北京大学国家发展研究院
National School of Development

NATIONAL COMMITTEE ON U.S. CHINA RELATIONS

U.S.-CHINA TRACK II DIALOGUE ON HEALTHCARE

CONSENSUS AGREEMENT

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The National Committee on U.S.-China Relations and the **National School of Development (NSD) at Peking University** convened the ninth U.S.-China Track II Dialogue on Healthcare in Tianjin, China, on June 16-17, 2024. The Dialogue brought together American and Chinese experts (attendee list below) from academia, think tanks, investment organizations, the social sector, and industry for off-the-record discussions on healthcare issues pertaining to both countries.

This session of the Healthcare Dialogue was the first in-person meeting in China since 2019 due to the COVID-19 pandemic. At a time of increasing tensions between the United States and China, participants from both countries were eager to meet in China to discuss how both nations can best address common and shared healthcare concerns domestically and worldwide while accounting for rising national security concerns that increasingly intersect with healthcare and public health issues. The participants agreed that maintaining in-person dialogues in both the United States and China helps ensure that channels of communication among academics, researchers, practitioners, and business, and between these communities and their governments, remain open.

KEY POINTS OF CONSENSUS

U.S.-China actions related to health and healthcare in this sensitive time for bilateral relations will have important consequences for each nation's citizens and for global health. Both teams recognize that, with aging populations, climate change, increasing obesity rates, and other risks, leveraging unprecedented opportunities in biomedical sciences and technology that can advance health is an increasingly important opportunity for all nations. These developments have, however, also led to rapidly evolving risk assessments in both countries, and, along with broader challenges in U.S.-China relations, this is leading to deepening strategic competition and fragmentation on important issues related to advancing biomedical science and improving health. Without careful analysis of these risks, with an emphasis on identifying opportunities for bilateral benefits while addressing national security concerns, this decoupling could create major avoidable lost opportunities for each country to improve the health of its own citizens, with implications for health and health equity across the world.

Increasingly tense bilateral relations have growing consequences on domestic and global health. Currently, both governments are taking actions that make collaboration more difficult, due to risks related to advanced biomedical technology, increasingly rich and sensitive health-related data, and

generative artificial intelligence. Legislation such as the BIOSECURE Act in the United States and the Biosecurity Law of the People's Republic of China (adopted in 2020) make it risky for companies and organizations from both nations to work together to develop new drugs, vaccines, devices, and treatments. The potential adverse consequences of such policies are being recognized by both governments. For example, the effective date of the BIOSECURE Act has been postponed to 2032 due to heavy U.S. dependence on medical products manufactured in China. Both countries can take further, more science-driven steps to help both Chinese and American citizens receive more advanced medicines and greater access to care.

U.S.-China health collaboration is imperative. The United States and China are not only the world's two largest economies, but also share similar research priorities and health value chain capabilities. Despite their policy and political differences, the two countries have long collaborated to improve health domestically and globally. In light of the recent chill in the bilateral relationship, an updated bilateral assessment of opportunities for targeted health projects on areas of common interest is urgently needed. Focusing on collaboration on specific projects that show clear opportunities for domestic and global health improvement, while addressing new security concerns, will fortify what has been a longstanding area of improving bilateral collaboration, with benefits for the rest of the world.

Artificial intelligence (AI) provides critical new opportunities and challenges for healthcare. Dialogue participants noted that AI and related technological advances have started to transform healthcare, with increasingly important implications to come. Both sides agree that AI will affect every stage of the development and use of new medical products and innovative care models, from drug discovery through clinical trial design, manufacturing, medical staffing, and care models. AI is already helping patients and practitioners by reducing the burden and cost of time-consuming tasks and increasing access to guidance and support for high-quality care. At the same time, both sides are cognizant of the risks that AI development in the healthcare field poses. These include universally recognized risks, such as the potential for bias and inequities in models trained on incomplete or inaccurate data, leading to safety risks, as well as a range of ethical concerns including around property rights, data sharing, with fundamental questions about best practices and appropriate regulation. These risk assessments are heightened in the current bilateral environment, especially in the context of security concerns arising from increasingly rich and interconnected electronic data, and from the potential for inappropriate use of advanced AI capabilities, such as in the context of advanced biomanufacturing.

Data is key to biomedical innovation. Today, all medical research and drug testing rely on rapidly growing and increasingly rich, interconnected, and standardized data for developing evidence on best medical practices and for powering generative AI capabilities. Accurate and validated data – with transparency about provenance and steps to assure reliability – is essential for companies and researchers to develop new medicines and treatments for people worldwide. However, alarm over data misuse, including the potential for reidentification, has heightened national security concerns and securitization over sharing data in both countries. Without reliable sharing of key data, developing new medical products and improving healthcare systems is slower, more costly, and less accurate. Regulatory agencies do not have the transparency needed to determine if clinical trials have been conducted effectively. Healthcare organizations developing better care models face the risk of greater uncertainty and bias in their supporting models. Updated rules on how data can be shared need to be developed in light of these new challenges.

Harmonized global regulatory standards remain crucial to improving healthcare around the world but need to be updated to address new threats. Both sides recognize that complementary regulations and practices will enhance access to essential health products and help save more lives. Important steps toward regulatory convergence have taken place, including China's participation in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and

commitment to implementing important ICH guidelines, such as for improving clinical trial protocols. Similarly, intellectual property (IP) protections for private companies have converged. But the new tensions create the need for work on new kinds of standards. This includes continued exchange of regulatory expertise between both countries (regulatory science exchanges and collaborations (e.g., on-site inspections) declined precipitously during the pandemic and have not recovered since). It also includes increasing adequate transparency into research data and methods for regulatory review and developing standards for parallel clinical trials and other analyses that do not require exchange of sensitive, identifiable individual data. Failure to do so will continue to lead to duplicative costs and efforts, and less progress in biomedical innovation and effective health AI. By clarifying areas where further regulatory alignment remains possible, both countries can continue to collaborate on critical global public health issues even in the presence of new biosecurity concerns.

RECOMMENDATIONS

As the world's two largest economies, China and the United States have a responsibility to lead improvements in global healthcare. Even while relations between the two governments remain tense, there are many opportunities in biomedical science, healthcare, and public health for both countries to coordinate better to improve public health across the globe. Indeed, such actions would improve the health security of both countries. Recommended next steps include the following:

Exchange best practices and strategies for AI in health. Both countries have a shared interest in developing their domestic AI abilities in a manner that prevents biased results and safety issues. Sharing best practices and strategies for AI development and implementation in such areas as data validation, documentation of applications and updates, diversity and adequacy of testing, and publication of results – foundations for emerging health AI assurance and regulatory frameworks – would help both countries avoid mistakes and increase AI safety, without the need for sharing sensitive data or IP related to AI algorithms or applications.

Carve out safe harbors for data sharing and advance parallel analysis methods that do not require sharing individual data. Parsing out specific areas of non-sensitive data for data sharing will contribute greatly to bilateral research and enhance opportunities for future data-sharing procedures. For example, sharing standardized aggregated epidemiological data for such public health threats as avian flu or maternal mortality could enable continued shared insights about trends in these areas and the impact of interventions to address these threats. Specifying the types of data that the countries can share, as well as the types of uses appropriate for the data, can create safe harbors where benefits of data exchange clearly exceed the potential risks of misuse.

Continue work to increase regulatory harmonization. While important progress has occurred in regulatory convergence, continuing gaps and new concerns about sharing data and IP with government agencies make joint research and other collaborations difficult. The key healthcare departments of both governments – in conjunction with global organizations such as ICH and the World Health Organization (WHO) – should identify bilateral priorities for further progress on clarifying and modernizing healthcare regulations and educating healthcare agencies and providers on proper interpretation and implementation. The United States and China should clearly define the requirements and regulatory processes in one country for the approval of innovative products developed in the other country.

Refine risk assessments associated with more - and less - advanced biomanufacturing capabilities. While some advanced, emerging, and potential future genetic and cellular manufacturing techniques have raised national security concerns about misuse and economic leadership, most manufacturing

of drugs and biologics involves well-understood chemistry and manufacturing techniques. With rising manufacturing costs and drug shortages, steps to create more diverse and reliable supply chains may not require U.S.-China decoupling. Biomanufacturing and national security experts representing both countries should explore whether a risk-based framework for addressing manufacturing needs on the one hand and potential biosecurity risks on the other could help both countries better assure access to needed medications while respecting their evolving biosecurity concerns.

Provide guidelines for non-governmental U.S.-China efforts. At a time when national security concerns are leading both governments to restrict bilateral cooperation, the two nations can work to define distinct areas where corporations, organizations, researchers, and agencies can work together. Specific recommendations for future collaborative efforts include defining how organizations can work together on AI applications in healthcare, specifying how data can be shared and used in the design and implementation of clinical trials, and detailing how to protect intellectual property rights.

Pursue common areas of mutual interest between the United States and China for research and collaboration. At a time when tense bilateral relations make it difficult for both countries to collaborate on major issues, it may be better for both the United States and China to focus on discrete, targeted areas of healthcare for joint work. This will help develop trust and concrete results that can then be expanded into other areas of mutual interest. Such collaboration might focus on areas where there are not distinct concerns about the biomedical technologies or services involved (e.g., small-molecule drugs or biologics where manufacturing techniques and mechanisms of action are well understood in both countries; assessments of innovative, low-cost care delivery mechanisms to increase access in underserved populations), where the data security concerns are limited (e.g., studies can be conducted in parallel with sufficient data sharing and validation to meet standards for academic journals or regulatory authorities), and where the health benefits to collaboration are high, both for each country and for the world. Examples of such collaborations could include the following:

- **Containing obesity and non-communicable diseases:** A growing number of drug manufacturers are rapidly scaling production of GLP-1 and related drugs that show substantial promise for impacting a broad range of increasingly high-burden diseases in the United States and China, including not only cardiovascular disease but also common cancers and many other conditions mediated by adipose tissue and inflammation. The two countries are also collaborating on work on chronic disease detection, management, and innovation. Shared standards for conducting real-world studies in diverse populations in China and the United States could help address important questions about long-term risks, differences in response across subgroups, ways to combine drug use with other steps to achieve sustained weight loss, and other questions that could increase the public health impact of these drugs, and that otherwise might take much longer to understand.

- **Combination cancer therapy:** Combination therapies, including those that activate or potentiate immune responses to cancers, are transforming cancer care. But studies of these drugs, especially in combination, take time and are more difficult if the United States and China are not actively participating. The result is less evidence and a slower learning curve on the optimal use of innovative cancer therapies. A bilateral group could identify opportunities to address these challenges. It could also help assess where greater transparency in trial conduct may be helpful, which continues to challenge bilateral approvals of innovative products tested in one country or the other.

- **Extending frontline workforces:** The clinical workforce in both China and the United States is inadequate to meet the challenges of population aging and frontline care delivery, especially in underserved areas. Many AI-enabled care improvements may involve augmenting the capabilities

of less intensively trained health workers. Many of these insights are unlikely to raise key data sharing or IP concerns.

- **Persistent global public health threats:** The United States and China can also continue to collaborate on improving the management of global public health threats, including persistent infectious disease threats (e.g., TB, HIV, polio) and noninfectious disease threats, through joint support of real-world clinical studies involving AI-enabled models of care delivery and analysis.

Prioritizing collaboration in areas that provide targeted and mutual benefits will help stimulate opportunities for further cooperation in additional areas of healthcare research, development, and treatment.

Map out the benefits of joint healthcare efforts. The United States and China have worked together to address healthcare issues for over one hundred years. Today, despite the recent downturn in bilateral relations, such cooperation continues. It is important that both countries recognize the mutual benefits each accrues from such actions and work together to understand and address new biosecurity concerns in an era of rapidly electronic data capabilities, biomanufacturing, and AI. To that end, the Dialogue participants will help develop a report of past bilateral collaboration to underline the need for and importance of such future work.

CONCLUSION

At a time of increasing global health concerns - including climate change, aging populations, future pandemics, rising levels of obesity, and increasing incidence of disease – it is more important than ever that China and the United States work together to address health issues facing both their populations and the world. The evidence is clear that such collaboration helps save lives.

Given the tense relations between the U.S. and Chinese governments, it is best for both nations to focus on key areas of cooperation to achieve some immediate benefit and enhance mutual trust in the healthcare field. The Dialogue participants will continue to work together to suggest projects that can help in this process.

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After the Healthcare Dialogue concluded, the Dialogue conveners held a public forum entitled “The U.S.-China Cancer Prevention and Treatment Forum.” Experts from both nations convened online and in person to discuss key issues like technological innovation, clinical diagnosis, and service management in cancer prevention and treatment. Events such as this show the deep U.S.-China connection in the field of healthcare and help develop common goals and aspirations for further exchanges and cooperation. Dialogue participants look forward to strengthening pragmatic cooperation on major public health issues, aiming to advance medical technology and to bring tangible benefits to the health and well-being of the people in both nations and around the world.

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