

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
MINORITY (202) 225-5051
<https://oversight.house.gov>

May 6, 2024

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Califf:

The Committee on Oversight and Accountability (Committee) is investigating Chinese Communist Party (CCP) economic warfare against America—specifically, its control over global pharmaceutical and tobacco product supply chains and the impact of that control on the health and well-being of Americans and our national security. The U.S. Food and Drug Administration (FDA) has a duty to identify and help address the People’s Republic of China’s (PRC) efforts to further dominate the pharmaceutical market and monopolize data collection¹ to the detriment of Americans. The PRC’s strict national security laws require companies associated with the PRC or CCP to share data with the Chinese government,² creating significant risks for American consumers. As the People’s Liberation Army (PLA) becomes more ingrained in the biotechnology sector, it becomes increasingly clear that the CCP seeks to weaponize genomic and medical data and use strategies like its united front work to selectively export drugs and medical supplies.³

Broader Committee Investigation

The Committee is conducting oversight of the federal government’s work to protect the American people from CCP “political warfare”⁴ and nefarious influence operations. For

¹ U. S. Trade Rep., *Findings of the Investigations into China’s Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act of 1974*, at 41 (Mar. 22, 2018).

² Wenxin Fan, *China detains Japanese employee from drugmaker Astellas*, *The Wall St. J.* (Mar. 27, 2023).

³ Alex Joske, *The party speaks for you: Foreign interference and the Chinese Communist Party’s united front system*, at 4 (Jun. 9, 2020).

⁴ “Political warfare seeks to influence emotions, motives, objective reasoning, and behavior of foreign governments, organizations, groups, and individuals in a manner favorable to one’s own political-military objectives.” Mark Stokes, *The People’s Liberation Army General Political Department: Political Warfare with Chinese Characteristics*, Project 2049 Inst. (Oct. 14, 2013).

decades, the CCP has sought to infiltrate and influence every aspect of American society.⁵ The CCP's goal is plain: defeat the "main enemy," which counterintelligence officials have identified as America.⁶ The fronts are multiple; according to the CCP itself: "[t]he battlefield will be everywhere."⁷ And the tools are myriad, with the "united front"⁸ leading as one of the PRC's⁹ "magic weapons,"¹⁰ as described by General Secretary Xi Jinping,¹¹ to advance the Party's aim of global domination.¹² United front work (UFW), which may be executed by the United Front Work Department (UFW) or elsewhere in the Party, is a "unique blend of engagement, influence activities, and intelligence operations" that the CCP uses to "influence other countries' policy toward the PRC and to gain access to advanced foreign technology."¹³ UFW "generally involves covert activity and is a form of interference that aids the CCP's rise."¹⁴ United front "networks" are used "to carry out relationship-focused influence campaigns through a multitude of proxies."¹⁵

Despite years of false promises to the West, the CCP openly seeks to achieve its destructive ambition. In 1999, two PLA Air Force colonels authored *Unrestricted Warfare*, which has been described as a strategic military vision for the PRC to defeat America through political warfare.¹⁶ Retired Brig. Gen. Robert Spalding, who has served in senior positions in strategy and diplomacy with the U.S. Departments of Defense and State for decades, characterizes the book as "the main blueprint for China's efforts to unseat America as the world's economy, political, and ideological leader," which "shows exactly how a totalitarian nation set out to dominate the West through a comprehensive, long-term strategy that includes everything from corporate sabotage to cyberwarfare to dishonest diplomacy; from violations of

⁵ See generally Constantine C. Menges, *China The Gathering Threat* (2005); H.R. Rep. No. 105-851 (1999) ("Cox Report"); Robert Spalding, *War Without Rules* (2022); Col. Grant Newsham, *When China Attacks: A Warning to America* (2023); Kerry K. Gershaneck, *Political Warfare: Strategies for Combating China's Plan to "Win without Fighting"* (2020); see also Larry Diamond & Orville Schell, *China's Influence & America's Interests: Promoting Constructive Vigilance*, Hoover Inst. (2019).

⁶ Menges, *supra* note 5; Gershaneck, *supra* note 5 ("The PRC is engaged in war against the United States. It is not mere competition or malign influence, but war by PRC definition."); Newsham, *supra* note 5, at 60 (The CCP "seeks global domination" and "will fight its main enemy, the United States, to achieve it").

⁷ Qiao Liang & Wang Xiangsu, *Unrestricted Warfare: China's Master Plan to Destroy America* (PLA Lit. & Arts Pub. House 1999) (China) (military colonels describing twenty-four varieties of warfare).

⁸ "While the CCP's United Front Work Department has functional responsibility for these [warfare] operations and activities, PRC united front work is a task of all CCP agencies and members." Gershaneck, *supra* note 5, at 22.

⁹ It is essential to understand that Xi Jinping has removed any "veneer of separation between the [CCP] and the Chinese state." Gershaneck, *supra* note 5, at 43 (quoting Ann-Marie Brady, *Exploit Every Rift: United Front Work Goes Global*, in David Gitter et al., *Party Watch Annual Report*, Ctr. for Adv. China Res. (2018)).

¹⁰ Ann-Marie Brady, *Magic Weapons: China's political influence activities under Xi Jinping*, Wilson Ctr. (Sept. 18, 2017); see also Sel. Comm. on the Chinese Communist Party, *Memorandum: United Front 101*, at 7 ("United Front 101 Memo").

¹¹ Alex Joske, *supra* note 3 (quoting Xi Jinping at 2015 Central United Front Work Meeting).

¹² See, e.g., Newsham, *supra* note 5, at 43 ("The People's Republic of China may settle for dominance rather than occupation, but it does indeed aim to rule us all.").

¹³ United Front 101 Memo, *supra* note 10, at 1.

¹⁴ Alex Joske, *supra* note 3, at 19.

¹⁵ Alex Joske, *Spies and Lies: How China's Greatest Covert Operations Fooled the World*, at 63 (2022).

¹⁶ Gershaneck, *supra* note 5.

international trade law and intellectual property law to calculated abuses of the global financial system.”¹⁷ Kerry Gershaneck, former counterintelligence officer who wrote a seminal book on combatting PRC Political Warfare, has explained that *Unrestricted Warfare* details CCP use of “any methods” where “the boundaries between war and non-war and between military and non-military affairs [have] systemically broken down.”¹⁸ To successfully combat these highly organized and pervasive warfares spawned by China, federal agencies must first recognize and understand them.

The CCP “know[s] the strength of the American people, of the American idea, and that’s why China has launched so many warfares to try to weaken us, divide us, and get us to hate ourselves and each other.”¹⁹ Retired Col. Grant Newsham, former U.S. Marine Liaison Officer to the Japan Ground Self-Defense Force and U.S. Foreign Service Officer, has advised that “the way out of this is to rediscover why we are an exceptional country, get to know each other better, and fight side by side.”²⁰

As all Americans are targets of the PRC’s warfare,²¹ federal agencies have responsibilities to (1) conduct outreach to citizens about the dangers they may encounter, and (2) provide appropriate incentives for Americans to proactively protect themselves—their communities, schools, houses of worship, businesses, finances, food, and more—from the threat. Federal agencies must prepare Americans to “take action.”²² To stop the CCP’s “destructive actions,” retired Brig. Gen. Spalding advises that it will “take macrolevel strategic changes by our government, but also microlevel actions by individuals, businesses and other civic institutions.”²³ The Committee is surveying each agency’s role to secure Americans and their communities.

Congress has recognized the threat posed by the PRC for some time. Notably, in 1999, the U.S. House Select Committee on U.S. National Security and Military/Commercial Concerns with the People’s Republic of China concluded that in the preceding decade, the PRC used a

¹⁷ Spalding, *War Without Rules*, *supra* note 5, at xii; *see also* Robert Spalding, *Stealth War*, at 12-13 (2019) (*Unrestricted Warfare* “should be required reading for all branches of the US government and for business leaders, because it outlines, in no uncertain terms, the strategy behind China’s policies,” including stating that the “new principles of war” are “no longer ‘using armed force to compel the enemy to submit to one’s will,’ but rather are ‘using all means, including armed force or non-armed force, military and non-military, and lethal and non-lethal means to compel the enemy to accept one’s interests.’”).

¹⁸ Gershaneck, *supra* note 5, at 16 (quoting Qiao Liang & Wang Xiangsu, *supra* note 7, at 6-7).

¹⁹ Newsham, *supra* note 5, at 341.

²⁰ *Id.*

²¹ “The Three Warfares, the traditional foundation of PRC political warfare, include public opinion/media warfare, psychological warfare, and legal warfare.” Gershaneck, *supra* note 5. It “requires efforts to unify military and civilian thinking, divide the enemy into factions, weaken the enemy’s combat power, and organize legal offensives.” Elsa Kania, *China Brief: The PLA’s Latest Strategic Thinking on the Three Warfares*, Jamestown Found. (Aug. 22, 2016).

²² Spalding, *War Without Rules*, *supra* note 5, at 214.

²³ *Id.*; *see also* Peter Mattis & Matt Schrader, *America Can’t Beat Beijing’s Tech Theft With Racial Profiling*, War on the Rocks (July 23, 2019) (“The U.S. government’s difficulties in telling a convincing story about the Chinese Communist Party point to a[n] important step: addressing a serious lack of ‘China literacy,’ both within the enforcement portions of the federal bureaucracy, and in U.S. society as a whole.”).

“variety of techniques including espionage, controlled commercial entities, and a network of individuals that engage in contact with scientists, business people and academics” as part of its warfare operations.²⁴

With varying degrees of effort and success, federal agencies have sought to address the CCP’s attack on what Col. Newsham has aptly described as “[t]he core of America.”²⁵ However, the threat is grave and work must be done across agencies to protect America.²⁶ Peter Mattis, former staff director of the Congressional-Executive Commission of China and counterintelligence analyst at the CIA counsels that

Only by being clear in public about the actions and intentions of the Chinese party-state, and being publicly accountable for the actions the U.S. government takes in response, will the United States be able to address Beijing’s challenges while upholding our democratic commitment to fair, transparent justice for all Americans.²⁷

To this end, the Committee is conducting this investigation and implores each federal agency to uphold its duty to the American communities for whom they are responsible.

CCP Supply Chain Warfare Via Military-Civil Fusion In Manufacturing & Data

The FDA’s purview in the PRC is wide-ranging. The PRC is a dominant manufacturer of active pharmaceutical ingredients (API) and finished drugs that are imported into the U.S.²⁸ Due to this significant market share, the U.S. depends on the PRC to maintain a steady supply of pharmaceuticals and medical devices.²⁹ Sometimes these products go into shortage due to quality-control issues or trade barriers.³⁰ The FDA has an office in China to coordinate its relationship with these manufacturers and monitor inspection protocols on the ground.³¹ However, the FDA’s monitoring in the PRC has not been compliant with regulatory requirements for some time, even prior to the COVID-19 pandemic.³²

²⁴ Cox Report, *supra* note 5, at xxxiii; *see generally* Menges, *supra* note 5.

²⁵ Newsham, *supra* note 5, at 33.

²⁶ *See* Newsham, *supra* note 5, at 309 (“We need to know, value, protect and build the strengths of the United States of America, and shed the light of truth on the corruption, in every sense of the word,” of the CCP. “That could mean in discussions with family, community, at school or wherever that understanding needs bolstering.” Education courses on PRC political warfare would benefit “[a]ny decision-makers who work with China.”); *see* Gershaneck, *supra* note 5, at 153 (outlining such courses to “build[] internal defenses”).

²⁷ Mattis & Schrader, *supra* note 23.

²⁸ U.S. Food and Drug Admin., China Office, *available at* <https://www.fda.gov/about-fda/office-global-operations/china-office>.

²⁹ *Id.*

³⁰ U.S. Food and Drug Admin., Drug shortages: Root cause and potential solutions, 6 (2019); Doug Palmer and Finbarr Birmingham, *U.S. policymakers worry about China ‘weaponizing’ drug exports*, Politico (Dec. 20, 2019).

³¹ U.S. Food and Drug Admin. China Office, *supra* note 28.

³² Joanne S. Eglavitch, *Unannounced FDA inspections have started in India, not China*, Regulatory Affairs Professionals Society (Apr. 7, 2022).

As part of the CCP's economic warfare, the PRC State Council's "Made in China 2025" initiative targets domestic innovation in biopharmaceutical and high-tech medical devices as a priority for centralizing PRC domestic manufacturing.³³ Additionally, the PRC's Ministry of Science and Technology (MOST) is prioritizing pharmaceutical innovation and development as a "megaproject" to reduce reliance on foreign intellectual property and empower state-owned enterprises to dominate key science and technology sectors.³⁴ In order to consolidate the market, the PRC is taking a number of steps to strengthen the CCP's role in the global economy.³⁵ These include military-civil fusion, central economic planning, technological advancement, and investment in PLA-affiliated and CCP-owned enterprises to develop domestic products.³⁶

The CCP is increasingly moving towards military-civil fusion by merging the military and pharmaceutical technology sectors.³⁷ The goal of this fusion is to advance military ends using civil sectors.³⁸ The PLA is affiliated with medical firms, like the Beijing Genomics Institute (BGI), that collect medical data and allow full access to the PRC government and its entities.³⁹ BGI is on the Department of Defense 1260H list of PRC military companies which applies to entities "directly or indirectly owned, controlled, or beneficially owned by" the PLA or any subordinate PLA military organization.⁴⁰ The PRC has collected and digitized medical and genomic data to become the information hub for any pharmaceutical company that wants to access this data to conduct medical research via artificial intelligence algorithms.⁴¹

An alarming example of PLA-backed medical data collection was the worldwide sale of prenatal tests, branded NIFTY (Non-Invasive Fetal Trisomy) by BGI.⁴² These tests, although not sold in the U.S., were used by more than 8 million women to collect genetic and personal information.⁴³ Alarming, a PLA-backed medical data collection company, WuXi STA, a subsidiary of WuXi AppTec, is currently building a \$500 million drug manufacturing facility in

³³ James McBride & Andrew Chatzky, *Is 'Made in China 2025' a threat to global trade?* Council on Foreign Relations (May 13, 2019); *Pharmacy of the world: China's quest to be the No. 1 drugmaker*, Nikkei Asia (Dec. 23, 2021).

³⁴ James McGregor, U.S. Chamber of Com., *China's Drive For 'Indigenous Innovation': A Web Of Indus. Policies*, 40-42 (2010); S. Comm. on Homeland Sec. and Gov't Affairs, Permanent Subcomm. on Investigations, *Threats to the U. S. Research. Enterprise: China's Talent Recruitment Plans*, 17 (Nov. 2019).

³⁵ U. S. Trade Rep., *supra* note 1.

³⁶ *Id.*

³⁷ Elsa B. Kania, *In military-civil fusion, China is learning lessons from the United States and starting to innovate*, The Strategy Bridge (Aug. 27, 2019).

³⁸ U. S. Dep't of State, *Military-Civil Fusion and the People's Republic of China*, available at <https://www.state.gov/wp-content/uploads/2020/05/What-is-MCF-One-Pager.pdf>.

³⁹ Joby Warrick & Cate Brown, *China's quest for human genetic data spurs fears of a DNA arms race*, Wash. Post (Oct. 19, 2023).

⁴⁰ William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, § 1260H, 134 Stat. 3965 (Jan. 1, 2021).

⁴¹ Daniel P. Goldman, "China's Grand Strategy" (lecture at The Claremont Inst. on Mar. 2, 2021), available at https://www.youtube.com/watch?v=Cg4WboRlmZc&ab_channel=ClaremontInstitute.

⁴² Kristy Needham & Clare Baldwin, *China's gene giant harvests data from millions of women*, Reuters (Jul. 7, 2021).

⁴³ *Id.*

Middletown, Delaware.⁴⁴ WuXi Group companies, including Wuxi AppTec and Wuxi Biologics, have close ties to the CCP and PLA and have received investments from PLA investment funds.⁴⁵ According to media reports, U.S. intelligence officials reported in late February 2024 that WuXi AppTec transferred a U.S. client's intellectual property to the PRC without consent.⁴⁶

To accelerate domestic innovation and manufacturing to meet its domestic goals, the PRC calls for borrowing from “imported technologies,” investing in “re-innovation,” and developing “original” innovation in key advanced manufacturing and technology sectors.⁴⁷ The PRC is seizing U.S. intellectual property in many ways, including via collaborative research with American scientists,⁴⁸ corporate espionage and cyberattacks,⁴⁹ and forced disclosures from manufacturing facilities operating in China.⁵⁰ Genomic data companies like BGI are required to share data with the PRC under strict national security laws.⁵¹ The National Counterintelligence and Security Center warns that the CCP's trajectory will lead to PRC owned and operated pharmaceutical firms overtaking U.S. firms, resulting in more U.S. dependency on the PRC and boosting the PRC economy with better business opportunities in the biotechnology sector.⁵²

The PLA has been successful in military-civil fusion of the technology sector for critical response projects like Ebola, SARS, and COVID-19.⁵³ The extent of this fusion is evident in the PRC's ability to conduct the earliest COVID-19 vaccine clinical trials in its Academy of Military Medical Sciences.⁵⁴ China's global marketing of COVID-19 tests gave the PRC access to

⁴⁴ WuXi STA's pharmaceutical manufacturing campus, Delaware, USA (Aug. 25, 2022), *available at* <https://www.pharmaceutical-technology.com/projects/wuxi-sta-manufacturing-campus-delaware/>; Michael McCoy, *House bill targets some Chinese outsourcing firms*, Chem. and Eng'g News (Jan. 31, 2024).

⁴⁵ Letter from Hon. Mike Gallagher et al., Chairman, Sel. Comm. on the Chinese Communist Party, to Hon. Gina Raimondo et al., Sec'y, U.S. Dep't of Com. (Feb. 12, 2024); *See also* James Mulvenon, *The WuXi Group: The National Security Risks Associated with its Government and Military Connections, Data Privacy Issues, and Corporate Reach* (Apr. 2024) (detailing WuXi Group's significant ties with the CCP and PLA).

⁴⁶ Michael Martina et al., *Exclusive: China's WuXi AppTec shared US client's data with Beijing, US intelligence officials told senators*, Reuters (Mar. 28, 2024).

⁴⁷ The State Council, The People's Republic of China, *The National Medium-and Long-Term Program for Science and Technology Development (2006-2020): An Outline*, *available at* https://www.itu.int/en/ITU-D/Cybersecurity/Documents/National_Strategies_Repository/China_2006.pdf; McGregor, *supra* note 34, at 15.

⁴⁸ *See* S. Comm. on Homeland Security and Governmental Affairs, *supra* note 34, at 20 (The PRC's “Thousand Talents” recruitment plan specifically targeted American researchers to facilitate “technology transfer”); *see also* Ellen Barry & Gina Kolata, *China's lavish funds lured U.S. scientists. What did it get in return?*, N. Y. Times (Feb. 7, 2020).

⁴⁹ Scott Pelley et al., *Global intelligence leaders warn against China's technology theft*, CBS News (Oct. 22, 2023).

⁵⁰ *Id.*

⁵¹ Off. of the Dir. of Nat'l Intel., Nat'l Counterintelligence and Sec. Ctr., *China's Collection of Genomic and Other Healthcare Data from America: Risks to Privacy and U.S. Economic and National Security*, 4 (Feb. 2021).

⁵² *Id.*

⁵³ *Pharmacy of the world: China's quest to be the No. 1 drugmaker*, Nikkei Asia (Dec. 23, 2021); Dyani Lewis, *China's coronavirus vaccine shows military's growing role in medical research*, Nature (Sept. 11, 2020); Christian Shepherd & Wang Xueqiao, *China's military takes centre stage in Covid-19 vaccine race*, Fin. Times (Aug. 10, 2020).

⁵⁴ *Id.* at Shepherd & Xueqiao.

worldwide healthcare data.⁵⁵ In recent years, the PLA has been scaling up its military-medical partnership by hiring civilian medical researchers.⁵⁶

During routine inspections, FDA inspectors must access manufacturing company records in accordance with due diligence and quality assurance regulations.⁵⁷ Under the PRC's amended Counter-Espionage Law,⁵⁸ drug manufacturing inspectors may be arrested for accessing CCP-owned drug companies' records if the PRC deems such access to constitute foreign access to "documents, data, materials, or items related to national security."⁵⁹ Recently, the PRC used this "law" to detain an employee of Japanese pharmaceutical company Astellas Pharma Inc., under suspicion of espionage, during a routine drug manufacturing site visit in China.⁶⁰ It is critical that the FDA do everything in its power to counter PRC influence in the American pharmaceutical market, and take necessary steps to protect its employees subject to Counter-Espionage laws and tasked with conducting important inspections for Americans.

CCP Ambition to Dominate the Global Pharmaceutical Market

CCP economic warfare targets the global pharmaceutical and medical device markets in an effort to solidify the PRC's position as the world's foremost manufacturing source and leverage the world's reliance on certain commodities to garner more power.⁶¹ The PRC's control of manufacturing and the U.S.'s dependence on the PRC for life-saving pharmaceuticals presents a critical threat to national security.⁶² The PRC is the third largest exporter of pharmaceuticals and foremost exporter of medical devices to the U.S.⁶³ Since the onset of the COVID-19 pandemic, U.S. imports of Chinese pharmaceuticals have increased from \$2.1 billion in 2020 to \$6 billion in 2023.⁶⁴ These statistics are alarming, and demonstrate that PRC warfare against our supply chains reveals serious economic and societal vulnerabilities.

The PRC has successfully gained a dominant global market share in generic antibiotics.⁶⁵ The U.S. market's capability to produce generic drugs—constituting 91 percent of prescriptions filled in the U.S.—is diminishing as generic drug production moves offshore to the PRC due to

⁵⁵ Off. of the Dir. of Nat'l Intel., *supra* note 51, at 2.

⁵⁶ Shepherd & Xueqiao, *supra* note 53.

⁵⁷ 21 U.S.C. § 374

⁵⁸ Chun Han Wong & Dan Strumpf, *China spy law adds to chilling effect of detentions*, Wall St. J. (Apr. 27, 2023).

⁵⁹ Nathaniel Taplin, *Beijing's Bain raid, espionage laws are self-sabotage*, Wall St. J. (Apr. 28, 2023).

⁶⁰ Fan, *supra* note 2.

⁶¹ McGregor, *supra* note 34, at 40–42; S. Comm. on Homeland Sec. and Gov't Affairs, *supra* note 34.

⁶² Sel. Comm. on the Chinese Communist Party, *Reset, Prevent, Build: A Strategy to Win America's Economic Competition with the Chinese Communist Party*, 23 (Dec. 12, 2023); Ana Swanson, *Coronavirus spurs U.S. efforts to end China's chokehold on drugs*, N. Y. Times (Mar. 11, 2020).

⁶³ U.S. Food and Drug Admin. China Office, *supra* note 28.

⁶⁴ U.S. Int'l Trade Comm'n, Gen. Imports Customs Value for Year 2023 - China, *available at* dataweb.usitc.gov.

⁶⁵ *Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products: Hearing Before the U.S.-China Economic and Security Review Commission* (Jul. 31, 2019)(Testimony of Rosemary Gibson, Senior Advisor, The Hastings Center).

slim profit margins.⁶⁶ The PRC has a competitive production advantage due to the low cost of raw production materials, large production-scale, and lax environmental regulations.⁶⁷ As the U.S. market share decreases, pharmaceutical manufacturing is at risk of being weaponized by the CCP, which has the power to limit exports at any time.⁶⁸ Li Daokui, a Chinese economist and former adviser to the People's Bank of China, has advocated withholding antibiotics and APIs from the U.S. as a retaliatory tactic in the ongoing trade war.⁶⁹ Intentional export bans would seriously harm the millions of Americans who rely on PRC-made medications and medical devices.⁷⁰

The FDA is responsible for ensuring imported pharmaceuticals and medical devices meet federal regulatory standards.⁷¹ In 2008, the FDA opened an office in Beijing in response to quality control concerns with Chinese products⁷² and to provide better engagement with inspection efforts in the PRC.⁷³ Notably, since then, the number of PRC manufacturers registered with the FDA has more than doubled.⁷⁴ Despite the FDA's presence in the PRC, FDA enforcement reports indicate a sharp increase in quality-related product recalls from 2018 to 2022.⁷⁵ During congressional testimony, then-FDA Deputy Commissioner Janet Woodcock stated, "we do not know whether Chinese facilities are actually producing APIs, how much they are producing, or where the APIs they are producing are being distributed worldwide, including in the United States."⁷⁶ Unfortunately, attempts to reduce reliance on the PRC by sourcing finished drugs from India do not account for the fact that the entire pharmaceutical supply chain is heavily integrated with the PRC.⁷⁷ According to the government of India, 68 percent of its

⁶⁶ *Id.*; U.S. Food and Drug Admin., Office of Generic Drugs 2022 Annual Report, 1 (Jan. 2023).

⁶⁷ *The great medicines migration: How China took control of key global pharmaceutical supplies*, Nikkei Asia (Apr. 5, 2022).

⁶⁸ Palmer & Bermingham, *supra* note 30.

⁶⁹ *Id.*

⁷⁰ Sel. Comm. on the Chinese Communist Party, *supra* note 62, at 48; Karen M. Sutter et al., Cong. Research Serv., R46304, COVID-19: China medical supply chains and broader trade issues, at 12-13 (Dec. 23, 2020); U.S. Department of Defense Office of Inspector General, DODIG-2021-126, Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain, at 1 (Sept. 20, 2021).

⁷¹ U.S. Food and Drug Admin., Importing FDA Regulated Products (Nov. 22, 2023), *available at* <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/importing-fda-regulated-products>.

⁷² Andrew Jacobs & Mark McDonald, *F.D.A. opens office in Beijing to screen food and drug exports*, N. Y. Times (Nov. 19, 2008).

⁷³ U.S. Food and Drug Admin. China Office, *supra* note 28.

⁷⁴ *Safeguarding Pharmaceutical Supply Chains in a Global Economy, Hearing Before the Subcomm. on Health, Comm. on Energy and Com.*, 116th Cong. 7 (Oct. 30, 2019) (statement of Dr. Janet Woodcock, Dir., U.S. Food and Drug Admin., Center for Drug Evaluation and Rsch.).

⁷⁵ Anna Edney & Riley Griffin, *The Pentagon wants to root out shoddy drugs. The FDA is in its way.*, Bloomberg (Dec. 5, 2023).

⁷⁶ Woodcock, *supra* note 74.

⁷⁷ Edney & Griffin, *supra* note 75.

API imports are from China.⁷⁸ Other accounts place India's dependence on China for API for antibiotics at 90 percent.⁷⁹

The opaqueness of the PRC's manufacturing quality and unfair trade practices provide inadequate transparency about pharmaceuticals frequently imported to the U.S.⁸⁰ Drugs manufactured in China have a history of contamination and excessive additives.⁸¹ This is partially because there is less visibility into the drug and device supply chain.⁸² As a result, quality issues increase shortages and contamination risk.⁸³ Recent events expose the vulnerabilities in the nation's drug supply chain and the FDA's ability to adequately monitor the safety and quality of foreign manufacturing with deadly consequences.⁸⁴ For example, counterfeit plastic syringes labeled with U.S. brand names but manufactured in the PRC were recently recalled due to quality and safety concerns.⁸⁵ In 2008, adulterated heparin, a common blood thinner, imported from the PRC caused 246 deaths in the U.S.⁸⁶ Despite acknowledging the FDA's information gaps in the PRC,⁸⁷ the FDA does not maintain adequate staffing to monitor the growing number of facilities in the PRC that are producing APIs and finished drugs that are exported to the U.S.⁸⁸

In addition to manufacturing, drugs developed in the PRC may be compromised due to outdated study designs and data integrity problems, posing serious risks to American consumers.⁸⁹ Recent drug shortages have increased America's reliance on foreign sources of finished drugs. At the time of this letter, the American Society of Health-System Pharmacists lists 255 drugs currently in shortage on its drug shortage database.⁹⁰ The cancer drug shortage has become so severe that the FDA temporarily authorized the importation of a common cancer drug, cisplatin, from a Chinese manufacturer.⁹¹

⁷⁸ Gov't of India, Press Info. Bureau, Ministry of Science and Technology: TIFAC releases report on 'Active pharmaceutical ingredients – status, issues, technology readiness and challenges' (Jul. 15, 2020), *available at* <https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=1638810>;

⁷⁹ Ravi Buddhavarapu, *India wants to be the 'pharmacy of the world.' But first, it must wean itself from China*, CNBC (May 26, 2022).

⁸⁰ S. Comm. on Homeland Security and Governmental Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages*, Maj. Staff Report, 118th Cong., 21-24 (Mar. 2023).

⁸¹ Maggie Fox, *FDA recalls are a reminder that China controls much of the world's drug supply*, NBC News (Aug. 14, 2018).

⁸² U.S. Food and Drug Admin. Drug Shortage Report, *supra* note 30, at 6, 44.

⁸³ *Id.*

⁸⁴ See generally Fox, *supra* note 81; Didi Martinez et al., *Tainted drugs: Ex-FDA inspector warns of dangers in U.S. meds made in China, India*, NBC News (May 10, 2019).

⁸⁵ U.S. Food and Drug Admin., *Do not use certain Cardinal Health Monoject Luer-Lock and Enteral Syringes – FDA Safety Communication* (Feb. 2, 2024).

⁸⁶ DODIG-2021-126, *supra* note 70, at 2.

⁸⁷ Woodcock, *supra* note 74.

⁸⁸ Palmer & Birmingham, *supra* note 30.

⁸⁹ Peter Loftus, *FDA raises concerns about China-developed drugs*, Wall St. J. (Feb. 9, 2022).

⁹⁰ Am. Soc'y of Health-Sys. Pharmacists, *Drug Shortage List*, *available at* <https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages> (last accessed May 2, 2024).

⁹¹ Joseph Choi, *FDA to import more Chinese cancer drugs amid shortage*, The Hill (Jul. 10, 2023).

At the onset of the COVID-19 pandemic, the PRC nationalized its production and control of medical supplies to retain crucial materials for medical products amid rapid demand.⁹² Simultaneously, the FDA postponed in-person inspections due to social distancing and isolation protocols.⁹³ This quickly led to supply chain shortages for these materials in the U.S. and exposed America's reliance on the PRC to maintain the medical product supply chain.⁹⁴ The CCP's united front propaganda efforts were utilized by the PRC to influence not only the global supply chain of medical supplies by selectively releasing medical products, but also to encourage a positive, altruistic vision of the CCP.⁹⁵

On the Ground in China

As we have previously written, the Committee is increasingly concerned with critical drug shortages and the FDA's failure to regulate the importation of foreign API and finished drugs.⁹⁶ Despite increasing reliance on the PRC for pharmaceutical and medical products, the FDA is not fulfilling its obligation to inspect foreign manufacturers.⁹⁷ There is a backlog of mandatory inspections of foreign companies that have either never been inspected or have not been inspected in the last five years.⁹⁸ Foreign drug manufacturing inspections remained 79 percent lower in 2022 compared to 2019.⁹⁹ Despite the Chinese economy reopening post-COVID-19, Chinese manufacturers received fewer inspections through 2023.¹⁰⁰ During COVID-19 travel restrictions, investigators in the FDA Office of Global Policy and Strategy's China Office (FDA China Office) conducted the majority of FDA inspections in the PRC.¹⁰¹ After in-person inspections by FDA investigators were restored, the FDA continued to provide advanced notice for inspections in the PRC, despite not doing the same in India, giving manufacturers the opportunity to hastily cover up improper practices prior to investigators appearing on the premises.¹⁰²

⁹² Sutter et al., *supra* note 70, at 15.

⁹³ U. S. Gov't Accountability Off., GAO-22-103611, Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program (Jan. 2022).

⁹⁴ *Id.*

⁹⁵ Alex Joske, *supra* note 3, at 4.

⁹⁶ Letter from Hon. James Comer, Chairman, H. Comm. on Oversight and Accountability and Hon. Lisa McClain, Chairwoman, Subcomm. on Health Care and Fin. Servs. to Hon. Robert M. Califf, Comm'r, U. S. Food and Drug Admin. (Nov. 2, 2023).

⁹⁷ Irena Hwang, *After pandemic delays, FDA still struggling to inspect foreign drug manufacturers*, ProPublica (Apr. 19, 2023); U. S. Gov't Accountability Off., GAO-24-107359, Drug safety: FDA has failed persistent challenges overseeing foreign drug manufacturing, 3 (Feb. 6, 2024).

⁹⁸ *Id.* at GAO-24-107359.

⁹⁹ Emily Cuddy et al., *FDA global drug inspections: Surveillance of manufacturing establishments remains well below pre-COVID-19 levels*, Health Affairs (Dec. 2023).

¹⁰⁰ *Id.*

¹⁰¹ GAO-22-103611, *supra* note 93, at 35.

¹⁰² GAO-24-107359, *supra* note 98, at 3; Egllovitch, *supra* note 32.

The FDA’s inability to inspect foreign manufacturing sites existed prior to the COVID-19 pandemic.¹⁰³ While the COVID-19 pandemic contributed to a drop in foreign manufacturing due to public health restrictions, the FDA’s capacity to adequately inspect Chinese manufacturers was compromised well prior to the pandemic.¹⁰⁴ Due to the grueling nature of foreign inspection trips, the FDA has difficulty retaining a fully-staffed inspection force.¹⁰⁵ In 2019, the FDA China Office was understaffed with 30 percent vacancy rates.¹⁰⁶

During the COVID-19 pandemic, emergency demand for personal protective equipment opened the door for non-FDA-approved Chinese-made products of unverified quality to flood the U.S. market.¹⁰⁷ The pandemic highlighted U.S. overreliance on the PRC for API and finished drugs, as well as the benefits of sourcing key medical ingredients from advanced U.S. domestic manufacturing.¹⁰⁸ The pandemic gave the CCP an opportunity to selectively export critical healthcare products of questionable quality and its increase market-share in the U.S.¹⁰⁹ The FDA has important responsibilities to protect the pharmaceutical and medical device supply chain from China, thus, safeguarding Americans from undue influence and the impacts of events, like a pandemic or trade war, on supply chains.

Illegal Tobacco Products

The Committee has ongoing concerns about the FDA’s inconsistent regulatory enforcement of nicotine products, such as disposable vapes, that are imported illegally from the PRC.¹¹⁰ While CCP economic warfare may have been visible during the pandemic, it persists in ways that affect American consumers engaging in everyday purchases of tobacco products. The FDA’s regulation of tobacco and nicotine products through its Center for Tobacco Products (CTP) has fostered uncertainty in the marketplace and has allowed unregulated products to proliferate.¹¹¹ CTP’s ineffectual regulation of the manufacturing, distribution, and marketing of tobacco products, including vapes and flavored electronic cigarettes, has allowed illicit and unregulated similar products from the PRC to infiltrate the U.S. market.¹¹²

¹⁰³ GAO-24-107359, *supra* note 98, at 3.

¹⁰⁴ Eglovitch, *supra* note 32.

¹⁰⁵ GAO-22-103611, *supra* note 93, at 33.

¹⁰⁶ U. S. Gov’t Accountability Off., GAO-20-626T, Drug Safety: COVID-19 Complicates Already Challenged FDA Foreign Inspection Program, 18 (Jun. 2, 2020).

¹⁰⁷ Vanessa Shaw-Dore et al., China office sees increase in use of misleading medical device registration “certificates” – points way to CDRH action (last updated Mar. 29, 2021), *available at* <https://www.fda.gov/international-programs/global-perspective/china-office-sees-increase-use-misleading-medical-device-registration-certificates-points-way-cdrh>.

¹⁰⁸ Sutter et al., *supra* note 70, at 29-30.

¹⁰⁹ *Id.* at 46-47.

¹¹⁰ Letter from Hon. James Comer, Chairman, H. Comm. on Oversight and Accountability to Hon. Robert M. Califf, Comm’r, U. S. Food and Drug Admin. (Mar. 28, 2023).

¹¹¹ *Id.*

¹¹² Aaron Kliegman, *Biden's FDA clears path for Chinese products to flood US tobacco, nicotine market*, Fox News (June 10, 2023); Christina Smith, *FDA Flavor Bans Create a Dangerous Black Market*, Citizens Against Government Waste (Jul. 13, 2023).

According to the *Associated Press*, thousands of unauthorized flavored electronic cigarettes “continue pouring into the country from China.”¹¹³ To that end, on December 14, 2023, the FDA announced the seizure of approximately 1.4 million unauthorized e-cigarettes worth \$18 million from the PRC, and many of which “were intentionally mislabeled as toys or shoes and listed with incorrect values” to evade customs detection.¹¹⁴ FDA has a “long history” of working with U.S. Customs and Border Protection (CBP) to “to protect the public from illegal or harmful products entering the U.S.”¹¹⁵ As the Committee brought to the FDA’s attention,¹¹⁶ both the Reagan-Udall Foundation (RUF) evaluation¹¹⁷ and a recent Department of Health and Human Services Office of Inspector General report highlight severe deficiencies in FDA’s enforcement capabilities.¹¹⁸

By failing to properly address enforcement of illegal and illicit products entering the U.S. from the PRC, the FDA demonstrates a failure to provide American consumers access to products “appropriate for the protection of public health”¹¹⁹ considering that unregulated PRC tobacco and flavored electronic cigarette products will endanger millions of Americans.¹²⁰ To date, and since the FDA began regulating tobacco and nicotine products,¹²¹ the FDA has denied at least one million flavored electronic cigarette applications.¹²² Coinciding with the FDA’s denial of U.S. manufacturer’s applications, the lack of a transparent regulatory system for their products has increased the risk of a black market with unsafe products developing with reports of illegal and illicit Chinese products finding their way to U.S. consumers.¹²³

Conclusion

It is critical that the FDA do everything in its power to counter undue CCP influence in Americans’ pharmaceutical, medical, and tobacco products. To assist the Committee in investigating this matter, we request a briefing from the FDA with Committee staff. Please

¹¹³ Matthew Perrone, *US seizes more illegal e-cigarettes, but thousands of new ones are launching*, A. P. (Dec. 30, 2023).

¹¹⁴ Nathaniel Weixel, *Federal agencies seize \$18M worth of illegal e-cigarettes from China*, The Hill (Dec. 14, 2023).

¹¹⁵ U.S. Food and Drug Admin., Press Release, *FDA and CBP bolster collaboration to protect public health and safety* (Apr. 4, 2019).

¹¹⁶ Comer, *supra* note 110.

¹¹⁷ Reagan-Udall Foundation, *Report: Operational Evaluation of Certain Components of FDA's Tobacco Program* (Dec. 2022).

¹¹⁸ U.S. Dep’t of Health and Human Servs., Off. of Inspector Gen., OEI-01-20-00241, *FDA’s Approach to Overseeing Online Tobacco Retailers Needs Improvement* (Dec. 2022)

¹¹⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 910(c)(2), 910(c)(4).

¹²⁰ Elizabeth Wright, *Moonshine Vaping Coming Soon to Your Neighborhood*, Citizens Against Government Waste (Feb. 7, 2020).

¹²¹ *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28973 (May 10, 2016) (codified at 21 C.F.R. pt. 1100, 1140, 1143).

¹²² *Wages and White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357 (5th Cir. 2024).

¹²³ Smith, *supra* note 112.

contact Committee staff as soon as possible, but no later than May 13, 2024. This briefing should address the following:

1. How the FDA strives to inspire and equip Americans to strengthen their communities, innovate, and create the technologies and phenomena that will secure a strong and prosperous future for our nation;
2. How FDA leadership ensures from the top down that all FDA employees are aware of CCP warfare and influence operations against America, and are equipped to address them wherever they arise;
3. How the FDA conducts outreach to the pharmaceutical and medical communities about the threat posed by the CCP and the PLA to U.S. intellectual property, genomic and medical information, data, technology, and national security;
4. How the FDA conducts outreach to the pharmaceutical and medical communities about the known quality risks to relying upon and importing PRC-sourced API, finished drugs, tobacco, and medical devices;
5. The FDA's efforts to train its employees and partners in the pharmaceutical and medical communities about the dangers of the CCP's destructive ambitions and the risks posed by collaboration with the PRC's pharmaceutical and medical sectors given the PRC's continuous theft of American intellectual property, data, and technology;
6. The FDA's efforts to train investigators assigned to complete inspections in the PRC and employees of the FDA China Office about the dangers of the CCP's destructive ambitions and the risks posed by their activities in the PRC given the PRC's counterespionage statutes criminalizing information gathering of "documents, data, or items related to national security"¹²⁴;
7. Measures in place to protect employees of the FDA China Office from influence operations or security threats;
8. The current justification for the FDA China Office;
9. Any FDA programs, processes, or mechanisms to incentivize the commercial sector to protect U.S. intellectual property and report CCP influence operations as well as intellectual property or trade secret theft by the CCP and its entities;
10. The FDA's efforts to effectively and consistently regulate tobacco and nicotine products to eliminate loopholes allowing for the importation of illegal and illicit Chinese products;

¹²⁴ *Id.*

The Hon. Robert M. Califf

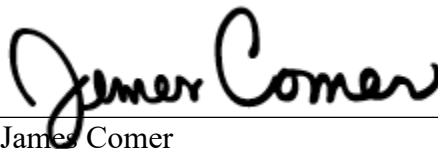
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11. How foreign inspection frequency fits into the FDA's latest annual budget request to Congress;
12. The FDA's efforts to clear the backlog of foreign inspections of pharmaceutical and medical manufacturing sites in the PRC; and
13. The FDA's efforts to bring foreign inspection frequency and protocols in line with domestic inspections, to ensure that foreign manufacturing meets the FDA's highest regulatory standards.

Please contact the Committee staff at (202) 225-5074 to schedule the staff briefing. The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you for your prompt attention to this important investigation.

Sincerely,

A handwritten signature in black ink that reads "James Comer". The signature is written in a cursive style with a horizontal line underneath it.

James Comer

Chairman

Committee on Oversight and Accountability

cc: The Honorable Jamie B. Raskin, Ranking Member
Committee on Oversight and Accountability