

Accidental Leaks

The rapid spread of COVID-19 also triggered conversations about the risks associated with GOF research. For scientists scrambling to develop a vaccine or antiviral treatments, it was crucial to understand the origin of the virus. A leading hypothesis emerged: the disease spread from a live animal market in Wuhan. But this did not satisfy the curiosity of many Americans, who proposed the theory that the disease in fact originated from gain-of-function experiments

Lab-leak theory *– The theory that the coronavirus was synthesized through gain-of-function research at the Wuhan Institute of Virology before "leaking" into the general population.*

at the Wuhan Institute of Virology in China (Weise & Weintraub, 2021). This became known as the **lab-leak theory**. While scientific and public health authorities refuted this idea at first, it began to pick up steam. Most scientists still endorse the **natural spillover theory**, but two government bodies — the Department of Energy's internal intelligence office and, notably, the FBI — have endorsed the lab-leak theory (Doucleff 2023). A report from the Office of the Director of National Intelligence in June 2023 said both theories are plausible (Eban 2023). A large proportion of the public believes the lab-leak COVID-19 theory, with a 2023 poll finding that 64% of Americans believe that coronavirus was the product of GOF lab studies and did not occur naturally (Blake, 2023).

Natural spillover theory *–The theory that the coronavirus originated naturally in an animal and was naturally transmitted to humans at a live animal market in Wuhan*

Congressional Action

Discussions concerning the viability of federal funding for gain-of-function research have become increasingly prevalent since the onset of the Covid-19 pandemic. The 117th Congress, which had many representatives who were concerned about the potential of experimentally-induced mutations in dangerous pathogens, saw multiple proposed bills aimed at reducing or limiting the amount of federal funds that are allocated and distributed to GOF research projects, especially those of which are related to viral pathogens. In October of 2021, Senator Roger Marshall (R-KS) introduced S.3012, the "Viral Gain-of-function Research Moratorium Act," was introduced to end the government's financial sponsorship of GOF research. Specifically, this bill would prohibit "the award of federal research grants to institutions of higher education or research institutes that conduct gain-of-function research reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses" (Congress.gov). The bill has not progressed through the Senate.

The Office of the Director of National Intelligence have said that both the lab-leak theory and the natural spillover theory are plausible.

Senator Marshall also introduced a second bill, S 4697, the SAFE Risky Research Act, to ban federal funding for GOF research in foreign institutions. He says he views GOF research as a "national security issue." Gain-of-function research at the National Institute of Health (NIH), Marshall says, receives limited oversight from Congress, which he says has "minimal insight into the amount of this research at NIH. There is no transparency into their risk evaluation process" (Motter, 2022). He went further to say that "we must pause this research until national security experts can help create appropriate risk metrics, guardrails and processes for this research" (Motter, 2022). A similar bill in the House, HR 4087, the Foreign Adversary Gain-of-Function Research Prevention Act of 2023, was introduced by Rep. Brad Wenstrup (R-OH). Marshall, Wenstrup, and their supporters favor a full moratorium, rather than one similar to the 2014 voluntary moratorium on GOF research (Motter, 2022). Because of usual Congressional stalemates due to an inability for

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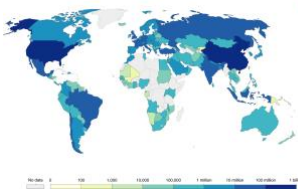
members of the House and Senate to bridge party divides, none of these bills have made it past their introductory stages.

Other Policy Action

Questions about the viability of gain-of-function research have also been addressed abroad by other governing bodies interested in weighing the risks and benefits of GOF studies. For example, in 2014 the European Academies Science Advisory Council (EASAC) released a set of recommendations for how scientists should go about conducting GOF research. The EASAC functions as a working group composed of advisors from nations that are a part of the European Union. The organization made special considerations related to biosafety, and ultimately concluded that in order to best manage biological risks, "options should be explored by which sequences are made available only from restricted access sources, following permission to experiment provided by national regulatory authorities" (Fears & Meulen, 2016). Additionally, the EASAC noted that scientists should take extra caution when publishing their findings, especially when they contain sensitive information.



Map showing the number of COVID-19 vaccine doses administered by each county
Natural Human Behavior (2021)

In 2017, the U.S. Department of Health and Human Services also released the *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* report. This document was prepared in response to the voluntary moratorium for GOF research that was implemented in 2014, and provided the NIH with newly reviewed guidelines that could better guide funding allocations by defining potential pandemic pathogens (PPPs), and describing the review process that GOF research would need to undergo prior to research funding approvals (US Department of Health, 2017).

IDEOLOGICAL VIEWPOINTS

Conservative View

While Republicans have proposed most bills that aim to regulate GOF research, recent polls have found that conservatives were far less worried about the COVID-19 pandemic and its impacts than liberals were (Conway et al., 2021). Researchers who have investigated the reasoning behind the significant difference between conservative and liberal opinion when it comes to coronavirus have concluded that the differences in these COVID-related ideological beliefs stem from variance in coronavirus infliction rates, modes of media consumption during the pandemic, and previously established political beliefs.

Generally, conservatives tend to favor cutting spending of federal funds to avoid the accumulation of a deficit and limiting government

intervention and regulation. This general viewpoint suggests that conservatives would prefer not to allocate large amounts of federal funding to gain-of-function research.

Still, many conservatives may be in favor of reasonably appropriating funds for GOF research, as the COVID-19 pandemic has clearly shown that a pandemic has expansive economic implications that can result in excess government spending. Many conservatives are strongly worried about China as a foreign adversary and may favor foreign-targeted GOF regulation to prevent a possible foreign bioweapon from being unleashed.

In 1 year, COVID-19 infected 94 million people, and killed 2 million. - USA Today

Liberal View

Liberals tend to show more concern for the COVID-19 pandemic and its consequences. They also typically favor regulations on private corporations more than conservatives, especially when public goods like public health are at stake. These points together would suggest that liberals could support safety regulations around GOF research. However, the lab-leak theory is more popular among conservative politicians than liberal ones, so liberals may view unregulated GOF research as a comparatively lesser threat.

Generally, liberals are also more in favor of appropriating federal funds toward public goods than conservatives, which includes spending related to public health and scientific research (Diffen). They may feel the scientific and medical benefits of GOF research outweigh any possible consequences and might oppose the idea of restricting funding to researchers.

AREAS OF DEBATE

Implement a Moratorium on GOF Research

To combat the risks associated with gain-of-function research, including the possibility of bioterrorism attacks and accidental lab leaks of more transmissible viruses, one solution would be to implement a moratorium on gain-of-function research. Doing so would cease all government funding for GOF, thus eliminating the risk of the unintended consequences of gain-of-function research and its findings. Such a moratorium could be temporary while further safety research is conducted, like the 2014 moratorium, or indefinite, meaning GOF research would be halted until a future Congress chooses to reverse the moratorium.

Those in favor of adopting this solution would argue that the risks of GOF studies, such as the possibility of “bad actors” using published GOF studies to back bioterrorism attacks, are not worth continuing this type of research. Additionally, viral outbreaks can have disastrous economic effects. This policy would be enforced by

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preventing the National Institute of Health, the main driving force behind medical and behavioral research in the US, from funding GOF research.

Those who would oppose a moratorium on gain-of-function research would argue that the benefits of GOF studies far outweigh its risks. Gain-of-function research is especially important when creating epidemiological models that help predict and prevent viral outbreaks and when using RNA and CRISPR gene editing technologies which assist in vaccine development (Adams, 2023). GOF findings are also integral to gaining approval for research from the FDA, as "the development of animal models, especially in the case of pathogens with pandemic potential, because to get approval to study a countermeasure compound in humans, the Food and Drug Administration's animal rule requires the presence of disease that mimics the human disease in an animal models" (Adams, 2023). Opponents might argue that it would be more prudent to regulate GOF research rather than ban it entirely.

Biosafety level 4 (BSL-4) labs *– labs designated BSL-4 work with highly sensitive pathogens with the potential to significantly endanger humans*

Political Perspectives on this Solution

Despite the typical conservative stance that is skeptical of government regulation, conservatives have in recent years been the ones pushing moratoriums for GOF research. They argue that this kind of research is unsafe, particularly with the potential for foreign adversaries like China to capitalize on newly mutated pathogens. Liberals might favor a moratorium but would likely want to make sure scientific research remains healthy and vibrant.

Additionally, the NIH and other public health organizations, would look unfavorably on halting GOF research as many of its studies could fall under this category.

Propose a Sanction Against countries Conducting GOF Research

There are 51 operational BSL-4 labs worldwide, including 14 in the US.

In response to the COVID-19 pandemic, many countries opted to enforce regulations limiting international trade and cooperation to disincentivize behaviors that pose risks domestically. One potential method to address gain-of-function research would be for the United States to propose a similar sanction against countries that are conducting ongoing GOF research. There are currently 51 **biosafety level 4 (BSL-4) labs** in 27 countries (Kaiser 2023). These labs work with highly sensitive pathogens, many of which pose significant dangers to populations should there be a viral leak. One solution to combat the potential risks of gain-of-function research would be to institute a sanction against countries currently conducting research deemed to be GOF studies. This sanction would function as an economic pressure against nations that are engaged in GOF studies that pose a risk to public health situations by either imposing a travel ban, restricting foreign trade, or even implementing a total trade

embargo (Radcliffe, 2022). Legislation for this policy would need to include specific stipulations that clearly outline which countries the sanctions apply to, and how, if at all, they may get those sanctions lifted.

Political Perspectives on this Solution

Regardless of political party alignment, most Americans agree about the far spreading impacts of U.S economic policy and its powerful influence on the global market and international relations. Both Democrats and Republicans have utilized economic sanctions in dealings with countries, such as China, to call for change abroad (Muchnick & Kamarck, 2022). According to a Pew study from 2020, "Republicans have long held more unfavorable views of China than Democrats, but unfavorable views have climbed rapidly among both parties over the past year" (Devlin et al., 2020). Legislators from across the aisle may be particularly inclined to sanction China, considering that these negative views extend to their handling of the pandemic and GOF research at the Wuhan Institute of Virology.

Propose a Formal Definition of Gain-of-Function Research

Within the federal government, there is also confusion over what can be considered gain-of-function research. Establishing a formal and standard definition of gain-of-function research would help create consistent and comprehensible regulations of this research.

While this proposal may seem obvious, the difficulty comes with the actual process of drafting a definition that includes potentially dangerous lab work while excluding other types of virology. Many virologists, such as Dr. Kanta Subbarao from the Institutes of Health (NIH), argue that since most research within the field of virology involves the use of experimentation to produce an outcome that has gained a desired function, it could all arguably be considered gain-of-function research. Subbarao explains that "In other words, any selection process involving an alteration of genotypes and their resulting phenotypes is considered a type of Gain-of-Function (GoF) research, even if the U.S. policy is intended to apply to only a small subset of such work" (Adams, 2023).

Political Perspectives on this Solution

Regardless of political ideology, most relevant stakeholders are in favor of proposing a formal definition of GOF research. Both conservatives and liberals concerned with regulating this research would favor a standardized definition for governmental use.

Create a New Supervisory Committee for GOF Research

Many politicians believe that the NIH does not receive as much oversight as it should from Congress. By creating a new supervisory committee with the power to collect data on GOF research funded by the NIH, Congress could better understand the scientific field and specific areas where regulation is needed.

Those in favor of this policy would agree that the NIH does not receive enough oversight from Congress, and currently has the freedom to fund potentially dangerous research. They might argue that the current committees overseeing the NIH need to play a more active role in monitoring and regulating the types of research being conducted in federally funded labs. This new committee could conduct more in-depth reviews of proposed GOF research and decide how the federal government will support the publication of such findings.

Political Perspectives on this Solution

Conservatives, who are distrustful of government spending and typically more concerned about GOF research, would likely support requiring more government surveillance of the NIH, stringently monitoring the type and amount of gain-of-function research. Liberals are also in favor of government oversight and regulation over public sectors of the government, which would include the research being conducted at the National Institute of Health. However, they may worry about the government having a chilling effect on scientific research and might advocate for a committee to be staffed with professional scientists or to have a limited scope.

BUDGETARY CONSIDERATIONS

For many of the proposed policies above, Congress will not need to make significant budgetary allocations. It will however be important to specify the amount and types of funding that you will use to enact your bills, even if those costs are low. Keep in mind the types of legislative language previously discussed in this briefing, so that you may be specific when deciding how you would like to appropriate funding to other institutions and how such funds could be used.

CONCLUSION

While in your committees, be sure to consider the far-reaching effects of gain-of-function research, and the historically significant uses it has had in developing new technologies that have been vital

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to public health responses. Remember that Congressional involvement in scientific issues can be precarious, but that ultimately delegates will need to balance the needs of your represented regions, the interests of scientists and public health officials, and American and foreign organizations acting as stakeholders.

Finding solutions to the complex issues surrounding the topic of gain-of-function research may not be easy, but its implications are becoming even more wide-spread with the increasingly interconnected nature of the modern world. The risk of bioterrorism has been exacerbated by the fact that accessing information and disseminating information has become even easier in recent years. The COVID-19 pandemic has also shown the world how disastrous an epidemiological outbreak can be, with effects that span across the global economy. Identifying a solution that adequately reflects a thorough risk-benefit analysis will ensure that global health systems are prepared for the inevitable vulnerabilities that public health systems have, while keeping public health research healthy and vital.

GUIDE TO FURTHER RESEARCH

Delegates are highly encouraged to conduct further research on gain-of-function research in order to inform the policy decisions you will make in your committees. Consult reputable sites that are the product of government publications, scientific organizations, and even individual stakeholders such as virologists and the companies spearheading GOF research. It will be useful to conduct further research about other countries' responses to the COVID-19 pandemic, and how such occurrences have impacted policy related to gain-of-function research. Additionally, identifying case studies which reflect the key issues highlighted in the "Scope of the Problem" section may be useful for better understanding the issue and gathering inspiration for your solutions.

In order to strengthen the arguments, you will be making in your committee, be sure to dive deeper into research on how often incidences related to GOF studies have occurred in the past, how associated risks have been mitigated, and also what steps legislators have discussed making in the future to strike the delicate balance of protecting the health and wellbeing of your constituents.

GLOSSARY

Biosafety level 4 (BSL-4) labs – labs designated BSL-4 work with highly sensitive pathogens with the potential to significantly endanger humans.

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Bioterrorism – The intentional use of a biological agent or pathogen to inflict harm on a population of humans, animals, or crops.

Gain-of-Function Research – Research that is the product of experimentation that introduces or amplifies a gene product, often resulting in an increase in the transmissibility of a pathogen.

Lab-leak theory – The theory that the coronavirus was synthesized through gain-of-function research at the Wuhan Institute of Virology before "leaking" into the general population.

Moratorium – a temporary or indefinite pause on an activity.

Natural spillover theory – The theory that the coronavirus originated naturally in an animal and was naturally transmitted to humans at a live animal market in Wuhan.

Pathogen – biological organisms that can cause disease, such as viruses.

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