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

July 10-11, 2023
Durham, North Carolina

The National Committee on U.S.-China Relations and the **National School of Development at Peking University** convened the eighth Track II Dialogue on Healthcare at the JB Duke Hotel in Durham, North Carolina on July 10 and 11, 2023. The dialogue brought together American and Chinese experts (attendee list below) from academia, think tanks, and industry for off-the-record discussions on healthcare issues pertaining to both countries.

This session of the Healthcare Dialogue was the first – in four years – to be held face-to-face: the previous three sessions had all been held virtually on Zoom due to restrictions as a result of the global COVID-19 pandemic. After such a long absence, the participants from both countries were eager to meet in person and discuss the issues confronting both nations. They also agreed that, with travel restrictions easing and renewed contacts between the two governments, the Dialogue presented an opportunity through academic, clinical, and business communities to discuss how China and the United States can work together to better address future health crises and develop long term cooperation in healthcare.

KEY FINDINGS

The universality of healthcare. Both teams recognize that innovation and improvements in healthcare delivery benefit all peoples and all nations. The more that China and the United States can work together to advance healthcare, the more their two populations and the people of the world will benefit.

Important opportunities exist to improve collaboration and enhance healthcare innovation for both countries. Advancements in healthcare, including the development of new medicines, vaccines and treatments occur when experts around the world are able to work together and share their research. Regulatory harmonization and clarity about opportunities for bilateral collaboration are key steps in this process, yet there are several issues that have made this more difficult. These include:

- **Different standards.** Standards for quality of care, clinical trials, medical education, and medical data management are not uniform either within each country or between countries. China has joined the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), and China's NMPA (National Medical Products Administration) has adopted guidelines to international standards, and has increased technical manpower and

internal capacity. Among the priority tasks for future work, more training opportunities for regulators, and further participation in multinational regulatory harmonization activities, can facilitate consistent interpretation and application of international standards. Meanwhile in the United States, more clarity about the expectations of the U.S. Food & Drug Administration (FDA) for trial diversity, data quality, and other regulatory issues could significantly facilitate the development of needed clinical trial evidence. While regulatory interactions between the NMPA and FDA have shown signs of picking back up as both countries move beyond the pandemic, there remains great room for improvement in how China and the United States work together to advance aligned and effective regulatory processes and standards for medical product development.

- **Clinical evidence development needs improvement.** While well-designed clinical trials provide valuable "gold standard" evidence on the safety and efficacy of medical products, both nations have opportunities to lead the way in augmenting traditional clinical trial evidence through thoughtful research and collaborations. For example, both nations can learn more from the rapid growth in electronic data in routine care and development of analytic methods to answer questions on topics such as effectiveness in diverse real-world settings and populations, longer-term endpoints, and the comparative effectiveness of alternative methods of care. With appropriate confidentiality and security protections, both countries can advance the use of real-world data and effective methods to develop real-world evidence (RWE) to improve and augment clinical trials and add pragmatic elements to trials. Well-curated digital health data, and emerging methods such as generative AI, can lead to better understanding of how to improve health in diverse populations, particularly if both countries work together to develop methods and conduct RWE studies.

- **National security restrictions.** Both governments are taking actions related to "national security concerns" that have had the effect of limiting many kinds of exchange for academic inquiries, including healthcare studies, without clarity about the national security interest at risk. Unclear rules make it more difficult for researchers to share key data or results across international borders or even between national institutions. Healthcare industries, medical centers, academic communities, and public health agencies have become increasingly reluctant to work together for fear of raising national security concerns. The lack of harmonization and cooperation on national security guidelines relevant to healthcare research makes the effective conduct of such research an increasingly challenging issue.

Developing healthcare systems that deal with societal challenges. While China and the United States have different healthcare systems, they face similar issues, including ageing populations, increases in the incidence of non-communicable diseases, rising costs, and inequities in healthcare delivery and health outcomes. China is dealing with cost containment under universal insurance coverage and inequalities in quality and access to innovative medicines between urban and rural populations. While the United States delivers many advanced healthcare services, the costs of such services are among the highest in the world, access and quality are uneven, and inequities between rich and poor and urban and rural also remain.

It is clear that, for both the United States and China, advanced primary healthcare systems that are well integrated with both community and specialist care services are essential to enable early intervention, preventative care, disease interception, and better health. Both nations are advancing reforms to create more resilient, innovative, and sustainable healthcare systems. Digital health, including tele-medicine, AI integrated tools and smart medical devices, may support patients to better access care, improve physician workforce productivity, promote medical education reforms, and strengthen the health system itself through logistics and medical record keeping, as well as improvements to the underlying insurance infrastructure.

Preparedness and response to future pandemics and other global health emergencies. After adopting different approaches to dealing with the COVID-19 pandemic, both the United States and China have found their own ways to manage the virus and future outbreaks and variants. At the same time, there are many lessons to be learned on both sides in limiting the health, economic, and social impacts of the pandemic, and in building and maintaining public trust. Gaps in effective communication – often in an evolving and uncertain environment – resulted in some public distrust and poor compliance with behaviors and medical decisions. Inadequate attention to robust global supply chains resulted in shortages of basic clinical equipment and materials, and coordination gaps resulted in stockpiling and hoarding of supplies. It became clear that both governments need to work not only with each other, but also with non-health experts such as behavioral scientists, economists, and other social scientists, to develop timely and effective responses to deal with future public health emergencies.

RECOMMENDATIONS

As the world's two largest economies, China and the United States have a responsibility to lead improvements in healthcare globally, in areas ranging from advancing biomedical science to innovating in healthcare delivery and preparing for future pandemics. Even while relations between the two governments remain tense, there are many opportunities in biomedical science, healthcare, and public health for both countries to better coordinate and cooperate to improve the health of both their peoples, as well as the peoples of the world. Indeed, such actions would improve the health security of both countries. Steps that should be taken include the following:

Provide clarity on appropriate areas of collaboration and data sharing. Scientists cannot work together if government rules are not clear. Most areas of potential collaboration for improving health seem to have no significant implications for national security, and intellectual property concerns can also be addressed. To help encourage collaboration, the two governments should clarify what constitutes national security interests and ensure that the use of national security concerns to restrict joint research is evidence-based. Both nations should also work together to clarify the rules under which data can be shared among researchers for academic inquiry and health improvement, while being mindful of data privacy concerns. These steps would effectively create "safety zones" for advancing healthcare innovation and development.

Re-establish contacts at various levels. Greater communication among key health personnel – whether among senior government officials or medical organizations, doctors and researchers – can result in increased innovation and improvements in healthcare. Both governments should encourage such contacts, by supporting more travel and opportunities for direct interactions between their two nations. In particular, they should re-establish relations between the FDA in the United States and the NMPA in China. This might include sending representatives from each nation to work in the other country to help improve regulatory science and promote efficient and effective global regulation. If in-person exchanges are not possible in the current climate, sharing good practices without sensitive information could be a starting point.

Work to increase regulatory harmonization. Inconsistent regulations and regulatory interpretations make joint research and other collaborations more difficult and costly. The key healthcare departments of both governments – in conjunction with global organizations such as ICH and WHO – should establish plans to develop and clarify healthcare regulations in various fields and to educate healthcare agencies and providers at various levels on the proper interpretation and implementation of such regulations. There are many past precedents for such collaborations. 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.

Collaborate to improve healthcare systems in both countries. Although their healthcare systems are different, there are numerous and growing ways that the two countries can learn from each other to provide more efficient, cost-effective, and high-quality healthcare to their respective peoples. Among the key areas to consider are the following:

- **Developing primary care that is well connected to specialist care and backed by electronic health infrastructure and strong analytics.** Government and industry in both countries are undertaking efforts to improve both public sector regulation and financing mechanisms to encourage private sector investment and innovation to improve primary care capabilities. Major hospitals in both countries are developing more community and population-based care models. Exchanges, "learning networks," and other collaborative efforts could provide insights to improve public and private sector health care initiatives and coverage models. To strengthen people-centered primary care, more research and collaboration on how to use emerging mobile health technology is recommended.

- **Addressing workforce issues that affect both the United States and China.** This includes developing better evidence on using digital technology to support more accessible and effective care, including through AI applications. It also includes developing innovative training programs for doctors, nurses, and other health professionals from both countries, supported by the appropriate technological tools, that can extend the ability of care teams to provide more accessible and quality care to patients, regardless of geographic or demographic conditions.

- **Developing patient-centered models that engage patients in their own community and situation,** enabling better care provision, satisfaction, and patient adherence, and empowering patient self-care through forward-thinking design.

- **Encouraging bilateral non-governmental health-related organizations to improve their reach and influence.** Suggested approaches include removing obstacles for philanthropic and private sector support of these organizations, facilitating cross-national communications and exchanges in initiatives that transcend current bilateral tension, and promoting effective strategies in overcoming barriers imposed by recent sociopolitical climate.

- **Pursuing common areas of high mutual interest between the United States and China for intentional research and collaboration.** These include technical collaborations on specific disease burdens, such as hypertension, diabetes, cancer, mental health, and other non-communicable diseases, as well as the promotion of healthy ageing, where there are substantial health needs and opportunities for health improvements from greater collaboration.

Work together to improve preparedness and response to future pandemics and global health emergencies. China and the United States must see that, as it pertains to global health crises, working together achieves better outcomes, limits economic downsides, and saves lives. The United States and China should work to re-establish channels of regular engagement, so as to ensure up-to-date and accurate information sharing and understanding among the key public agencies and academic communities. Areas that could be discussed include: surveillance and early detection using automated electronic health data systems, early response plans for containment, developing rapid and real-world evidence on potential biomedical responses (including testing, treatment, vaccines, and other care innovations), coordination of public information, and encouraging the development of more robust global manufacturing and supply chain capabilities to enable faster and more equitable response and assistance.

A world confronted by climate change, ageing populations, and inequities in healthcare – despite unprecedented biomedical capabilities – needs China and the United States to work together and lead in addressing these vast challenges. At a time of tense bilateral relations, both nations should and can develop better trust by re-establishing collaboration in specific areas that can bring about concrete results. The Dialogue participants will continue to work together to suggest projects that can help in this process.

CHINESE PARTICIPANTS

CHEN Xi	Associate Professor, Health Policy and Economics, Yale University
DONG Ying	President, Starr International Investment Advisors (Asia) Limited; Chairman, Starr Property & Casualty (China) Co., Ltd
GU Dongfeng	Academician, Chinese Academy of Sciences; Professor, Peking Union Medical College; Acting Vice President of Southern University of Science and Technology
GUO Yan	Professor, School of Public Health, Peking University
Gordon G. LIU	Peking University (PKU) BOYA Distinguished Professor, National School of Development; Dean, PKU Institute for Global Health and Development (Co-Organizer of the Dialogue)
LIU Qian	President, Chinese Hospital Association, Professor; former Vice-Minister, Ministry of Health; Vice Chairman of the Education, Science, Culture, and Public Health Committee of the 13th National People's Congress (China Co-chair, U.S.-China Track II Dialogue on Healthcare)
WANG Tao	Chairman, Chronic Disease Management Committee, China Aging Well Association; Professor, Department of Nephrology, Peking University Third Hospital
XIAO Rui-Ping	Chair Professor and Dean, College of Future Technology, Peking University
YAN Lijing	Professor (with tenure) of global health, Duke Kunshan University; Adjunct Professor, Peking University Institute for Global Health and Development and Wuhan University School of Public Health
YU Xuefeng	Co-Founder, Chairman and CEO, CanSino Biologics Inc.
ZHANG Lee Ligang	Founder, Chairman and CEO, iKang Healthcare Group, Inc.

AMERICAN PARTICIPANTS

Olivier Brandicourt	Former CEO, Sanofi and Bayer Healthcare
Lawrence D. Brown	Professor, Health Policy and Management, Mailman School of Public Health, Columbia University
Christopher Colwell	Executive Director, Asia-Pacific and China Policy, Merck & Co.
Carlos del Rio	Executive Associate Dean, Emory School of Medicine & Grady Health System; Distinguished Professor, Department of Medicine, Division of Infectious Diseases, Emory University School of Medicine
Christopher J. Hickey	Senior Director, Global Policy & Public Affairs – Emerging Markets, Pfizer
Carolyn Magill	Chief Executive Officer, Aetion, Inc.

Mark B. McClellan	Director and Robert J. Margolis, M.D., Professor of Business, Medicine and Health Policy, Margolis Center for Health Policy, Duke University (U.S. Co-chair, U.S.-China Track II Dialogue on Healthcare)
Paul Neureiter	Executive Director, International Government Affairs, Amgen
Stephen Orlins	President, National Committee on U.S.-China Relations (Co-Organizer of the Dialogue)
David Rind	Chief Medical Officer, Institute for Clinical and Economic Review
Soumi Saha	Senior Vice President of Government Affairs, Premier, Inc.