

Department of Commerce
Bureau of Industry and Security

Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices

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AUTHORS

Samantha Ravich

*Distinguished Fellow, FDD's Center on Cyber and
Technology Innovation*

Johanna Yang

*Research and Editorial Associate, FDD's Center
on Cyber and Technology Innovation*

Jack Burnham

Research Analyst, FDD's China Program

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Introduction

China's considerable presence within the U.S. healthcare and public health sector poses a grave threat to U.S. national security. The National Institute of Health (NIH) estimated that in 2019, 9.2 percent of U.S.-imported pharmaceuticals and medical equipment came from China — a percentage that “likely understates” American reliance on China for medical products, NIH warned.¹ This understatement is in part due to the complex nature of medical supply chains — China is both a supplier of raw materials used in medical products and the final point of assembly for goods bound for the United States, obscuring its reach into the American medical system. This percentage also does not account for the value-add or criticality of these goods, particularly those related to biodefense and managing long-term acute health issues.

China has exploited this reliance, selling and exporting technology that is deliberately compromised, forcing healthcare providers to unwittingly and unwillingly play Russian roulette with patient treatment plans. Moreover, as witnessed during the pandemic, China can take advantage of the United States during a range of biodefense contingencies when regular supply chains may be severely interrupted — American doctors should never again be forced to rely on garbage bags instead of proper personal protective equipment (PPE).²

To secure the U.S. medical equipment and pharmaceutical supply chains, the Department of Commerce's Bureau of Industry and Security (BIS) must hinder the ability of China and other foreign adversaries to control critical aspects of America's healthcare industry. BIS's investigation into imports of PPE, medical consumables, and medical equipment, including devices, should address the national security and public health implications of Chinese medical technology imports, reaffirming America's ability to protect its citizenry from the threats posed by the Chinese Communist Party (CCP).

This comment will provide further detail on the holistic implications of Chinese infiltration of the U.S. healthcare system.

Overview of the Threat That Chinese Ownership Poses to the American Medical Supply Chain

China's Sweeping Presence in American Medical Supply Chains

China's growing role within the U.S. medical device supply chains is largely due to the combination of Beijing's industrial policy and the shifting landscape of American healthcare. Beginning in 2015, the CCP sought to establish China as a major player within the medical

¹ Wallace J. Hopp, Lisa Brown, and Carolyn Shore, “Building Resilience into the Nation's Medical Product Supply Chains,” *National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Committee on Security of America's Medical Product Supply Chain*, March 3, 2022.

(<https://www.ncbi.nlm.nih.gov/books/NBK583730>)

² Sophia Ankel, “Photos show how shortages are forcing doctors and nurses to improvise coronavirus PPE from snorkel masks, pool noodles, and trash bags,” *Business Insider*, April 23, 2020.

(<https://www.businessinsider.com/photos-show-doctors-nurses-improvising-due-to-lack-of-ppe-2020-4>)

device market under the auspices of “Made in China 2025,” the country’s premier industrial policy.³ This drive, which included state subsidization of manufacturing, from the central government downwards, allowed Chinese firms to rapidly expand their production capacity and capture significant global market share.⁴ Along with providing economic benefits to the country, this push was also spurred in part by demographic pressures, particularly China’s rapidly aging population, and by the CCP’s efforts to improve the country’s perennially poor health outcomes.⁵

Broader trends within the American healthcare system have also opened the door to China. Healthcare spending has risen over the past decade — from \$3.2 trillion in 2015 to \$4.9 trillion in 2023 — with nearly a quarter spent on durable and non-durable medical goods, a category that includes medical devices.⁶ Once isolated, the rise in medical device spending roughly matches the rate of increase in overall healthcare spending — meaning that as U.S. healthcare spending increases, the size of the U.S. medical device market will grow.⁷ As the American healthcare system prepares to confront a rapidly aging population, which typically accounts for most medical spending, China will be even better positioned to meet a surging American demand signal.

This dynamic was perhaps best encapsulated by the COVID-19 pandemic and its aftermath. At the onset of the pandemic, it was difficult for American hospitals and physicians to obtain PPE, for example, since 95 percent of surgical masks were manufactured overseas, beginning with materials produced in China.⁸ Despite efforts to build a national stockpile of critical resources such as PPE prior to a crisis, the United States was unable to equip frontline providers with adequate resources during the pandemic, in large part due to both snarled supply chains and

³ Camille Boullenois, Malcolm Black, and Daniel H. Rosen, “Was Made in China 2025 Successful?” *Rhodium Group*, May 5, 2025. (<https://rhg.com/research/was-made-in-china-2025-successful>); Jack Burnham, “New Report Finds Beijing Has Successfully Achieved ‘Made in China 2025’ Policy Goals, Catching Up to the U.S.” *Foundation for Defense of Democracies*, May 7, 2025. (https://www.fdd.org/analysis/policy_briefs/2025/05/07/new-report-finds-beijing-has-successfully-achieved-made-in-china-2025-policy-goals-catching-up-to-the-u-s)

⁴ Research and Markets, Press Release, “China Among Top 10 Largest Medical Device Markets Worldwide,” June 26, 2025. (<https://www.globenewswire.com/news-release/2025/06/26/3105604/28124/en/China-Among-Top-10-Largest-Medical-Device-Markets-Worldwide.html>)

⁵ Mihajlo Jakovljevic, Hanyu Chang, Jay Pan, Chao Guo, Jin Hui, Hao Hu, Danko Grujic, Zhong Li, and Lizheng Shi, “Successes and challenges of China’s health care reform: a four-decade perspective spanning 1985—2023,” *BMC: Cost Effectiveness and Resource Allocation*, August 30, 2023.

(<https://pmc.ncbi.nlm.nih.gov/articles/PMC10469830>); Robert Postings, “Ruby Wang on How Tech is Driving China’s Healthcare System,” *The Wire China*, September 14, 2025. (<https://www.thewirechina.com/2025/09/14/ruby-wang-on-how-tech-is-driving-chinas-healthcare-system>)

⁶ Matthew McGough, Emma Wager, Aubrey Winger, Nirmita Panchal, and Lynne Cotter, “How has U.S. spending on healthcare changed over time?” *Peterson-KFF Health System Tracker*, December 20, 2024. (<https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time>)

⁷ Gerald F. Donahoe, “Estimates of Medical Device Spending in the United States,” *AdvaMed – Advanced Medical Technology Association*, June 2021. (<https://www.advamed.org/wp-content/uploads/2021/12/Estimates-Medical-Device-Spending-United-States-Report-2021.pdf>)

⁸ Debashree Bora, “Surgical Masks Market Size & Outlook, 2025-2033,” *Straits Research*, August 2025. (<https://straitsresearch.com/report/surgical-masks-market>)

halted Chinese exports.⁹ The critical need for hospital gowns, hazmat suits, gloves, respirators, and surgical masks led to a near \$17 billion increase in U.S. imports from China between 2019 and 2020.¹⁰ Globally, this reliance had profound political ramifications, as China used shipments of masks and other PPE to curry favor with traditional American allies and partners, particularly within Latin America.¹¹

Nearly six years later, the United States now relies on Chinese products for more than 50 percent of perennially necessary medical supplies, such as gauze, needles, syringes, gloves, and catheters.¹² Devices like pacemakers and insulin pumps are the difference between life and death for millions of people. Presently, 14 percent of U.S. marketed medical devices are manufactured in China.¹³

China Exploits the Medical Products It Exports to the United States

China's role within the American medical device market poses a dramatic risk to national security. In addition to weaponizing Washington's dependence to compromise the nation's biodefense systems, Chinese firms are installing backdoors in their products, allowing malicious actors to interfere with the safe function of the devices.

In January 2025, the Cybersecurity and Infrastructure Security Agency released an advisory announcing the discovery of a vulnerability in patient monitors produced by Contec Medical Systems, a China-based medical device manufacturer.¹⁴ The device — the CMS8000 monitor, which the Miami-based manufacturer and distributor Epismed relabeled and sold as the Epismed MN-120 — monitors a patient's vital signs, including respiration, pulse rate, oxygen saturation, and blood pressure. It houses patient personal health information (PHI), including patient number, hospital department, admission date, name, and date of birth, as well as information on the attending physician.¹⁵

⁹ Chad P. Brown, "How COVID-19 Medical Supply Shortages Led to Extraordinary Trade and Industrial Policy," *Asian Economic Policy Review*, July 29, 2021. (<https://pmc.ncbi.nlm.nih.gov/articles/PMC8441910>)

¹⁰ Chad P. Brown, "How COVID-19 Medical Supply Shortages Led to Extraordinary Trade and Industrial Policy," *Asian Economic Policy Review*, July 29, 2021. (<https://pmc.ncbi.nlm.nih.gov/articles/PMC8441910/#aepr12359-supitem-0001>)

¹¹ Megan L. Ranney, Valerie Griffeth, and Ashish K. Jha, "Critical Supply Shortages — The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic," *The New England Journal of Medicine*, March 25, 2020. (<https://www.nejm.org/doi/full/10.1056/NEJMp2006141>)

¹² Garrett Murch and Scott Maier, "Medical Manufacturing: A Critical Supply Chain at Risk," *American Affairs Journal*, 2025. (<https://americanaffairsjournal.org/2025/02/medical-manufacturing-a-critical-supply-chain-at-risk>)

¹³ Sarah Haj-Maharsi, "U.S. Tariffs and the Medical Device Industry," *Knobbe Martens IP + Technology Law*, April 28, 2025. (<https://www.knobbe.com/blog/u-s-tariffs-and-the-medical-device-industry>)

¹⁴ Department of Homeland Security, Cybersecurity and Infrastructure Security Agency, "TLP:CLEAR Contec CMS8000 Contains a Backdoor," January 30, 2025. (<https://www.cisa.gov/sites/default/files/2025-01/fact-sheet-contec-cms8000-contains-a-backdoor-508c.pdf>)

¹⁵ Samantha F. Ravich and Johanna Yang, "China Wants Our Hearts. Literally." *The Cipher Brief*, June 13, 2025. (<https://www.thecipherbrief.com/china-medical-devices>); Department of Homeland Security, Cybersecurity and Infrastructure Security Agency, "TLP:CLEAR Contec CMS8000 Contains a Backdoor," January 30, 2025. (<https://www.cisa.gov/sites/default/files/2025-01/fact-sheet-contec-cms8000-contains-a-backdoor-508c.pdf>)

CISA researchers discovered that the backdoor embedded in the devices enabled immediate exfiltration of all data stored on the monitor, including information from the patient's chart. Pre-installed instructions sent the information to an external IP address linked to a university in China.¹⁶ The backdoor also allowed the external IP to remotely download, execute, and overwrite files on the monitor.¹⁷

Other code on the monitor enabled malicious actors to conduct these operations without discovery, hiding this unauthorized activity from the hospital or end customer. These devices are used widely across the United States and European Union. Following the discovery of the compromise, CISA directed healthcare providers to “unplug the device and stop using it,” eventually recalling over 7,000 monitors, but the devices remain on the market.¹⁸

The consequences of continued use of compromised medical technology could be profound. The backdoor in the CMS8000 monitor, for example, allows for “remote code execution and device modification,” which means that bad actors can remotely control and potentially input inaccurate information on the device.¹⁹ With incorrect information, physicians may prescribe and perform the wrong treatment plan. For example, the monitor may reflect tachycardia (fast heart rate), when in fact the patient is maintaining sinus rhythm (normal) or suffering from bradycardia (low heart rate). Under the impression that the monitor's information can be trusted, healthcare providers may then administer treatment to slow a patient's pulse rate, when in fact the treatment is potentially deadly.

Current industry regulations are not equipped to address the threat from China. The Food and Drug Administration requires all new medical devices to meet its cybersecurity standards. It also mandates that companies attest to several cybersecurity maintenance, mitigation, and risk management procedures. The FDA's latest guidance from June notes that pre- and post-market devices should meet these standards,²⁰ but the requirements are not mandatory for devices that were certified before the 2022 congressional mandate.²¹ The CMS8000 monitor received

¹⁶ Michael Kan, “Chinese-Made Patient Monitor Contains a Secret Backdoor,” *PC Mag*, January 31, 2025. (<https://www.pcmag.com/news/chinese-made-patient-monitor-contains-a-secret-backdoor>)

¹⁷ Ionut Arghire, “CISA, FDA Warn of Dangerous Backdoor in Contec Patient Monitors,” *Security Week*, January 31, 2025. (<https://www.securityweek.com/cisa-fda-warn-of-dangerous-backdoor-in-contec-patient-monitors>)

¹⁸ Department of Homeland Security, Cybersecurity and Infrastructure Security Agency, “TLP:CLEAR Contec CMS8000 Contains a Backdoor,” January 30, 2025. (<https://www.cisa.gov/sites/default/files/2025-01/fact-sheet-contec-cms8000-contains-a-backdoor-508c.pdf>); Food and Drug Administration, “Medical Device Recalls,” October 7, 2025. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=96046)

¹⁹ Ionut Arghire, “CISA, FDA Warn of Dangerous Backdoor in Contec Patient Monitors,” *Security Week*, January 31, 2025. (<https://www.securityweek.com/cisa-fda-warn-of-dangerous-backdoor-in-contec-patient-monitors>)

²⁰ Food and Drug Administration, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff,” June 27, 2025. (<https://www.fda.gov/media/119933/download>)

²¹ Annie Fixler and Erik Thomas, “Cyber Vulnerabilities in Medical Devices Put Patients at Risk,” *Foundation for Defense of Democracies*, July 22, 2022. (<https://www.fdd.org/analysis/2022/07/22/cyber-vulnerabilities-in-medical-devices-put-patients-at-risk>)

certification more than a decade earlier in 2011.²² Moreover, even if a new version of this device were seeking certification, the FDA's requirements likely would not have identified the flaw. Device manufacturers must provide the FDA with a list of the software on the device. They do not need to demonstrate that the software is free of vulnerabilities or backdoors.

Healthcare Data Feeds China's Military-Civil Fusion

Exfiltration of personal data and sensitive information through these backdoors also contributes to China's policy of military-civil fusion (MCF), which links the People's Liberation Army (PLA) with the private sector and educational institutions. The MCF strategy integrates civilian industry, higher education, and private-sector research with the military, all with the aim of developing an "intelligentized" force.²³ China has reportedly shown an interest in galvanizing its pharmaceutical and biotechnology innovations to modify soldiers' genetics, making them stronger and more resilient.²⁴ China needs vast volumes of healthcare data to execute this strategy.

A widely known case of joint MCF development and genetic data theft concerns BGI Group, formerly Beijing Genomics Institute. According to Reuters, BGI group "store[d] and re-analyze[d] leftover blood samples" from prenatal tests, developed with the Chinese military, that determine fetal abnormalities.²⁵ Sold in 52 countries and taken by 8 million women globally, the tests collected genetic data from the mother, including country-of-origin and other anthropometric data such as height and weight.²⁶

BGI's policy indicates that its genomic data can be shared when "directly relevant to [China's] national security or national defence security."²⁷ Reuters found that BGI's work with the PLA began as early as 2010, later collaborating in 2019-2020 to expand the list of genetic abnormalities screened for in the prenatal test.²⁸ In 2018, BGI used a military computer to access

²² Food and Drug Administration, Corporate Filing, "Premarket Notification; Section 510(k) Submission; Section II 510(k) Summary," Entity Number 3006979678, accessed October 9, 2025.

(https://www.accessdata.fda.gov/cdrh_docs/pdf10/K101692.pdf)

²³ Craig Singleton, "Biotech Battlefield: Weaponizing Innovation in the Age of Genomics," *Foundation for Defense of Democracies*, January 15, 2025. (<https://www.fdd.org/analysis/2025/01/15/biotech-battlefield/>); Maj. Jonathon Lee, "The Role of Military-Civil Fusion in PLA Strategy: How China's Military-Civil Fusion Strategy Supports PLA Modernization and Enhances Operational Capabilities," *Marine Corps University Press, China Military Studies Review*, September 3, 2025. (<https://www.usmcu.edu/Outreach/Marine-Corps-University-Press/China-Military-Studies-Review/CMSR-2025-Role-of-Military-Civil-Fusion>)

²⁴ Stephen Chen, "Chinese Team Behind Extreme Animal Gene Experiment Says It May Lead to Super Soldiers Who Survive Nuclear Fallout," *South China Morning Post* (China), March 29, 2023. (<https://www.scmp.com/news/china/science/article/3215286/chinese-team-behind-extreme-animal-gene-experiment-says-it-may-lead-super-soldiers-who-survive>)

²⁵ Kirsty Needham and Clare Baldwin, "China's gene giant harvests data from millions of women," *Reuters*, July 7, 2021. (<https://www.reuters.com/investigates/special-report/health-china-bgi-dna>)

²⁶ Ibid.

²⁷ Kirsty Needham and Clare Baldwin, "EXCLUSIVE: Prenatal test developed with Chinese military stores gene data," *Reuters*, July 7, 2021. (<https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-prenatal-test-developed-with-chinese-military-stores-gene-data-2021-07-07>)

²⁸ Ibid.

the test data, using it to genetically identify Tibetan and Uyghur minorities and test for compromised health in Chinese women.²⁹

In 2021, lawmakers warned of BGI's sizable collection of genetic data and that it could be used to further China's military and economic development. The risk remains.

As China increasingly prepares dual-use capabilities that it could use to produce a biological weapons program, or more likely spark an accidental pandemic, the CCP's pattern of leverage will pose a dramatic risk to U.S. national security.

Conclusion

Doctors, nurses, physician assistants, and other medical professionals must be able to trust the technology that has enabled them to provide the best healthcare in the world. The ramifications of improper oversight of Chinese medical technology imports could be life-threatening.

China's infiltration of the U.S. healthcare system poses a long-standing and continuously growing threat to U.S. national security, introducing vulnerabilities into the medical device supply chain, bolstering China's military development, and putting American lives at risk. BIS's timely investigation into the national security implications of imports of PPE, medical consumables, and medical equipment, including devices, will illuminate the scope of the threat and provide avenues for remediation to protect the United States and its citizenry.

²⁹ Ibid.