ELIJAH BEHNKE
STATE REPRESENTATIVE • 89th ASSEMBLY DISTRICT

01/18/2024

Testimony on Senate Bill 401
Senate Committee on Health

Chair Cabral-Guevara and Members of the Senate Committee on Health, thank you for holding a public hearing today and allowing me to testify in favor of Senate Bill 401, which would prohibit institutions of higher education from conducting gain of function research on potentially pandemic pathogens and require reporting of the intention to conduct research on potentially pandemic pathogens.

I will leave some of the more detailed explanations as to why we should be so concerned over this type of research to experts testifying later today. It is my understanding that gain of function research involves improving the ability of a pathogen to cause disease. It is also my understanding that there has been very little (if any) benefit from running this type of research, and there is immense risk. It is also my understanding there are only a handful of labs conducting this type of research in the whole country, and one of them is right here in Madison.

We know of multiple documented incidents that have happened at the UW-Lab. While these are the close calls that we know of, I do wonder how many they have had that we don't know about. If even one accident were to result in a spillover to the general population, the results would be catastrophic. I've been told that the H5N1 virus they have worked with would be far worse than COVID-19. If people were to become infected, the resulting lawsuits could bankrupt the whole UW System. If there is little to no benefit, why would we risk that?

It is my understanding that across the state, it is just the one lab at UW-Madison that is conducting this type of research. I was more than a little troubled when I read the fiscal report where they are anticipating thousands of applications for this type of research each year, and are estimating DHS would need 6 full time employees to administer oversight. Is it just one lab, or is this type of research occurring across the state? Are our first responders that may need to respond in case of an incident even aware of what they would be exposed to?

Experts from across the world are chiming in on the necessity of this legislation. You will hear from some of them later today, and many more have taken to social media and news outlets to share their concern over this type of research and have voiced their support for Senate Bill 401.

Thank you again for holding this hearing on Senate Bill 401 and allowing me to testify in favor of it. I am happy to answer any questions you may have.

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Testimony before the Senate Committee on Health

Senator André Jacque
January 18, 2024

Madam Chair and Colleagues, thank you for the opportunity to testify as the author of Senate Bill 401.

Gain-of-function (GoF) experimentation involves the augmentation of deadly pathogens to artificially make a viral or bacterial disease more infectious - and more lethal.

Previously a very small segment in the field of virology, GoF has the potential for disproportionately disastrous consequences resulting from lapses in biosecurity, and the U.S. government recently identified 'gain of function research of concern' funded by U.S. agencies at the Wuhan Institute of Virology in violation of funding stipulations.

Here in Wisconsin, incidents at the University of Wisconsin-Madison have raised questions as to whether UW researchers followed federal guidelines and timely reported two biosecurity breaches during GoF experiments: One involved a researcher being exposed to a virus while examining a sample in 2013; another incident involved false information provided to investigators after a researcher's respirator became disconnected while collecting samples of a lab-enhanced bird flu in 2019.

In 2010, UW-Madison paid a $40,000 fine to federal regulators for allowing unauthorized experiments involving a dangerous bacteria, where graduate students and a post-doctoral researcher conducted unapproved experiments involving Brucella, a highly regulated bacteria that can infect cattle and humans, and introducing genes to the bacteria that could have compromised the antibiotic used to control the disease. University officials concluded Prof. Gary Splitter knew and/or participated in the experiments but later denied knowledge of them and failed to supervise his laboratory, which is a biosafety level 3 lab under federal guidelines. The designation is reserved for exotic agents that cause serious and potentially lethal disease if inhaled.

Senate Bill 401 would prohibit institutions of higher education in this state from conducting gain-of-function research on potential pandemic pathogens. The risks of these dangerous GoF experiments are not only catastrophic, they are unnecessary. Viruses mutate very rapidly all by themselves; they do not require humans to conduct genetic engineering experiments to make them more lethally infectious.

Experimentation seeking to enhance potential pandemic pathogens (PPP) represents less than 0.01% of biomedical research. This proposal is not directed at non-GoF infectious disease research conducted by scientists in Wisconsin that is crucial to the discovery of life-saving vaccines and anti-viral treatments. I am extremely pleased that we have testimony submitted in support of this legislative effort today from several prominent researchers. I would also like to share that just last week renowned virologist Dr. Simon Wain-Hobson of the Pasteur Institute, Board Chair of the Foundation for Vaccine Research and the first researcher to record the genome sequence of HIV, recorded a public statement in support of this specific legislation and referenced the widespread concern in the scientific community over Dr. Kawaoka's experiments.

Thank you for your consideration of Senate Bill 401. I would be happy to answer any questions.

DailyMail.com

Chinese scientists 'create' a mutant coronavirus strain that attacks the BRAIN and has a 100% kill rate in mice - as they admit there's a 'risk it spills over to humans'

- **Eight rodents infected with the pathogen 'surprisingly' died within eight days**
- **Critics of the study said: 'This madness must be stopped before [it is] too late'**
- **READ MORE: World leaders meet to thrash out plan to protect against 'Disease X'**

By CAITLIN TILLEY, HEALTH REPORTER FOR DAILYMAIL.COM
PUBLISHED: 12:59 EST, 16 January 2024 | **UPDATED:** 16:34 EST, 16 January 2024

Chinese scientists have been experimenting with a mutant **coronavirus** strain that is 100 percent lethal in mice — despite concerns such research could spark another pandemic. Scientists in Beijing — who are linked to the Chinese military — cloned a Covid-like virus **found in pangolins**, known as GX_P2V, and used it to infect mice.

The mice had been 'humanized', meaning they were engineered to express a protein found in people, with the goal being to assess how the virus might react in humans.

Every rodent that was infected with the pathogen died within eight days, which the researchers described as 'surprisingly' quick.

The team were also surprised to find high levels of viral load in the mice's brains and eyes - suggesting the virus, despite being related to Covid, multiplies and spreads through the body in a unique way.

Writing in a scientific paper that has not yet been published, they warned the finding 'underscores a spillover risk of GX_P2V into humans'.

Professor Francois Balloux, an infectious disease expert based at University College London, wrote on Twitter (X): 'It's a terrible study, scientifically totally pointless.

'I can see nothing of vague interest that could be learned from force-infecting a weird breed of humanized mice with a random virus. Conversely, I could see how such stuff might go wrong...'

Professor Richard Ebright, a chemist at Rutgers University in New Brunswick, New Jersey, told DailyMail.com he wholeheartedly agreed with Professor Balloux's assessment.

He added: 'The preprint does not specify the biosafety level and biosafety precautions used for the research.

'The absence of this information raises the concerning possibility that part or all of this research, like the research in Wuhan in 2016-2019 that likely caused the Covid-19 pandemic, recklessly was performed without the minimal biosafety containment and practices essential for research with a potential pandemic pathogens.'

According to the study, carried out by the **Beijing** University of Chemical Technology, the virus was discovered in 2017 prior to the Covid outbreak.

It was discovered in Malaysia in pangolins - scaly mammals that are known harborers of coronaviruses and were heavily speculated to be the intermediate host that passed Covid from bats to humans.

The researchers cloned the virus and stored multiple copes in the Beijing lab, where it continued to evolve.

It is unclear when the newly surfaced study was conducted. But the researchers said it was possible the virus had undergone a 'virulence-enhancing mutation' in storage, which made it more deadly.

For the new research, eight mice were infected with the virus, eight were infected with an inactivated virus and eight were used as a control group.

All mice infected with the virus died. They succumbed to the infection between seven and eight days after being infected.

Symptoms included their eyes turning completely white, rapid weight loss and fatigue.

Researchers found 'significant amounts' of the virus in the rodents' brains, lungs, noses, eyes and windpipes.

By day six, the viral load had 'significantly decreased' in the lungs, but the animals' brains had shrunk and there were 'exceptionally high' virus levels in their brains.

The results suggest that the virus infects via the respiratory system and then migrates to the brain - unlike Covid which causes lower lung infections and pneumonia in severe cases. However, there have been examples of Covid being found in brain tissue of severely sick patients.

'Severe brain infection during the later stages of infection may be the key cause of death in these mice,' the researchers said.

They concluded: 'This is the first report showing that a SARS-CoV-2-related pangolin coronavirus can cause 100 percent mortality in hACE2 mice, suggesting a risk for GX_P2V to spill over into humans.'

However, the original strain of Covid also killed 100 percent in mice in some studies, meaning the new results may not be directly applicable to humans.

Dr Gennadi Glinsky, a retired professor of medicine at Stanford, said on social media: 'This madness must be stopped before [it is] too late.'

DailyMail.com exposed in 2022 how similar research virus-manipulation research was being carried out by Boston University.

Researchers were found to have created a new Covid strain that had an 80 percent death rate among mice.

It sparked nationwide debate about whether the experiments were an illegal form of research known as 'gain of function' - which involves purposefully making viruses more deadly or infectious to study their evolution.

The Biden Administration tightened rules around such research in October 2022, but the definition of gain of function remains contested.

Dr Christina Parks, a molecular biologist from the University of Michigan, said the Chinese study was 'classic gain of function, whether they tell you it is or not.'

One of the Chinese researchers was Dr Yigang Tong, who trained at the Academy of Military Medical Sciences, a Chinese military medical research institute run by the People's Liberation Army.

Dr Tong studied there between 1988 and 1991 for a master of science and then again between 1997 and 2000 for a PhD.

He also co-authored a paper in 2023 with 'bat woman' Zheng-Li Shi, who helps run the Wuhan Institute of Virology (WIV).

The WIV has been designated the most likely source of the Covid pandemic by the FBI and US Department of Energy in what has been dubbed the 'lab leak' theory.

Researchers there, with US Government grants, were performing gain of function experiments on coronaviruses in the months leading up to the Covid outbreak.

The virus first emerged miles away from the WIV, where researchers were known to be working on coronaviruses found in bats.

It comes as Dr Peter Daszak, head of the New York based non-profit EcoHealth Alliance, which funded controversial experiments in **Wuhan** which some fear started the pandemic, presented the **discovery of a never-before-seen virus** with 'almost' as much potential to infect humans as Covid.

Dr Daszak, a friend of Dr **Anthony Fauci**, the ex-chief medical advisor to the US President, revealed his team have already found one bat coronavirus of considerable interest.

'We found a lot of SARS-related coronaviruses, but one in particular we found was quite common in bats where people were commonly exposed,' he told the WHO event, attended by MailOnline.

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Senate Committee on Health

2023 Senate Bill 401

Prohibiting institutions of higher education from conducting gain of function research

January 18, 2024

The University of Wisconsin–Madison, and the Medical College of Wisconsin (MCW) thank the committee for the opportunity to provide testimony on Senate Bill 401 (SB 401).
First, and foremost, while our organizations oppose SB 401, we acknowledge and appreciate authors Rep. Behnke and Sen. Jacque for their commitments to public health and safety in biomedical research, and the legislative intention to ensure that biomedical research does not result in the harmful spread of infectious disease. UW–Madison and MCW are also committed to these goals and to upholding the highest safety standards of biomedical research.

However, as the state's leading research universities, UW–Madison and MCW oppose SB 401 and its attempt to limit research and innovation in Wisconsin. The bill could limit research that contributes to the development of treatments and vaccines to protect humans, plants and animals from diseases that threaten public health, the food supply and the state's economy.

UW–Madison is the flagship institution of public higher education in the state, ranks 8th in the country for federal research expenditures and continues to be a national powerhouse in federally funded research. MCW is the top-funded private institution conducting biomedical research in Wisconsin and leads the state in dollars invested in clinical trials research. Both are R1 research institutions, a designation that recognizes our very high research activity.

UW–Madison and MCW are responsible for a large portfolio of biological research that provides diagnostic testing and surveillance for pathogens of concern in the state and contributes to global understanding of basic biological and disease processes for common and extraordinary ailments. Between them, both institutions have hundreds of research labs with Biosafety Level 2 (BSL-2) or higher designation, all of which adhere to an extensive set of institutional and federal regulations to ensure safety for lab personnel and our community.

MCW's extensive research portfolio focuses entirely on biomedical and health-related research and includes handling agents which individuals often have exposure to in the community. This research is highly varied and diverse, and encompasses many agents, including common cold viruses, RSV and pneumonia. MCW researchers are also investigating the role of HSV (Herpes

simplex virus), HCMV (human cytomegalovirus) and SARS-CoV-2 as drivers of dementia and Alzheimer's disease, which critically affects Wisconsin residents.

UW–Madison also has an extensive biomedical research portfolio focused on, for example:

- developing vaccines and antiviral treatments for new and emerging diseases;
- understanding how Epstein-Barr virus, Human Papilloma Virus and other viruses cause cancer;
- understanding and preventing common foodborne illnesses caused by E. coli and Salmonella contamination;
- tracking and mitigating common hospital-associated infections such as those cases by Staphylococcus aureus bacteria and Candida fungi; and more.

In addition, the UW School of Veterinary Medicine and the Wisconsin Veterinary Diagnostic Lab perform research and testing on strains of avian influenza that have had significant economic impact on our state's poultry industry. UW–Madison researchers also study the bacteria that cause bovine mastitis, a disease that plagues the dairy industry, and the pathogens that cause blight in Wisconsin potatoes.

These are examples of the kind of work that could be prohibited by SB 401 because the definitions are so broadly drafted as to prohibit any research that may reasonably be anticipated to enhance the transmissibility or virulence of a range of pathogens, including viruses, fungi and bacteria that do not have any pandemic potential. This would create significant uncertainty with respect to what is and is not allowed under the legislation.

The bill also calls for oversight at the state level without any provision for the infrastructure necessary to support it. As such, the proposal could result in the delay or discontinuation of many kinds of critical research, posing significant risks to the health of Wisconsin's residents and its economy.

The proposal would limit the ability of public health authorities to prepare and respond to health threats. Wisconsin would need to rely on researchers in other states without these prohibitions to serve the state's needs. The bill would also risk the potential loss of millions of dollars of federal grant funding that benefits the state and its taxpayers and could hamstring the growth of Wisconsin's biotech and biomedical sectors.

Both of our institutions believe the privilege of conducting essential research comes with extraordinary responsibility and we strongly support transparent and rigorous oversight of pathogen research. We are also committed to ensuring that our researchers who work with high-risk and other pathogens have safe, secure laboratories, and receive extensive training and certification to ensure their investigations are conducted safely.

Research on potential pandemic pathogens is highly regulated at the federal level. While studying pathogens does not come without risk, federal laws, regulations, and guidelines aim to balance the risk of this research with its public health and economic benefits. Several layers of institutional oversight also help ensure this important work is performed safely and transparently. We stand by our records of safety and compliance with federal and institutional oversight.

Despite media stories that have repeatedly mischaracterized the same few incidents at UW–Madison, the university's lab personnel and biosafety professionals maintain an excellent record of safety and regulatory compliance. When incidents have occurred, UW–Madison staff have followed emergency protocols and research oversight requirements, and the university continuously works with federal, state, and local agencies to update protocols as research and requirements change.

MCW and UW–Madison take great pride in the contributions of our scientists in combatting current and future public health threats and welcome further discussion about oversight of pathogen research. However, as proposed, SB 401 will not meaningfully improve oversight, transparency, or safety. Rather, it is poised to significantly hinder the ability of researchers in Wisconsin to conduct research of extreme importance to the state.

We urge legislators to oppose this proposal. Any further questions can be directed to MCW Vice President for Government Relations Nathan Berken (nberken@mcw.edu; 414-955-8588) or UW–Madison Senior Director of State Relations Crystal Potts (crystal.potts@wisc.edu; 608-265-4105).

Written testimony to the Senate Committee on Health in support of Senate Bill 401

18 January 2024

Justin B. Kinney, PhD

Associate Professor, Cold Spring Harbor Laboratory

Co-founder, Biosafety Now

1. Introduction

Chair Cabral-Guevara, members of the Senate Committee on Health, thank you for considering my testimony.

My name is Dr. Justin Kinney. I am an Associate Professor of Quantitative Biology at Cold Spring Harbor Laboratory in New York. I run an active biological research laboratory and serve as principal investigator on two grants from the US National Institutes of Health. I am also a co-founder of Biosafety Now, a nonpartisan 501c(3) nonprofit based in New Jersey, whose goal is to prevent future lab-generated pandemics. I not receiving any financial compensation for this testimony, either from Biosafety Now or from any other organization or individual.

2. Why Senate Bill 401 is needed

I urge you to support Senate Bill 401. This bill is needed to protect the public from the hazards of a very narrow but extremely dangerous type of scientific research.

Laboratory accidents happen. They happen because scientists are human, and humans make mistakes. The overwhelming majority of scientific research is safe, and only a small fraction of laboratory accidents pose risks to the public. Accidents involving potential pandemic pathogens, however, can have catastrophic consequences. Potential pandemic pathogens are viruses and bacteria that, if released, could spread uncontrollably through the human population and potentially cause a devastating pandemic.

Senate Bill 401 will protect the public from the hazards of research on potential pandemic pathogens. The bill will do this without having significant costs or adverse impacts. This is commonsense, nonpartisan legislation that deserves broad-based support.

Senate Bill 401 contains two important provisions.

The bill's first provision will establish public transparency for research on potential pandemic pathogens. Currently, laboratories that study potential pandemic pathogens are not required to inform state or local governments about where the research is performed, which pathogens they possess, or the potential public health impacts if a pathogen escapes. Senate Bill 401 will require these laboratories to provide this information to the Wisconsin Department of Health Services (DHS).

Disclosure of this information is essential. First-responders need this information to help them avoid accidental infection when responding to laboratory emergencies. Healthcare providers need this information to diagnose and prevent the spread of laboratory-acquired infections. In the event of a laboratory accident, first-responders and healthcare providers having this information could well make the difference between rapid pathogen containment and an uncontrolled disease outbreak.

The bill's second provision prohibits "gain of function" research on potential pandemic pathogens, i.e., research that makes these pathogens even more dangerous to humans than they already are.

Some have expressed concerns that this prohibition would hamper biomedical research. These concerns are unfounded. Gain-of-function research on potential pandemic pathogens constitutes less than 0.01% of biomedical research. And importantly, gain-of-function research on potential pandemic pathogens is not needed for developing vaccines or disease treatments, nor have the results of such research ever been used for developing vaccines or disease treatments.

Based on publicly available information, the bill's second provision will affect at most one laboratory in Wisconsin—a virology laboratory at the University of Wisconsin, Madison, led by Dr. Yoshihiro Kawaoka. This provision is important because the Kawaoka laboratory has performed gain-of-function research that poses extreme risks to public health. In 2011, the Kawaoka laboratory constructed, then over the next decade studied, genetically engineered avian influenza viruses that can transmit efficiently among mammals. The natural forms of these avian influenza viruses kill up to two-thirds of people they infect, but transmit poorly from person to person. If the genetically engineered avian influenza viruses constructed by the Kawaoka laboratory were to escape, they may be able to transmit easily from person-to-person and cause a pandemic even more devastating than COVID-19.

The U.S. federal government has—for decades—failed to enact legislation that protects the public from accidents at laboratories that study and genetically engineer potential pandemic pathogens. Shockingly, federal inaction continues despite the FBI and the Department of Energy assessing that the COVID-19 pandemic was most likely caused by an accident at a laboratory in Wuhan, China, doing exactly this kind of research.

States must therefore act to protect their residents. By establishing public transparency for high-risk pathogen research, and by prohibiting the highest-risk type of pathogen research, Senate Bill 401 will provide urgently needed protections for the residents of Wisconsin, for the citizens of the United States, and for all members of the global community.

3. Recommended changes to Senate Bill 401

Dr. Ebright and I recommend that three amendments be made to Senate Bill 401. These amendments are needed to properly scope the type of research that is covered, as well as the role of DHS in handling disclosures.

Amendment 1 would change the definition of "potential pandemic pathogen" to the definition in the January 2023 recommendation by the US National Science Advisory

Board for Biosecurity (NSABB). The definition of potential pandemic pathogen that is currently in Senate Bill 401 is overly broad. The mismatch between the specific language of the bill and the intent of the bill appears to be a major driver behind inaccurate cost assessments by the DHS and the University of Wisconsin System.

Amendment 2 would further clarify the NSABB definition by listing explicit examples of pathogens that match the NSABB definition.

Amendment 3 would clarify that research performed on potential pandemic pathogens that are the products of previous gain-of-function experiments are also prohibited. The laboratory of Yoshihiro Kawaoka has performed multiple gain-of-function experiments in the past and likely has in storage multiple pathogens that are the product of this research. This amendment is needed to ensure that those pathogens are not grandfathered in, as experiments on those pathogens is just as dangerous as new gain-of-function experiments would be.

4. Discussion of costs and impacts

Senate Bill 401, if amended as suggested, will not incur significant costs and will not have significant adverse impacts.

- The bill will not impose significant costs on the taxpayers of Wisconsin, on the University of Wisconsin System, or on individual scientific laboratories operating in Wisconsin.
- The bill will not adversely impact the competitiveness or productivity of scientific laboratories in the University of Wisconsin System or of Wisconsin biotechnology companies.
- The bill will not adversely affect the development of vaccines or disease treatments.

In particular, the substantial costs and adverse impacts that are anticipated by DHS and by the University of Wisconsin System will not be realized if the three amendments are adopted.

4a. Wisconsin Department of Health Services (DHS)

DHS assesses that the bill will generate a "high volume" of disclosures, and that handling these disclosures will require the hiring of 6 full-time employees at a cost of approximately $1.7M/year.

This assessment greatly overstates the cost of the legislation as intended. The legislation, as intended, would likely not require the hiring of any new employees, or at most would require the hiring of one part-time employee. The inaccuracy of the DHS estimates appears to have resulted from incorrect assumptions about the role of DHS, as described by the legislation, and by the overly-broad definition of potential pandemic pathogen, which our proposed amendments would fix.

Specifically, DHS assumes that

> "[T]his proposal requires the Department to review all research proposals pertaining to potential pandemic pathogens...In addition to review of the written proposal, it is assumed that the Department would also inspect physical research facilities to ensure compliance with security and environmental standards... Currently, the Department does not have staff who conduct these activities and would need a new unit to review the proposals."

These assumptions are incorrect. Researchers will be submitting disclosures, not scientific proposals that require in-depth technical review. The role of DHS will be only to (1) communicate information in the disclosures to the relevant federal, state, and local authorities, (2) ensure that adequate resources are in place to respond to an accidental pathogen escape, and (3) determine whether the risks of the research, as described by the scientists submitting the disclosure, poses an unjustified risk to public health, and to seek an injunction in cases where there is unjustified risk. I emphasize that the bill requires that the likely consequences of an accidental pathogen escape be assessed and described by the researcher submitting the disclosure, not by DHS. The legislation does not mandate any technical assessment of the science in the disclosures, and does not establish any new inspection regime.

DHS also states that,

> "Based on the broad definition of pandemic pathogen, it is difficult to estimate the number of proposals that will be submitted annually, but it is assumed that there will be a high volume of proposals to review."

This statement makes it clear that the overly-broad definition of potential pandemic pathogen that is currently in the legislation is causing the number of disclosures to be vastly overestimated. We estimate that at most one to three dozen labs in the entire state of Wisconsin work on bona fide potential pandemic pathogens. Consequently, there are unlikely to be more than a few dozen disclosures per year if the language in the legislation is appropriately scoped. The three suggested amendments will provide this appropriate scope.

4b. University of Wisconsin System

The University of Wisconsin System estimates that,

> "thousands of research projects would require DHS review each year resulting in the loss of faculty productivity and competitiveness."

This vastly overestimates the volume of projects that would be received, the role of DHS, and the resulting effect on researchers. Again, we estimate that at most one-to-three dozen labs in the state of Wisconsin handle potential pandemic pathogens and would need to submit disclosures. These disclosures would not be "reviewed" by DHS; they would simply be disclosed to DHS. And the work that researchers put into each disclosure would be minimal and largely redundant with grants and progress reports that those researchers have already prepared.

The University of Wisconsin System also states that,

"Additionally, most research grants would not allow the research to begin 90 days or more from the date of the award which could result in the returning of grant monies or declining an award."

This is simply not true. The proposed bill explicitly permits the disclosure of anticipated research, and imposes no requirement whatsoever that funds be in place to support that anticipated research prior to disclosure. There is no reason why a disclosure of anticipated research cannot be made to DHS more than 90 days before any grant funds are awarded. Indeed, it commonly takes 8-12 months from the date of a grant submission to the notice of award. If a disclosure is made to DHS at the time of grant submission, there is no reason why any awarded funds would need to be returned.

In summary, if the above amendments are adopted,

1. There will be no impact at all on the vast majority of faculty in the University of Wisconsin system, including on an overwhelming majority of faculty in the biological sciences.
2. There will be no significant adverse impact on the productivity or competitiveness of the small fraction of University of Wisconsin faculty that would be subject to the disclosure requirement.
3. The ban on gain-of-function research would likely affect at most one laboratory—the laboratory of Yoshihiro Kawaoka—and even then would affect at most a subset of the research done in that laboratory. It is possible that none of the ongoing research projects in Dr. Kawaoka's lab will be affected by this ban. If any research projects are affected by this ban, we anticipate that Dr. Kawaoka would be able to repurpose existing awards towards research that is not subject to the ban.

We therefore do not anticipate any substantial adverse impact of Senate Bill 401 on the University of Wisconsin System.

5. Proposed Amendments

We propose the following three amendments, which are needed to properly scope the definition of potential pandemic pathogen and to avoid the products of prior gain-of-function research on potential pandemic pathogens from being grandfathered in.

Amendment 1: Replace the definition of "Potentially pandemic pathogen" in 36.41, 38.35, and 39.295, with the definition proposed by the NSABB:

"Potentially pandemic pathogen" means a virus, bacterium, fungus, or eukaryotic parasite, or any strain or variant of a virus, bacterium, fungus, or eukaryotic parasite, that is:

1. Likely moderately or highly transmissible and likely capable of wide and uncontrollable spread in human populations; and/or

2. Likely moderately or highly virulent and likely to cause significant morbidity and/or mortality in humans;

and, in addition,

3. Likely to pose a severe threat to public health, the capacity of health systems to function, or national security.

Amendment 2: Append the following text to the definition of "Potentially pandemic pathogen" in 36.41, 38.35, and 39.295:

Potentially pandemic pathogens include: influenza viruses other than seasonal influenza viruses, SARS and MERS coronaviruses, henipah viruses, filoviruses, arenaviruses, orthopoxviruses, and the bacterium Yersinia pestis.

Amendment 3: In 36.41, revise the Prohibition to read:

PROHIBITION. No institution or college campus may conduct or provide funding to another entity to conduct gain of function research on potentially pandemic pathogens or to conduct research on potentially pandemic pathogens that are the product of prior gain of function research.

In 38.35, revise the Prohibition to read:

PROHIBITION. No district board or technical college may conduct or provide funding to another entity to conduct gain of function research on potentially pandemic pathogens or to conduct research on potentially pandemic pathogens that are the product of prior gain of function research.

In 39.295, revise the Prohibition to read:

PROHIBITION. No institution of higher education may conduct or provide funding to another entity to conduct gain of function research on potentially pandemic pathogens or to conduct research on potentially pandemic pathogens that are the product of prior gain of function research.

Written Testimony of Richard H. Ebright

Board of Governors Professor of Chemistry and Chemical Biology, Rutgers University

Laboratory Director, Waksman Institute of Microbiology

Submitted in support of Senate Bill 401 to the Wisconsin Senate Committee on Health

January 18, 2024

Chair Cabral-Guevara and members of the Committee:

I am Board of Governors Professor of Chemistry and Chemical Biology at Rutgers, The State University of New Jersey, and Laboratory Director at the Waksman Institute of Microbiology. I direct a biomedical research laboratory and serve as project leader on two National Institutes of Health (NIH) research grants. I conduct research on the mechanism of bacterial RNA synthesis and on the development of new antibacterial therapeutic agents able to treat bacterial infections resistant to current drugs. My research involves both priority public health bacterial pathogens (e.g., the pathogens responsible for Staph infections, Strep infections, and tuberculosis) and priority biodefense bacterial pathogens (e.g., the pathogens responsible for anthrax, plague, and tularemia). I am a member of the Institutional Biosafety Committee of Rutgers University, and I have been a member of the Working Group on Pathogen Security of the state of New Jersey, the Controlling Dangerous Pathogens Project of the Center for International Security Studies, and the Biosecurity Advisory Board of the Center for Civilian Biodefense. Here, I discuss the definition of gain-of-function research on potential pandemic pathogens (also referred to as "enhanced potential pandemic pathogen research"), risks and benefits of the research, US oversight of the research, and recommended steps to strengthen US oversight of the research. In my written comments, I also include an appendix addressing the origin of SARS-CoV-2 and the possibility that lapses in US oversight of gain-of-function research on potential pandemic pathogens contributed to the origin of SARS-CoV-2. My assessments are based on information in published NIH, Health and Human Services (HHS), Office of Science and Technology Policy (OSTP), and Congressional Research Service (CRS) documents, on published press reports, on published scientific papers, and on my knowledge of biosafety and biosecurity standards for work with pathogens.

Gain-of-function research on potential pandemic pathogens

Definition

Gain-of-function research on potential pandemic pathogens (also referred to as "enhanced potential pandemic pathogen research") is defined as research activities reasonably anticipated to enhance a potential pandemic pathogen's transmissibility or pathogenesis. Gain-of-function research on potential pandemic pathogens involves the creation of *new health threats*--health threats that did not exist previously and that might not come to exist by natural means for tens, hundreds, thousands, or tens of thousands of years.

Most gain-of-function research on potential pandemic pathogens to date has been performed in the US with US funding or overseas with US funding.

Gain-of-function research on potential pandemic pathogens is a small part of biomedical research (less than 0.1% of all biomedical research and less than 1% of virology). However, because gain-of-function research of on potential pandemic pathogens can cause pandemics, this small part of the biomedical research enterprise is highly consequential and requires effective oversight.

Risks

Gain-of-function research on potential pandemic pathogens poses high--potentially existential--risks. Gain-of-function research on potential pandemic pathogens poses both material risks and information risks.

Gain-of-function research on potential pandemic pathogens poses *material risks* by creating new or enhanced potential pandemic pathogens. If a resulting new potential pandemic pathogen is released into humans, either by accident or deliberately, this can cause a pandemic.

Gain-of-function research on potential pandemic pathogens poses *information risks* by providing information on the construction and properties of new potential pandemic pathogens. Publication of the research provides instructions--step-by-step "recipes"--that can be used by a rogue nation, organization, or individual to construct a new potential pandemic pathogen and release it to cause a pandemic. With current biotechnology, the technical means to do this are within the reach of most nations. With improvements in biotechnology in the next decade, the technical means to do this likely also will be within the reach of most sub-state organizations and individuals.

The risks posed by gain-of-function research on potential pandemic pathogens are *inherent risks*. In some cases, the risks can be mitigated, but in no case can the risks be eliminated.

Benefits

Gain-of-function research on potential pandemic pathogens provides limited benefits.

Gain-of-function research on potential pandemic pathogens can advance scientific understanding and, in some cases, can do so more quickly than alternative research strategies.

However, gain-of-function research on potential pandemic pathogens has no civilian practical applications. In particular, gain-of-function research on potential pandemic pathogens is not needed for, and does not contribute to, the development of vaccines and drugs. (Companies develop vaccines and drugs against pathogens that exist and circulate in humans. Not against

pathogens that do not yet exist and do not yet circulate in humans.)

Gain-of-function research on potential pandemic pathogens is performed because it is easy and fast (much faster and much easier than vaccine or drug development) and because, it is fundable and publishable. Not because it is needed.

Risk-benefit assessment and risk-mitigation review

Because gain-of function research on potential pandemic pathogens poses high--potentially existential--risks and provides limited benefits, the risk-benefit ratio for the research almost always is unfavorable and in many cases is extremely unfavorable.

Therefore, it is imperative that gain-of function research on potential pandemic pathogens be subject to national- or international-level oversight to ensure that, before the research is started, risk-benefit assessment is performed, risk-benefit profiles are acceptable, and mitigable risks are mitigated..

Effective oversight includes three components:

First, research proposals that include gain-of function research on potential pandemic pathogens must be identified

Second, a risk-benefit assessment and a risk-mitigation review must be performed. This entails enumerating anticipated risks, enumerating anticipated benefits, weighing risks and benefits, and reaching a decision either (i) to proceed as proposed, (ii) to proceed with additional risk mitigation, or (iii) not to proceed.

Third, compliance with the decision from the risk-benefit assessment and risk-mitigation review must be mandated, monitored, and enforced.

US oversight of gain-of-function research on potential pandemic pathogens

US oversight, before 2014

Before 2014, there was no national-level US oversight of gain-of-function research on potential pandemic pathogens.

US oversight, 2014-2017

In 2014-2017, there was a moratorium on federal funding for "selected gain of function research," defined as research activities reasonably anticipated to increase transmissibility or pathogenicity of influenza, SARS, or MERS viruses. The policy was referred to as the "US Government Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses," or, for short, as the "Pause." (https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf).

Under the Pause, 18 projects were paused.

However, at least 7 of the 18 projects that were paused were allowed to re-start almost immediately (based on a certification by the NIH Director that the projects were "urgently necessary to protect the public health or national security"). More important, other projects that met the definition for coverage under the Pause--including a project on engineering of SARS-

and MERS-related coronaviruses by EcoHealth Alliance and the Wuhan Institute of Virology--were not paused, due to the failure of the NIH to identify and flag all covered projects

US oversight, 2018-present

In 2018-present, there has been a requirement for HHS-Secretary-level risk-benefit assessment prior to awarding HHS funding for "research involving enhanced potential pandemic pathogens," defined as research activities reasonably anticipated to increase transmissibility or pathogenicity of a potential pandemic pathogen. The policy is referred to as the "HHS Framework for Research Involving Enhanced Potential Pandemic Pathogens," or, for short, as the "P3CO Framework" (https://www.phe.gov/s3/dualuse/documents/p3co.pdf).

Under the P3CO Framework, covered projects are to be identified and flagged by HHS funding agencies (i.e., the NIH and the CDC), and covered projects are to be reviewed by a committee appointed by the HHS Secretary (i.e., the HHS P3CO Committee).

The P3CO Framework applies to funding for proposed research and operates before funding and conduct of the research (not after completion of the research). Accordingly, identification of covered projects coverage under the policy is based on proposed research and evaluates "reasonably anticipated" results of the proposed research (not results after completion of the research). The "reasonably anticipated" standard employed by the policy is equivalent, in all respects, to the "reasonable person" standard employed in US administrative and civil law.

The definitions of the research activities covered by the P3CO Framework, and the definitions of research activities exempted from the P3CO Framework, are clear. They are as clear as in any US statute or rule having a "reasonable person" standard. The policy covers research activities

reasonably anticipated to increase the transmissibility or the pathogenicity of a potential pandemic pathogen, including research activities in which neither the pathogen to be modified nor the enhanced pathogen to be generated is known to infect humans.

In principle, the P3CO Framework provides for risk-benefit assessment and risk-mitigation review for gain-of-function research on potential pandemic pathogens. *However, in practice, the P3CO Framework largely has existed only on paper.* In the four-and-one-half years since the policy was announced, *only three projects have been reviewed*: two projects that had been carried over from the Pause, and one new project. Most covered projects--including the project on engineering of SARS- and MERS-related coronaviruses by EcoHealth Alliance and the Wuhan Institute of Virology--were not reviewed, due to a failure by the NIH to identify covered projects, flag them, and forward them to the HHS P3CO Committee for review. In addition, the HHS P3CO Committee has operated with complete non-transparency and complete unaccountability. The names and agency affiliations of its members have not been disclosed, its proceedings have not been disclosed, and even its decisions have not been disclosed.

Shortcomings in US oversight of gain-of-function research on potential pandemic pathogens

Current US oversight of gain-of-function research on potential pandemic pathogens has serious shortcomings:

- Responsibility for oversight is assigned to federal agencies that perform research and/or fund research. This constitutes an inherent conflict of interest.

- Oversight applies only to HHS-funded research.

- Oversight is not codified in regulations with force of law, and, as a result, compliance is neither mandated, monitored, nor enforced.

- Oversight is undermined by the failure of federal research funding agencies to identify covered projects, flag them, and forward them to the HHS P3CO Committee for review.

- Oversight is not transparent and accountable, neither at the level of the federal research funding agencies, nor at the level of the HHS P3CO Committee .

Strengthening oversight of gain-of-function research on potential pandemic pathogens

Rationale

Lapses in US oversight of gain-of-function research on potential pandemic pathogens may have caused the current pandemic (see Appendix 1), and could cause future pandemics The US government funded high-risk gain-of-function research on potential pandemic pathogens at the Wuhan Institute of Virology in 2016-2019. The research overlapped the US Government Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses (the Pause) that was in effect in the 2014 to 2017, and met the criteria to be paused, but was not paused. The research also overlapped the HHS Framework for Research Involving Enhanced Potential Pandemic Pathogens (the P3CO Framework) that has been in effect in 2018 to the present, and met the criteria for federal risk-benefit review under the P3CO Framework, but did not undergo federal risk-benefit review under the P3CO Framework. The research was performed at biosafety level 2--a biosafety level that is inadequate for research with potential pandemic pathogens. The research may have generated SARS-CoV-2 or a proximal

progenitor, and an accident in the research may have been responsible for entry of SARS-CoV-2 or a proximal progenitor into the human population.

These facts--and these statements indeed are facts--are an indictment of the current system of US oversight of gain-of-function research on potential pandemic pathogens and are a testament that strengthening oversight of gain-of-function research on potential pandemic pathogens is essential.

States must therefore act to protect their residents. By establishing public transparency for high-risk pathogen research, and by prohibiting gain-of-function research on potential pandemic pathogens, Senate Bill 401 will provide urgently needed protections for the residents of Wisconsin, for the citizens of the United States, and for all members of the global community.

Appendix 1: Origins of SARS-CoV-2

SARS-CoV-2 may have entered humans through a research-related accident.

The genome sequence of SARS-CoV-2 indicates that its progenitor was a bat coronavirus.

Bat coronaviruses are present in nature in multiple parts of China. Therefore, the first human infection could have occurred as a natural accident, with a virus passing from a bat to a human, possibly through another animal. There is clear precedent for this. The first entry of the SARS virus into the human population occurred as a natural accident in a rural part of Guangdong province in 2002.

But bat coronaviruses also are collected and studied by laboratories in multiple parts of China, including the Wuhan Institute of Virology. Therefore, the first human infection also could have occurred as a research-related accident, with a virus accidentally infecting a field-collection staffer or a laboratory staffer, followed by transmission from the staffer to the public. There also is clear precedent for this. The second, third, fourth and fifth entries of the SARS virus into human populations occurred as a laboratory accident in Singapore in 2003, a laboratory accident in Taipei in 2003, and two separate laboratory accidents in Beijing in 2004.

At this point in time, there is no scientific or other secure basis to assign relative probabilities to the natural-accident hypothesis and the research-related-accident hypothesis. Nevertheless, there are three lines of circumstantial evidence that should be noted:

First, the outbreak occurred in Wuhan, a city of 11 million persons that is more than 800 miles from, and outside the flight range of, known bat colonies with SARS-related coronaviruses.

Second, the outbreak occurred in Wuhan, on the doorstep of the laboratory that conducts the world's largest research project on bat viruses, that has the world's largest collection of bat viruses, and that possessed and worked with the bat virus that, at the time SARS-CoV-2 emerged, was the world's closest known relative of SARS-CoV-2. The laboratory actively searched for new bat viruses in bat colonies in caves in remote rural areas in Yunnan province, brought those new bat viruses to Wuhan, and then mass-produced, genetically manipulated, and studied those new bat viruses, year-round, inside Wuhan.

Third, the bat-SARS-related-coronavirus projects at the Wuhan Institute of Virology, including projects involving the construction and initial characterization of novel chimeric SARS-related coronaviruses having enhanced viral growth and enhanced lethality, used personal protective equipment (usually just gloves; sometimes not even gloves) and biosafety standards (usually just biosafety level 2) that would pose high risk of infection of field-collection or laboratory staff upon contact with a virus having the transmission properties of SARS-CoV-2.

SARS-CoV-2 may have entered humans through US-funded gain-of-function research and lapses in US oversight of gain-of-function research.

The research at the Wuhan Institute of Virology included activities that met the definition of "selected gain of function research" in the US policy in effect in 2014-2017 and that met the definition of "enhanced potential pandemic pathogen research" in the US policy in effect in 2018-present. Using US funding, provided by the NIH in 2014-2019, the Wuhan Institute of Virology: (1) constructed novel chimeric SARS-related coronaviruses that combined the spike gene of one bat SARS-related coronavirus with the rest of the genetic information of another bat SARS-related coronavirus, (2) showed that resulting viruses efficiently infected human airway

cells and efficiently replicated in human airway cells, and (3) showed that the resulting viruses exhibited up to 10,000-fold enhancement of viral growth in lungs, and up to 4-fold enhancement of lethality, in mice engineered to display human receptors on airway cells ("humanized mice").

Although this research met the definition of selected gain-of-function research in the US policy in effect in 2014-2017 (the Pause) and exceeded--by more three orders of magnitude--the threshold set by the NIH for enhancement of viral growth that should trigger immediate cessation of work, and although the NIH was informed of project objectives and results in annual project progress reports in 2016-2018, the NIH failed to flag the project as being covered by the policy, failed to pause the project as required by the policy, and failed to stop the project as required by the Terms and Conditions of the grant.

Although the research also met the definition of enhanced potential pandemic pathogen research in the US policy in effect in 2018-present (the P3CO Framework), and although the NIH was informed of project objectives and results in a proposal for renewal of the grant for 2019-2024, the NIH failed to identify the project as being covered by the policy, and failed to forward the proposal to the HHS P3CO Committee for the risk-benefit assessment required by the policy.

On October 20, 2021, in response to a request from the Ranking Member of the House Oversight Subcommittee, the NIH Acting Director, Lawrence A. Tabak, D.D.S., Ph.D., released a letter on NIH-funded research on bat SARS-related coronaviruses conducted at the Wuhan Institute of Virology and Wuhan University in 2014-2019 (https://www.documentcloud.org/documents/21674679-tabak-letter-to-comer-oct-20-2021). The Tabak letter addressed: (1) NIH funding under grant AI110964, awarded by the NIH to EcoHealth Alliance with subcontracts to the Wuhan Institute of Virology and Wuhan University;

(2) the virus WIV1 SHC014 S (mis-rendered as "SHC014 WIV1"), a virus constructed and characterized in Wuhan using NIH funding under NIH grant AI110964;; and (3) the possibility that the virus WIV1 SHC014 S was a proximal progenitor of SARS-CoV-2.

WIV1 SHC014 S is a novel chimeric SARS-related coronavirus that combines the spike gene of one bat SARS-related coronavirus with the rest of the genetic information of another bat SARS-related coronavirus. It is an artificial, laboratory-constructed virus that has no counterpart in viruses that circulate in nature. It is one of at least three artificial, laboratory-constructed chimeric coronaviruses that were constructed by EcoHealth Alliance and its Wuhan partners using NIH funding and that were shown to infect human airway cells, to replicate in human airway cells, and to exhibit 10,000-fold higher viral growth and higher lethality than the parental natural coronavirus in infection studies in mice engineered to display human receptors on airway cells ("humanized mice"; https://www.documentcloud.org/documents/21055989-understanding-risk-bat-coronavirus-emergence-grant-notice; https://republicans-oversight.house.gov/wp-content/uploads/2021/10/Year-5-EHAv.pdf).

The year-4 progress report for the first 5-year term of the NIH grant (submitted to the NIH in March 2018) and the proposal for the second term 5-year term of the NIH grant (submitted to the NIH in November 2018) reported the construction of the three chimeras, the 10,000-fold enhanced viral growth in humanized mice of the three chimera, and the enhanced pathogenicity in humanized mice of one of the three chimeras (https://www.documentcloud.org/documents/21055989-understanding-risk-bat-coronavirus-emergence-grant-notice).

The year-5 proposal for the first 5-year term of the NIH grant (submitted to NIH in August 2021, more than two years overdue, and released to the Ranking Member of the House Oversight Subcommittee together with the Tabak letter) reported that the chimeras exhibited enhanced viral growth in brains as well as in lungs of humanized mice, and exhibited 2- to 4-fold increased lethality in humanized mice (https://republicans-oversight.house.gov/wp-content/uploads/2021/10/Year-5-EHAv.pdf).

The Terms and Conditions of the first 5-year NIH grant stated (https://www.documentcloud.org/documents/21055989-understanding-risk-bat-coronavirus-emergence-grant-notice):

> Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.

The term "1 log" means "a factor of 10". EcoHealth Alliance and its Wuhan partners created novel chimeras of SARS-related coronaviruses that showed enhanced viral growth by greater than a factor of 10,000...which exceeded, *by three orders of magnitude*, the trigger point for stopping work and reporting results to NIH under the Terms and Conditions of the NIH grant.

The Tabak letter confirms that research reported in the reported in the year-4 and year-5 progress reports of the first 5-year grant and in the renewal proposal for the second 5-year grant--research

in Wuhan that generated a potential pandemic pathogen with a greater than 10,000-fold enhanced viral growth, enhanced pathogenicity, and enhanced lethality in humanized mice-- occurred. The Tabak letter thus confirms that NIH funds supported gain-of-function research on potential pandemic pathogens and construction and characterization of an enhanced potential pandemic pathogen--a pathogen reasonably anticipated, indeed likely, to have enhanced transmissibility and/or pathogenicity in humans--in Wuhan.

The Tabak letter reveals that EcoHealth Alliance and it Wuhan partner failed to report to NIH in a timely manner that they had obtained evidence of enhanced viral growth greater than 1 log over the parental backbone strain. Thus the Tabak letter confirms that EcoHealth Alliance and its Wuhan partner violated the Terms and Conditions of the first 5-year grant,

The Tabak letter also reveals that EcoHealth Alliance failed to submit the year-5 progress report for the first 5-year grant report until more than two years after the submission deadline. Thus the Tabak letter also confirms that EcoHealth Alliance and its Wuhan partner again violated the Terms and Conditions of the first 5-year grant,

The Tabak letter correctly states that WIV1 SHC014 S and the other novel chimeric SARS-related viruses reported to the NIH by EcoHealth Alliance and its Wuhan partners in their 2018 grant progress report and 2018 grant renewal proposal are insufficiently closely related to SARS-CoV-2 to have served as a proximal progenitor of SARS-CoV-2.

However, the Tabak letter leaves unstated the crucial fact that the NIH has received no information on novel chimeric SARS-related viruses constructed by EcoHealth Alliance and its Wuhan partners subsequent to the 2018 grant progress report and 2018 grant renewal proposal., and therefore that the NIH cannot rule out the possibility that the project created a proximal

progenitor of SARS-CoV-2, and cannot even rule out the possibility that the project used NIH funding to create a proximal progenitor of SARS-CoV-2.

The Tabak letter also leaves unanswered the questions of why the NIH, which was provided with relevant data in March of 2018 and again in November of 2018, and which became aware of the failure to submit the year-5 progress report in 2019: (1) failed to act on the violations of the Terms and Conditions of the first 5-year grant, (2) awarded a second 5-year grant period despite the violations of the Terms and Conditions of the first 5-year grant, (3) awarded a second 5-year grant period for a project that proposed continuation of enhanced potential pandemic pathogen research--specifically proposing to construct and characterize additional novel chimeric SARS-related coronaviruses--without forwarding the proposal for HHS-level risk-benefit review as required under the HHS P3CO Framework, and (4) falsely asserted that NIH funding had not supported gain-of-function research or enhanced potential pandemic pathogen research in Wuhan.

Appendix 2

Policy document: US Government Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses (https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf).

Policy document: HHS Framework for Research Involving Enhanced Potential Pandemic Pathogens (https://www.phe.gov/s3/dualuse/documents/p3co.pdf).

Statement to the Wisconsin State Senate Committee on Health

Dr. Stuart A. Newman

17 January 2024

Introduction

My name is Stuart Newman. I am a Professor of Cell Biology and Anatomy at New York Medical College, Valhalla, New York. I was educated at Columbia University, and at the University of Chicago, where I received a Ph.D. in chemistry. I also received postgraduate training in molecular embryology at the University of Pennsylvania and the Marine Biology Laboratory, Woods Hole, Massachusetts. My scientific field of specialization is the embryonic development of animals, a subject on which I have published articles and books and performed research for more than 40 years as director of a federally funded (National Science Foundation and National Institutes of Health) laboratory. During that period, I also taught cell and tissue biology to medical students and have served (for the past two decades) on my university's federally mandated Institutional Biosafety Committee (IBC).

As a professional scientist and private citizen, I have long been concerned with the double-edged nature of advanced technologies and have sought to prevent deliberate and inadvertent misuse of the products of biological research. I was a cofounder in 1980 of the Council for Responsible Genetics (Boston), the first U.S. organization set up to scrutinize the safety and societal effects of genetic science and technology. Recently I joined the governing board of Biosafety Now, a nonpartisan 501c(3) nonprofit based in New Jersey, whose goal is to prevent future lab-generated pandemics. My statement to this Assembly is voluntarily offered without financial compensation.

The importance of Senate Bill 401

I write in strong support of Senate Bill 401. My experience as an IBC member has given me an inside view of what can go wrong in even the normal course of research involving genetic modification of microorganisms, particularly those with pathogenic potential in their natural state.

The IBCs, established in the late 1970s and now required of all institutions receiving federal research funds, are mandated to enforce protocols to physically contain potential microbial pathogens, regulate and monitor genetic modifications to bacteria, viruses, and other organisms. The objective is to ~~prevent~~ their acquisition of dangerous new properties and escape from the laboratories that produce them.

The mandate of the IBC also includes evaluation of experiments that could result in bioweapons in addition to benign applications (dual use) and continuous monitoring of the adequate functioning of containment facilities. In addition to meeting monthly to discuss in detail and approve (or disapprove) research protocols submitted by our colleagues, the New York Medical College IBC also received periodic updates from our institutional safety officer on accidental leaks at other venues around the country and the world. A 2001 research report in the *Journal of Virology* that showed that adding what seemed to be a harmless mouse gene into a mildly

pathogenic virus in mice turned it into a fatal one (summarized in Scientists inadvertently create lethal mousepox virus: Trends in Immunology (cell.com)), was the kind of thing that caught our attention and made us redouble our scrutiny.

Despite the federal IBC mandates, laboratories that study pathogens (including ones that have the potential to cause pandemics such as Covid-19) are not required to inform state or local governments about which pathogens they possess or the potential public health impacts if a pathogen escapes. Senate Bill 401 will require these laboratories to provide this information to the state Department of Health Services. It will thus establish public transparency for research on such agents and enable healthcare providers and first responders to take appropriate measures if they escape.

The bill also prohibits "gain of function" research on potential pandemic pathogens, i.e., genetic modifications that could increase the harm they cause to humans, like the 2001 experimental enhancement of mousepox did in mice. Given the recent experience of Covid-19, the infectious agent of which is now thought by many objective scientific observers to have originated in a Wuhan laboratory as a result of a U.S.-China gain-of-function research collaboration, it would be a small price to pay if this rare and generally unproductive line of research were banned.

The changing regulatory landscape and the need for state action

Research is an enterprise conducted by fallible humans. While the IBCs, therefore, cannot prevent with certainty physical escape of experimental microorganisms and infection of laboratory workers by such agents (many cases of both having been documented), they have generally been deemed effective. However, the IBCs are only required in institutions hosting federally funded projects. Reports from colleagues involved in commercial biotechnological enterprises and from monitors from communities where such laboratories are being sited indicate that even the relative security afforded by the federal biological and physical level (BSL) standards implemented by IBCs are being attenuated or disregarded where they are not legally mandated.

This troubling regulatory slippage places even greater importance on state legislative actions like Wisconsin's Senate Bill 401. While the public as a whole is at risk from gain of function research, implementing protective measures may require local initiatives from those most immediately affected. In this way, Wisconsin might provide national leadership in a new phase of biosafety.

Written testimony to the Senate Committee on Health in support of Senate Bill 401
18 January 2024

Bryce E. Nickels, PhD
Professor, Department of Genetics; Rutgers University
Lab Director, Waksman Institute of Microbiology
Co-founder, Biosafety Now

Chair Cabral-Guevara, members of the Senate Committee on Health, thank you for considering my testimony.

My name is Dr. Bryce Nickels. I am a Professor of Genetics at Rutgers University and a Laboratory Director at the Waksman Institute of Microbiology. I manage an active biological research laboratory and serve as the principal investigator on a grant from the US National Institutes of Health. Additionally, I am a co-founder of Biosafety Now, a nonpartisan, New Jersey-based 501(c)(3) nonprofit organization. Our mission is to enhance public safety by reducing the likelihood of laboratory-generated pandemics. I am not receiving any financial compensation for this testimony from Biosafety Now or any other organization or individual.

Biosafety Now comprises a coalition of experts in biomedicine, mathematics, public health, public policy, law, social science, and public advocacy. We are working towards a future where scientific research on pathogens supports human life without posing a threat to it and where public trust in science is restored. Senate Bill 401 (SB 401) represents a significant step towards this future.

Firstly, SB 401 aims to prohibit research that enhances potential pandemic pathogens (ePPP research). This type of research generates extremely dangerous pathogens that are not found in nature and pose an existential risk to humanity. I believe that halting this research, which I consider unethical, amoral, and a risk to the public without their consent, is crucial for achieving Biosafety Now's vision. This vision includes a future where the public can benefit from pathogen research without facing unnecessary threats to their lives. Although this is Wisconsin legislation, its impact could be global—enhanced potential pandemic pathogens do not adhere to state borders. Therefore, an incident involving an ePPP in a Wisconsin lab could have worldwide consequences.

Secondly, SB 401 will enforce legally binding public transparency for researchers working with potentially pandemic pathogens. Public transparency is vital. Scientists like myself cannot expect public trust if we are not transparent about our activities, especially since most of our research is publicly funded. Thus, SB 401 is a necessary step towards restoring public trust in science.

Biosafety Now's mission includes prioritizing the public's perspective in evaluating whether the benefits of research that enhances potential pandemic pathogens justify the existential risks to humanity.

In line with this, I have included brief statements from members of the Biosafety Now leadership team for my written testimony. These members represent the public, particularly those whose voices have been marginalized or overlooked in previous discussions on this topic.

Steve and Nina Goodale are Silicon Valley, CA residents who have been advocating for environmental health and safety in their local community for several years.

Steve writes - *"Protect the future of Wisconsin or sleepwalk toward disaster. The life sciences industry, a potential boon, is a ticking time bomb due to regulatory failures. As exemplified by the Reedley lab scandal right here in California, the next pandemic isn't a Hollywood fantasy; it could be brewing in an unregulated lab right around the corner. SB401 isn't about stifling Wisconsin's innovative spirit; it's about responsible oversight, the kind we've always demanded for chemical manufacturers and nuclear reactors.*

Wisconsin has weathered every storm. Let's face this bio-challenge head-on, not wait for disaster. SB401 is the resilient choice, the proactive choice. Choose safety, choose SB401. Thank you!"

Nina writes – *"Like countless Americans, I remain deeply concerned by the unprecedented impact of the COVID-19 pandemic, the troubling origins of which remain unresolved to date, while in its wake years later, the world continues to strive towards fundamental institutional trust and global stability. Today, an immense opportunity presents itself to you in Senate Bill 401. The wisdom of SB401 is that it simultaneously aims to increase scientific research transparency while reducing costly, potentially irreversible biological research risks–risks which have historically yielded no public health benefit yet dramatically heighten pandemic threat potential. Today, your constituents, and even citizens worldwide, entrust you to conscientiously deliberate on the sensible legislation that SB401 advances towards public health and safety, and ultimately, towards genuine pandemic prevention. We trust you to vote on the right side of history, towards a safer future for all."*

Another member of Biosafety Now's leadership team, **Megan Gafford** is an artist and mother of two small children living in New York.

Megan writes – *"For the past ten years, I have devoted my career to creating art that celebrates science. Today, I continue to celebrate science by supporting this legislation, which would help safeguard science as a public good rather than a hazard. For the past three years, I have been a mother to two small children. Today, I ask you to please join me in supporting this legislation that would help safeguard all of our children from the hubris of a handful of scientists."*

I conclude my comments with a call to all legislators to support the enactment of legislation that bans ePPP research and mandates transparency in studies involving deadly pathogens. It is imperative that all lawmakers act as protectors of public health and safety, safeguarding the public from the unchecked and potentially hazardous activities of larger entities, often corporations, but sometimes academic institutions as well. There is a widespread expectation among voters for their representatives to protect them from such unregulated risks, which is the fundamental issue here.

Because the proposed regulations focus on scientific research rather than industries like tobacco or oil, some have wrongly criticized this bill as being anti-science. As a scientist myself,

I implore you to endorse actions that reduce the likelihood of another pandemic and insist on transparency in research that fails to provide preventive insights for future crises.

SB 401 presents an opportunity for bipartisan, or more aptly, non-partisan cooperation among lawmakers. Approving this bill would establish crucial research safeguards to protect public health and safety while enhancing transparency. This is a vital step towards building a much-needed foundation of trust between scientists and the public.

SB 401 also has the potential to become a template for lawmakers to address various non-partisan concerns, such as environmental, food, and water safety, independently. Recognizing the diversity in viewpoints is essential: while some may view research regulation as a personal freedom issue, others might see it as a matter of environmental and research justice. It's crucial to understand that these differing perspectives should ultimately lead to the same goal--especially considering the significant dangers posed by the accidental release of an enhanced potential pandemic pathogen from a laboratory.