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Biosafety and Biosecurity in the Era of Synthetic Biology: Perspectives from the United States and China

Meeting Report

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BIOSAFETY AND BIOSECURITY IN THE ERA OF SYNTHETIC BIOLOGY: PERSPECTIVES FROM THE UNITED STATES AND CHINA

MEETING REPORT

On July 26, 2019, researchers, policymakers, and other stakeholders gathered at the St. Regis Hotel in Washington, DC, for a day-long dialogue on safety and security in an era of synthetic biology. The meeting, co-sponsored by the Johns Hopkins Center for Health Security and Tianjin University Centre for Biosafety Research and Strategy, drew more than 100 attendees and featured speakers from China, Europe, and the United States.

The United States and China are at the forefront of research and investment in synthetic biology. As leading countries in this rapidly evolving field, they have a responsibility to work together to promote safety and security. The goal of this meeting was to bring representatives from China and the United States together to develop a mutual understanding of each country's current governance structures and to begin a dialogue on what is required to promote global safety and security. This report recounts the meeting's activities and shares several key themes derived from the presentations and conversations of the day.

OVERARCHING FINDINGS

- Synthetic biology has the potential to have a positive impact on international economies, sustainability, human health, and security. China and the United States, as 2 leaders in synthetic biology, have both the opportunity and the responsibility to help set the pace and the standards for promoting responsible conduct in research.
- The international governance structure for biological sciences is currently ill-equipped to deal with the challenges brought on by emerging biological technologies. It will require increased investment and a concerted global effort to create norms that support biosafety and security.
- Although the existing tools used to manage biosafety and biosecurity have direct applications to new challenges posed by synthetic biology, there is also a need for novel and expanded approaches to biosafety and biosecurity.
- Sufficient governance of synthetic biology will require a combination of hard law, soft law, internal governance, guidelines, and international collaboration. Some work has been done in this area, such as the model code of conduct for biological scientists proposed by China and Pakistan to the Biological Weapons Convention (BWC). However, more work is needed to develop additional governance structures.
- International, multidisciplinary dialogues should continue to discuss opportunities to support synthetic biology while also proactively identifying and managing risks.

OPENING REMARKS

Dr. Tom Inglesby and Dr. Weiwen Zhang opened the meeting by highlighting the opportunity that the United States and China have to lead the world in beneficial, safe, and secure synthetic biology practices.

Dr. Inglesby led with a synopsis of recent global biological advances, a description of their benefits and new challenges, and further details on the goals and objectives of the meeting. While introducing the building blocks of topics that would appear in more detail later in the meeting, Dr. Inglesby also posed a number of key questions to guide discussions throughout the workshop:

- What is the ideal balance of hard law, guidance, and self-governance?
- To what degree can technical safety systems be built into this work?
- What is the role of international agreements and norms in the governance of these new technologies?
- Do states have any right to know when other states are doing work that could lead to uncontrolled spread of pathogens that could potentially be lethal to humans, animals, or plants?

Dr. Zhang underscored the need for engagement by both the United States and China and remarked on the good timing of this meeting. Both states are global leaders in the realm of biotechnology, and both states have a strong interest in ensuring that the continued adoption of these technologies is incorporated in a safe manner, with China considering a number of new biosafety approaches and biosafety law. Dr. Zhang noted that a meeting featuring speakers from both countries was a unique opportunity that could not have occurred at a more relevant time.

THE PROMISE OF SYNTHETIC BIOLOGY

This opening panel featured remarks from Dr. Pamela Silver, founding core faculty at Harvard's Wyss Institute, and Dr. Weiwen Zhang, speaking on behalf of Dr. Yingjin Yuan, the vice president of Tianjin University and professor at the School of Chemical Engineering of Tianjin University, who was unable to travel to the United States for the meeting. Dr. Silver reflected on MIT's efforts to form groups dedicated to synthetic biology in the early 2000s, and she referenced the beginning of iGEM and how it grew as a global synthetic biology community over time. She argued for synthetic biology as an answer to the question, "How do we build a world for 10 billion people?" Dr. Silver presented a number of potential biotechnology solutions for the future, and she offered the argument that it will be key to solving some of the biggest global challenges.

Dr. Yuan's remarks, as delivered by Dr. Zhang, presented some of the big milestones of biotechnology development in China. iGEM helped inform Chinese leaders and scientists about the promise of synthetic biology. A series of major Chinese synthetic biology investments were made, including the 863 and 973 national programs announced in 2011, as well as the 2018-2022 national 5-year plan,

which invested US\$330 million for synthetic biology research. There was also recognition that an emphasis on safety and security needs to grow along with the development of the technologies. Attendees engaged the panelists in a discussion on a variety of issues, including educational practices regarding biosafety. The need for a meeting of international experts, similar to the Asilomar Convention, was raised, to ensure that the scientific community can stay ahead of new security threats linked with this technology.

SYNTHETIC BIOLOGY'S NEAR-TERM OPPORTUNITIES AND CHALLENGES

In this session, Dr. James Le Duc, the director of Galveston National Laboratory at the University of Texas Medical Branch, described biosafety concerns associated with the advent of advanced biological technologies. Dr. Le Duc noted that although these technologies present different challenges than traditional biological threats, there are already effective tools in place to mitigate common risks that can be leveraged. He listed 4 lessons learned from traditional biosafety that have great relevance to synthetic biology:

- Human error is the source of greatest risk. Ensure that those working in synthetic biology are well prepared to conduct research safely through personalized training and laboratory mentorship.
- Secure the facility by adhering to regulated requirements, controlling access, and ensuring a trusted workforce.
- Practice strong, effective leadership to create a culture of safety and security, thereby setting the standard for responsible conduct. Leaders have a responsibility to ensure the laboratory and staff are safe, reliable, and compliant with regulations.
- Leadership also happens at the institutional and industry levels. Leaders can contribute to setting standards and norms in their institutions and fields—for example, through institutional biosafety committees or through industry-wide groups like the International Gene Synthesis Consortium.

EMERGING ISSUES AND FUTURE GOVERNANCE OPTIONS FOR OVERSIGHT OF ADVANCED LIFE SCIENCES

This session offered attendees an opportunity to learn about governance history and mechanisms in both China and the United States. The first presentation came from Professor Youhai Sun, the dean of Tianjin University's School of Law. Professor Sun opened with an outline of recent efforts in China to protect national and international biosafety and biosecurity. This included a draft model code of conduct for biological scientists; China's compliance with the BWC, including its incorporation into their national law; and actions taken to restrict the storage of pathogens of pandemic potential to those with a specific clearance.

Additionally, Dr. Sun presented on a number of relevant regulations including those pertaining to dual-use technologies (2002) and biosafety guidelines passed in 2004 and revised in 2015. Professor

Sun shared that the regulatory landscape still has room for improvement, especially in the realm of enforcement. Professor Sun noted that the 2018 work to genetically alter 2 human embryos, which took place in China, subverted regulations. Following this detailed review of China's biosecurity policy, Professor Sun outlined a potential path forward for effective regulation. He called for policy that strengthened the enforcement mechanisms for those who break biosecurity laws, and he noted the need for international and national dialogues to build norms of safe practice and to build proactively in preparation for new developments in biological technologies.

Following Professor Sun, Dr. Chris Hassell, a senior advisor in the Office of the Assistant Secretary for Preparedness and Response in the US Department of Health and Human Services, provided a brief overview of the current US mechanisms to govern the advanced life sciences. His comments focused on several key areas of concern in biological sciences and offered guidance on ways to implement effective governance. The following topics were discussed during his presentation:

- Potential Pandemic Pathogen Care and Oversight (P3CO): A set of recommendations developed to control and oversee high-risk pathogens
- Dual-use biosecurity and biosafety concerns
- Ensuring that potential benefits justify concerns
- Sciences, Safety, and Security (S3): A tool developed by the Public Health Emergency section of HHS to serve as a resource for safe practice in the biological sciences

Dr. Hassell closed with a call for oversight mechanisms to keep pace with synthetic biology through a mixture of hard law, soft law, and internal guidance to ensure that the future of biological science is safe and secure.

Following the presentation, attendees engaged the presenters in a discussion that provided further specifics on aspects of American and Chinese governance, such as standards of approval needed to conduct potentially risky research. In general, both presenters stressed that there needs to be a dialogue among researchers, industry representatives, and members of each country's governing agencies. There was also additional discussion on the nuances of governance, specifically in the areas of funding research with potential risks, and the balance of transparency and privacy. Together, the presentations and subsequent dialogue provided a view of US and Chinese history of governance in biotechnology and set a foundation for additional discussion and meetings regarding best practices moving forward.

EXPLORING OPPORTUNITIES FOR INTERNATIONAL COOPERATION IN THE AGE OF SYNTHETIC BIOLOGY

This panel featured 4 experts who have worked in or around major international efforts to build a safe and secure implementation of new biological technologies. The first presentation came from Ljupco Jivan Gjorgjinski, the head of the Macedonian Mission to the United Nations. Mr. Gjorgjinski served as the chair of the 2018 Meeting of States Parties of the Biological Weapons Convention. Mr.

Gjorgjinski opened his remarks with a description of the current scale of the BWC, highlighting its value as a global threat mitigation tool. He advocated for more attention on biosafety and biosecurity as the world moves into a new era of synthetic biology. He promoted the idea of a dedicated effort to implement 3 different types of codes of conduct: aspirational (code of ethics), educational (code of conduct), and enforceable (code of practice). Lastly, Mr. Gjorgjinski shared that interstitial norms can bind a wide range of norms and principles together, and that there is a role to expand the BWC's implementation support unit to help advance these global governance efforts.

Following Mr. Gjorgjinski, Mrs. Xiaodong Lyu, the deputy director for the Department of Disarmament with the China Ministry of Foreign Affairs, shared her perspective on the need for international collaboration in overseeing synthetic biology. Mrs. Lyu argued that although science is built on collaboration, the current state of international collaboration is not satisfactory. Despite global efforts, including the BWC, she identified a need to do more to ensure safety. Mrs. Lyu closed by calling for additional efforts to keep pace with the rapid advances of scientific research, especially in the area of synthetic biology for chemical products.

Following Mrs. Lyu, Christopher Park, from the Office of Biological Policy in the US Department of State, gave a presentation. Mr. Park argued that there is not sufficient international cooperation and information sharing about the risks of synthetic biology, and that international frameworks like the BWC are not sufficient for addressing these new risks. Mr. Park said that there is no single entity that governs or oversees the governance of dual-use technologies, and that the risks fall into silos. He closed by saying that new guardrails, principles, tools, and guidelines are needed, and that the international community must work together to create and test these new systems.

The session closed with remarks by Dr. David Relman, a professor of microbiology and immunology and a senior fellow at the Freeman Spogli Institute for International Studies at Stanford University. Dr. Relman echoed calls for collaborating projects and meetings and urged the inclusion of bench scientists and other users in conversations about governance. He noted that there is a lack of funding to support work on promoting safe and secure research, and that a better understanding of the "sociology of science" would improve the design and implementation of biosafety and biosecurity practices. He also expressed the view that there are some scientific projects that should not be done because of the level of risk, and he said it was important for governments to consider the issue of what projects might entail such high risk that they should not be done at all.

FOSTERING THE NEXT GENERATION OF LEADERS TO PROMOTE RESPONSIBLE SCIENCE

The next generation of synthetic biologists will be far greater in number and have tools that are more powerful than the current generation of leaders. This panel asked young synthetic biologists to reflect on ways to promote responsible science as an integral part of synthetic biology training.

Dr. Piers Millett of the International Genetically Engineered Machines (iGEM) Safety Committee spoke to the capacity of the next generation to lead a world that reaches new scientific heights with safe and responsible research. He focused on the development of iGEM and on the organization's

efforts to promote responsible science among its participants. He highlighted how iGEM's efforts to prioritize and value safety established a culture of safe and responsible science in the competition, and noted that it could serve as a model for a larger incorporation of future synthetic biologists.

The second speaker in this panel was Dr. Chonghui Liu from the Chinese Academy of Agriculture Science. He spoke about the application of synthetic biology within the framework of his research. Working with the Chinese Academy of Agriculture Science, Dr. Liu has implemented genetic alterations to an invasive snail that has contributed to food insecurity and ecosystem damage. This effort was funded by the Invasive Alien Species (IAS) 1000 Program, which is looking at creative ways to reduce the effects of what were deemed the 1,000 invasive species with the most negative impact.

Dr. Lauren Oldfield, an assistant professor at the J. Craig Venter Institute, provided an overview of her personal journey into the world of biosecurity, and how that progression has led her to value and promote responsible science. Part of her work at the J. Craig Venter Institute involves a project that synthesizes a herpes virus. The institute mandated that the project complete a dual-use review. Undertaking that review shaped Dr. Oldfield's own thinking about the possible risks and benefits of her work. From this, she learned how measures within institutions can help promote biosecurity and biosafety, leading to a generation that operates with these expectations.

Lastly, Dr. Fangzhong Wang, a lecturer at the Center for Biosafety Research & Safety at the Tianjin University, spoke on the importance of training. He emphasized the need to train individuals through all phases of higher education, not just at a single time point.

CHALLENGES POSED BY DUAL-USE TECHNOLOGY: STRATEGIES FOR PRACTITIONERS

The final panel of the day featured presentations from 3 individuals. First, Dr. Renee Wegrzyn from the US Defense Advanced Research Projects Agency (DARPA) noted that DARPA prefers to have a team bring dual-use issues to the Department of Defense proactively, identifying the vulnerabilities themselves and offering transparent solutions. She argued that building biosafety and biosecurity into the front end of a project leads to better products and a faster path to market. Through her role as a program officer, she has found that when you challenge the scientific community, they rise to the occasion.

Second to speak was Dr. Patrick Boyle, head of codebase at Ginkgo Bioworks. Ginkgo is one of the leading synthetic biology companies that has integrated both machine learning and new synthetic biology tools to create products with a wide number of applications. Dr. Boyle observed that advances in biotech are lowering the barriers to entry; for example, the price to sequence 1kb is decreasing at a rate much faster than Moore's law. He argued that integrating biosafety and biosecurity into private industry business models is something that will be increasingly important as the biotechnology space continues to grow.

The final speaker of the day was Dr. Weiwen Zhang, the director of the Centre for Biosafety Research and Strategy at Tianjin University and professor of Synthetic Biology at the School of Chemical Engineering of Tianjin University. Dr. Zhang spoke on the complicated nature of dual-use technology and argued that unintentional or deliberate misuse would have grave consequences for security and the economy. He observed that biosafety measures alone are not enough and are often poorly implemented. Furthermore, there is a shortage of experts working in this space and a dearth of programs that would advance these issues in higher education. He proposed that more work is needed to promote responsible conduct in the practitioner community.

NEXT STEPS

The meeting discussions highlighted many common views between US and Chinese speakers. There was broad support for increasing attention to biosafety and governance, and for the need for new approaches that take into account rapid advanced and new tools of synthetic biology. The day ended with calls by Dr. Inglesby and Dr. Zhang to continue this engagement and deepen it in an effort to identify approaches that might best be developed together. There was agreement that an additional session, tentatively scheduled for 2020 in China, would be useful for continuing these discussions.

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