

**HEARING EXPLORING THE GROWING U.S. RELIANCE ON CHINA'S
BIOTECH AND PHARMACEUTICAL PRODUCTS**

HEARING
BEFORE THE
U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

ONE HUNDRED SIXTEENTH CONGRESS
FIRST SESSION

WEDNESDAY, JULY 31, 2019

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UNITED STATES-CHINA ECONOMIC AND SECURITY REVIEW
COMMISSION

WASHINGTON: 2019

August 7, 2019

The Honorable Chuck Grassley
President Pro Tempore of the Senate, Washington, DC 20510
The Honorable Nancy Pelosi
Speaker of the House of Representatives, Washington, DC 20515

Dear Senator Grassley and Speaker Pelosi:

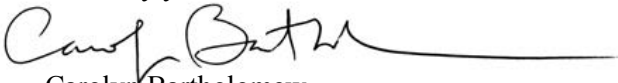
We are writing to notify you of the Commission's July 31, 2019 public hearing on "Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products." The Floyd D. Spence National Defense Authorization Act for 2001 § 1238, Pub. L. No. 106-398 (as amended by the Carl Levin and Howard P. "Buck" McKeon National Defense Authorization Act for Fiscal Year 2015 § 1259b, Pub. L. No. 113-291) provides the basis for this hearing.

At the hearing, the Commissioners received testimony from the following witnesses: Christopher Priest, Chief of Staff, Defense Health Agency Operations Directorate (J-3); Rosemary Gibson, Senior Advisor, Hastings Center, Author, "China Rx"; Ben Westhoff, Author, "Fentanyl, Inc."; Dr. Jennifer Bouey, Tang Chair in China Policy Studies, RAND Corporation; Associate Professor, Georgetown University's School of Nursing and Health Studies; Dr. Mark Kazmierczak, Scientist and Associate, Gryphon Scientific LLC; Benjamin Shobert, Director of Strategy for Health Business Strategy, Microsoft; Senior Associate, National Bureau of Asian Research; Katherine Eban, Author, "Bottle of Lies"; Dr. Yanzhong Huang, Senior Fellow for Global Health, Council on Foreign Relations; Professor, School of Diplomacy and International Relations, Seton Hall University; and Craig Allen, President, US-China Business Council. Mark Abdo, Associate Commissioner for Global Policy and Strategy, Food and Drug Administration, submitted testimony for the record. The hearing assessed China's role in global health, pharmaceuticals, and medical products. In addition, it examined the activities of Chinese health and biotech firms in the United States, and U.S. access to China's health market. Finally, the hearing considered the implications for U.S. public health and national security of growing U.S. dependence on Chinese health products.

The full transcript of the hearing, prepared statements, and supporting documents are posted to the Commission's website, www.uscc.gov. Members and the staff of the Commission are available to provide more detailed briefings. We hope these materials will be helpful to the Congress as it continues its assessment of U.S.-China relations and their impact on U.S. security.

The Commission will examine in greater depth these issues and the others in our statutory mandate this year. Our 2019 Annual Report will be submitted to Congress in November 2019. Should you have any questions, please do not hesitate to have your staff contact one of us or our Congressional Liaison, Leslie Tisdale Reagan, at 202-624-1496 or lreagan@uscc.gov.

Sincerely yours,


Carolyn Bartholomew
Chairman


Robin Cleveland
Vice Chairman

cc: Members of Congress and Congressional Staff

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

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The Commission was created on October 30, 2000 by the Floyd D. Spence National Defense Authorization Act for 2001 § 1238, Public Law No. 106-398, 114 STAT. 1654A-334 (2000) (codified at 22 U.S.C. § 7002 (2001), as amended by the Treasury and General Government Appropriations Act for 2002 § 645 (regarding employment status of staff) & § 648 (regarding changing annual report due date from March to June), Public Law No. 107-67, 115 STAT. 514 (Nov. 12, 2001); as amended by Division P of the “Consolidated Appropriations Resolution, 2003,” Pub L. No. 108-7 (Feb. 20, 2003) (regarding Commission name change, terms of Commissioners, and responsibilities of the Commission); as amended by Public Law No. 109-108 (H.R. 2862) (Nov. 22, 2005) (regarding responsibilities of Commission and applicability of FACA); as amended by Division J of the “Consolidated Appropriations Act, 2008,” Public Law Nol. 110-161 (December 26, 2007) (regarding responsibilities of the Commission, and changing the Annual Report due date from June to December); as amended by the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year 2015, P.L. 113-291 (December 19, 2014) (regarding responsibilities of the Commission).

The Commission’s full charter is available at www.uscc.gov.

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EXPLORING THE GROWING U.S. RELIANCE ON CHINA'S BIOTECH AND PHARMACEUTICAL PRODUCTS

WEDNESDAY, JULY 31, 2019

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Washington, DC

The Commission met in Room 428A of Russell Senate Office Building, Washington, DC at 9:30 a.m., Senator James M. Talent and Commissioner Michael Wessel (Hearing Co-Chairs) presiding.

OPENING STATEMENT OF SENATOR TALENT HEARING CO-CHAIR

COMMISSIONER TALENT: Okay, well, we'll get going a couple of minutes early because we have only a short period of time for our first panel anyway, so we'll expand it a little by starting a couple minutes early and several Commissioners are on their way, I know.

Good morning to everybody. Welcome to the seventh hearing of the U.S.-China Commission's 2019 report cycle. Thanks to everyone for joining us today.

Today's hearing will examine China's role in global health in the national security, economic, and public health concerns stemming from American dependence on Chinese health products. Our witnesses will also discuss the activities of Chinese health and biotech firms in the United States, as well as the opportunities and challenges U.S. health firms encounter while operating in China or trying to sell into the China market.

China is the biggest global source of generic drugs, pharmaceutical ingredients, and other health products including dietary supplements, biologics, and medical devices. There are serious deficiencies in health and safety standards in China's pharmaceutical sector and inconsistent and ineffective regulation by the Chinese Government. Yet, the U.S. imports of these health products, either directly from China or indirectly through companies and third countries continues to increase.

According to the Food and Drug Administration, 13.4 percent of U.S. drugs and biologic imports are from China, as well as 39.3 percent of medical device imports, making China one of America's top sources for medical products. These numbers understate significantly the true sourcing of health products in China because China is also the primary supplier of precursors for pharmaceutical companies in other countries such as India which, in turn, are major suppliers of finished product to the United States.

China has emerged as the second largest pharmaceutical market in the world by revenue only behind the United States. There are several factors contributing to China's attractiveness as both a market and a production site including the low cost of production, a large consumer base, and a deep talent pool. And as China's market power continues to expand, U.S. consumers are becoming increasingly reliant on drugs sourced from the country which presents economic and national security risks that we will explore today.

As the largest source of fentanyl, China also plays a key role in the on-going U.S. opioid epidemic. Beijing's weak regulatory and enforcement regime allows chemical and pharmaceutical manufacturers to export dangerous controlled and uncontrolled substances. We will explore that as well.

Each of these topics warrants a thorough investigation. Taken together, they raise very serious concern for American leaders.

I want to thank all of our witnesses, we have a number of great ones today, for sharing their expertise with us. We're certainly looking forward to hearing from all of them.

Before we get started, I'd like to thank the Senate Committee on Small Business and Entrepreneurship in which I was once honored to serve, for reserving this space for our use today.

I now turn the floor over to my co-chair for this hearing, Commissioner Wessel.

PREPARED STATEMENT OF SENATOR TALENT HEARING CO-CHAIR

Good morning and welcome to the seventh hearing of the U.S.-China Commission's 2019 report cycle. Thank you all for joining us today.

Today's hearing will examine China's role in global health, and the national security, economic, and public health concerns stemming from the American dependence on Chinese health products. Our witnesses will also discuss the activities of Chinese health and biotech firms in the United States, as well as the opportunities and challenges U.S. health firms encounter while operating in China or trying to sell into the China market.

China is the biggest global source of generic drugs, pharmaceutical ingredients, and other health products, including dietary supplements, biologics, and medical devices. There are serious deficiencies in health and safety standards in China's pharmaceutical sector, and inconsistent and ineffective regulation by the government; yet U.S. imports of these health products—either directly from China or indirectly through companies in third countries—continue to increase.

According to the Food and Drug Administration, 13.4 percent of U.S. drugs and biologics imports are from China, as well as 39.3 percent of its medical device imports—making China one of the United States' top sources for medical products. These numbers probably understate significantly the true sourcing of health products from China, because China is also the primary supplier of precursors for pharmaceutical companies in other countries, such as India, which are major suppliers of finished product to the United States.

China has emerged as the second largest pharmaceutical market in the world by revenue—only behind the United States. There are several factors contributing to China's attractiveness as both a market and a production site, including the low cost of production, a large consumer base, and a deep talent pool. And as China's market power continues to expand, U.S. consumers are becoming increasingly reliant on drugs sourced from China, which presents economic and national security risks.

As the largest source of fentanyl, China also plays a key role in the ongoing U.S. opioid epidemic. Beijing's weak regulatory and enforcement regime allows chemical and pharmaceutical manufacturers to export dangerous controlled and uncontrolled substances.

Each of these topics warrants a thorough investigation—taken together they raise very serious concerns for American leaders.

I want to thank our distinguished witnesses for sharing their expertise with us. We look forward to hearing from each of you. Before we get started, I would like to thank the Senate Committee on Small Business & Entrepreneurship for reserving this space for our use today. I now turn the floor over to my co-chair for this hearing, Commissioner Wessel.

OPENING STATEMENT OF COMMISSIONER WESSEL HEARING CO-CHAIR

COMMISSIONER WESSEL: Thank you, Senator Talent. Good morning. I'd like to thank everyone for joining us and thank our witnesses for the time and effort they have put in to their testimonies.

While this Commission deals with a variety of issues in the U.S.-China relationship ranging from economics to military and security affairs to media freedom, the subject of today's hearing touches upon the daily lives of our citizens.

Healthcare is an issue for every family. Millions take life-sustaining drugs on a daily basis, including blood pressure medications, diabetes control pills, and a variety of other medications. And based on the latest statistics, 68 percent take a dietary supplement on a regular basis. Few know where the ingredients for those products come from. The packaging rarely indicates. Increasingly, those products are coming from China.

What is the quality and safety of those products and what is our exposure? Should the public be concerned? Should they have more information? Are the regulatory standards sufficient to protect their interests, and how are the facilities being inspected?

These are important questions, but they just touch the surface of bilateral health sector relationships between the U.S. and China. Today, we want to understand the current landscape, as well as trace emerging trends and potentially risks. Consider the advances taking place in the field of biotechnology and its potential for new therapies, medicines, and other products. China has designated biotechnology as a strategic emerging industry and is pouring billions into developing biotech and genomic products as a part of its industrial plans.

The Chinese Government encourages investments through venture capital investments in U.S. biotech and health firms. Through a variety of programs, China is seeking to acquire the knowledge of some of our key researchers and the intellectual property of leading companies. Both legal and illegal means are being used.

China's activities in the U.S. biotech sector has fueled technology transfer enabling the rapid development of China's domestic industry. To support its goals, Chinese companies have accumulated private and medical data on millions of our people.

Earlier this year, federal prosecutors charged two Chinese nationals for the 2015 hack of health insurance giant Anthem which resulted in the theft of nearly 80 million Americans' health data. But unlike other hacks that were targeted at personally-identifiable information, the hack was targeted at obtaining longitudinal patient data to help support the development of their healthcare sector including new drugs and treatments. These are the confidential health records that our doctors and healthcare professionals keep.

While healthcare should be an area for cooperation in addressing many of the world's most challenging problems, we have to ask whether we can protect U.S. intellectual property and valuable health data while deepening collaboration. Scientific research should not be subject to competitive games and strategies.

U.S. health and biotech firms meanwhile continue to face regulatory and other market barriers that limit their ability to sell into the China market and compete with Chinese firms. In recent years, China's government has improved regulatory procedures to allow foreign medical products to enter the Chinese market more quickly. Concerns remain, however, over China's weak commitment to protecting intellectual property rights and enduring willingness to favor domestic providers of health services and products.

Our hearing will closely examine the question of market access, outlining the regulatory challenges and market opportunities for U.S. firms accessing China's health market.

I'd like to remind our audience that witness testimonies and the hearing transcript is available on our website, www.uscc.gov. Our next hearing, examining key trends in the U.S.-China relationship in 2019 will take place on September 4th.

**PREPARED STATEMENT OF COMMISSIONER WESSEL
HEARING CO-CHAIR**

Thank you, Senator Talent. Good morning. I would like to thank everyone for joining us and thank our witnesses for the time and effort they have put into their testimonies.

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These are important questions, but they just touch the surface of the bilateral health sector relationship between the U.S. and China. Today we want to understand the current landscape as well as trace emerging trends and, potentially, risks.

Consider the advances taking place in the field of biotechnology and its potential for new therapies, medicines, and other products. China has designated biotechnology as a Strategic Emerging Industry and is pouring billions into developing biotech and genomic products as a part of its industrial plans. The Chinese government encourages investments—including venture capital investments—in U.S. biotech and health firms. Through a variety of programs, China is seeking to acquire the knowledge of some of our key researchers and the intellectual property of leading companies. Both legal and illegal means are being used.

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Before we introduce our first panel, I would like to remind our audience that witness testimonies and the hearing transcript is available on our website, www.uscc.gov. Our next hearing, examining key trends in the U.S.-China relationship in 2019, will take place on September 4.

PANEL I INTRODUCTION BY COMMISSIONER WESSEL

It's now my honor to introduce our first panel which will provide the perspective of the Defense Health Agency. I'd also like to note that the Food and Drug Administration had submitted a statement for the record for this panel which is available on our website.

Today, we will hear from Christopher Priest who currently serves as the interim Deputy Assistant Director for Healthcare Operations under the Defense Health Agency. He is responsible for the policy, procedures, and direction of healthcare administration in military medical treatment facilities. Earlier in his career, Mr. Priest served in the U.S. Army and retired as a colonel after 30 years of service.

Mr. Priest, welcome. Please keep your remarks to seven minutes so that we can ask questions. We appreciate your time and effort to be here and also thank you for your service to this country. Please.

OPENING STATEMENT OF CHRISTOPHER PRIEST, CHIEF OF STAFF, DEFENSE HEALTH AGENCY OPERATIONS DIRECTORATE (J-3)

MR. PRIEST: Senator Talent, Mr. Wessel, fellow commissioners, I am honored to represent the military health system and the Defense Health Agency to discuss the safety and sourcing of materials critical to medical support for our service members and all of the 9.5 million beneficiaries for whom we are responsible.

I have both a profound professional and personal interest in the subject of today's hearing. As a retired Army officer, followed now by five years in civil service, both my family and I have relied and continue to rely on military medicine for our care as I have done for most of my adult life.

My colleagues still in uniform and those who have now retired and all of their families have placed their trust and confidence in this system to protect and care for them, both on the battlefield and here at home.

I share in the responsibility to sustain that trust and to ensure that they receive high quality and safe care. The growing reliance of the U.S. on foreign sources for critical defense related material is an issue that must be addressed at the national level. Relying on DoD or other departments to address this issue piecemeal or in isolation will deliver sub-optimal solutions that could result in the departments competing with each other for finite amounts of production resources or product.

The most effective way to address this issue is to use the buying power of the federal government in conjunction with effective laws and funding to partner with the nation's pharmaceutical producers as one example; to maintain necessary infrastructure and capabilities to independently meet the U.S. domestic and defense needs, and to compensate the producers adequately for providing and maintaining those capabilities.

DoD is wholly dependent on the consumer market to produce and distribute pharmaceutical products it requires, spending approximately \$7.5 billion annually. DoD must work with the constraints of the commercial sector and the market forces that drive and shape it.

Depending on the commercial sector is a two-edge sword. It enables DoD to reap the efficiencies of the competitive, commercial marketplace and it also makes DoD dependent on the sources that competition produces.

DoD, through our colleagues at the Defense Logistics Agency and at the policy level, monitors available stocks and production capabilities, plans and prioritizes them to meet contingencies and work with the other departments responsible for U.S. pharmaceutical production capabilities. Like other federal agencies, we rely on existing laws and those other federal agencies including the Department of Health and Human Services, particularly the FDA, and the Department of Commerce to monitor foreign investment in the commercial production and distribution of medical supplies.

The Trade Agreements Act, or TAA, requires certain products sold to the United States Government to be manufactured in the United States or in one of the designated countries with which the U.S. has a free trade agreement or other special trade related arrangement. The TAA applies to all federal supply schedule contracts, including drugs, medical supplies, medical devices, as noted by the chairs. The DHA and DLA abide by the TAA and ensure appropriate references are included in our procurement contracts.

There are processes in place to manage exceptions when products are not available from TAA-compliant countries. And I've addressed that issue in some detail in the written testimony,

but would be happy to address that further if you have questions.

Although DoD purchases a very small amount of finished pharmaceutical products from Chinese sources, we are aware that 80 percent of the active pharmaceutical ingredients, the API has noted, used by commercial sources to produce finished products come from China and other non-TAA compliant countries such as India.

We are concerned about any situation where foreign actors, including China, control substantial access to critical war-fighting material. We expect the trend towards Chinese dominance of global APIs to continue following past trends.

The issues raised by the increased Chinese dominance in the global API market cannot be overstated. There is risk that existing regulations, programs, and funding are insufficient to guarantee U.S. independence from unreliable foreign suppliers. Our concern is the ability of the domestic manufacturing capability to adjust to that risk, alternate sources, if any, and how long the solutions would take to produce results.

The challenges being explored by this Commission have existed for some time and they are growing as again the opening statements from the co-chairs. There is not a single solution to these challenges. It requires a sophisticated approach that entails national security, economic, health and diplomatic considerations. We are working closely with our colleagues within DoD and across the federal government towards this end.

Thank you again for inviting me here to speak with you today and to demonstrate how we currently integrate our efforts with DoD and other federal agencies to better support health and readiness for those that we're proud to serve.

I look forward to answering your questions. Again, within the lens -- scope that the Defense Health Agency, we provide and ensure healthcare delivery across a number of venues through our Army, Navy, and Air Force partners who currently are responsible for management administration of our military treatment facilities. And as you may know, we have been transitioning that activity to the Defense Health Agency for management administration under NDAA 2017 legislation. We also maintain the Tricare program which is one of the divisions that falls under my purview. Therefore, if there are any questions that extend beyond my area of responsibility, I will take those questions for the record and ensure you have a timely response. Thank you.

**PREPARED STATEMENT OF CHRISTOPHER PRIEST, CHIEF OF STAFF, DEFENSE
HEALTH AGENCY OPERATIONS DIRECTORATE**

Prepared Statement
Of
Mr. Christopher Priest
Principal Deputy, Deputy Assistant Director, Healthcare Operations
Defense Health Agency

REGARDING
THE MILITARY HEALTH SYSTEM

BEFORE THE
U.S.-China Economic and Security Review Commission

July 31, 2019

Not for publication until released by the Commission

Senator Talent, Mr. Wessel, fellow Commissioners, I am honored to represent the Defense Health Agency (DHA), to discuss this important subject. The safety and sourcing of materials critical to medical support for our service members, and all of the 9.5 million beneficiaries for whom we are responsible, is a serious medical readiness matter.

The growing reliance of the U.S. on foreign sources for critical defense-related material is an issue that must be addressed at the national level. Relying on DoD, or other departments, to address this issue piecemeal or in isolation will deliver suboptimal solutions that could result in the departments competing with each other for a finite amount of production resources or products. The most effective way to address this issue is to use the entire buying power of the federal government, in conjunction with effective laws and funding, to compel the nation's pharmaceutical producers, as one example, to maintain the necessary infrastructure and capabilities to independently meet U.S. domestic defense needs, and to compensate the producers adequately for providing and maintaining these capabilities.

DoD is neither authorized, by law, nor funded to produce commercial pharmaceuticals. Therefore, DoD is wholly dependent upon the consumer market to produce and distribute the pharmaceutical products it requires to ensure the health, safety and wellbeing of the DoD personnel and beneficiaries who require them. DoD spends approximately \$7 billion annually on pharmaceuticals, which is less than 2 percent of the total US commercial market. Given its relatively small footprint in the commercial marketplace, DoD must work within the constraints of the commercial sector and the market forces that drive and shape it. Depending on the commercial sector, it is a two-edge sword. While it enables DoD to reap the efficiencies of the competitive commercial marketplace, it also makes DoD totally dependent on the sources that competition produces. These sources are increasingly foreign and non-compliant with the Buy

American Act, as amended by the Trade Agreements Act of 1979. DoD's compliance with these acts drives up DoD pharmaceutical costs while having little or no effect on the primary production arc of the commercial sector, which is bending toward foreign production sources.

DoD monitors available stocks and production capabilities, plans and prioritizes them to meet contingencies and works with other departments responsible for US pharmaceutical production capabilities. Like other federal agencies, it relies on the Department of Health and Human Services (HHS), Food and Drug Administration and the Department of Commerce (DoC) to monitor and react to foreign involvement in the commercial production and distribution of medical supplies of the US.

HHS is the lead to develop national plans and programs to mobilize the health industry and health resources for the provision of health, mental health, and medical services in national security emergencies; develop national plans to set priorities and allocate health, mental health, and medical services' resources among civilian and military claimants; and develop guidelines that will assure reasonable and prudent standards of purity and/or safety in the manufacture and distribution of food, drugs, biological products, medical devices, food additives, and radiological products in national security emergencies.

DOC is the lead to develop control systems for priorities, allocation, production, and distribution of materials and other resources that will be available to support both national defense and essential civilian programs in a national security emergency; analyze potential effects of national security emergencies on actual production capability, taking into account the entire production complex, including shortages of resources, and develop preparedness measures to strengthen capabilities for production increases in national security emergencies; and perform industry analyses to assess capabilities of the commercial industrial base to support the national

defense, and develop policy alternatives to improve the international competitiveness of specific domestic industries and their abilities to meet defense program needs.

While DoD coordinates its needs, capabilities and requirements with HHS and DoC, these other departments have the lead in promoting U.S. pharmaceutical production independence.

The Defense Logistics Agency (DLA)

DHA works closely with DLA to procure military medical supplies and equipment. DLA is DoD's medical material logistics enabler and its Executive Agent (EA) for Medical Materiel. As the logistics enabler, DLA accepts material requirements, generated by medical clinical decisions through DoD, and obtains the material to meet them at fair and reasonable prices from the commercial sector.

As DoD's EA for Medical Materiel, DLA develops, implements, and integrates end-to-end supply chain processes and end-to-end supply chain and logistics support plans to support the medical materiel requirements of the Combatant Commands (COCOMs) and the Military Departments. DLA, in coordination with the COCOMs, the Chairman of the Joint Chiefs of Staff, and the Secretaries of the Military Departments, programs and budgets to acquire, maintain, and preposition medical materiel, or provides access to materiel, as necessary, to meet global DoD contingency requirements for surge and sustainment.

In acquiring material, DLA is bound by the Federal Acquisition Regulation, the Defense Federal Acquisition Regulation Supplement and the Buy American Act as amended by the Trade Agreements Act (TAA), to use TAA-compliant sources if they are capable of meeting DoD's

needs. In fact, DLA is the “middleman” driven by DoD clinical and readiness requirements and bound to acquire the material competitively from the commercial sector.

Authorities and Regulatory Framework

The Trade Agreements Act (TAA) requires certain products sold to the U.S. Government to be manufactured in the U.S. or in one of the “designated countries” with which the U.S. has a free trade agreement or other special trade-related arrangement. The TAA applies to all Federal Supply Schedule contracts, including medical supplies and equipment. The DHA abides by the TAA and ensures appropriate references are included in our procurement contracts.

Contractors must certify, in their proposals to the Government, that the products listed for sale on those contracts comply with the TAA. If such certifications turn out to be false, the contractor may face unwelcome consequences, including monetary liability under the False Claims Act, potential of criminal charges, and debarment from U.S. Government contracting.

The TAA requires end products delivered to Government customers to be “substantially transformed” in either the U.S. or a “designated country” identified in the Federal Acquisition Regulation (FAR). “Substantial transformation” occurs when a product is transformed from its component parts into new and different articles. If substantial transformation happens outside the U.S. or a designated country—for example, in China, India, or Malaysia—then the end product is NOT TAA compliant and it typically cannot be sold to the U.S. Government.

There are processes in place to manage exceptions. If the Department cannot find TAA compliant generic products in quantities sufficient to meet the DoD needs, we determine if a TAA compliant brand name product is available in sufficient quantities. We must buy that before

a Non-Availability Determination (NAD) will be issued. Once DoD's demand exceeds a single TAA compliant manufacturer's ability to meet that demand a NAD will be issued opening the DoD market to all non-TAA compliant products.

Specific to medical and surgical products, there are 22 Non-Availability Determinations (NADs, e.g., waivers) that allow use of non-TAA products. Unless the waiver specifically states the country, it allows for product offerings from any TAA non-compliant country. It should be noted that one NAD may encompass multiple products. Of the 22 NADs, only 4 waivers (e.g., exam gloves, surgical gloves/airways), named a specific country of origin (in this case Thailand and Malaysia). For drug products, there are currently 147 active NADs issued by the DLA, out of the average 6,800 drug products that DLA purchases annually. For these NADs, the primary country of origin is India. Consequently, we believe the total amount of spending on products manufactured in China is low.

We have also reviewed prescription drug purchases made under waivers by our mail order and retail pharmacy network contract partners, ExpressScripts, Inc (ESI). They have confirmed that none of the prescription medications purchased in the past two years were manufactured in China.

Purchases by Government Purchase Card (GPC) are also a concern as spending by GPC are relieved of TAA compliance requirements. An example would be a repair part for a medical device, where the device is TAA compliant, but the repair part could come from multiple vendors. Repair parts might be purchased through a GPC and would therefore be exempt from TAA compliance.

DHA Role in Overseeing Chinese Activities of Health-Related Product Manufacturing

The DHA has no legal authority in overseeing Chinese activities of health-related product manufacturing in China. DHA's role in overseeing the U.S. health, biotech and dietary supplement industries is limited to making clinical decisions that promote the availability, safety and quality of products we prescribe and use to ensure the health and wellbeing of the Warfighters and beneficiaries we support. DHA partners with the Defense Logistics Agency and the Food and Drug Administration to promote acquisition of these products from reliable, safe and cost-effective sources.

Concerns regarding China's activities in the U.S. biotechnology industry; sufficiency of existing regulations

Although DoD purchases a very small quantity of finished pharmaceutical products from Chinese sources, we are aware that approximately 80 percent of the active pharmaceutical ingredients (APIs) used by commercial sources to produce finished products come from China and other non-TAA compliant countries, such as India. DHA is concerned about any situation where foreign actors, such as China, control substantial access to critical warfighting materiel and potential serious risk of interruptions in the supply chain or posed by contaminated APIs. This concern is compounded by the fact that there is no required registry for API sources making it extremely difficult to gauge the extent of the risk. Based on reports of China's increasing control of APIs, there is risk that existing regulations, programs and funding are insufficient to guarantee U.S. independence from unreliable foreign suppliers.

U.S. pharmaceuticals and dietary products industry reliance on supply chains involving manufacturing plants based in and/or active ingredients sourced from China

As mentioned in the previous section, it is DoD's understanding, based on business intelligence from the FDA and the commercial sector that 80 percent of the APIs use by the commercial production industry are sourced from China, India, and other non-TAA compliant countries. We also understand that this dependence on Chinese sources is increasing. The lack of a reliable API registry to accurately gauge the Chinese prowess in the global API business makes it difficult to independently confirm these estimates and trends.

Expectations for change in domestic U.S. pharmaceutical and dietary supplement industries to in the next five years with regard to where active ingredients, labor, or other inputs are located and sourced from

The DHA relies on other agencies and organizations to monitor industry trends. The narrative in this section reflects these insights rather than original analysis from DHA. Given the commercial marketplace competitive forces at play, DHA expects the trend toward Chinese dominance of global API to follow past trends and increase over the next five years.

National security risks—including the ability to protect and address the health needs of our men and women in uniform, emergency responders, and the public—from current and potentially increasing levels of dependence on Chinese health products

The national security risks of increased Chinese dominance of the global API market cannot be overstated. Pharmaceuticals that are crucial to DoD's ability to promote the health of its Warfighters and protect them from nuclear, biological and chemical threats. Should China decide to limit or restrict the delivery of APIs to the U.S. it would have a debilitating effect on U.S. domestic production and could result in severe shortages of pharmaceuticals for both domestic and military uses. Our concern is the ability of the domestic manufacturing capability to adjust to that risk, alternate sources, if any, and how long those solutions would take to produce results.

Agreements (including formal agreements and any commitments made during JCCT, S&ED or other fora) between the U.S. and China governing pharmaceuticals, medical products, dietary supplements, and biotechnology; Compliance and impact of such agreements

DHA is unaware on any formal agreements or commitments that exist between the U.S. and China governing pharmaceuticals or other related medical products. Even if such agreements exist, there would be concern that they present no guarantees in the event of conflict or heightened tensions between the two countries.

Sufficiency of existing authorities and regulations to address the challenges presented by China's role in global medical and pharmaceutical supply chains

Existing authorities and regulations simply restrict the ability of DoD to purchase pharmaceuticals and other medical products from China and other non-TAA compliant sources.

They do not restrict the U.S. commercial sector from using APIs from these sources to produce domestic pharmaceuticals. In fact, DHA is unaware of any current laws and regulations that address the challenge of Chinese dominance of the commercial API marketplace, on enables the U.S. to accurately gauge that dominance and intent risk.

The challenges being explored by this commission have existed for some time and they are growing. There is not a single solution to these challenges – it requires a sophisticated approach that entails national security, economic, health, and diplomatic considerations. Thank you for inviting us here today to speak with you about how we can integrate our approach with other US Government agencies in support of better readiness and health.

PANEL I QUESTION AND ANSWER

COMMISSIONER WESSEL: Thank you for your testimony, again, your service, and appreciate your being here.

Senator Talent for the first question.

COMMISSIONER TALENT: I want to join in thanking you and I know that the Defense Health Agency has a wide range of responsibilities and many challenges you're confronting and it's frustrating to have another one on your plate that as you point out in your statement is really not because of anything that was within the responsibilities of the Department of Defense.

So you mentioned in your statement that there's like, I think 140 or 150, about 150 lines of drugs or pharmaceuticals, out of over 6,000, that you are purchasing from countries outside the Buy American Act, in other words, according to a special exception.

So can you tell us how much of the total, which drugs are the most sensitive? In other words, if there were an issue, either national security or otherwise, and access to drugs or precursors from China were substantially limited, do you all know the areas where you would have immediate problems? Are you aware of that? Are you at the point where you know that?

MR. PRIEST: Sir, I think we're collecting that information as we speak. There's a number of government activities and I think actually being driven from the White House through the National Security Council, from the Office of Science and Technology Policy is looking at this. We do have an inventory of those. I don't have that readily available. And I think as stated in the written testimony, overall, the number that we've received directly from China is not very large. However, that risk still continues, so I think as we can collect that information and look at it.

We do know and I'll give one example, and I think actually Ms. Gibson is going to talk a little bit about it later in her panel, but doxycycline and Cipro, which obviously we use prophylactically and in response to anthrax are not produced domestically. In fact, a large portion of that, I believe, is actually produced in China. But I think that's a leading indicator of the seriousness of this conversation.

COMMISSIONER TALENT: Yes, because this is a -- I mean in certain aspects this is a potential operational or battlefield issue. And so I would think that you all would be preparing at least on that level and exploring possibilities like stockpiling and I don't know how feasible that is with a lot of these medications.

All right, well, thank you. I might, if we have another round, I might have another one or two.

COMMISSIONER WESSEL: Thank you. Let me ask a couple of questions, if I can, and one of them you talked about the Trade Agreements Act and having spent some time with the Buy American statute, et cetera, over the period. My understanding is that to qualify under the act, and I understand you may not be a trade lawyer, is simply pressing a pill into its final form will designate origination, so that when we say we're going to buy it from Japan or wherever else, all of the APIs, you pointed out, I believe, 80 percent are coming from China. Simply pressing the pill after they've bought all the supplies from China would designate it as acceptable under the act. And that's a trade policy issue.

But what it says to me is we don't have really the ability to pierce through the supply chains as well as we might like to protect those warfighters and their families, that as they are out on the battlefield and subject to being in harm's way and subject potentially to injury, our primary interest is in making sure that are able to come home to their families. And you do a

tremendous job, DoD, that the advances are startling in terms of survivability for what you, your colleagues, and people on the battlefield are able do.

But it seems to me we don't even have all the information we need to assess the risks and if we -- if conflict potential with China increases, our vulnerability will increase as well and we need to have some way of assessing that.

Is that kind of assessment -- would that assessment be helpful to you and your colleagues as you look at the treatment options for the people under your care?

MR. PRIEST: Sir, I think the answer is absolutely. I think the value of all of your panels that you're doing, the work you're producing, along with the work also being conducted within the administration, across all of the departments, absolutely gets to that point.

In representing the bottom of that supply chain and particularly that provider-patient interaction and I'd like to give a shout out to my good friend, Captain Rick Freedman, who is currently commanding the hospital in Bagram. He's a dental officer, but we don't hold that against him. But I think he represents, he and his team that are actively taking care of patients in an active theater, represent the risk that you talk about, the risk to that supply chain.

I do believe and I think the FDA comments in their written statement also points to the murkiness of that data. That just adds to the risk.

And you're absolutely right, and again, not being a trade lawyer and a simple healthcare administrator, I think simply having a TAA-compliant does not necessarily guarantee safety, either from those sources coming in from China or frankly, any source of production. There's always that risk that those drugs are not as effective as they should be, or there may be manufacturing defects.

And again, a lot of this conversation we're talking about is on the pharmaceutical side and I think there are other hosts of implications when you start looking at med devices, laboratory services, genomics, again, the whole sphere of bioeconomics of which healthcare is only one small piece.

But sir, I agree with you that that is our concern. Our obligation is to provide the best services, using those materials. And again, what we have achieved over the last 20 years, almost now 20 years of operation, 18 years anyway, across those theaters, the survivability rate is highly dependent again on technology, research, and development, and having those tools, including supplies and equipment, that we know are safe and effective.

COMMISSIONER WESSEL: Thank you. Commissioner Fiedler.

COMMISSIONER FIEDLER: Thank you. I have a couple of questions. You testified that you spend \$7.5 billion a year on pharmaceuticals. Obviously, U.S. pharmaceutical companies are going to China in seeking low-cost production. So have you seen any diminution in the costs of pharmaceuticals as a result of sourcing in China, costs of pharmaceuticals being on everyone's minds in the United States?

MR. PRIEST: Trust me, Commissioner, it's actually on everybody's mind everywhere.

COMMISSIONER FIEDLER: Yes.

MR. PRIEST: Actually looking -- I think the military health system is not immune to the pressures of cost. And obviously, we work hard and there are certain provisions in how we, obviously, are able to deliver that service and we use it through three points of delivery and there's different mechanisms and economic mechanisms to try and control those costs.

So it's a little hard to gauge the impact overall, but I'll give you a couple of examples of how we actually execute the pharmacy benefit. We obviously have in-patient, out-patient pharmaceuticals that we deliver to our patients through our military treatment facilities. Those

stocks are procured through DLA. And in conjunction with the VA and other federal partners in the federal ceiling crisis, as part of the federal supply schedule, obviously, they negotiate up front those rates -- for all that we'll call the big four. So those are cost avoidance mechanisms where are not part of that \$6 billion spend. It actually would be higher without those particular incentives. And we appreciate the fact that the buying power of the federal government across those big four including HHS, VA and DoD obviously keep that cost lower.

We also deliver our benefit through the mail order program and through our commercial partner, contract partner, ESI Incorporated, as our pharmacy benefit manager. We replenish their particular stocks. Now, as I think I've noted in our testimony, we actually have talked to the ESI CEO and they have indicated they procure none of their drugs through China. But all of their sources obviously are TAA-compliant as well.

The third source is through the retail network that's obviously our third thing and there's obviously, although there are FDA-compliant -- all three sources are FDA compliant, we don't always necessarily know where the large companies, and again, we contract through ESI who produce the claims, but out of the 6,500 I believe or so pharmacies in the United States, 5,500 are actually part of our program and deliver benefits to some of our patients.

COMMISSIONER FIEDLER: I have a quick two other questions. You're dependent on the FDA inspection process. You don't have anything of your own, do you, on the -- you don't test any pharmaceuticals?

MR. PRIEST: That's correct.

COMMISSIONER FIEDLER: What is the anecdotal evidence anyway, if you have it, of any of the drugs that are administered to our warfighters being inadequate, counterfeit, or not effective?

MR. PRIEST: I don't know that we have any specific data on that, but I do think that there's been a recent experience with valsartan that think may illustrate the risk. Valsartan, as you know, is a generic drug, but in that -- now there's a wide variety of companies that produce it. What we have seen generally speaking with valsartan is a continuing trend where different manufacturers and different lots and different mixtures are coming across with those contaminated drugs that have carcinogens.

And I think Ms. Gibson probably can speak a little bit more and some of your other panel members, much more eloquently than I can. But I think that's an illustration and a little bit of a wake-up call although I think there are others historically, whether we go back to the heparin issue ten years ago. But I think anecdotally, my concern from a healthcare delivery standpoint is trying to communicate to beneficiaries. And I think it was a bit of an eye opener, certainly for myself, that normally when we post or have the FDA post those notices, it's usually sort a one and done.

But here we have the continual, on-going, at issues with valsartan particularly, not limited to one source, but multiple sources, again in different mixtures. And is that indicative potentially --

COMMISSIONER FIEDLER: Is that both India and China given the fact that APIs are going to India from China in the production of those drugs?

MR. PRIEST: What I think you're pointing to is the second order risk, so yes. I think it is, what's in India, but the fact that the APIs are coming from China to India just exacerbates that risk. If anything, I think that's an interesting case study on the potential risk that we have by relying on those foreign sources.

COMMISSIONER FIEDLER: Thank you very much.

COMMISSIONER WESSEL: Chairwoman Bartholomew.

CHAIRMAN BARTHOLOMEW: Thank you very much. Thank you, Mr. Priest, for coming and testifying today and thanks to DoD for facilitating your participation.

Forgive my ignorance here. I'm trying to understand in terms of sort of the production and the purchasing chain, is there any way that the seller or even the producer of the components of either the drug or the device would know that it's the Department of Defense system that these drugs or devices are going into?

MR. PRIEST: That's a great question. And I'd like to actually take it for the record because I think that's a question our friends, our colleagues at the Defense Logistics Agency may be able to better address.

I think that line of question alone is a question that increases risk. So I absolutely think that that's something to explore. I personally don't know whether or not the supplier or by default then those that are providing those active ingredients, potentially would know that it is coming to a U.S. DoD facility or to a prepositioned stock, or into a Level 3, like my good friend, Captain Freedman represents that hospital sitting in Bagram, or the man sitting on the front line. I don't know whether or not it's trackable to that extent, but that, I think, is a question I would like to add --

CHAIRMAN BARTHOLOMEW: And if I can add into that, are there certain -- again, forgive my ignorance, but are there certain drugs or material that are primarily used on the battlefield so that even if somebody doesn't know specifically that the Department of Defense would be purchasing it, it would be obvious that it would be for use in a Department of Defense situation, a war-time situation?

MR. PRIEST: Well, I think based on some of the emerging technologies that we've deployed in the battlefield, obviously, and I talked about the joint trauma system. And again, marvelous work has been done, but those things, whether it's a HemCon Bandage, whether it's obviously, different blood products in lieu of. And clearly, yes, I think those are somewhat limited, although I think those are proliferating across the trauma systems in the United States. And I think DoD is proud to have led the way in the trauma system evolution.

Again, I think as noted, our battlefield survival rates are unparalleled in history, but I think it does certainly point to those specific items that would be military items that it could be traceable from that perspective.

CHAIRMAN BARTHOLOMEW: Thanks. I look forward to the answer from the record.

MR. PRIEST: Thank you.

COMMISSIONER WESSEL: Senator Goodwin.

COMMISSIONER GOODWIN: Thank you, Mr. Chair. Thank you, sir, for your time this morning.

As a follow-up to Commissioner Fiedler's question where you were discussing the purchasing power of the federal government and bringing that to bear in your role as someone who procures these pharmaceuticals, the focus, of course, is on keeping the price down. And you alluded to Ms. Gibson, her testimony, which we'll hear later today suggests that this focus on cost at least the focus on cost alone or exclusively is part of the problem to the extent that it has resulted in a concentration of a single supply source, and the resulting shortages and contamination issues that we've seen.

I want to get your sense of that assertion. And also she discusses in her testimony, not to put you on the spot, some private initiatives that I believe, private hospitals have undertaken to

broaden their perspective on negotiating for drug procurements, not focusing on cost alone, but also quality.

MR. PRIEST: No, thank you, Senator. Again, as a healthcare administrator, we always look through the paradigm of cost, quality, and access. That's sort of the trio of things that are important to delivering healthcare.

For the Defense Health Agency and the military health system, operates under a paradigm of what we call the quad aim, quadruple aim, readiness being at the focus, and the main thing that we all focused on. But besides that, obviously, we're talking about better health, better care, and lower cost.

Now as I sort of mentioned, I think I've alluded to and specified in the written statement, the drive on cost is huge. Obviously, the budget for it is \$7.6 billion. We have done well to obviously maintain and sustain that at a reasonable rate, actually lower than the U.S. average. But a lot that is because again of the assistance we get with federal ceiling price discounts and obviously, the sharing with patients on co-pays when necessary.

But I do think that when we focus on the readiness, the buying power, we should not be solely focused on the cost, but yet, obviously that is a major piece within, obviously, the defense line and the overall defense health program that we're responsible for. So we try to balance the fact that even though by law that we can't go outside of obviously how DLA does that procurement and the stipulations we write into our actual contracts, whether they're DHA contracts, DLA contracts or other department contracts to be TAA-compliant.

We note, like you stated, that there are other civilian commercial entities, hospital systems, that have formed a conglomeration to look at different ways to do that to -- whether as to leverage their own buying power or to leverage actual manufacturing capability. And I think that as we look at strategic partnerships for the Defense Health Agency and the military health systems are ones we'd like to explore further.

COMMISSIONER WESSEL: Senator Talent for a follow-up?

COMMISSIONER TALENT: Yes, was this subject included in the defense industrial base study?

MR. PRIEST: Sir, I do not know.

COMMISSIONER TALENT: It might be a good to -- you might want to consider that as a recommendation. Thank you.

MR. PRIEST: Thank you, sir.

COMMISSIONER WESSEL: Commissioner Lewis.

COMMISSIONER LEWIS: Thank you very much for appearing today. This is a subject that really astounded me when I found out what the facts are in terms of our reliance on China for so many of the drugs that are consumed in the United States.

It seemed to me the briefing paper that the staff gave us indicated that the FDA was inspecting some of the pharmaceutical companies in China as they were producing things to make sure that the ingredients were proper. And they found out with one particular drug that's used for high blood pressure that they were using degraded materials. And rather than stopping the import of those items, the inspector was overruled by FDA because we needed those drugs, even though they might be bad.

It seems to me that there are two reasons why we need to find alternative sources. Number one, if the FDA cannot inspect the way that the Chinese companies are producing these drugs, then we don't really know whether they're good or not, similar to the way that food is inspected before it comes into this country. That also impacts the military.

The second reason is if China were to stop producing these goods or to restrict the exports to the United States, we'd be really stuck for these drugs. It seems that we need to arrange an alternative source from European drug manufacturers or other places in the world.

So what is the DoD doing to make sure that we're not totally dependent on Chinese goods that aren't actually inspected?

MR. PRIEST: Well, sir, as you've sort of stated, the FDA has primary responsibility, the Department of Commerce as well.

COMMISSIONER LEWIS: But we heard the budget restraints are stopping them from doing things that need to be done.

MR. PRIEST: Yes, sir, but again, I think that responsibility within the administration falls under those departments. Again, from DHA's perspective, since we neither procure nor have the ability to test, and that's really outside of our purview. But I would certainly agree with you that the risks that you stated are accurate.

COMMISSIONER LEWIS: Well, aren't there other alternative sources from Europe even if the price is higher?

MR. PRIEST: Yes, sir. And actually, I think I commented on that in the statement. My understanding, again, not being a procurement specialist either, but if I can paraphrase from the statement, what we also know is the processes that we have to manage by exception, the department cannot find TAA-compliant products in the quantity sufficient to meet our needs, we determine if a TAA-compliant brand name, so this goes from generic to brand name, is available in sufficient quantities. We must buy that before a non-availability determination is issued by DLA.

Once DoD's demand exceeds a single TAA-compliant manufacturer's ability to meet that demand, then a non-availability determination will be issued opening the DoD market to all non-TAA compliant products.

So clearly, I think what that indicates from our DLA partners is they will exhaust whatever other sources they can in order to meet our particular needs.

COMMISSIONER LEWIS: Well, if in fact, we can't find alternative sources to give us the quantity we need, wouldn't it be worthwhile to make a large enough contract over several years that it would encourage the alternative manufacturers to build facilities so that we would have the quantities we need in the future?

MR. PRIEST: Well, sir, I think that's exactly what I was pointing to in the statement about the recommendation about using the buying power of the federal government writ large and looking at that domestic capability. Also, those are long-term solutions, those aren't easy, quick fixes.

What you're kind of I think stressing is what we do in the current procurement cycles for those where we have other sources and do we stockpile in sufficient quantities. Again, not being a logistician or a contracting officer, I do surmise though because we do have prepositioned stocks worldwide of equipment and material for the warfighters, that we do do that.

Obviously the problem with that, our overall stockage then becomes -- those drugs in particular, then obviously become outdated and out of compliance.

COMMISSIONER LEWIS: If the FDA cannot inspect the drugs that are being exported to the United States, I don't understand why we would buy any goods from China that might not meet the requirements that we need, rather than European drugs, even if they're at a higher price. I don't understand that.

MR. PRIEST: Well, sir, and I think and I believe, and again, I will go back and ensure

with my DHA colleagues that I'm speaking correctly, but my understanding is we would. And I think through another shortage recently, and that's exactly where we went and looked at buying from Europe, from other markets, particularly western Europe.

COMMISSIONER LEWIS: Thank you very much. I don't understand why we're buying any products from China when we can't inspect how they're being built. Thank you.

MR. PRIEST: Yes, sir.

COMMISSIONER WESSEL: Commissioner Bartholomew for a follow-up.

CHAIRMAN BARTHOLOMEW: Yes, thank you. And thank you again, Mr. Priest. Are you a Californian? Did I see that you're --

MR. PRIEST: I did.

CHAIRMAN BARTHOLOMEW: Excellent. Always good to see Californians out here. I want to make sure that I understand even when we are getting drugs from a TAA-compliant country or company, right, the components of those drugs are still being produced in China or India or somewhere else, right? So there's no guarantee of them -- of sort of the safety of the component even though we're buying it through a system that is acceptable to us. Is that right?

MR. PRIEST: I think that's a fair assessment. At least I think we would agree based on our understanding that that would be true, that the TAA compliance doesn't necessarily guarantee safety. And obviously, that's why we believe and agree with the chair's opening comments that that poses risk to our beneficiaries.

CHAIRMAN BARTHOLOMEW: Some of this, of course, is just a level of education and understanding. Commissioner Wessel mentioned it in his opening statement, but people, DoD related or not, get up in the morning, they take vitamins, they take their blood pressure pills, they take whatever, anti-depressants, they take whatever. And don't think about or don't have to think about what it is that has gone into it that they're taking. So it's an important issue. I think in terms of public education, too, which Commissioner Lewis, I think that would be some of the answer, if people knew sort of the potential daily risk of what they're doing, they might be a little bit more concerned and raising concerns to people who could make decisions.

COMMISSIONER WESSEL: Thank you. And Mr. Priest, appreciating the context and the rules within which you need to operate, the trade agreement authorities limit what you can do and so, for example, Chinese products that are simply stamped into a pill form in another country under the trade agreements confers transformation, and you don't have the ability to look through. You have to comply with existing law. That's where some of the risks are and something we may want to look at.

Commissioner Fiedler.

COMMISSIONER FIEDLER: The Commission, a couple of years ago, staff did a good very report on fentanyl importation. There's other testimony we're going to get about morphine which I still imagine is served immediately to wounded warfighters.

What is the opioid problem that exists in society, how does it exist within the military?

MR. PRIEST: Actually, our overall incidents of opioid issues is actually lower than the U.S. average as you would kind of imagine.

COMMISSIONER FIEDLER: You have greater control over prescription issuance than they do in the civilian world.

MR. PRIEST: We do. Correct. Actually, I think that's something to be very proud of on what we've been able to achieve.

COMMISSIONER FIEDLER: I think you should be.

MR. PRIEST: We also now track and have been looking at chronic opioid usage and

what's being prescribed. And obviously, in a lot of our military treatment facilities we have dedicated pain clinics, but we do look at what they do versus the average provider and we're able to drill down to the provider level to ensure that what we're giving is the accurate dosage and is being done properly and in accordance with clinical practice guidelines. We take a very hard look at that and want our provider force to be well aware of what they are actually prescribing and our chief medical officer is leading that effort within the DHA. He and I actually co-chair a group, the Medical Operations Group, now called the Enterprise Solutions Board, and that's one of our key topics.

So we do want to make sure that therapeutically we're providing those particular opioids when necessary, but we also want to ensure that it's done in a safe and effective manner and we watching how those drugs are actually being prescribed. And I think again our providers are to be commended for what we actually are able to achieve.

We're also trying to wean, obviously, looking at pain overall, to try and determine alternative sources, so there's complementary medicine sources, acupuncture, all the rest, that reduce our reliance on opioids is obviously a direction we're headed as far as the Defense Health Agency's policies.

COMMISSIONER FIEDLER: Thank you very much.

COMMISSIONER WESSEL: Commissioner Wortzel.

MR. PRIEST: It's good to see you, sir.

COMMISSIONER WORTZEL: Thank you for your willingness to be here. I'm sorry to have shown up late and then don't ask a question, but this, the line of questions and responses just struck me and I have to say I'm a military retiree. As a consequence, if I take regular prescriptions, I'm required to use Express Scripts. They do a great job.

In the past three months, I have had four blood pressure medications recalled. When I tracked down the sourcing, they all came out of India, but originally sourced in China, from four different U.S. manufacturers, supposed manufacturers or at least provider companies.

In each case, that particular medication was contaminated with rocket fuel. If you did a little work on the internet, you could figure that out.

So I know it's not your fault, but I think it's really important that something be done about this by the Department of Defense and the U.S. Government in general.

The other medication wasn't contaminated with rocket fuel, but again, three recalls in a three-month period. I imagine active duty people have the same problem. And that affects the readiness of our force.

MR. PRIEST: Sir, I think that risk is well stated and I'm not sure if you were referring to valsartan particularly.

COMMISSIONER WORTZEL: I am.

MR. PRIEST: We actually talked a little bit about valsartan in a previous question. That actually from my perspective monitoring or having the pharmacy benefit under my purview was disturbing for exactly the reasons you stated.

The fact that we couldn't and I think I'll just kind of restate briefly, the fact that as you just indicated, multiple recalls over an extended period of time, different doses, different packaging, not knowing what was sort of next, thinking as we normally see recalls, they're sort of one and done. It's a single instance. It's a particular lot, self-disclosed from the manufacturer. But it's just been a non-ending saga on valsartan and I think that that is a disturbing trend.

And I do agree that that is something we need to pay close attention to and identify because part of my obligation is to be able to inform patients like yourself, again, as a fellow

veteran, and for others that may be veterans as well, the obligation to do that so we can try and provide those drugs that we know are safe and effective.

COMMISSIONER WORTZEL: Well, the interesting thing is, of course, probably six times I had to get emergency refills at a local pharmacy and in each case they had tons of it from a manufacturer that the Department of Defense did not use that were not contaminated. They'd seen the problem earlier apparently. Again, it's a bureaucratic problem, but it's a big one.

MR. PRIEST: I understand, but retail sources are not necessarily TAA-compliant. So it goes both ways. What we want to make sure is, and I think Mr. Wessel said it, that's what we are required to do and you go through that whole process of looking at the sources, are they TAA-compliant. But it's well stated that there's active ingredients going into a pill form and that data, the murkiness, I think the FDA commented on it in testimony, that's troubling for all of us. That's not unique to the Department of Defense.

The fact that the retail sources can buy from other sources where we have to obviously use TAA-compliant sources. In this particular case, that may have been very true, but think about the implications on the other end of the spectrum, where retail sources, retail pharmacies are buying their drugs that are not TAA-compliant. So I understand and I appreciate your comment.

COMMISSIONER WESSEL: Mr. Priest, thank you for your testimony.

Mr. Lewis.

COMMISSIONER LEWIS: The more I think about this problem, the more I don't understand why large contracts are not being given to either European or American manufacturers which would encourage them to then create the components that Commissioner Bartholomew talked about for two reasons. Number one, that would avoid the contaminations. Number two, it would ensure the supply chain. I don't understand why large contracts are not being considered by Department of Defense to encourage the construction of facilities to make the components that go into the drugs.

MR. PRIEST: Sir, I appreciate the sentiment and the question and your comment. And certainly, we'll carry that back to my colleagues in the Department. But part of the issue is what's occurring today. And I think as the chairs have stated and others have stated, we are reliant on where right those ingredients actually exist. We ask why sort of in my opening statement I reference the fact that we think through the federal response and an integrated inter-agency response, we should be looking at those alternative sources. But I would imagine, again, I have no facts to back up my point, that we do do those contracts where we can today.

Manufacturing capability either in Western countries or in the United States, those alternative sources is exactly the point I was trying to make. I agree with your assessment.

COMMISSIONER LEWIS: Thank you.

CHAIRMAN BARTHOLOMEW: Can I get clarification, which is even the European pharmaceutical companies are having to purchase the precursors and the components of the drugs from China, correct? So it's not as -- I think it's a great idea, but simply shifting to a different pharmaceutical company isn't necessarily going to solve the problem if everybody is buying the pieces that go into that drug from someplace else.

COMMISSIONER LEWIS: China doesn't have a monopoly on the construction of these components.

CHAIRMAN BARTHOLOMEW: Correct, that's different.

COMMISSIONER LEWIS: So why do we need to have even European companies buying those? We could put in the contract they cannot use components made in China.

COMMISSIONER WESSEL: I think we will hear more today from some of our other witnesses about the change in the supply chains over the past couple of years. There are certain APIs that are only sourced from China.

COMMISSIONER LEWIS: They're only --

COMMISSIONER WESSEL: That are only sourced from China. And that's why we're here today.

And Mr. Priest, we appreciate all that you're doing. We understand that the regulations often prescribe certain activities. I think today's hearing and I assume follow-on work will help us and Capitol Hill understand some of the challenges that exist in a changing sourcing landscape.

We didn't talk about technologies, et cetera, as we talked about offline earlier today, you know, remote technologies that are subject to hacking, and remote medicine for the battlefield, et cetera, all of those are a different vector that poses new challenges as well.

And we are appreciative of your testimony. We know that your primary duty and what you do so well is to protect our warfighters, their families, and the retirees, and that's what we're hoping to do.

We're proud of the fact that over the last I think 11 years, 8 of our reports have been bipartisan, have been unanimous. I think the issue we're here about today is not partisan, it's a question of how do we serve our men and women in uniform and their families and thank you for what you and your colleagues do.

MR. PRIEST: Thank you, Mr. Wessel. Absolutely sure, and I guess if I remark, we spent most of our time talking about pharmaceuticals. If we had more time there is a plethora of things we'd love to be able to discuss the Defense Health Agency and the military health system are endeavoring on. As you know, there's a recent -- yesterday, the VA transitioned their AHLTA records, medical records, over to the Millennium Center that we have that we now co-share with them.

The joint information domain now of the medical records, the fact that we're going to have a single instance of an electronic health record so that Mr. Wortzel and I, as veterans, and others and maybe veterans don't have to carry paper records around or a provider in one system can't show what's going on in the other system. The fact that we are actually partnering much more closely with the VA and I think the electronic health record allows us to do that.

Medical devices, just one quick comment on medical devices. We know the risks that that potentially has as well. And part of what we're doing with movement of that electronic health record into a secure space is obviously then tying in those devices. And I think that goes to our procurement activities. We are looking at -- because right now hospital commanders, our military troop facility commanders can buy generally what they think they need. We're saying no, that actually adds additional risk. We're going to centralize those procurements a little to what Mr. Lewis I think was sort of talking about, but in a different context because that way we can assure that we do look at the cyber implications of those devices and certify them for a connection within our networks.

Lab services. That's another whole plethora of issues, looking at genomics and sequencing and data sharing and where all of that information is going. What we're also looking at as far as what we're doing inside of DoD with our genetic -- trying to not rely solely on external sources for our own genetic testing where appropriate for therapeutic and clinical value.

So those are some additional things I thought may be worthwhile to point out to the

Commission and obviously we've been very focused on pharmaceuticals.

COMMISSIONER WESSEL: Again, thank you. We look forward to continuing to collaborate with you and your staff. We will take a 15-minute break. Thank you.

MR. PRIEST: Thank you, ladies and gentlemen.

(Whereupon, the above-entitled matter went off the record at 10:21 a.m. and resumed at 10:31 a.m.)

PANEL II INTRODUCTION BY SENATOR TALENT

COMMISSIONER TALENT: All right, if Commissioners could resume their seats, we will begin the second panel. Our second panel will assess China's role in global health and activities in the United States.

We'll start with Rosemary Gibson. I introduce everybody first and then we'll go to Ms. Gibson. We'll start with Rosemary Gibson who is -- and whose name has been mentioned already several times if you were here, who is Senior Advisor at the Hastings Center and Perspectives Editor at the JAMA Internal Medicine. She's author of *China Rx: Exposing the Risk of America's Dependence on China for Medicine* which documents the dramatic shift in where medicines are made and the implications for American health security and national security.

Next, we'll hear from Ben Westhoff, an award winning investigative journalist. Mr. Westhoff's new book *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*, will be published in September. The book focuses on fentanyl which now kills more Americans annually than any drug in history.

Our third panelist is Jennifer Bouey who is a Senior Policy Researcher and Tang Chair in China Policy Studies at the RAND Corporation. As an epidemiologist with training in clinical medicine and quantitative methods, Dr. Bouey's research centers on social determinants of health among marginalized populations.

And finally, we'll hear from Mark Kazmierczak, who is a scientist with Gryphon Scientific. He's a molecular biologist with expertise in performing risk assessments to support government decision making on issues of biosecurity, public health, and biodefense. He's also one of the authors of *China's Biotechnology Development: The Role of U.S. and Other Foreign Engagement*, a report prepared for the Commission and published in February 2019.

We welcome all of you. We ask that you would keep your remarks to seven minutes and Ms. Gibson, we'll start with you.

OPENING STATEMENT OF ROSEMARY GIBSON, SENIOR ADVISOR, HASTINGS CENTER, AUTHOR, "CHINA RX"

MS. GIBSON: Good morning. Thank you, Senator Talent, Commissioner Wessel, and all the Commissioners for the chance to be here today to talk about what has been a really hidden and overlooked threat to our national health security, economic prosperity, and national security, and that is our dependence on China for medicine.

As was discussed in the earlier panel, these are the medicines used by members of Congress, presidents, members of the military, veterans, and all Americans. These are the medicines bought in retail pharmacies, in pharmacies in supermarkets and big box stores.

The focus of my testimony today will be on generic drugs because they are 90 percent of the medicines that Americans take.

We can no longer make penicillin and that happened in 2004 when the last plant in the United States closed and that happened and this is indicative of the predatory trade practices, happened when a handful of Chinese companies dumped the chemical material to make penicillin on the global market and it drove out all the U.S., European, and even Indian producers. And then after it gained dominance, prices went back up. That's the playbook that we see, the same practice with the Vitamin C cartel is emblematic of how we have lost the capability to make so many of the core components in our medicines and I think this playbook will extend to finished generic drugs eventually.

In 2001, after the anthrax attacks when the U.S. Government needed to buy 20 million doses of doxycycline, we don't make it here, the United States turned to a European company that, in turn, had to get the starting material from a plant in China.

I have four main points and then will highlight four recommendations. The first is our industrial base to make our medicines is collapsing. We have virtually no manufacturing capability left in the United States to make generic antibiotics. These are the medicines that you give to your kids for ear infections, strep throat, and we're talking also about superbug treatment and last resort antibiotics.

In five to ten years we'll have virtually no manufacturing capacity left for generic drugs. And again, this is 90 percent of our medicines.

The second point is China's dominance is global. In February, Dutch Public Television aired a documentary reporting the Netherlands' dependence on China for medicine. A former industry official said on camera that they're concerned that China may not supply them with medicine.

And as mentioned earlier, even India is dependent on China for 80 percent of the key ingredients it needs for its generic industry. And when you control the supply of medicines, you control the world. That's what we're looking at.

We are losing control over the supply of our medicines and when we lose control over supply, we lose control over quality. That's why we have blood pressure medicines with carcinogens in them and we can go into this more later in the Q and A, but the FDA cannot fix this problem. It's already in the position of having to make tradeoffs between defective medicines and shortages. And when we lose control over supply we also lose control over price. China will be the price setter and we will be the price taker. And members of Congress will not be able to bring in CEOs of Chinese companies and ask them not to raise prices.

The national security risks are pronounced. China could withhold supply. It could put lethal contaminants in medicine or have no medicine at all, and I do believe it's in the realm of

possibility to target certain subjects having access to medical records and distribute products to certain subjects.

The most surprising thing I learned from reading China Rx -- from working on China Rx and reading it again, it took three years to do it, is that it's no one's job in the federal government to know who controls the supply of our medicine. We wouldn't do that for oil. We wouldn't do that for food. We consider our medicine as a cheap commodity to be purchased at the cheapest possible price. That's the root cause. That's what needs to change.

I have four recommendations that I'll highlight here. First is we need a whole of government review of our vulnerability, similar to the defense industrial base report, what was done for the DoD. My understanding is I looked at that report, Senator, I didn't see any mention of medicines. It's sort of outside of the DoD purview and understandable. I think we need a whole of government review that's on-going and that identifies our vulnerabilities and recommendations for how we can rebuild our industrial base.

Second, I believe the DoD and VA should have the flexibility to purchase medicines not at the cheapest price, but based on value because right now American tax payers will be shocked to learn that their hard-earned money is going to help build China's generic industry as our domestic industry collapses.

Third, there's tremendous opportunity with advanced manufacturing technology to make active ingredients here and finished generic drugs. It's been done on a pilot basis for generics. We need to take that to commercial scale. It could revitalize communities' economies around the country.

And finally, I'm sure you're aware, the Africa swine flu that is devastating the pig population, worse than what it was 12 years ago when we had the heparin contamination that killed hundreds of Americans, one of the recommendations I have in my testimony is that the Committee on Foreign Investment in the United States, CFIUS, review the purchase of Smithfield by a Chinese company, not so much for food security, but for our national health security and that's because pig intestines are a rare earth of our healthcare delivery system.

So I have 28 seconds left and I'll leave that to all of you and I look forward to your questions and comments.

**PREPARED STATEMENT ROSEMARY GIBSON, SENIOR ADVISOR, HASTINGS
CENTER, AUTHOR, "CHINA RX"**

**Testimony of Rosemary Gibson, Senior Advisor, The Hastings Center and
Author, “China Rx: Exposing the Risks of America’s Dependence on China for Medicine”
Before the U.S.-China Economic and Security Review Commission
“Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products”
July 31, 2019**

Thank you for the opportunity to testify at today’s hearing. I am Rosemary Gibson, Senior Advisor at the Hastings Center and author of “China Rx: Exposing the Risks of America’s Dependence on China for Medicine.”

I. Introduction

Millions of Americans are taking prescription drugs made in China and don’t know it and neither do their doctors. These are prescription drugs in the legal supply chain that are distributed to U.S. hospitals, sold in corner drug stores and grocery store pharmacies, and distributed to military hospitals and clinics around the world. These are *not* the counterfeit drugs bought on the internet, or illicit drugs such as illegal versions of fentanyl.

The public and many policymakers have been kept in the dark about U.S. dependence on China for medicine and the health security and national security risks of this dependence. It’s time to turn on the lights. The focus of this testimony is on generic drugs which are 90 percent of the medicines that Americans take.

II. National Health Security at Risk

National health security and national security are threatened by U.S. dependence on China for thousands of ingredients and raw materials to make our medicines. China’s aim is to become the pharmacy to the world, and it is on track to achieve it.

China’s dominance is global. European countries depend on China for medicines. A Dutch Public Television documentary in February 2019 reported the national security risks of the Netherlands’ dependence on China for medicine. A retired Dutch industry official said, “Now we’re afraid that China will do things to deprive us of our medication.”

India’s large generic drug industry may be perceived as a viable alternative supplier. Its generic manufacturers, however, depend on China for 80 percent of the active ingredients and chemical intermediates essential for production. If past performance is indicative of the future, China will eventually overtake India in generic drug production

The centralization of the global supply chain of medicines in a single country, whatever country it may be, makes it vulnerable to interruption, whether by mistake or design.

Meanwhile, as U.S. factories have shut down, causing the loss of tens of thousands of manufacturing jobs to China, the U.S. industrial base and our capacity to make most of our medicines is rapidly collapsing.

1. *The U.S. Has Lost Virtually All of Its Industrial Base to Make Generic Antibiotics* The nation’s health security is in jeopardy. The U.S. can no longer make penicillin. The last U.S. penicillin fermentation plant closed in 2004. Industry data reveal that Chinese companies formed a cartel, colluded to sell product on the global market at below market price, and drove all U.S. European, and Indian producers out of business. Once they gained dominant global market share, prices increased.

The U.S. can no longer make generic antibiotics. Because the U.S. has allowed the industrial base to wither, the U.S. cannot produce generic antibiotics for children's ear infections, strep throat, pneumonia, urinary tract infections, sexually-transmitted diseases, Lyme disease, superbugs and other infections that are threats to human life. We cannot make the generic antibiotics for anthrax exposure. After the anthrax attacks on Capitol Hill and elsewhere in 2001, the U.S. government turned to a European company to buy 20 million doses of the recommended treatment for anthrax exposure, doxycycline. That company had to buy the chemical starting material from China. What if China were the anthrax attacker?

2. *Beyond Antibiotics, the U.S. Industrial Base for Generic Drug Manufacturing Is on the Brink of Collapse. Generic Drugs are 90 Percent of the Medicines Americans Take* Beginning in 2007, China turned its attention to encourage its domestic companies to manufacture generic drugs for the U.S. The first was an HIV/AIDS medicine. China's generic industry is thriving as exports to the U.S. grow rapidly. Examples of generic drugs made in China by domestic companies and sold in the United States include: antibiotics, anti-depressants, birth control pills, chemotherapy for cancer treatment for children and adults, medicine for Alzheimer's, HIV/AIDS, diabetes, Parkinson's, and epilepsy, to name a few. If past performance is indicative of future performance, China's generic drug companies will engage in cartel formation and predatory pricing, and drive out U.S. and other western generic companies.

3. *If China Shut the Door on Exports of Medicines and Their Key Ingredients and Raw Materials, U.S. Hospitals and Military Hospitals and Clinics Would Cease to Function Within Months, if Not Days* A natural disaster, global public health crisis, or adverse foreign government action could disrupt the supply of medicinal ingredients and finished drugs. Surgeries could not be performed at Walter Reed National Military Medical Center (Bethesda Naval Hospital), Johns Hopkins Hospital, George Washington University Hospital, INOVA/Fairfax, every other U.S. hospital, and military hospitals around the world. Children and adults with cancer will suffer without vital medicines. For people on kidney dialysis, treatment would cease, a veritable death sentence.

4. *Presently, the pharmaceutical and chemical industry's successful requests to the U.S. Trade Representative not to impose tariffs on medicinal products made in China corroborate that much of the US industrial base, and our self-sufficiency in manufacturing products essential for life, has collapsed.*

As documented in *China Rx: Exposing the Risks of America's Dependence on China for Medicine*, within four years of the U.S.-China Trade Relations Act of 2000, the last penicillin fermentation plant in the U.S. closed; China's vitamin C (ascorbic acid) cartel forced the closure of the last U.S. production facility, and the last aspirin (acetylsalicylic acid) manufacturing facility ceased business because of predatory pricing by Chinese firms. Baxter Healthcare switched heparin suppliers from Wisconsin to China, and a lethal contaminant in heparin was later found that killed hundreds of Americans.

Nearly twenty years later in 2018 and 2019, U.S. industry has advocated successfully to keep medicinal products—prescription drugs and their core components—off U.S. tariff lists. The rationale for this position is tariffs would increase drug prices and health spending.

It is unclear whether, or how much, costs will rise absent transparency on the price paid to manufacturers by a handful of companies that buy generic drugs from manufacturers in China in large quantities, and absent the ability to compare this price with the amount consumers, hospitals, the military and the VA pay.

Second, emphasis on monetary price ignores a very high price the U.S. is paying: the loss of trust in medicines by doctors and the public because of substandard, defective, and lethal drugs sold to U.S.

hospitals and consumers. Ninety-five percent of Americans don't trust medicines made in China. A prominent physician said to me, "We are becoming like a developing country with our medicines."

Third, the absence of protection for U.S. generic and pharmaceutical chemical manufacturers from China's medicine cartels and predatory pricing has caused the near collapse of U.S. manufacturing, and remaining capacity faces an imminent existential threat.

Fourth, once China gains even more domination in production of generics, consumers, hospitals, and the government will lose control over the price they pay for medicines. China will be the price setter, and the U.S. will be the price taker.

Fifth, at that point, the FDA will have an even more difficult time than it does now to inspect and regulate the quality of medicines.

These points are discussed in greater detail below and illustrate that protecting China's industry and helping it grow, while causing the collapse of U.S. generic manufacturing, is a mistake of epic proportions to the country's health security and national security that will have serious adverse effects for generations to come.

5. As the U.S. Rapidly Loses Control Over the Production and Supply of Vital Medicines, It Loses Control Over the Price of Medicines Consumers and Hospitals Pay As China gains more control over America's supply of medicines, it could charge American consumers and patients higher prices, or extort concessions from the federal government to keep prices affordable. This is not mere speculation. China's domestic companies formed a vitamin C cartel in the early 2000s and increased prices up to 600 percent, which increased the cost to American consumers and businesses. When U.S. businesses sued the Chinese companies for antitrust violations, the Chinese government asserted in federal court that Chinese law *required* its domestic companies to fix prices and control exports of vitamin C to the United States. This assertion reveals China's clear strategy to control the supply and price of health-related commodities in the United States.

6. Risks of Contaminated and Potentially Lethal Medicines Are Increasing The deaths of 246 Americans who were administered the blood thinner heparin in 2007 and 2008 were reported to be associated with a lethal contaminant that was deliberately placed during the manufacturing process in China for economically motivated reasons. More recently, millions of Americans were sold blood pressure medicines that contained a cancer-causing genotoxic impurity. While many manufacturers have been forced to recall their products, the most troubling was a manufacturer in China whose blood pressure medicine, valsartan, contained per pill more than 200 times the acceptable interim limit for the carcinogen. Even more concerning is the manufacturer knew its product did not meet U.S. standards but sold it anyway to unsuspecting U.S. hospitals and patients. In the case of this company, the FDA banned all products from its facility from entry into the United States.

7. The FDA Cannot Fix the Underlying Cause of These Threats to National Health Security The FDA cannot fix the underlying cause of the proliferation of contaminated and potentially lethal medicines in the legal supply of America's medicines. It cannot fix the penchant of large purchasers of generic drugs to pay manufacturers the cheapest price rather than a price based on value, which includes quality, an uninterrupted supply, and health security.

The current approach of hammering down on manufacturers on price is the root cause of contaminated and lethal drugs in the legitimate supply chain and shortages and unavailability of life-saving medicines. Since the early 2000s, hundreds of medicines at any point in time are in short supply or unavailable

altogether in the United States. In 2015, the FDA banned twenty-nine products from a manufacturing plant in China. But because of concerns about shortages of vital medicines, the FDA exempted fifteen from its ban including products to make chemotherapy for children and adults with cancer, and to treat an AIDS-related cancer.

The FDA can regulate only the medicines that large buyers of generic drugs purchase. It cannot dictate *what* they buy. The FDA is caught in the “regulator’s dilemma” whereby it is in the unenviable position of weighing the relative risks of allowing vital but defective medicines to remain on the market or exacerbating shortages.

8. *More than 10 Percent of Generic Drugs Tested Do Not Meet Quality Standards* A growing number of Americans and their doctors are concerned about the quality and safety of their medicines and rightly so. An online pharmacy Valisure is reportedly the first pharmacy that chemically tests every batch of every medication it sells. At its laboratory located at the Yale Science Park in New Haven, Connecticut, more than 10 percent of the batches of medicines it has tested are rejected for not meeting quality metrics. Reasons for rejection include issues with dosage, dissolution, marketing claims related to dissolution or levels of probable human carcinogens.

9. *Procurement of Medicines from Trustworthy Manufacturers Based on Value, Not Cheap, is the Antidote to Threats to National Health Security* The threats to national health security are driven by the race-to-the-bottom on price paid to generic manufacturers. This price is different from the higher price that consumers pay. This practice is driving production to China, the only country whose government subsidizes its domestic manufacturers. It is building China’s industry while rapidly dismantling U.S. manufacturing.

C. National Security Risks

1. *Medicines Can Be Used as a Strategic and Tactical Weapon Against the United States* Medicines in the hands of an adversary can be weaponized. Supplies can be withheld. Medicines can be made with lethal contaminants or sold without any real medicine in them, rendering them ineffective. These products can be distributed to specific targets. Detection is time-consuming at best, and virtually impossible at worst.

2. *Dependence on China is a Risk to the U.S. Military, Combat Readiness, and Force Protection* The thousands of men and women on U.S. aircraft carriers in the South China Sea are dependent on the adversary for many of their essential medicines. Combat readiness and force protection are at risk with the military vulnerable to disruptions in supply and contaminated and toxic medicines. In 2018, more than 31,000 active duty military personnel, veterans, and their family members were notified they may have been given blood pressure medicines containing a cancer-causing ingredient.

3. *No one in the federal government is responsible for knowing who controls the U.S. supply of medicines.* The federal government lacks a locus of responsibility for conducting ongoing risk assessments to the U.S. supply of medicines. There is no point of accountability to take all means necessary to assure an uninterrupted supply of quality medicines produced by trustworthy manufacturers.

4. *Medicines should be treated as a strategic asset similar to oil and other energy supplies and agricultural commodities such as wheat and corn.* The United States would cease to function within days if supplies of energy and food commodities were disrupted. The same is true of medicines.

Recommendations

Recommendation #1: Require a whole of government review and assessment of the nation’s vulnerabilities in the medicine supply chain and recommendations to strengthen the U.S. industrial base to be able to meet the nation's critical generic drug needs.

A whole of government review and assessment of vulnerabilities in the medicine supply chain and industrial base to manufacture generic medicines and their ingredients is essential and should include the Department of Health and Human Services, Department of Homeland Security, Department of Defense, Department of Veterans Affairs, the National Security Council, and other relevant departments, agencies and other entities.

A framework for consideration that can be drawn upon is the 2018 Department of Defense report, Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States. The effort assessed the status of U.S. manufacturing and the defense industrial base, identified current risks, and identified action steps for risk mitigation.

Similarly, a whole of government review and assessment of the nation’s vulnerabilities in U.S. manufacturing of generic medicines and their ingredients should, inter alia:

- (i) identify finished drugs and essential components necessary for the manufacture of medicines vital for civilian and military use whose supply chains are at risk of safety and quality concerns and disruption;
- (ii) identify the defense, homeland, economic, geopolitical and other contingencies that may disrupt, strain, compromise, or eliminate supply chains of medicines and their essential components that are sufficiently likely to arise and require preparation for their occurrence;
- (iii) assess the resilience and capacity of the manufacturing base and supply chains to support health security and national security needs in the event of the contingencies including an assessment of: the manufacturing capacity of the United States; gaps in domestic manufacturing capabilities including non-existent, extinct, threatened, and single-point-of-failure capabilities; and supply chains with single points of failure and limited resiliency;
- (iv) recommend legislative, regulatory, and policy changes and other actions to avoid, and prepare for, contingencies identified; and
- (v) recommend federal investments to strengthen the U.S. manufacturing base and increase self-sufficiency in the manufacture of priority generic medicines and their ingredients in the interest of the country’s health security and national security.

Recommendation #2: The National Health Security Strategy, the National Security Strategy, and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) strategy should include actions to strengthen the U.S. industrial base to assure an uninterrupted supply of generic medicines and the ingredients to make them. This is vital for the continuity of day-to-day operations of the nation’s hospitals, health care systems, and military hospitals and clinics around the world.

A robust and resilient industrial base capable of manufacturing generic medicines and their essential ingredients should be a national health security and national security priority. Further, it should be the policy of the federal government to reduce the nation’s vulnerability to disruptions in the supply of medicines and their essential ingredients.

Identification of actions in the above strategic plans to strengthen the U.S. industrial base will elevate the importance of domestic capacity to manufacture generic medicines most vital for continuity of operations in the civilian and military health care systems.

Recommendation #3: Manufacturers of generic medicines who sell medicines to the Department of Defense and VA should be required as a condition of receipt of taxpayer dollars to disclose to the Department of Defense and VA whether their products and the active ingredients, chemical intermediates, and raw materials contained in them are sourced from countries that are adversaries or strategic competitors to the United States. This information is vital for the Department of Defense to conduct its mission on behalf of the nation.

Some generic drug manufacturers will not disclose the country-of-origin of medicines to the Department of Defense. Lack of transparency in country-of-origin poses a risk to combat readiness and force protection.

Recommendation #4: The Department of Defense and the VA should have the flexibility to procure medicines based on value and not the cheapest price. Currently, the DoD and VA buy medicines based on price alone. This practice undermines force protection and combat readiness. It also increases the military's dependence on China. Further, American taxpayers will be dismayed to learn that their money is helping China grow its domestic generic industry while enabling the imminent collapse of U.S. generic manufacturing.

The Department of Defense and the VA buy the cheapest medicines to assure prudent use of taxpayer money. This practice exposes the U.S. military to dependence on China and helps build China's industry as U.S. manufacturers face an imminent existential threat. This practice stands in contrast to military procurement of nuclear submarines and aircraft carriers for which outsourcing of manufacturing to China is not an option on grounds of national security. The same rationale should apply to vital medicines such as generic antibiotics.

Combat readiness and force protection will be strengthened by providing the Department of Defense the flexibility to procure medicines based on value (price, quality, reliable supply, and security).

U.S. hospitals are using their procurement dollars to launch the purchase of prescription drugs based on value not just price. Civica Rx is a non-profit formed by the Mayo Clinic and 900 hospitals representing one-third of licensed hospital beds in the U.S. It pays manufacturers a fair, sustainable, and transparent price, not a race-to-the-bottom price. The country-of-origin and manufacturer are transparent to the purchasers. Long-term contracts with manufacturers enable them to invest in their facilities and assure an uninterrupted supply of quality medicines. Civica Rx is procuring life-saving generic antibiotics that will be manufactured in Ohio.

The combined purchasing power of the Department of Defense and the VA, coupled with long-term contracts with manufacturers, could spur production in the United States and deliver quality medicines for the men and women in uniform, their families, and America's veterans.

Recommendation #5: Congress should provide funding for pilot projects to demonstrate the feasibility of commercial-scale advanced manufacturing technology to produce generic drugs and their essential ingredients to meet national health security needs. This funding will enable medicines to be produced much faster, at lower cost, more reliably with real time quality control, and a smaller environmental footprint.

The Defense Advanced Research Projects Agency (DARPA) has supported the development of advanced manufacturing technology to strengthen battlefield medicine in field hospitals and remote areas with disease outbreaks among other applications.

Currently, applications of this technology have successfully demonstrated small-scale production of the active ingredients in a number of essential medicines.

While pharmaceutical companies with new drugs under patent are beginning to adopt advanced manufacturing technology, U.S.-based generic companies are unlikely to invest in innovative manufacturing because it is financially infeasible due to severe price competition from Chinese domestic firms.

Federal investment is needed to show proof-of-concept of commercial-scale domestic production for generic drugs, their active ingredients, and chemical starting materials. This action will create a robust and resilient manufacturing base and secure the nation's health security and national security.

Recommendation #6 The Committee on Foreign Investment in the United States (CFIUS) should review the health security and national security implications of Chinese company ownership of Smithfield Foods, the world's largest pork processor and hog producer. Pig intestines are the "rare earths" of medical care and vital for the day-to-day functioning of U.S. civilian and military hospitals.

The U.S. and the world depend on China for an estimated 80 percent of the pig intestines to make heparin, a blood thinner which is ubiquitous in hospitals. It can be said that pig intestines are the "rare earths" of medical care. Rare earths are essential components for electric vehicles, consumer electronics, other high-tech devices, and the defense industry. In the health care sector, pig intestines are essential components for the functioning of the U.S. medical care system. It takes one pig to make a vial of heparin.

In 2018, African swine flu virus erupted in China and the US Department of Agriculture estimates a nearly 20 percent decline in China's pig population in 2019 from 428 million to 350 million. Twelve years ago, blue ear disease in China decimated its pig population, not as severely as the present situation. Facing a shortage of the authentic ingredient at that time, economically motivated criminals in China's heparin manufacturing industry developed a lethal substitute that mimicked the real one. Product was shipped to the United States and other countries, and the estimate of 246 deaths is a likely underestimate because of the insidiousness of lethal ingredients in medicine and the challenge of linking cause and effect.

In the short term, severe heparin shortages are predicted for the U.S. and other countries. In the medium-term, global demand for heparin will increase because of U.S. and global population growth coupled with the expansion of China's hospital and health care sector. Meanwhile, the land carrying capacity for an increase in the pig population, and the threat of more disease outbreaks, suggest supply will not keep pace with demand.

In 2014, the FDA Science Board, which advises the FDA Commissioner on matters of scientific affairs, discussed heparin supplies and shortages. It was noted that if the U.S. has virtually all the heparin coming from a single country, no government agency can order U.S. pig producers "to put all of their pig guts after slaughter into heparin production" to assure continuity of health care provision in the United States. It was suggested that this concern be elevated to the highest levels of national security.

The Committee on Foreign Investment in the United States (CFIUS) should review the national security implications of Chinese ownership of Smithfield. According to the CFIUS website, its members do not

include the Secretary of the Department of Health and Human Services, who oversees national health security and public health emergencies. This needs to change. Components of medicinal products are essential to the business continuity of the U.S. medical care system.

Conclusion

I want to thank the Commission for holding today's hearing and drawing attention to U.S. dependence on China for medicines and the impact on the nation's health security and national security. Thank you for the opportunity to testify and I look forward to your questions and helping the Commission in any way going forward.

OPENING STATEMENT OF BEN WESTHOFF, AUTHOR, “FENTANYL, INC.”

COMMISSIONER TALENT: You're yielding back the 28 seconds. Thank you for that and for your testimony.

Mr. Westhoff.

MR. WESTHOFF: Thank you, Senator Talent, Commissioner Wessel, and the distinguished members of the Commission for allowing me to testify today.

The U.S. opioid crisis began with the over prescription of pharmaceutical opioids like OxyContin. When users' prescriptions ran out, many turned to street heroin. Now the crisis has entered its third wave led by fentanyl. Fentanyl was already a widely used medical drug, but illicitly-produced fentanyl is mainly abused today. This fentanyl is mostly made in China and then sent directly to U.S. consumers through the mail or funneled into the country by Mexican cartels.

U.S. political leaders have harshly criticized China for allowing large quantities of fentanyl, fentanyl analog, fentanyl precursors, and other new drugs called novel psychoactive substances, or NPS, to be smuggled into America. In response, China has pledged strong action to stem the tide.

However, my deep reporting and research for my new book, *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*, shows that China has not been acting in good faith. I will explain.

A critical part of China's rapidly-growing economy is its sprawling chemical and pharmaceutical industries. Most companies produce legitimate chemicals, some make illicit ones, and others are in between. Reforms have been promised, but inspections remain sporadic. China's clumsy, understaffed bureaucracy involving at least eight different agencies has a difficult time controlling these industries. Thus, dodgy companies that keep their heads down can operate without problems.

Many Chinese officials don't seem to fully understand the laws governing the manufacture and sale of these chemicals and companies manipulate the legal gray areas to their advantage. At the same time, China encourages these industries through lucrative tax incentives and subsidies. These incentives have undoubtedly driven legitimate innovation in exports, but the rise of fentanyl and NPS has been a terrible side effect.

Quietly, money has gone to Chinese companies exporting deadly drugs that are killing tens of thousands of Americans annually. For example, China designates certain companies as new and high technology enterprises which helps these companies, including those exporting dangerous drugs to the U.S., receive lucrative incentives.

Also exploited are various programs administered by China's Ministry of Science and Technology. Chinese companies showered with these types of government benefits include one called Yuancheng, based out of the city of Wuhan. It receives them even while by its own admission it sells ingredients to make fentanyl called precursors all over the globe including to the U.S.

It is possible that Chinese Communist Party officials don't realize this is happening. Then again, it's possible they do considering the Chinese tax code directly encourages the export of these drugs through reimbursements called the value-added tax rebate or VAT rebate. Not every exported chemical gets a VAT rebate, but thousands do including fentanyl, other fentanyl analogs not used for medical purposes anywhere, synthetic cannabinoids, and anabolic steroids.

The U.S. says stemming the flow of illicit synthetic opioids and other NPS from China is

a top priority. And China says it shares this commitment. Indeed, on May 1, 2019, China scheduled all fentanyl analogs including those not yet created.

China has difficulty enforcing its drug laws, but this was the most far reaching and potentially significant type of action China has taken in this realm, yet there's much more the U.S. can do to stem the flow of these drugs from China.

My first suggestion is pressuring China to eliminate tax rebates, grants, and subsidies to companies making and exporting these dangerous chemicals. It makes sense for legitimate Chinese pharmaceutical companies to receive VAT rebates for exporting fentanyl for medical use. But it is outrageous that China offers these tax rebates for many other fentanyl analogs that are illegal for Chinese manufacture and export.

China also needs to eliminate incentives given to these companies by the Ministry of Science and Technology.

My next suggestion is that the U.S. schedule more fentanyl precursors and pressure China to do the same. Making fentanyl from scratch is a complicated process, but making it from precursors is a fairly simple one. This is the process favored by Mexican cartels who usually import the precursors from China. Yet, currently, all but two of the known fentanyl precursors are unscheduled, not just in China, but in the U.S. and worldwide.

The U.S. should also pressure China to allow the DEA and the FDA to do their work. China's pledge to control fentanyl analogs are meaningless without enforcement. It's not just the American agencies, however. China's own drugs and medicine regulating agencies need to be properly staffed and funded.

My final suggestion is that the U.S. should do more at home. China believes U.S. demand is driving the opioid crisis and indeed predatory tactics by U.S. pharmaceutical companies and sales policies here have helped create the world's largest market for opioids. Therefore, even if China reigns in its rogue industries, if American demand for these drugs does not subside, production will simply shift to other countries. Promoting harm-reduction measures is critical. Advocates of harm reduction believe drug use is inevitable and that we must work to make it as safe as possible.

I suggest much increased funding for medication-assisted treatment for addicted users. In addition, first responders and others who encounter overdose victims should be better supplied with naloxone which should be available and affordable to everyone.

Users need better access to drug-checking kits. These are inexpensive tests that inform users what's actually in their drug and can detect fentanyl. Studies have shown these tests save lives.

Also critical is overturning the Illicit Drug Anti-Proliferation Act of 2003, known as the RAVE Act which effectively inhibits concert organizers from allowing drug checking at their events and festivals.

Information campaigns about NPS are also critical, especially when it comes to children. Parents, in particular, need to be properly educated. They need to believe that an overdose can happen to their kid because it can happen to any kid. Thank you.

PREPARED STATEMENT OF BEN WESTHOFF, AUTHOR, “FENTANYL, INC.”

Panelist Name: Ben Westhoff

Author of *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*

Testimony before the U.S.-China Economic and Security Review Commission

“Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products.”

July 31, 2019

Introduction

The U.S. opioid crisis began with the overprescription of pharmaceutical opioids like OxyContin; when users' prescriptions ran out, many turned to street heroin. Now, the crisis has entered its third wave, spurred by fentanyl. Though fentanyl was already a widely-used medical drug produced by legitimate pharmaceutical companies, illicitly-produced fentanyl is mainly abused today. This fentanyl is mostly made in China, and then sent directly to U.S. consumers through the mail, or funneled into the country by Mexican cartels.

China has been harshly criticized by U.S. political leaders for allowing large quantities of fentanyl, fentanyl analogues, fentanyl precursors and other new drugs known as Novel Psychoactive Substances (NPS) to be smuggled into America. Yet most of China's critics recognize the difficulty of controlling the country's vast chemical and pharmaceutical industries, where legal and illegal production can take place in the same facilities. Further, China has pledged strong action to stem the tide of these drugs. Earlier this year the country scheduled all fentanyl analogues, a move that was applauded by President Trump and others.

My deep reporting and research for my new book *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*, however, shows that China has not been acting in good faith. The country's stated goal to crack down on these drugs has been undercut by its monetary policies, which directly support rogue Chinese chemical companies, the very same ones that are fueling America's opioid crisis.

Factors contributing to China's emergence as a global hub of illicit and counterfeit medicines and pharmaceuticals

A critical part of China's rapidly growing economy is its sprawling chemical industry. Its 400,000 chemical manufacturers and distributors (by U.S. Department of State estimates) span the country, making and selling everything from fertilizers to industrial solvents to antibiotics to psychoactive drugs. Most operate legally, some operate illegally, and others are in between. Driven in part by government subsidies and incentive programs, as well as a large population of skilled chemists, China's pharmaceutical industry has also been growing at a breakneck pace for decades, especially since the normalization of U.S.–China trade relations in 2000.

This chemical and pharmaceutical industry expansion has been driven in large part by exports, which are seen as critical to the country's continued growth. At the same time, China has been under fire for years for its record on food and medicine safety. Its medicines and supplements have been responsible for hundreds of deaths and thousands of hospitalizations around the world (exact numbers are unknown).

Reforms have been promised, but inspections remain sporadic and American officials have not been satisfied. For a variety of reasons, Chinese companies making medicines tend not to be inspected as thoroughly as those in Western countries. Though the U.S. FDA has a presence in China and is permitted to do some (though not all) of its desired inspections, it is, by all accounts, understaffed and underfunded.

Meanwhile, China's clumsy, understaffed bureaucracy has a difficult time controlling the country's chemical industry. Different layers of government are sometimes at odds with one another, local officials are corruptible, and industry regulations are confusing and poorly enforced. Thus, dodgy companies that keep their heads down can often operate without problems. Many have websites advertising legitimate products, while also making chemicals intended for illicit use.

“Lack of coordination and competing regulatory oversight...creates opportunities for some firms to hide unregulated activities in plain sight,” testified the RAND Corporation's Bryce Pardo, an expert on drugs in China, to Congress in 2018.

While American chemical and pharmaceutical companies tend to portray themselves as focused and streamlined, many of their Chinese counterparts offer an extraordinary range of products. Regulating this industry—where chemicals that speed up rubber manufacturing and those combating erectile dysfunction are peddled by the same people—is complicated by the fact that China's chemical bureaucracy involves at least eight different agencies, including its Food and Drug Administration, Ministry of Chemical Industry, and General Administration of Quality Supervision, Inspection, and Quarantine.

Because there are so many regulatory agencies, and because so many chemical companies make both legitimate and illicit products, the Chinese government has a difficult time finding and penalizing those who break the law. “Many of China's chemical production facilities are described as ‘semi-legitimate’ producers, which are allowed to make chemicals but unlicensed to sell them to pharmaceutical companies,” reads a 2016 report by Sean O'Connor of the U.S.—China Economic and Security Review Commission.

Being unlicensed doesn't necessarily stop these producers from selling to pharmaceutical companies, however. To further deceive the government, some companies set up "shadow factories," facilities shown to inspectors that are not actually where their drugs are made. Fentanyl-precursor manufacturers, for example, can evade scrutiny by labeling their products as industrial chemicals instead of pharmaceutical ones.

Few people seem to understand the laws governing the manufacture and sale of Chinese chemicals. Long and complicated ordinances are enacted at the whim of the central government, and then enforcement often falls to regional agencies, who may not fully understand what Beijing has commanded or may have their own, competing interests. Chemical companies manipulate the large amount of gray area to their own advantage to reap profits.

How the Chinese government supports its rogue chemical industry

For more than a decade, China has been encouraging its chemical and pharmaceutical industries by offering companies lucrative tax incentives, subsidies, and other direct financial support. The government has devoted enormous resources to the task, and these incentives have undoubtedly driven innovation and helped expand these industries and their exports. But the rise of fentanyl and NPS has been a terrible side effect. Quietly, money intended to spur legitimate innovation has gone to companies exporting deadly drugs that are killing tens of thousands of Americans annually. It's unclear how aware the Chinese central government is of this. Neither China's National Narcotics Control Commission, nor the Chinese embassy in Washington D.C., responded to my requests for comment.

One method the government uses to promote its chemical and pharmaceutical industries is by designating companies as New and High Technology Enterprises [NHTEs]. This is a critical designation toward receiving financial incentives. "Since China's new Enterprise Income Tax Law took effect in January 2008, the country's national and provincial governments have implemented a series of tax incentives for [NHTEs]," reads a briefing by the Asian business advisory firm Dezan Shira & Associates. "A hugely profitable industry in China, proactively applying for the different subsidies, tax exemptions and government funding schemes can significantly reduce a high tech company's tax burden and improve its market position."

It might seem strange to call these chemical and pharmaceutical companies "tech" companies, but the term tech is used differently in China. "It's not just those that make computers or chips or semiconductors," said Lucy Lu, research analyst for the Washington, DC-based Peterson Institute for International Economics. "If you're a chemical company and, say, invent some new chemicals or new drugs, you will be considered a tech company in China."

Other programs benefiting Chinese companies exporting illicit drugs include the Spark Program, which according to a Chinese government website is “aimed at popularizing modern technology in rural areas,” as well as something called the Innovation Fund, both of which are administered by the Ministry of Science and Technology. This organization also administers the Torch Program, which helps these companies by assisting with marketing and personnel training, and in other areas. “In size, scale and commercial results China’s Torch Program,” wrote the Huffington Post, “is the most successful entrepreneurial program in the world. Of all the Chinese government programs, the Torch Program is the one program that kick-started Chinese high-tech innovation and start-ups.”

The Torch Program also helps establish special industrial zones, which seek to promote Chinese businesses through subsidized land, subsidized rent, shared manufacturing infrastructure, and other resources. “China has been very generous in building these industrial parks as attractions for companies,” said Gary Hufbauer, a trade expert at the Peterson Institute for International Economics. “It’s a nice break, certainly on the land, and maybe even the building.” The benefits of operating in these zones can significantly impact a company’s bottom line. “The high-tech zones have become a major engine to China’s economic growth,” Zhang Zhihong, director of the Torch High Technology Industry Development Center, told China’s state-run news agency Xinhua.

Many Chinese companies exporting dangerous drugs for illicit use are showered with government benefits. One particularly egregious example is Yuancheng Group, which is located in the city of Wuhan and sells huge quantities of fentanyl precursors. As shown in *Fentanyl, Inc.*, the government designated Yuancheng an NHTE in 2011, entitling it to preferential tax policies and also making it eligible for various rebates and reimbursements related to research-and-development efforts and staff training. Beginning in 2012 Yuancheng was sponsored for three years by the Torch Program, and has also been a beneficiary of the Spark Program and the Innovation Fund. It has also won government grants, and some of its sub-companies list an address in a special industrial zone. All of this has taken place while Yuancheng has been, by its own admission, selling fentanyl precursors all over the globe. Its clients include Mexican cartels, American drug dealers, and many others. This is perfectly legal under Chinese law; when one fentanyl precursor is banned in China, Yuancheng simply halts its sale and focuses on others that remain unscheduled.

Another company selling fentanyls and NPS that was incentivized by the Chinese government is 5A Pharmatech Co., led by Yan Xiaobing, a Chinese national who has been placed on the U.S. Justice Department’s list of most prolific international drug traffickers. Indicted in September, 2017, Yan, who is also based in Wuhan, stands accused of conspiring to manufacture a host of NPS, including Flakka, N-bombs, synthetic cannabinoids, methylene, fentanyl, and fentanyl analogues, and then distributing them in the United States and twenty other countries. China has

refused to extradite him to the U.S. 5A claimed to make legitimate chemicals for export, and to work with large firms including Johnson & Johnson and Pfizer, but representatives from both companies denied this. Nonetheless, 5A -- which is a subsidiary of Wuhan Livika Technology Co., and until early 2016 was known as 9W Pharmaceutical Technology Co. – had the support of the Chinese government. According to a company profile on Hubei Province’s official website, the company was located in an economic development zone. (The company also claimed to have received certification as an NHTE, but this could not be confirmed.)

It is possible that Communist Party officials don’t realize companies they support are exporting illicit fentanyl products and other NPS. Then again, it’s possible that they do, considering that the Chinese tax code directly encourages these exports.

This practice apparently stems from China’s desire to upgrade its pharmaceutical industry. While the US pharmaceutical industry makes expensive, patent-protected, brand-name drugs, China specializes in cheap generic drugs, which is why its legal, aboveboard chemical revenue is smaller than America’s, despite greater output.

China is trying to change this, however. A countrywide initiative called “Made in China 2025” seeks to upgrade the country’s manufacturing status, to move it up the “value chain,” using policy changes and government investment. The Chinese pharmaceutical industry is a major part of this initiative, and the government has moved to incentivize increased spending on research and development, and to promote industry consolidation. The goal is to produce higher-quality, more expensive medical drugs, for use at home and abroad.

One way China works to expand these exports is by offering tax reimbursements via the value-added tax rebate, or VAT rebate. Companies are reimbursed for tax money they have already paid in the process of making their products—for example, taxes they paid when they bought the ingredients needed to make a certain chemical compound.

The VAT rebates go as high as 16 percent; a 16 percent rebate means the exporters receive a full tax reimbursement. Not every exported chemical gets one, but thousands do, and the rebates vary wildly. According to China’s State Administration of Taxation website, aspirin and sildenafil (the drug in Viagra) get no VAT rebates. Melamine, the industrial chemical used to adulterate milk powder products that was linked to infant deaths in 2008—but which also has safe uses—gets a 10 percent rebate. So does fentanyl. And beyond that at least ten fentanyl analogues—including 3-methylfentanyl, which is not used for legitimate medical reasons, anywhere—get a 13 percent rebate. In September 2018, China announced it would raise VAT rebates on about four hundred different products for export, from chemicals to semiconductors, in what Reuters described as “a bid to boost prospects for shipments amid its trade war with the United States.” Also in 2018, the VAT rebate for fentanyl was increased, from 9 percent to 10 percent. It was not

one of the four hundred products from the September announcement, and it is unclear when exactly in 2018 this occurred, or whether it was also in response to the trade war.

China began issuing VAT rebates in 1985. It doesn't explain why particular chemicals get the rebates they do; one possibility is that products with a "value add" get higher rebates, while generics get lower rebates or nothing. There is no doubt that if a particular chemical's VAT rebate rate is higher, companies are more likely to export it.

Among the beneficiaries of these rebates are legitimate Chinese companies legally manufacturing fentanyl for medical use. Only three types of fentanyls are legally permitted to be made in China for domestic medical use or export: fentanyl, sufentanil, and remifentanil. It's unclear why at least eight other fentanyl analogues get VAT rebates. And while it's also unclear how many Chinese companies exporting fentanyls or fentanyl precursors for illicit use are receiving these tax rebates, the CEO of Yuancheng Group, which exports fentanyl precursors that are used illicitly, says his company is included among them.

There is little doubt that China is undercutting its publicly stated goal of stopping the export of dangerous drugs for illicit use. Besides encouraging their export through its tax code and high-tech subsidies, it has been ineffective at ensuring such exports don't end up in the wrong hands.

"If China had a subsidy on lead, you'd probably see a lot more bullets coming out of China, and that's what's happening here with the precursors. They're just subsidizing whatever is a high-value commodity, and in this case it just happens to be really potent synthetic opioids or opioid precursors," said RAND's Bryce Pardo. "The Chinese government doesn't have a good capacity for regulating its own industry. At the same time, it wants to export and make as much money as possible. They're getting ahead of themselves and causing a lot of harm in the process."

Dr. Katherin Tobin, former Commissioner for U.S.–China Economic and Security Review Commission, said my findings fit with a pattern of Chinese government activities that the Commission has long been tracking.

"The primary incentive, particularly for local-level Chinese government officials, is to support economic growth," said Tobin. "Therefore, it is likely Chinese regulators and policymakers have chosen to look the other way regarding the production and export of fentanyl products. This incentive structure persists despite the Chinese government's repeated promises to crack down on narcotic flows, a sign that Beijing is guilty of gross negligence in enforcing its chemical regulations, bad faith in its negotiations with the United States, or both."

How to stem the flow of illicit synthetic opioids from China

The U.S. says stemming the flow of illicit synthetic opioids and other NPS from China is a top priority. U.S. Senators Chuck Schumer and Tom Cotton, who are targeting fentanyl produced in China, wrote recently in *USA Today* that legislation they proposed would “require the imposition of sanctions on criminal organizations that traffic these drugs into the United States, the financial institutions that assist them and the drug manufacturers that supply them. The legislation would also urge diplomatic efforts with U.S. partners to establish multilateral sanctions against foreign traffickers, and authorize new streams of funding across the U.S. government to combat opioid trafficking.” It would also “allow the U.S. to apply pressure to the Chinese government to boost regulatory enforcement on pharmaceutical companies that create and distribute the drug.”

Such actions could be beneficial in numerous ways, including potentially cutting into illicit drug manufacturers profits; I’ve found that these organizations sometimes stash money in American-owned banks or banks owned by countries with U.S. partnerships, for example.

Greater regulatory enforcement by China is also critical. President Xi Jinping has sought tighter regulations in drug production and increased penalties for rogue actors, and in March 2018 it was announced that the Chinese FDA was being reorganized to strengthen its oversight capabilities. But more action is needed.

A sticking point has been China’s lag behind the U.S. in scheduling dangerous fentanyls and NPS, often for years. For this reason the U.S. lobbied China to “blanket ban” fentanyls, similar to America’s Federal Analogue Act. Signed by President Reagan in 1986, this law specifically targeted fentanyls and NPS (then known as designer drugs) by making anything deemed “substantially similar” to schedule I or II psychoactive drugs—in either effect or structure—automatically illegal from the moment of creation. The effectiveness of this law has been debated; it is difficult to enforce, and some scientists say it inhibits their ability to do scientific research and develop effective new medicines.

But President Trump got his wish when, on May 1, 2019 China scheduled all fentanyl analogues, including those not yet created. This is the most far-reaching, and potentially significant, type of action China has taken in this realm. It is far from a panacea -- China has difficulty enforcing its drug laws -- and yet it may be effective, considering that, in the past, shortly after China schedules a specific chemical, U.S. seizures of that chemical drops, something that is not true when a chemical is scheduled in the U.S. or internationally. Further, a large percentage of the dangerous recreational chemicals made in China are synthesized not by cartels or criminal organizations, but by companies operating legally. The leaders of these organizations often follow the letter of the law.

The effectiveness of China’s “blanket ban” of fentanyl analogues should be judged by the amount of seizures of novel fentanyls in the U.S. in the coming years. If the numbers drop

significantly, the blanket ban should be considered a success. However, even if China succeeds in substantially lowering its illicit NPS output, the industry may simply migrate to other countries, like India.

There is much more the U.S. can do to effectively stem the flow of illicit synthetic opioids and other NPS from China. My suggestions:

1) Pressure China to eliminate tax rebates, grants, and subsidies to companies exporting illicit fentanyl, fentanyl precursors, and NPS.

Beyond its illicit uses, fentanyl is an important medical drug. For this reason it is fine for legitimate Chinese companies to receive VAT rebates for exporting it and other chemicals used in medical settings. But it is outrageous that China offers these tax rebates for at least eight other fentanyls that are illegal for Chinese export, including chemicals that have never been used for legitimate medical reasons, anywhere.

And it's not just VAT rebates. As detailed above, Yuancheng and other companies selling fentanyls, fentanyl precursors, and NPS receive other subsidies and grants from the Chinese government, including from programs run by China's Ministry of Science and Technology. These are clear and obvious examples of China encouraging the production of dangerous drugs that are killing Americans, and the U.S. should pressure them to cease doing so.

2) Schedule more fentanyl precursors and pressure China to do the same.

Making fentanyl from scratch is a complicated process, but making it from precursors is a fairly simple one. Mexican cartels, for example, tend not to have access to trained chemists capable of making it from scratch, and thus tend to import the precursors from China.

Controlling the flow of fentanyl precursors, then, is of critical importance, and yet currently Chinese companies are able to export them to anyone for illicit use, with no controls whatsoever.

According to the DEA, there are sixteen different known precursor chemicals that can be used to make fentanyl. Only two are scheduled, NPP and 4-ANPP. The U.S. scheduled NPP in 2007, and 4-ANPP not long after, but they weren't scheduled in China until November, 2017, ten years later. As a result, when the current fentanyl crisis began to gain speed in the 2010s, Chinese companies were well-positioned for legal NPP and 4-ANPP sales, with virtually no oversight from the Chinese government.

To this day, the rest of the known fentanyl precursors remain unscheduled, not just in China but in the U.S. and worldwide. And so Chinese companies are able to sell them, for illicit use, with

no consequence. Since 2017, for example, Yuancheng Group has been pushing fentanyl precursors known as N-phenylpiperidine-4-amine and 4-anilino-1-benzylpiperidine. The company's salespeople offer to send these precursors in phony packaging to fool U.S. customs. - purporting to contain, say, banana snacks or dog food.

Much has been made over China's scheduling of fentanyl analogues, but their scheduling of fentanyl precursors could potentially have an even larger impact. They are unlikely to do so, however, unless the precursors are first scheduled in the U.S. and internationally.

3) Pressure China to allow the DEA and the FDA to do their work.

Sean O'Connor's 2017 U.S.–China Economic and Security Review Commission report noted “several recorded instances of Chinese law enforcement and drug regulators delaying visa approvals for FDA officials and deleting laboratory test records.” The DEA is also sometimes not allowed to do its work in China. According to Katherine Tobin, former member of the U.S.–China Economic and Security Review Commission, China's pledge to control fentanyls are meaningless without enforcement. “The Chinese government's promises have not been fulfilled until U.S. officials and law enforcement on the ground in China—such as the DEA and FDA—observe these controls being implemented in a manner consistent with Beijing's pledge to crack down on flows of fentanyl, as well as fentanyl analogues and precursors.”

It's not just the American agencies, however. China's own drugs- and medicine-regulating agencies need to be properly staffed and funded, before there can be any hope of consistent enforcement of China's drug laws.

4) Promote harm reduction at home

China believes the U.S. bears a great deal of responsibility for the opioid crisis, considering the overwhelming demand for opioids here. Indeed, predatory tactics by U.S. pharmaceutical companies and failed U.S. policies have helped create the world's largest market for opioids. Therefore, even if the above tactics are effective in diminishing China's export of illicit fentanyls and NPS, if American demand for these drugs does not subside, the production will simply shift to other countries.

According to nearly every drug and addiction expert I spoke with for *Fentanyl, Inc.*, decades of War on Drugs policies have failed to protect American users from overdose and death. Fortunately, America's political leaders are beginning to believe that care and treatment are more effective than incarceration, as shown by President Trump's signing of a pair of 2018 bills: one providing for better opioid treatment options, and another focused on criminal justice reform, which reduces some drug sentences. However, the criminal justice reform law specifically

excluded fentanyl offenders -- which was a mistake -- and many politicians continue to make the dubious distinction between users and dealers, considering that many addicted users become dealers simply to support their habits. “These aren’t two distinct sets of people,” Maryland public defender Kelly Casper told *Mother Jones*. “They want to charge all of these people with drug dealing, when in fact the core of the problem is that they’re users.

Advocates of harm reduction believe that drug use is inevitable, and that we must work to make it as safe as possible. Curbing the tide of U.S. opioid deaths will require sweeping new harm reduction-focused public-health initiatives, including much-increased levels of funding for treatment programs like medication-assisted treatment. First responders, police, firefighters, and others who encounter overdose victims need to be better supplied with naloxone, which should be available and affordable to everyone.

Also critical is increasing users’ access to drug-checking kits. These are inexpensive tests that inform users what’s in their drugs, and can immediately detect the presence of drugs like fentanyl. These tests, made by companies like Bunk Police, serve as a form of prevention and save lives. A 2017 study carried out in Vancouver, British Columbia found that those who discover fentanyl in their drugs are ten times likelier to lower their dose, which makes them 25 percent less likely to overdose. “Drug users are far more rational than we make them out to be,” said Dan Ciccarone, a University of California, San Francisco doctor who is an expert in this field, told *The Cut*. Also critical is overturning the Illicit Drug Anti-Proliferation Act of 2003, known informally as the RAVE Act, which effectively inhibits concert organizers from allowing drug-checking at their events and festivals. Many young people die of drug overdoses at these events every year, lives that could be saved if this legislation were overturned.

Information campaigns about fentanyl and NPS are also critical. Rather than simply preaching “Just Say No,” users must have reliable, accurate information, to know the dangers of hyper-potent new synthetic drugs like fentanyl and K2/Spice (also known as synthetic cannabinoids), compared to traditional, plant-based drugs like heroin and marijuana. It’s one thing to experiment, but when people know that the drugs in their hands could kill them instantly, they’re more likely to use caution.

Information campaigns are vital at schools, hospitals, youth centers, treatment centers, and elsewhere. During my reporting I visited the suburbs of Dallas, Texas, which has been hit especially hard by these new drugs. A substance abuse counselor there named Grace Raulston told me that the K2 menace in the area was significantly reduced after an information campaign was disseminated. “The biggest thing we’re fighting now is education. The majority of people out there—parents especially—do not have any idea the scope of the problem we’re dealing with today,” said Courtney Pero, a narcotics sergeant from Plano, Texas.

Parents need to believe that an overdose could happen to their kid, because it can happen to any kid.

**OPENING STATEMENT OF DR. JENNIFER BOUEY, TANG CHAIR IN CHINA
POLICY STUDIES, RAND CORPORATION; ASSOCIATE PROFESSOR,
GEORGETOWN UNIVERSITY'S SCHOOL OF NURSING AND HEALTH STUDIES**

COMMISSIONER TALENT: Thank you. Dr. Bouey. Am I pronouncing your name correctly?

DR. BOUEY: Bouey, yes.

COMMISSIONER TALENT: Bouey, okay. Go ahead. Thank you.

DR. BOUEY: Senator Talent, Commissioner Wessel, and distinguished members of the U.S.-China Economic and Security Review Commission, thank you for inviting me to testify before you on China's activities on global health.

My testimony will have three sections. First, I will give a brief overview of China's global health assistance activities and their motivations. Secondly, I will summarize U.S.-China's collaborations of health and their differences in their approach. And lastly, I will give some recommendations.

China's current global health assistance can be grouped into five categories: Chinese medical team; the hospital, clinic construction; medicine and medical equipment donation; health related humanitarian aid and disaster relief programs; and health professional training programs.

The Chinese medical team and hospital construction have the longest history. Dating back to 1959, China built a TB hospital for Mongolia. And back in 1963, they dispatched their first medical team to Algeria during the war.

Over the past years, China has built more than 150 hospitals, dispatched more than 25,000 medical professionals to 69 countries. These activities help to fill in some of the gaps when there is a severe lack of health professionals and basic health infrastructures in resource poor areas.

And more recently, China has impressed the global health community with its timely and unprecedented response to the 2014 and '16 Ebola pandemic in West Africa. China's donation of the anti-malaria medicine and vaccines has also peaked during 2010 and '12.

Even though China's global health assistance activities are often overshadowed by the Western developed countries' activities, no one can deny the significance of China's fast transformation from a major recipient of foreign aid to a critical provider of resources.

One may ask why China is scaling up its global health activities. In my opinion, I put into three reasons. First, China felt that it had something unique to offer. A developing country not long ago, they were in the same position as the recipient countries now. So they believe that China's success in domestic public health can be easier translated into other developing countries.

Secondly, like many other countries in this era of globalization, China realized the impact of pandemic on their national economy. In 2003, SARS cost China 25 billion USD in interrupted international trade and productivity. In 2016, the first case of yellow fever was diagnosed -- this is the first case in Asia, was diagnosed in Beijing. The patient was a Chinese migrant in Africa.

So at the time when there are over a million Chinese migrants in Africa and over 100,000 Africans in China, China wants to strengthen its pandemic preparedness capacity and protect its own economic activities and investment.

And lastly, China has always considered global health assistance as a soft power and wants to be part of the global governing.

So what are the U.S.-China's collaboration on global health? Well, the majority of the collaboration so far has been focused on the infectious diseases and within China. GAP, the Global AIDS Program, helped set up the first U.S. CDC office in Beijing. And in 2004, the Chinese National Influenza Center and the U.S. CDC initiated the collaborative agreement to build capacity in influenza surveillance in China. In my view, this is a long-term collaboration that provided sustainable data sharing and research exchange and benefits both countries as well as WHO and should be considered as a model for the future collaborations.

In terms of collaborations in developing countries, so far there are not so many. Under the previous administration, U.S. CDC has reached out to China's Chinese CDC and to jointly sponsor five CDC centers in Africa. This is, as I see, the start of this type of collaboration. Otherwise, U.S. and China's programs mostly parallel in these countries and they're quite different in terms of philosophy and approach. On paper, for example, China's aid to Africa is pitched as on a peer-level assistance. China does not impose any political or economic conditions for the recipient countries.

On a technical level, the U.S. global health activity favors a vertical approach that focuses on a few infectious diseases. China's global health aid tends to be more like a horizontal approach and building infrastructures to create a system-wide expansion of access to medicine. So these activities and their good coordination can be complementary to each other.

So my recommendations for the U.S. policymakers, well, in general, the global health community considers China's contributions so far as positive. Most of the criticism on China's activities are the lacking of transparency and the coordination. I suspect these problems were caused partly by the severe under staff and the lack of capacity at a central government level in China. I hope U.S. can collaborate with Chinese Government on global health capacity building, especially on personnel and project management, cultural and language integration, and program impact evaluation.

It will be also helpful to encourage Beijing's continued collaboration with multi-lateral organizations and help integrate their global health activities with other global initiatives.

In terms of other risks, as my fellow panelists have highlighted, China has become the largest manufacturer of health products, providers of pharmaceutical ingredients, and the producer of vaccines in the world. It is critical that Chinese Government strengthen the regulatory structure to ensure the quality control of these products.

I would encourage continued collaboration between the U.S. FDA and China FDA and hope to help accelerate the process of adopting the consistent best practice. Capacity building in biomedical regulatory science, similar to that for the global health professionals, is an urgent need in China.

And finally, since we talked about fentanyl and China's drug policy, I would like to point out two successful cases in the past and see what we can learn from them. One is China's tobacco control. For many years, Chinese Government were reluctant to work to act on the tobacco control because of the worry of the lost revenues from the tobacco industry and WHO's Framework Convention on Tobacco Control eventually changed the government's attitude.

So what I think we can learn here is if we can frame fentanyl crisis not just as a U.S. problem or U.S.-China problem, but as a global issue on synthetic drugs, similar to the methamphetamine and ketamine epidemic in Asia and codeine and tramadol in Africa, it will be easier to engage Chinese Government if we invite them to be part of alliance to have -- to fight against the synthetic drug crisis.

And finally on building a surveillance system and data-sharing system, I'll go back to the successful case of the influenza collaborations between U.S. and China. And given the time, I'll stop here.

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Implications of U.S.-China Collaborations on Global Health Issues

Jennifer Bouey

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Testimony presented before the U.S.-China Economic and Security Review Commission on July 31, 2019.



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Implications of U.S.-China Collaborations on Global Health Issues

Testimony of Jennifer Bouey¹
The RAND Corporation²

Before the U.S.-China Economic and Security Review Commission

July 31, 2019

Thank you, Senator Talent and Commissioner Wessel and distinguished members of the U.S.-China Economic and Security Review Commission, for inviting me to testify today. My testimony on China and global health will have five sections: The first provides a brief history of China’s engagement with global health assistance in the pre–market reforms era (1950s to 1980s). The second summarizes China’s current global health activities and their impact (1980s to the present). The third describes the Chinese government’s motivations and future plans for global health. The fourth focuses on past U.S.-China collaborations in global health and their different strategies. The fifth and the final section contains suggestions for actions U.S. policymakers could take to address the challenges associated with China’s global health activities.

China and Global Health in the Pre–Market Reform Decades (1950s-1980s)

If we accept the goals for *global health* that Robert Beaglehole and Ruth Bonita suggested in 2010 as “actions for promoting health for all,”³ then China’s most significant contribution to global health indexes is arguably its own success in the domestic public health program that reduced mortality, increased life expectancy, and built a comprehensive health system for 1.3 billion Chinese. China’s growth in life expectancy at birth from 35 years in 1949 to 65.5 years in

¹ The opinions and conclusions expressed in this testimony are the author’s alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

² The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

³ Robert Beaglehole and Ruth Bonita, “What Is Global Health?” *Global Health Action*, April 6, 2010.

1980 ranks as among the most rapid sustained increase in documented global history.⁴ During this time, China embedded its public health improvement goals in political campaigns and achieved its goals in the expansion of maternal and child health services, immunization, infectious disease reduction, primary health care services (e.g., Barefoot Doctor Program⁵), and general improvements in water, sanitation, and hygiene. Many believed that the significant improvement in health, in partnership with a strong primary education, prepared the workforce for the massive transformation of economy and society in 1978 and laid the foundation for China's economic miracle in the past three decades.⁶ China's experience during these years also helps to inform its strategies for foreign aid programs.

In the early 1950s, as a new and politically isolated country, China had limited activities on foreign aid. Egypt was the first African country to establish the ambassadorial diplomatic relationship with China in 1956.⁷ China's premier, Zhou Enlai, then visited Africa three times between 1963 to 1965 and announced China's "Five Principles in Foreign Relationship" and "Eight Principles in Foreign Aid."⁸ China's global health assistance programs started in this context as it deployed its first medical team to Algeria following the Algerian War and the flight of the country's trained health professionals in 1963.⁹ In the following years, China sent medical teams to Zanzibar (1964), Laos (1964), Somalia (1965), Yemen (1966), Congo (Brazzaville, 1967), Mali (1968), Mauritania (1968), Vietnam (1968), and Guinea (1968).¹⁰ Many attributed the success of China gaining a seat at the United Nations (UN) in 1971 to the support from the delegates of African countries. In 1972, China joined the World Health Organization (WHO) and continued to expand its Chinese Medical Teams (CMTs) to 28 countries.¹¹ In 1978, as WHO announced the Declaration of Alma-Ata to highlight the importance of primary care in the new global paradigm for health care, the Chinese health care system's rural Barefoot Doctor Program was featured.¹²

⁴ Kimberly Singer Babiarz, Karen Eggleston, Grant Miller, and Qiong Zhang, "An Exploration of China's Mortality Decline Under Mao: A Provincial Analysis, 1950–80," *Population Studies: A Journal of Demography*, Vol. 69, No. 1, 2015.

⁵ Officially instituted in 1968, the program sought to shift domestic health policy away from urban centers to severely understaffed rural areas by educating and empowering locals with sufficient medical education to act as basic primary care practitioners. At the program's height, it had created roughly 1 million new paramedical workers, dramatically increasing access to health care across the country.

⁶ Judith Banister and Xiaobo Zhang, "China, Economic Development and Mortality Decline," *World Development*, Vol. 33, No. 1, 2005, pp. 21–41.

⁷ Chu Shulong and Jin Wei, "时事出版社 [China's Foreign Strategy and Policy]," in *China's African Policy [中国对非洲政策]*, Shishi Publisher, 2008, p. 268.

⁸ W. A. C. Adie, "Chou En-lai on Safari," *The China Quarterly*, No. 18, 1964, pp. 174–194.

⁹ Huang Yangzhong, "Pursuing Health as Foreign Policy: The Case of China," *Indianan Journal of Global Legal Studies*, Vol. 17, No. 1, 2010.

¹⁰ Li Anshan, "李安山: 中国援外医疗队的历史、规模及其影响 [History and Impact of the Chinese Foreign Aid Programs]," *Jingluecn*, January 1, 2013 (<http://www.jingluecn.com/zt/zhongguozaiifeizhou/2013-01-07/324.html>).

¹¹ Georgetown University Initiative for U.S.-China Dialogue on Global Issues, *U.S.-China Dialogue on Global Health Background Report*, Washington, D.C., 2017.

¹² T. Hesketh and W. X. Zhu, "Health in China: From Mao to Market Reform," *BMJ*, May 24, 1997.

Less visible but no less significant in China's early global health aid was the role of hospital construction. China's first hospital construction project was building a 100-bed tuberculosis sanatorium in Mongolia in 1959.¹³ This less-known assistance program signaled the start of infrastructure building as a critical part of China's global health aid. In 1969, China built a hospital in Tanzania as part of its growing involvement in the region. In much of Africa and other parts of the world, however, these efforts were overshadowed by the greater health assistance provided by the United States, the Soviet Union, and their allies.

Another Chinese contribution to global health during this period was the discovery of the antimalarial drug artemisinin through a military research program. This top-secret effort was initiated to help North Vietnamese troops suffering from malaria in their jungle warfare during the Vietnam War. Artemisinin later gained WHO's recognition as an antimalarial in 1993¹⁴ and eventually earned a Nobel Prize for Medicine in 2015 for the Chinese scientist, Dr. Tu Youyou, who discovered the medicine. Nowadays, artemisinin is one of the few medical innovations from China that has been approved by WHO. In East Africa, artemisinin combination therapy (ACT), became the preferred treatment for malaria ten years ago.¹⁵

China's Current Global Health Activities (1980s to Present)

Two government white papers on China's overseas development aid, published in 2011 and 2014, did not contain detailed data on development health aid (DHA). A few research papers on China's DHA made inconsistent estimates using data mostly from online or unpublished records. Perhaps the understanding of the scale and scope for each DHA activity is more meaningful. Currently, China's DHA activities can be grouped into the following categories: CMTs, hospital construction, pharmaceutical and equipment donations, public health and health security programs, and health professional training programs.¹⁶ According to a forthcoming book, since 1963, China has sponsored and built more than 150 hospitals in foreign countries, its CMT program cumulatively dispatched more than 25,000 medical professionals to 51 African counties and provided health care for more than 280 million patients, its artemisinin donations reached 40 million people outside China, the international emergency humanitarian response teams reached out more than 60 times, and more than 20,000 foreign health professionals were trained.¹⁷

Chinese Medical Team Program

The primary goals of the CMT program are to provide expert medical services to the host population and to train local health care professionals on-site.⁹ A bilateral agreement between

¹³ Wang Chen, *Chinese Strategy in Health Aid*, Beijing: International Economic and Trade Collaborative Research Center, Chinese Ministry of Health, in press.

¹⁴ Li Anshan, *Chinese Medical Cooperation in Africa: With Special Emphasis on the Medical Teams and Anti-Malaria Campaign*, Uppsala, Sweden: Nordic Africa Institute, 2011.

¹⁵ Chen, in press.

¹⁶ S. Chen, M. Pender, N. Jin, M. Merson, S. Tang, and S. Gloyd, "Chinese Medical Teams in Africa: A Flagship Program Facing Formidable Challenges," *Journal of Global Health*, Vol. 9, No. 1, 2019.

¹⁷ Chen, in press.

China and an aid recipient country on sending a CMT is usually first processed by China's National Health Commission. The agency will then ask a designated provincial government to make decisions on the number of health professionals and their different disciplines for the mission. Once in the host country, the teams are overseen by the Chinese embassy's Economic and Commercial Counselor's office. Most teams consist of the health professionals with necessary medical specialties, a team leader, a translator, and a chef. The size of the teams ranges between a half dozen to more than 100 people, with an average of 20–30 members per team. In 2017 alone, 1,059 Chinese health care workers served in long-term CMTs (rotations of six months to two years) in 51 countries, helping address the gap in the global health workforce.¹⁰ Although most of the CMTs were dispatched for routine clinical operations, China also sent teams to perform specific advanced procedures, such as cataract surgeries, cleft lip repair, and congenital heart disease surgeries.¹⁸

The criticisms of the CMT program pointed out that the program has remained mostly unchanged in terms of its organization and management for 60 years, with little internal or external evaluation since its inception.¹⁹ CMTs also focus exclusively on clinical treatment instead of combining clinical work with public health prevention programs or health care system building. Suggestions have been made to centralize the demand and providers for CMTs instead of letting individual provinces be the primary respondents, diversify and open the selection of health professional at the national level, and align CMT program activities with the local public health system, China's other health aid programs, and the other international donor programs.²⁰

Hospital Construction

China has carried out more than 150 foreign aid projects by building or upgrading clinics, hospitals, antimalaria centers, medicine storage, medical centers and labs, and centers for disease control. Between 2013 and 2017, China completed the initial planning of 50 health care facility infrastructure implementation projects, 70 percent of which were in Africa. In recent years, hospital construction was often accompanied by local infrastructure development (roads and power generators) and donations of Chinese medical equipment and medicines.²¹

One example is the 100-bed Sino-Congo Friendship Hospital completed in 2013 in Brazzaville that provides general clinical services. The hospital, with over 300 staff and a 23-member CMT, provides health care for a population of more than 200,000 people, half of whom are farmers. The Chinese government contributed more than USD 6 million for the construction. The hospital currently ranks among the top three public hospital in the capital area.²² Similar Chinese government donation projects also included the Levy Teaching Hospital in Lusaka,

¹⁸ “Chinese Doctors Perform Surgery upon Cleft Lip, Palate Patients,” *The News*, July 14, 2019 (<https://www.thenews.com.pk/print/486214-chinese-doctors-perform-surgery-upon-cleft-lip-palate-patients>).

¹⁹ S. Chen, M. Pender, N. Jin, M. Merson, S. Tang, and S. Gloyd, “Chinese Medical Teams in Africa: A Flagship Program Facing Formidable Challenges,” *Journal of Global Health*, Vol. 9, No. 1, 2019.

²⁰ Chen et al., 2019.

²¹ Chen, in press.

²² AIDATA, “China Contributes \$6 Million for Construction of China-Congo Friendship Hospital,” undated (<https://china.aiddata.org/projects/30201>).

Zambia and the Mazka Hospital near Kigali in Rwanda. Last year, construction of the first private-funded Chinese hospital was launched as a part of the Belt and Road Initiative (BRI): the Seychelles Afei Holding is backing a \$30 million, 600-bed hospital contract in Ethiopia.²³

Critics have noted that, although this facility construction often filled gaps in critical infrastructure, it is not always well integrated into the local health system. Whereas in China the state might be able to use its authority to integrate the new infrastructure, more-decentralized African health systems cannot typically do so. There were also concerns that China's piecemeal approach to supplying personnel and infrastructure cannot substantially contribute to the health improvement of Africans. Ray Yip, the former director of the China Program at the Bill and Melinda Gates Foundation, stated, "Those all represent a substitution approach. [The Chinese] go to a hospital, they run the service for a year, and during that time people in the catchment area benefit. But when they leave, there is not much left behind. So, it's not a bad thing but in terms of impact, it's relatively small."²⁴

Health Professional Training Programs

In addition to infrastructure and CMT support, China also provides professional training, especially in such medical specialties as obstetrics and gynecology (ob-gyn), surgery, pathology, cancer treatment, neurology, Chinese medicine, trauma, and cardiac surgery. One example is the China-Canada West Africa Cardiology Collaboration Program implemented in Ghana in 2014. The program has trained dozens of cardiology doctors and nurses and raised clinical capacity for countries in West Africa. One graduate conducted the first cardiac surgery in Ghana. In addition to the clinical training, the program also helped organize the first epidemiologic survey on cardiovascular disease risks in the region, which provided critical evidence used by the health policymakers at Ghana's Ministry of Health.

Public Health and Health Security Program Support

Eager to change the country's damaged public health image associated with the initial mishandling of the 2002–2003 severe acute respiratory syndrome (SARS) outbreak, the Chinese government launched an unprecedented response to the Ebola epidemic in West Africa in 2014–2016.²⁵ On March 24, 2014, right after Guinea health authorities confirmed the presence of an Ebola outbreak, the Chinese embassy sent warnings to Chinese nationals there. In early April, the Chinese government provided Guinea emergency humanitarian aid and followed with emergency assistance to Liberia and Sierra Leone. In August, China's State Council mobilized action across 23 ministries and departments, dispatching a CMT to West Africa days after WHO declared Ebola a Public Health Emergency of International Concern. The Ebola team deployed to West Africa was one of the largest CMTs, with about 1,200 clinicians, public health experts,

²³ "“Silk Road’ Hospital Breaks Ground in Ethiopian Capital,” *Xinhua*, September 14, 2017 (http://www.xinhuanet.com/english/2017-09/14/c_136609571.htm).

²⁴ Quoted in Ted Alcorn, "New Orientation for China's Health Assistance to Africa," *Lancet*, December 15, 2015.

²⁵ Huang Yanzhong, "China's Response to the 2014 Ebola Outbreak in West Africa," *Global Challenge*, Vol. 1, 2017, e1600001.

and military medical officers. They opened a 100-bed treatment unit in Liberia and established three field demonstration sites while providing free treatment.²⁶ Within six months, China also built a biosafety level-3 laboratory in Sierra Leone, transporting all construction materials in 87 days.²⁷

Domestically, China accelerated the development of Ebola diagnostic kits and medical countermeasures. In November 2014, the Chinese Food and Drug Administration (FDA) approved the test reagent developed by three Chinese firms, making China one of the few countries that could produce diagnostic kits. One diagnostic test was approved by WHO in May 2015.²⁸

Although China's overall humanitarian contributions to the 2014–2016 Ebola pandemic was dwarfed by those from the United States and the United Kingdom,²⁹ the Chinese government's efforts impressed the international community and may set precedent for China's future engagement in public health emergencies.

Another global health aid milestone is China's contribution to the establishment of the African Center for Disease Control (ACDC). ACDC was proposed by the African Union to help Africa build capacity in pandemic surveillance and responses, including disease surveillance, rapid responses, laboratory systems, information systems, and public health research. The headquarters is in Addis Ababa, the capital of Ethiopia and the headquarters for the African Union. The Chinese government signed the agreement to construct the ACDC headquarters building on June 24, 2019.³⁰ The new office of Global Health under the Chinese Center for Disease Control and Prevention also sent public health experts to serve as technical advisors and provide training at the ACDC headquarters.

Pharmaceutical Donations, Production, and Investment

According to the Chinese Ministry of Commerce, China has donated 38 million doses of antimalarial medicine and USD 10 million worth of equipment to antimalaria centers in more than 40 countries since 2006.³¹ From 2010 to 2012, China donated 60 batches of antimalarial medicine, hepatitis A vaccine, and cholera vaccine. China's donations peaked in 2012 and were halted because of the concerns of the quality of the medicine, tied to a lack of brand recognition and clinical trial evidence.

²⁶ Christina Larson, "China Ramps Up Efforts to Combat Ebola," *Science*, November 3, 2014.

²⁷ Kun Tang, Zhihui Li, Wenkai Li, and Lincoln Chen, "China's Silk Road and Global Health," *Lancet*, Vol. 390, No. 10112, 2017, pp. 2595–2601.

²⁸ Tang et al., 2017.

²⁹ Yanzhong, 2017.

³⁰ Africa Centres for Disease Control and Prevention, "AUC and Government of China Sign Exchange of Letters of Agreement for the Construction of Africa CDC Headquarters Building," June 27, 2019 (<http://www.africacdc.org/press-centre/news/93-auc-and-government-of-china-sign-exchange-of-letters-of-agreement-for-the-construction-of-africa-cdc-headquarters-building-2>).

³¹ Wang Chen et al., "中非卫生合作-国际发展援助理论的探索与创新 [Relationship Between Aid and Development of African Healthcare and Public Health System]," in 中非卫生合作-国际发展援助理论的探索与创新 [*Sino-Africa Health Collaborations: Innovations in Global Development Assistant Theory*], Beijing: Ren Min Wei Sheng Publisher, 2015.

Even though artemisinin has been approved by WHO and ACT became the preferred treatment for malaria in East Africa ten years ago, the appreciation of China's donation of antimalarial medicine was hampered by counterfeit medicines resulting from regulatory failure in East African countries and unscrupulous business practices that flooded the markets with fake drugs. As the journalist Kathleen McLaughlin reported in 2013, "The deadliest problem remains counterfeiting and fakes, risking lives and threatening to kill China's potential for real medical aid in Africa."³²

China is also the world's largest provider of active pharmaceutical ingredients (APIs) for the production of antiretroviral treatment (ART) HIV medicine. In 2010, 873 tons of APIs were produced in China, but only 1.9 percent were used in China for ART medicine production. The majority of the APIs were exported to pharmaceutical manufacturers outside China.³³ Currently, only a few medicines and testing kits from China for HIV and malaria were approved by the U.S. FDA or WHO. Even though China produces a sufficient supply of 48 vaccines for 28 diseases for its 1.3 billion population, only one vaccine (Japanese encephalitis) has been prequalified by WHO.

The lack of international qualification for Chinese medical products is partly attributable to the fragmented Chinese pharmaceutical sector. Researchers estimate there are 5,300 to 7,000 local manufacturers, each with a small share of the Chinese domestic market.³⁴ The market, however, is the second largest in the world, grew at a compound annual rate of 16 percent between 2010 and 2014, and is forecasted to grow 9.1 percent between 2015 and 2019.³⁵ The market is currently dominated by generic medicines without patent protection, and many companies have a varying degree of API business mixed in with formulation business, conduct both a distribution and a manufacturing business, and sell both traditional Chinese medicines and Western medicines. The reliable data are often associated with supply chains for hospital sales of prescription drugs in the top-tier cities and large hospitals. Those that provide supply only for smaller cities tend to have little or unreliable data.³⁶ The government has been seeking to consolidate the pharmaceutical sector and increase the average size of firms to support quality inspection and improvement. The latest national recommendation for the 13th Five-Year Plan specifically aimed to have all medicine on the National Essential Drug List go through bioequivalence testing by 2020.³⁷

China is the largest manufacturer of vaccines in the world, producing 1 billion doses each year—about 20 percent of the global supply. Currently, the majority of the vaccines produced in

³² Kathleen McLaughlin, "Fake Fake Drugs from China: What's Stopping a Cure for Malaria in Africa?" *Atlantic*, June 11, 2013 (<https://www.theatlantic.com/china/archive/2013/06/fake-fake-drugs-from-china-whats-stopping-a-cure-for-malaria-in-africa/276750/>).

³³ McLaughlin, 2013.

³⁴ Rachel Lee and Lawton Robert Burns, "China's pharmaceutical sector," in Lawton Robert Burns and Gordon G. Liu, eds., *China's Healthcare System and Reform*, New York: Cambridge University Press, 2017.

³⁵ International Trade Administration, "2016 Top Markets Report Pharmaceuticals: Country Case Study," 2016 (https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_China.pdf).

³⁶ Lee and Burns, 2017.

³⁷ "重磅：医药工业十三五规划完整版 [Chinese National Recommendation for the 13th Five-Year Plan (2015–2020)]," *Sina*, November 8, 2016 (https://med.sina.com/article_detail_103_1_14074.html).

China supply the domestic market, contributing to China's record-low immunization expenditure per capita (\$20 per person in 2009). In 2011, China passed the WHO vaccine regulatory assessment, which allowed Chinese suppliers to qualify for UN procurement. In 2013, the WHO prequalification of the Japanese encephalitis vaccine licensed by China's FDA was another big step forward for China being competitive in the global supplier market. Dr. Lance Rodewald, the head of WHO's Expanded Programme on Immunization (EPI) in China, commented that the news was "really terrific, as they have made it possible for the United Nations and other agencies to procure life-saving vaccines for countries without the capacity to make high quality vaccines or the resources to purchase them."³⁸

However, the hope for a fast and widespread vaccine prequalification may prove to be unrealistic because of the lack of incentives for Chinese manufacturers. Many would rather focus on the domestic market than invest in a lengthy and expensive prequalification process. The Japanese encephalitis vaccine prequalified by WHO succeeded only after years of wide-ranging technical support from PATH,³⁹ with funding from the Bill and Melinda Gates Foundation.

In recent years, the Chinese government has encouraged Chinese pharmaceutical enterprises to invest in Africa. In 2017, Liaoning-based Neusoft Medical Systems signed a deal with the Tanzanian government to build a medical equipment manufacturing facility, the largest in Africa.⁴⁰ In doing so, China is hoping to invest in the long-term market in Africa and capitalize on vertical integration with the Chinese suppliers of APIs—that is, the factories will obtain Chinese APIs without additional payment before the production. The commitment of Chinese API supply will help small African manufacturers reduce preproduction cost and become more competitive.

Motivations and Vision

Even though China's global development assistance was historically overshadowed by the United States, United Kingdom, Japan, and other Organisation for Economic Co-operation and Development (OECD) countries, no one can deny the significance of China's transformation from a recipient of foreign aid to a critical provider of development resources in the Global South. A 2017 analysis showed that China had emerged as an important participant in global health, serving as a source of overseas development assistance and DHA, sharing concerns about cross-border infectious disease threats, joining in global health governance, and participating in global sharing of knowledge and technology.⁴¹ To understand China's plan for global health, we can first review China's motivations in the historical context.

China's early external assistance programs in the 1950s to 1980s were clearly motivated by finding global political partners when facing the pressure of perceived U.S. containment and

³⁸ Quoted in World Health Organization, "China Enters the Global Vaccine Market," *Bulletin of the World Health Organization*, Vol. 91, 2014, pp. 626–627.

³⁹ PATH is a global nonprofit health organization aims to provide health equity.

⁴⁰ "Tanzania: Govt Enter Pact With Chinese Firm to Build Hospital Equipment Factory," September 18, 2017 (<https://allafrica.com/stories/201709190237.html>).

⁴¹ Tang et al., 2017.

competing with Taiwan for diplomatic recognition. China's total foreign aid amounted to 6.9 percent of its GDP in the last years of Mao's era.⁴² After a relatively quiet period during the 1980s and 1990s, when China received global donors' assistance in its own economic reform and development, China reinitiated its foreign aid program in the mid-1990s. China's foreign aid in this later era was designed to pursue common economic development and was overseen by the Ministry of Commerce. In 2000, China hosted the first Forum on China-Africa Cooperation, a new multilateral venue that became the main platform for cooperation between Beijing and African partners. In recent years, China has been aware of the skeptics and criticisms from international societies on the lack of transparency and coordination among its foreign aid projects.

In this context, several specific reasons for China's current increasing contributions to global health emerge.

Pandemic and National Security

Like other countries in the era of globalization, China realized the outbreaks of infectious disease and increased global mobility have posed increasing challenges to global health security. The 2002–2003 SARS pandemic and the provincial governments' mishandling of the early cases is still a fresh memory of many Chinese officials and public health workers. SARS—a deadly and highly contagious virus-borne disease—originated in southern China. For three months, the local government denied the epidemic, causing the deadly virus eventually to spread to 37 countries. This resulted in more than 8,000 infections and 775 deaths, cost China \$25.3 billion from the interrupted international trade and productivity, and slowed its GDP growth by 1–2 percent in 2003.⁴³ In 2016, China announced its first imported yellow fever case associated with a 32-year-old Chinese citizen who had worked in the Luanda Province, Angola, since 2009. The patient developed a fever and chills on March 8, 2016 (day 1), Beijing time and returned to Beijing on March 10, 2016 (day 3), after 22 hours of traveling. He was admitted to the intensive care unit at an infectious disease hospital in Beijing and died on day 9, despite an aggressive treatment.⁴⁴ This first yellow fever case in Asia, which originated from an outbreak of yellow fever in Angola, confirmed China's pandemic concerns, particularly at a time when the scale of China-Africa trade and travel volume had been rapidly increasing. With 1.1 million members of Chinese diasporas in Africa and 100,000 African migrants among many other immigrants in China,⁴⁵ China has legitimate concerns about pandemics' impacts on its own national security.

⁴² Tang et al., 2017; Lin Shi, 当代中国的对外经济合作 [*Contemporary China's External Economic Cooperation*], Beijing: Chinese Social Science Press, 1989, p. 68.

⁴³ Wen Hai, Zhong Zhao, Jian Wang, and Zhen-Gang Hou, "The Short-Term Impact of SARS on the Chinese Economy," *Asian Economic Papers*, Vol. 3, No. 1, 2004, pp. 57–61.

⁴⁴ Zhihai Chen, Lin Liu, Yanning Lv, et al., "A Fatal Yellow Fever Virus Infection in China: Description and Lessons," *Emerging Microbes & Infections*, Vol. 5, No. 1, 2016.

⁴⁵ United Nations, *International Migrant Report 2017: Highlights*, New York, 2017.

Protecting China's Economic Activities and Investments

Another global health concern is pandemics' impact on China's economy, given its increasing dependence on active global trade and developments. BRI is committed to the financing and implementation of large infrastructure projects in many countries in Africa, Latin America, and Asia. Many BRI projects attract international and domestic migrants and concentrate a large quantity of labor and capital in small areas that traditionally have high disease burdens and an underdeveloped health care system. Protection against disease risks and pandemics will be essential to achieve BRI's economic goals.⁴⁶ Therefore, although BRI is primarily economic, there are important health dimensions. In a 2017 BRI meeting to promote health cooperation, a Beijing communiqué was adopted by more than 30 health ministers. Seventeen bilateral memoranda of understanding were signed between China and BRI countries and agencies, such as UNAIDS (Joint United Nations Programme on HIV/AIDS), Global Fund, and Gavi, the Vaccine Alliance. The agreement covered health security, maternal and child health, health policy, health systems, hospital management, human resources, medical research, and traditional medicine. The Chinese government plans to launch four networks—public health, policy research, hospital alliance, and health industry—to promote global health collaborations along its BRI projects.⁴⁷

Improving China's Global Image

As the antiglobalization sentiment rose in many Western countries and the traditional global DHA funding from the United States and its allies plateaued, China's overseas aid budget grew between 2013 and 2015, and China is poised to become a vital global donor.⁴⁸ In a way, the recent establishment of a department of global health at China CDC and China International Development Cooperation Agency (CIDCA) was China's response to some of the international criticism of its global development programs.⁴⁹ The agencies were tasked to lead reforms to improve the efficiency and effectiveness of China's foreign aid by reinforcing central government control and providing coordination of its historically decentralized foreign aid activities (such as province-based CMT and friendship programs). This transition will also include the growing differentiation of foreign aid programs (coordinated by CIDCA) from the commercial financing packages (under Ministry of Commerce). China also seems to want to counter some of the foreign concerns about the financial and environmental risks of BRI infrastructure programs (rogue donor and debt trap diplomacy) by starting to carefully integrate a greater range of socially conscious projects in environmental protection, public health, and education.⁵⁰

⁴⁶ R. Horton, *China's Rejuvenation in Health*, *Lancet*, Vol. 389, 2017.

⁴⁷ Tang et al., 2017.

⁴⁸ Elanah Uretsky, Jennifer Bouey, and Rebecca Katz, "China's Emerging Role in Global Health," *Health Affairs*, January 17, 2018.

⁴⁹ Cheng Cheng, "The Logic Behind China's Foreign Aid Agency," Carnegie Endowment for International Peace, May 21, 2019.

⁵⁰ Matthew P. Goodman and Jonathan E. Hillman, "China's Second Belt and Road Forum," Center for Strategic and International Studies, April 24, 2019 (<https://www.csis.org/analysis/chinas-second-belt-and-road-forum>).

In addition, CIDCA hopes to promote and facilitate policy research and recommendations pertaining to Chinese foreign aid. Compared with many Western countries, China is still new to building its professional and organizational capacity for global governing (e.g., global linguistic, cultural, and political research). Global health is a brand-new academic field in China.⁵¹ There is also a gap in the scholarly work and research on international development and an urgent need to provide adequate training to global health professionals. The agencies working on aid can barely keep pace in recruitment and training with the growth of China's aid-related ambition and its ever-expanding on-the-ground operations and expenditures. Both the department of global health at China CDC and CIDCA are currently encountering difficulties with recruiting sufficient numbers of suitable staff. Many criticisms regarding the transparency of China's aid programs⁵² are often due to the decentralization of the aid programs and the fact that China's current system fails to coordinate data collection and evaluations. As a consequence, China has a difficult time showcasing its global health contributions and impact, compared with the leading countries in the field. The new agencies are expected to change that.

Vision—Future Plan

In the next decades, China will focus on a number of global health areas.⁵³ First, the Chinese government hopes to consolidate and centralize the governing body on global development aid projects and conduct comprehensive evaluations of the projects, especially on sustainability measures and clarifications on the long-term (aid-recipient) country responsibilities to ensure the sustainability of the aid impact. Second, the government hopes to design and implement capacity-building programs in global health, focusing on training in policy, technology, and management. Focus areas include health finance, public health policy design, pandemic preparedness and response, quality control on health products, and traditional Chinese medicine development. The capacity building will rely on on-the-job training, new academic department and management degrees in medical and public health programs, and academic exchange programs. Third, China hopes to emphasize more public health intervention and health system building rather than clinical aids in its DHA programs. Examples including antimalaria surveillance and intervention in the Mekong basin, schistosomiasis control in Africa, and implementing 100 maternal and child health promotion projects in developing countries. Fourth, the government hopes to strengthen collaborations between its DHA programs with multilateral organizations, such as WHO, UNICEF, Global Fund, and Gavi, the Vaccine Alliance. Lastly, the government proposes to combine China's DHA and financial investment with infrastructure-building programs to facilitate biomedical industry development in Africa.

⁵¹ Tang et al., 2017.

⁵² Deborah Brautigam, "U.S. and Chinese efforts in Africa in Global Health and Foreign Aid," in Xiaoqing Lu Boynton, ed., *China's Emerging Global Health and Foreign Aid Engagement in Africa*, Center for Strategic and International Studies, 2011.

⁵³ Chen, in press.

U.S.-China Collaborations in Health

The United States and China have collaborated for more than two decades on infectious disease control (HIV/AIDS, influenza, and emerging infections), cancer, and other noncommunicable diseases.⁵⁴

- As HIV emerged as a crisis in China and the United States, both countries increased their bilateral cooperation to combat the pandemic. The Chinese government partnered with the U.S. CDC to establish China CDC's Global AIDS Program (GAP) in China in early 2003. GAP quickly developed and implemented a comprehensive HIV prevention and mitigation plan across 15 Chinese provinces to promote increased surveillance of high-risk populations. The U.S. CDC, in partnership with China's National Center for AIDS/STD Control and Prevention, has assisted with capacity building, including improving the quality and geographical reach of laboratory testing capabilities, developing an epidemiological surveillance system, and expanding treatment options.
- U.S.-China collaboration was an important part of the anti-SARS campaign in 2003. In October 2003, U.S. Secretary of Health and Human Services Tommy Thompson visited China and forged a multiyear partnership with the Chinese Ministry of Health to develop a more robust public health infrastructure. Thompson also established a U.S. Department of Health and Human Services health attaché at the U.S. embassy in Beijing.
- In 2004, the Chinese National Influenza Center (CNIC) and the U.S. CDC initiated cooperative agreements to build capacity in influenza surveillance in China. The two agencies collaborated on (1) developing human technical expertise in virology and epidemiology in China; (2) developing a comprehensive influenza surveillance system by enhancing influenza-like illness reporting; (3) strengthening analysis, utilization, and dissemination of surveillance data; and (4) improving early response to influenza viruses with pandemic potential. In 2014, China expanded its surveillance and response system to include 408 laboratories and 554 sentinel hospitals and trained 2,500 public health staff. CNIC established viral drug resistance surveillance and platforms for gene sequencing, reverse genetics, serological detection, and vaccine-strain development. CNIC also built a bioinformatic platform to strengthen data analysis, publishing weekly online influenza surveillance reports in English and Chinese. The surveillance system collects 200,000–400,000 specimens and tests more than 20,000 influenza viruses annually, which provides valuable information for WHO influenza vaccine strain recommendations. CNIC now provides training for other countries to improve global capacity for influenza control.
- Beyond infectious diseases, the National Institutes of Health and the Natural Science Foundation of China also signed an implementing arrangement in 2010 to develop the U.S.-China Program for Biomedical Research Cooperation “to stimulate collaborative basic, translational, and clinical research between United States (U.S.)-based researchers and Chinese researchers in the areas of cancer, environmental health, heart disease, blood

⁵⁴ Georgetown University Initiative for U.S.-China Dialogue on Global Issues, 2017.

disorders, diseases of the eye and visual system, mental health, and neurological disorders. Partnering U.S. and Chinese investigators must work jointly to submit identical applications to NIH and National Natural Science Foundation of China (NSFC), respectively.”⁵⁵

These collaborations share common goals for improving the practice of public health and strengthening public health institutions in detecting and responding to public health problems in the United States and China.

Despite common goals and challenges faced by both countries, there are ideological and strategic differences in the United States’ and China’s approaches to foreign assistance. Whereas most U.S. foreign aid is provided by grants, China’s programs are financed by loans.⁵⁶ The West’s approach to aid includes conditionality and selectiveness, which assumes that aid works best in well-governed countries where corruption is not a significant problem; therefore, poorly governed countries are often denied aid.⁵⁷ One could argue that a problem with such an approach is that the countries that fail to fulfill these conditions are the ones most in need of assistance. In contrast, China’s aid to Africa is claimed to be unconditional with “no ties,” which means that China does not impose any political or economic conditions for the recipient countries.

On a tactical level, China and the United States take different approaches to global health crisis situations. The United States and other Western nations tend to favor a “vertical” approach that focuses on capacity building to eradicate a disease’s burden through boosted personnel, medical resources, and research. For example, the United States’ largest global health program—the President’s Emergency Plan for AIDS Relief (PEPFAR)—accounted for 61 percent of U.S. global health funding in FY 2018, or USD 6.6 billion. The funding targets the prevention and the treatment and care of HIV/AIDS.⁵⁸ In FY 2019, three-quarters of the USD 11 billion in U.S. global health assistance funding focused on three diseases: HIV, tuberculosis, and malaria. After adding 5 percent for health security, 80 percent of the U.S. DHA focuses on infectious diseases.⁵⁹

China’s global health aid tends to take a “horizontal” approach centered on building infrastructure to create a system-wide expansion of access to medicine and health care. As mentioned, the 2017 Beijing BRI health forum featured collaborative agreements with 30

⁵⁵ U.S. Department of Health and Human Services, U.S.-China Program for Biomedical Collaborative Research (R01 Clinical Trial Optional), RFA-CA-19-009, January 2019 (<https://grants.nih.gov/grants/guide/rfa-files/rfa-ca-19-009.html>).

⁵⁶ Charles Wolf Jr., Xiao Wang, and Eric Warner, *China’s Foreign Aid and Government-Sponsored Investment Activities: Scale, Content, Destinations, and Implications*, Santa Monica, Calif.: RAND Corporation, RR-118, 2013 (https://www.rand.org/pubs/research_reports/RR118.html).

⁵⁷ Junyi Zhang, “How Does Chinese Foreign Assistance Compare to That of Developed Countries?” Brookings, August 25, 2016 (<https://www.brookings.edu/opinions/how-does-chinese-foreign-assistance-compare-to-that-of-developed-countries/>).

⁵⁸ Henry K. Kaiser Family Foundation, “The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR),” January 31, 2019 (<https://www.kff.org/global-health-policy/fact-sheet/the-u-s-presidents-emergency-plan-for/>).

⁵⁹ Henry K. Kaiser Family Foundation, “Breaking Down the U.S. Global Health Budget by Program Area,” May 31, 2019 (<https://www.kff.org/global-health-policy/fact-sheet/breaking-down-the-u-s-global-health-budget-by-program-area/>).

ministries of health and multilateral organizations in such areas as health security, maternal and child health, health policy, health systems, hospital management, human resources, medical research, and traditional medicine, without naming any specific disease. Instead, the Chinese government highlighted the goals to build four networks—public health, policy research, hospital alliance, and health industry—to promote global health.⁶⁰

It is not a conclusion that disease-specific approaches will neglect system building, nor that infrastructure- and network-building approaches would ignore the local epidemics. This type of labeling of the programs and funding reflects the different measures for outcomes. It raises concerns because many developing countries are experiencing epidemiologic transition—where chronic diseases cause the majority of deaths and limit economic productivities.⁶¹ The infectious-disease-driven global health approach may miss the target.

Nevertheless, these different approaches, while making collaboration difficult, can also be complementary in nature to benefit the recipient countries. African nations have also benefited from the competition introduced into the field of international assistance by China's more-robust foreign aid activities since 2006. This competition has given African governments (including the less stable countries) options and leverage with respect to foreign donors.

Recommendations for Future U.S.-China Collaborations in Global Health

As the world's two largest economies, the United States and China face increasingly similar challenges in health: Domestically, both face a rapid increase in health expenditures because of aging societies, an increase in chronic medical conditions, and an increase in substance use disorders. Globally, both face pandemics, climate-change-induced health problems, mass migration, and bioterrorism. Past U.S.-China collaboration in data and technology sharing on pandemic surveillance, public health system building, and biomedical research have benefited both countries and the world. Unfortunately, given the increased tension between the two countries on trade, technology sharing, and security concerns, bilateral collaborations on health—such as data sharing on surveillance and innovative biomedical research—may suffer. In this context, I would recommend for your consideration the following initiatives.

Collaboration on Global Health Capacity Building

How much China can contribute to global health depends on its personnel and management capability. Until the Chinese government builds a professional workforce to configure its long-term national global health strategy, collect reliable programmatic data, conduct timely evaluations on program effectiveness, and build confidence to embrace the recipient country's culture and language, we will continue to see China's global health aid programs fragmented and in a "hit-or-miss" style without much transparency (e.g., lack of systematic data records),

⁶⁰ Tang et al., 2017.

⁶¹ Thomas Bollyky, "Health Without Wealth: The Worrying Paradox of Modern Medical Miracles," *Foreign Affairs*, November/December 2018 (<https://www.foreignaffairs.com/articles/2018-09-26/health-without-wealth>).

compared with those from more established countries. It may take China five to fifteen years to train its public health professional cohort to work abroad with a more comprehensive vision. Meanwhile, the U.S.-China collaborations should continue on global health training, including scholar and student exchange programs, short-term training on program management, and global health research conferences to help China accelerate its progress toward building an efficient global health workforce. Unfortunately, the concern surrounding the security, technology, and political calculations from both countries will inevitably hurt the established networks on pandemic preparedness and hinder further integration of a global health alliance. I hope the U.S.-China Strategic Economic Dialogue can reopen and be used to incorporate global health collaborations.

Encourage Beijing's Greater Collaborations with Multilateral Organizations

In the past 60 years, China has responded positively to and made progress as a participant in global governance. China's recent prominence in global health has contributed to the UN agencies' missions and opened China to being more receptive to feedback and guidance from WHO, the World Bank, and the International Monetary Fund. The Chinese government holds its reputation working with international institutions in high regard. In a way, one might say that the United States has been quite successful in its Cold War-era goal of reaching out to then-isolated China and including it in the global order. It seems to be counterintuitive to discredit China's contributions when it is starting to take more responsibilities and contributing more as an active member of the global governing system.

Work Toward Regulatory Harmonization

Because China became the largest manufacturer of health products, provider of pharmaceutical ingredients, and producer of vaccines in the world, it is critical that the Chinese government strengthen regulatory structures to ensure the quality control of these products. The government is consolidating the fragmented pharmaceutical sector and fostering larger and stronger companies in its recent five-year national plan. Such action will pave the way for the rigorous regulation implementation. Continuing collaborations between the U.S. FDA and Chinese FDA can help strengthen the process of adopting consistent best practice to regulate medical product manufacturing and development. Capacity building in biomedical regulatory science, similar to that for the global health professionals, is an urgent need in China.

Collaboration on China's Drug Policy

Recent RAND research has brought up concerns about China as an exporter of the vast majority of illicitly sourced synthetic opioids. Lack of regulatory oversight, local corruption, and an abundance of chemical manufacturers in China contribute to this potential global health risk. The Chinese government has taken some steps to stop the trend, but producers are quick to

adapt.⁶² Since most of these synthetic drugs are exported to other countries, China itself has not yet faced the prospect of user-associated morbidity and mortality consequences experienced in other countries. The current concern is whether the Chinese government has the political will and capability to control the situation. I recommend that the United States consider employing lessons from the two recent successful public health programs in China—tobacco control and influenza surveillance—and apply these models to the synthetic drug epidemic.

- **Leverage multilateral organizations’ action on synthetic drugs and provide a cost model—the tobacco control case study:** China is the world’s largest producer and consumer of tobacco. The Chinese government has resisted the WHO Framework Convention on Tobacco Control (FCTC) for years out of fear of losing large government revenue from the tobacco industry. Eventually, however, the government’s pursuit of international recognition in public health and the demonstration that the cost on health care for tobacco users exceeded the profit gained led to the government’s decision to implement the WHO FCTC.⁶³ As we learned from the tobacco control process, working with the multilateral international organizations, such as WHO, may be the best channel to obtain the Chinese government’s collaboration on this action, since the government values its reputation at the UN. In addition, cost-effectiveness analysis, particularly when projecting the increased use of synthetic drugs in China, can provide strong evidence for the public health agencies to convince the government to take action on the illegal practice.
- **Build a surveillance and response system on synthetic drug use—the influenza surveillance system case study:** CNIC and U.S. CDC collaborated on capacity building in seasonal and novel influenza prevention and control strategies in China and beyond. The collaboration also strengthened real-time data analysis and dissemination and provided critical technical support when the Chinese government committed USD 46 million to expand the pandemic response system to influenza and other emerging diseases.⁶⁴ CNIC, in return, provided valuable clinical, lab, and epidemiological research and data to WHO and the U.S. CDC. CNIC became the sixth WHO Collaborating Centre for Influenza in 2010 and now provides training for countries to improve global capacity for influenza control. Expecting a growing epidemic of synthetic drug use in China and other countries, I recommend applying a similar surveillance model to that of influenza to document synthetic drug use and inform the coordinated response.

⁶² Bryce Pardo, Beau Kilmer, and Wenjing Huang, *Contemporary Asian Drug Policy: Insights and Opportunities for Change*, Santa Monica, Calif.: RAND Corporation, RR-2733-RC, 2019 (https://www.rand.org/pubs/research_reports/RR2733.html).

⁶³ Yang Gonghuan, *Tobacco Control in China*, Singapore: Springer, 2018.

⁶⁴ Michael A Stoto1, Min Kang, Tie Song, Jennifer Bouey, Matthew R. Boyce, and Rebecca Katz, “At the Frontier of the Global Battle Against Emerging Infections: Surveillance and Management of Avian Influenza A(H7N9) in Guangdong Province, China,” *Journal of Global Health Reports*, Vol. 3, 2019, e2019017.

OPENING STATEMENT OF DR. MARK KAZMIERCZAK, SCIENTIST AND ASSOCIATE, GRYPHON SCIENTIFIC LLC

COMMISSIONER TALENT: Thank you. Dr. Kazmierczak.

DR. KAZMIERCZAK: Thank you, Senator Talent, Commissioner Wessel, and the rest of the Commission for inviting me to provide this testimony today.

Over the past five years, China has advanced its biotech capabilities and offerings primarily through three industries: therapeutics, contract research and manufacturing, and DNA sequencing, and related technologies. Although in many cases China is still catching up to the major players in the global biotech market, they are beginning to make inroads and in some cases notably genomics, are along the leading edge of technology.

Many of the biologic drugs being developed in China are biosimilars, meaning a highly-similar molecule to an existing approved biologic drug, similar to producing generic drugs. Common biosimilar targets include popular drugs like Humira, Avastin, and Herceptin used for treating chronic conditions such as arthritis, psoriasis, and cancer. Few of these drugs have made it to market, however, and China has yet to become a significant source of biologics in the U.S.

Supporting pharmaceutical and biologics R&D are contract research organizations, CROs, companies that provide outsourced services for pre-clinical and clinical development. In 2017, there were more than 1100 CROs worldwide, with around 400 of them in China. China's WuXi AppTec is a leading global CRO, managing over 200 projects in pre-clinical and clinical development through its biologic-focused component WuXi Biologics. Unfortunately, data are not available on how many U.S. companies or what portion of the U.S. market are using CROs in China.

China also hosts several companies providing DNA sequencing services including some of the world's largest. BGI is the third largest sequencing company behind U.S.-based Illumina and Thermo Fisher, and offers DNA sequencing machines and services for basic research and pharmaceutical R&D. BGI has formed numerous clinical research partnerships with U.S. institutions providing DNA sequencing and analysis services.

The growth of China's biotech industry has come in large part through investments in U.S. biotech. Chinese firms spent \$3.5 billion in direct investment and venture capital from 2013 to 2017 with very little investment activity before then. In 2018, the health and biotech sector became the top recipient of Chinese foreign direct investments, due both to sustained investment in the sector and a significant decline in the Chinese investment in the U.S. overall.

Similarly, Chinese venture capital in U.S. biotech which increased overall since 2014 and became the top industry for Chinese-led VC in 2018 has also dropped significantly. Chinese investors provided 40 percent of the venture funding in U.S. biotech in the first three quarters of 2018, but in the first half of 2019, Chinese-led rounds dropped 83 percent. The drop in Chinese investment in U.S. biotech has largely been credited to the reforms passed last year for the CFIUS review process as firms are limiting or restructuring investments to avoid scrutiny. Whether or not this effect was intended, the changes to review of foreign transactions are causing a major shift in the investment landscape, resulting in uncertainty in the near term. The effects of these changes will need to be monitored closely to ensure U.S. biotech companies don't suffer due to lack of capital.

Others testifying before you today will describe the large extent to which China supplies generic drugs and active pharmaceutical ingredients for the U.S. In the traditional pharmaceutical market, the chemical entities that are the active ingredients in drugs can be

synthesized through relatively simple processes and generic versions of drugs can be inexpensively produced and quickly marketed.

Biopharmaceuticals, however, are highly complex large molecules produced by engineered cells or organisms and do not have generic versions. Instead, companies wishing to duplicate successful biopharmaceutical products must reengineer cell systems to produce a biosimilar drug, an endeavor that requires more advanced technology, is more expensive to produce, and has greater regulatory hurdles. These difficulties provide a significant barrier that limit China's ability to produce low cost drug alternatives as they have done for traditional pharmaceuticals.

Although China's biologic industry focuses heavily on biosimilars, it is too nascent to yet have produced significant results. Currently, no biosimilars from China are approved in the U.S., and only a handful are marketed in China.

China's rise in biotech may potentially present economic risks from increased competition in the marketplace, such as potential loss of market share and transfer of wealth overseas. Chinese companies are not yet challenging the U.S. as a major producer of biopharmaceutical products, however. Sustained and increased investment by the U.S. Government in biotech R&D will help to ensure they do not catch up in the near future.

Where China is becoming a global leader is in DNA sequencing, genomics, and related fields. Their advances in this arena are already providing competition to U.S. companies, as well as raising concerns over privacy and human rights. The investments China is making into genomics and artificial intelligence, including a \$9 billion precision medicine initiative, and cross-sector coalitions like the Digital Life Alliance, provide opportunities for Chinese companies to make significant advances in biologics, diagnostics, and other medical biotechnologies.

We are still at the dawn of the machine learning and artificial intelligence age with the most transformative discoveries likely yet to come. Today, however, the U.S. appears to under value healthcare-related data at least when compared to the major efforts underway in China and by Chinese firms.

Going forward, the U.S. can take several steps to maintain its position as a global biotech leader and safeguard against increased competition from China and other countries. By increasing and sustaining federal funding for basic and applied research across the sciences, the U.S. can help drive innovation and economic prosperity and reduce the likelihood that U.S. researchers turn to China and other countries for support.

The U.S. also must prepare to take advantage of advances in genomics and big data in healthcare. Given the growing importance of personal data in biotech and other industries, the U.S. must rebuild its data protection laws to delineate acceptable use of, and access to personal data while protecting individuals' rights and privacy.

Finally, to guide these and other efforts, the U.S. needs to take a close look at the economic opportunities afforded by its biotech industry, as well as the sector's needs. This includes identifying dependence on foreign industries, recognition of rising players on the world stage such as China, and analysis of the industry's health, stability, and vulnerability to foreign competition.

Thank you again for this opportunity to speak today. I look forward to answering your questions.

**PREPARED STATEMENT OF PANELIST DR. MARK KAZMIERCZAK, SCIENTIST
AND ASSOCIATE, GRYPHON SCIENTIFIC LLC**

Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products

A hearing before the

U.S.-China Economic and Security Review Commission

July 31, 2019

Testimony of
Mark Kazmierczak, Ph.D.
Gryphon Scientific, LLC

Thank you, Senator Talent, Commissioner Wessel, and the Commission for inviting me to provide this testimony on China's biotechnology industry. Most of the information presented in this testimony I collected while researching the report "China's Biotechnology Development: The Role of U.S. and Other Foreign Engagement," submitted to the Commission in February of this year, and in following the trends and developments in this arena since. The scope of that report encompassed biotechnology applications in healthcare and other industries, including biopharmaceuticals (i.e., biotech drugs), but did not include the traditional pharmaceutical industry (i.e., "small molecule" drugs). As such, I will describe how advances in China in the biopharmaceutical industry, as well as related biotechnology fields such as genomics, are impacting the U.S. with respect to its own biotechnology industry as well as its economic and national security.

Biotech products and services provided to the U.S. by Chinese firms

Over the past five years, China has advanced its biotechnology capabilities and offerings primarily through three industries: therapeutics (i.e., biopharmaceuticals), contract research and manufacturing, and DNA sequencing and related technologies. Although in many cases China is still catching up to the major players in the global biotechnology market, they are beginning to make inroads and, in some cases (notably genomics), are along the leading edge of technology.

Development of therapeutic biologics has contributed a large part of China's biotechnology growth in the past five years. According to a 2017 analysis of China's biologics market by Goldman Sachs, investigational new drug (IND) filings (i.e., applications for drug candidates to be used in clinical trials) for biologics in China have increased from fewer than ten per year before 2013 to 30-40 annually during 2014-2017.¹ The types of biologics being developed are primarily protein-based therapeutics targeting chronic diseases such as cancer, diabetes, and autoimmune diseases, especially antibodies and antibody-based drugs. Many of the biologic drugs being developed in China are biosimilars, meaning a highly similar—although not identical—molecule to an existing approved biologic drug. Such products have a lower risk associated with development because the compound has already been shown to be effective, although the economic return is diminished as a result (similar to producing generic drugs). Existing biologic therapies drawing a lot of attention from Chinese biosimilar developers include Humira (adalimumab—an immunosuppressive drug for treating conditions such as arthritis, psoriasis, and ulcerative colitis), Avastin (bevacizumab—an immunotherapy for several types of cancer), Rituxan (rituximab—for treating non-Hodgkin's lymphoma and chronic lymphocytic leukemia), and Herceptin (trastuzumab—an immunotherapy for breast, stomach, and esophageal cancer).

The biologic R&D activity of Chinese biotech companies, however, is largely focused on developing products for the Chinese domestic market. Many of the biologic drugs sold in China are imported, and

¹ Yeh et al. (2018) China: Healthcare: Biotechnology: Biologics: Balancing quality and affordability; Fosun Pharma up to Buy.

Chinese companies are looking to take a larger share of that market. Biologics developed in China are also not yet making it into the U.S. market. Few, if any, biologic drugs currently approved by the Food and Drug Administration (FDA) were developed by Chinese companies (although I have not performed a thorough assessment of FDA approvals, I am not aware of any such products). In at least one case, a Chinese company has acquired an FDA-approved biologic through direct investment: in 2017, Sanpower Group, a private Chinese technology conglomerate, bought Dendreon, producer of the prostate cancer immunotherapy Provenge. Provenge is not a blockbuster drug, however, and Dendreon was struggling to find a successful market at the time of the sale.

Supporting the boom in biologics R&D in China and globally is a large contract research and manufacturing industry. Contract research organizations (CROs) support pharmaceutical, biologics, and medical device companies by providing outsourced services for preclinical or clinical development. CROs can perform preclinical studies for a drug candidate, such as safety and efficacy trials and pharmacodynamics studies, as well as conduct Phase I-IV clinical trials. CROs play a prominent role in drug development worldwide, with more than half of all pharmaceutical companies employing them. In 2017, there were more than 1,100 CROs worldwide, with around 400 of them in China.² China's WuXi AppTec is a leading global CRO—according to the company, its biologics-focused component WuXi Biologics managed 205 projects at the end of 2018, including 97 in the pre-clinical development stage, 94 in phase I and II clinical development, 13 in phase III development, and one in commercial manufacturing. Unfortunately, determining the customer base of WuXi Biologics or any other CRO is a difficult endeavor, and data are not available on how many U.S. companies, or what portion of the U.S. market, are using CROs in China. Because a large part of CRO services is navigating regulatory requirements, use of foreign CROs for advanced-stage clinical development would likely be for products intended to be marketed in that country, although services such as pre-clinical development and manufacturing will still be valuable regardless of the location of the company.

China also hosts several companies providing DNA sequencing services, including some of the world's largest sequencing companies. BGI is the third largest company behind U.S.-based companies Illumina and Thermo Fisher and offers sequencing for basic research and pharmaceutical purposes as well as reproductive-health services. As part of its business strategy, BGI has formed numerous clinical research partnerships with U.S. institutions, including leading U.S. academic research centers, providing DNA sequencing and analysis services. (BGI also sells DNA sequencing machines, which are competitors to those sold by Illumina and Thermo Fisher.) Other top genomics companies in China include WuXi NextCODE, Novogene, and CloudHealth Genomics, which provide services such as DNA sequencing and bioinformatics (i.e., computational analysis of genetic data). WuXi NextCODE was formed in 2015 when WuXi PharmaTech acquired U.S.-based NextCODE Health. In addition to sequencing and genomics, Chinese companies can provide molecular diagnostics services (i.e., detection of specific proteins or genetic sequences to indicate disease), such as “liquid biopsy” for cancer diagnostics and noninvasive prenatal testing—including HaploX Biotechnology, Singlera Genomics, Berry Genomics, and Annoroad Genomics.³

In the U.S., clinical testing providers need certification to show that they comply with the requirements set in the Clinical Laboratory Improvement Amendments (CLIA) program, which assures appropriate standards are in place to ensure the validity of test results. Certification can occur through third-party accreditation, the most prominent being the College of American Pathologists (CAP). In our research for our report to this commission, my colleagues and I identified 23 companies with a Chinese nexus that have CLIA/CAP accreditation and perform genome sequencing, molecular diagnostics, or other genetic

² Chiu N. (2017) Contract Research Organization Market. GF Securities (Hong Kong) Brokerage LTD.; PR Newswire. (2018) Contract Research Organizations Global Market Opportunities and Strategies To 2021.

³ GenomeWeb. (2018) Chinese Firm HaploX Biotechnology Raises \$32M in Financing. GenomeWeb.; Singlera Genomics. (2018) Singlera Genomics Raises \$60 Million in Series A+ Financing. <https://www.prnewswire.com/news-releases/singlera-genomics-raises-60-million-in-series-a-financing-300619990.html>; Sun Y. (2017) China Doubles Down on the Double Helix. Neo.life. <https://medium.com/neodotlife/cloudhealth-the-booming-genomics-industry-in-china-2e5476f469b0>; Illumina. (2015) Berry Genomics NextSeq CN500 Instrument and Non-Invasive Prenatal Testing Reagent Kit Receives Chinese FDA Premarket Clearance. <https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=2030982>; GenomeWeb. (2017) Chinese Genomics Firm Annoroad Raises \$105M. <https://www.genomeweb.com/business-policy-funding/chinese-genomics-firm-annoroad-raises-105m#.XSuTbOhKIuk>

testing, including WuXi NextCODE and Novogene. Unfortunately, we don't know how many U.S. customers or what share of the U.S. market they have.

In January 2017, Chinese artificial intelligence company iCarbonX announced the Digital Life Alliance, a new collaborative effort designed to give people a deeper understanding of the medical, behavioral, and environmental factors that contribute to proper health. iCarbonX was founded in China in 2015 by the former CEO of BGI and aims to build an internet-based ecosystem of digital life based on artificial intelligence and an individual's biological, behavioral, and psychological data.⁴ The consortium ultimately aims to merge comprehensive biological and patient-generated data with artificial intelligence (AI) technology and predictive algorithms to provide data-based insights into an individual's health, disease progression, and aging and deliver a personalized guide for living well. The system could also be leveraged by the healthcare industry to improve precision medicine. Companies within the Digital Life Alliance bring expertise in fields such as protein measurement, microbial detection and isolation, human health modeling, enzymatics, the study of immune system regulation, data analysis, and artificial intelligence, and include the U.S.-based companies SomaLogic, HealthTell, AOBiome, and GALT. PatientsLikeMe, a U.S.-based company that collects health records and other data from U.S. patients (through self-submission) was also part of the consortium until they were made to divest from the alliance earlier this year following review by the Committee on Foreign Investment in the United States (CFIUS).

Activities of Chinese biotechnology firms in the United States

Several Chinese biotechnology companies have started new R&D facilities in the U.S., generally focused in major biotech hubs such as Boston, San Francisco, and the Research Triangle area in North Carolina. By locating in major U.S. biotech regions, Chinese companies are seeking access to advanced technologies and expertise, a well-educated workforce, and top-tier research universities and biotech companies to foster collaboration. Two high-profile examples are QLB Biotherapeutics, a branch of Qilu Pharmaceutical, and VcanBio USA, started by VcanBio Cell & Engineering Corporation, one of the largest biotech companies in China. Both startups are located in the Boston area and develop cancer immunotherapy products and related technologies. Companies operating in genomics and molecular diagnostics are also opening research centers in the U.S. Novogene established a genome sequencing center on the campus of the University of California, Davis, and Genetron Health opened their molecular diagnostics and precision medicine center, Genetron Health Technologies, in Research Triangle Park, NC.

In addition to R&D startups, and sometimes in combination with them, some Chinese biotech companies have opened biotech incubators in the U.S. Startup incubators refer to a range of commercial facilities and organizations that provide infrastructure and support to help new companies grow and develop. The simplest biotechnology incubators provide laboratory space and equipment, allowing fledgling companies to share and distribute those startup costs, which in biotechnology are high. Incubators also frequently provide business support, including leveraging their expertise and networks to facilitate expansion and marketing, as well as providing basic legal and accounting support. Incubators are often linked to or sponsored by investors in the companies within the incubator, thereby increasing the probability that those investments result in a successful company and a positive return to those investors. In the case of Chinese biotechnology incubators in the U.S., parent companies are often looking to help companies develop products for the Chinese market while benefiting from access to U.S. expertise and technologies. Some of the large companies have opened incubators that are collocated with their U.S. R&D facilities, including Qilu Pharmaceutical's Qilu Boston Innovation Center. Although most endeavors are from private companies, the China-U.S. Biotechnology Innovation Center currently being built in Houston, which specializes in IT, biomedicine, and nanotechnology, is a product of the Jiangsu Industrial Technology Research Institute, a major nonprofit research institute founded and supported by the Jiangsu provincial government.

⁴ iCarbonX. (2017) iCarbonX Expands Digital Life Alliance to Accelerate Development of Global Health Ecosystem. <https://www.businesswire.com/news/home/20170105005285/en/iCarbonX-Expands-Digital-Life-Alliance-Accelerate-Development>.

Chinese biopharmaceutical companies looking to develop drugs for the global market also conduct clinical trials in the U.S. For example, Chinese biopharmaceutical leader Innovent has three drug candidates for which they have received IND approval from the FDA (the initial step in starting clinical trials for a drug), all for monoclonal antibody therapeutics. As of yet, though, no such products have successfully advanced to commercialization.

These activities of Chinese biotechnology companies in the U.S. are for the most part spearheaded by private industry (only three percent of investment involved state-owned enterprises) and are seemingly driven by market forces. The Chinese government, whether at the national or provincial level, does not appear to be providing significant incentives specifically for biotech companies to be doing business internationally. Of course, several prominent national plans and industrial policies promote the development of biotechnology as a key industry to the country's growth and economic advancement, including the 13th Five-Year Plan, Made in China 2025, and numerous industry development plans and roadmaps. These policies direct development of China's biotechnology industry—one of nine strategic emerging industries, along with others like clean energy, next generation IT, and high-end equipment manufacturing—to create a strong domestic market but also to be competitive globally. Some of the major national policies identify utilization of foreign capital and markets as a means for doing so but do not provide specific pathways or mechanisms for doing so.

Trends and implications of Chinese investment in the U.S. health, biotech, and pharmaceutical industries

In our report to the Commission, my colleagues and I described a rapidly growing landscape of Chinese investments in the U.S. biotechnology industry. \$3.57 billion was spent by Chinese firms (in 144 transactions) on direct investments and venture capital from 2013-2017, with very little investment activity in the 13 years prior (\$256 million in 49 transactions). Over this period of rapid growth, the number of transactions increased year over year, as did total investment value for all years but one. In 2018, the health and biotechnology sector (encompassing all of the healthcare sector, including traditional pharmaceuticals) became the top recipient of Chinese capital (foreign direct investment) in the U.S., surpassing more traditional sectors such as real estate and transportation. While overall Chinese investment in the U.S. has faced a tremendous decline recently—from \$46 billion across all industries in 2016 to \$5 billion in 2018—health and biotechnology has shown to be more resilient than other industries.

The detailed data on Chinese investments in U.S. biotech through 2017 showed a few key points:

- 1) Almost all Chinese investment in U.S. biotechnology occurred in medically related segments. Seventy percent of total Chinese investment has been in biologics and contract research and manufacturing, reflecting China's stated policy interest in biopharmaceuticals and demand on the healthcare market and mirroring the high level of biologics development activity occurring domestically in China. Another 22 percent was in genomics, molecular diagnostics, and precision medicine.
- 2) Chinese investment in the U.S. biotech sector is overwhelmingly private—only three percent of the total Chinese investment in biotech since 2000 came from formally state-owned actors. The role of state-owned investors is much smaller in biotech than in overall Chinese investment in the U.S., where an average of 24 percent of investment dollars come from state-owned enterprises.
- 3) Both acquisitions and venture capital (VC) financing have contributed significantly to the rise in Chinese investment in U.S. biotech, comprising 96 percent of all investment value (67 percent in acquisitions of U.S. companies and 29 percent in VC and other portfolio investment).

Experts in the U.S. biotechnology industry paint a similar picture of recent abundance of Chinese financing, especially VC. Biotech-specific funds were created starting in early 2017 to get in on the biotech investment boom. This is not unique to China, as biotech investments are a new trend globally. Chinese biotech investors have many of the same qualities as U.S.-based venture capitalists. They are interested in the same companies and the same technologies as they follow trends looking for value and

high returns. Like investment firms globally, Chinese biotech investors span a range of sophistication from highly professional to questionable, but there is nothing to indicate that they are on average more or less legitimate than investors in other countries. U.S. investment firms may tend to provide greater biotechnology or drug development expertise than Chinese firms, though; as a result, Chinese investors may provide higher valuations for startups or otherwise offer better deals in an attempt to close the gap.

Chinese venture capital in U.S. biotech has increased overall since 2014, and in the second half of 2018 surpassed the other major industry for Chinese VC, information and communications technology. In the past year, however, Chinese investment in the U.S. has dropped significantly, and biotech has not been spared. According to a report by Bay Bridge Bio, the number of venture rounds led by Chinese investors in the first half of 2019 dropped 83 percent compared to the same period in 2018.⁵ These investors provided 40 percent of the venture funding in the first three quarters of 2018, but that has virtually disappeared in 2019. Fortunately, U.S. investors seem to be picking up the slack in biotech; Series B investment, where the biggest shift has occurred, has been stronger in the first two quarters of 2019 than in any quarter of 2018.

The drop in Chinese investment in the U.S., and in biotech specifically, has largely been credited to the reforms passed last year to the CFIUS review process. Because of CFIUS's expanded review authority for transactions involving critical technologies, many Chinese biotech investors are restructuring their deals or pulling out completely. The president of Fosun Healthcare Holdings, a major Chinese biopharmaceutical investor, said the firm would be limiting its investments in U.S. biotech to avoid such scrutiny. Caution is being exercised on both sides, as U.S. startups are also turning down Chinese money to avoid attracting attention from regulators. Whether or not this was the intended effect, the changes to regulatory review of foreign transactions are causing a major shift in the investment landscape, resulting in uncertainty in the near term. The effects of these changes will need to be monitored closely so that adjustments can be made, if necessary, to ensure U.S. biotech companies don't suffer due to lack of capital.

Risks of Chinese biotechnology activities to U.S. economic and national security

Chinese biotechnology investments and research ventures help to bring technologies and products into the Chinese market, advancing China's stated goals of becoming a global leader in biotechnology. A large focus of Chinese investments is geared toward advancing their capabilities in developing biologics for healthcare. It is still too early to determine how effective these investments have been, as drug development can take a decade or more, but so far, the number of innovative biopharmaceuticals coming from China remains low.

The risks presented by China's increased activities in U.S. biotechnology are largely economic and are associated with increased competition in the marketplace, such as potential loss of market share and transfer of wealth overseas. (Because the R&D in China is largely in therapeutics, and the products being developed are very specific to their purpose, there is little opportunity to subvert these technologies for offensive uses.) Chinese startups in the U.S. take advantage of the research knowledge and innovation pipeline here to try to produce drugs for both the Chinese and U.S. markets. Utilizing U.S. research infrastructure and personnel to develop products that will be marketed and sold abroad or domestically by a foreign company does represent a drain on U.S. R&D capital and a loss of potential return on investment. However, we have no indication that China is doing this more so than other countries, or that they are particularly successful yet. More importantly, the sizeable lead we have—China's biotech market is less than a tenth the size of the U.S.'s—and the superior innovation infrastructure and technological expertise suggest that China will not threaten the U.S. global standing in the near future. In the long-term, a sustained increase in technology investment by the federal government will help to ensure our continued dominance in this field.

⁵ Bay Bridge Bio. (2019) Chinese investment in US biopharma startups down over 80% in 2019. https://www.baybridgebio.com/blog/chinese_investment_down_1h2019.html.

Theft of intellectual property by foreign nationals has been a concern in technology fields for many years and will continue to be. Several instances of theft of trade secrets by Chinese researchers and technology employees in the U.S. have been documented, going back decades, although the rate of known such occurrences is very small compared to the number of opportunities. Recently, the National Institutes of Health (NIH) has addressed this issue and has taken steps to ensure disclosure of foreign sources of funding by its researchers. Last year, it began an investigation and has since sent letters to over 60 institutions regarding 180 individuals suspected of violating disclosure rules; 18 of these have been escalated to the Department of Health and Human Services for further investigation. The course of action taken by the NIH is necessary, but also a measured one—no new restrictions have been enacted, the agency is simply improving enforcement of existing rules. Additionally, NIH has increased outreach to its funding recipients to increase their awareness of potential security risks and how to properly mitigate them. This approach serves as a good model for how to monitor and mitigate potential risks from China and other countries without imposing restrictions that may hinder research.

Perhaps the most significant potential risk stemming from China's biotechnology development is their advancement in medical and genetic sequence data collection and analysis. China is prioritizing genetic and healthcare data as a valuable resource, perhaps to a much greater extent than is the U.S.—as evidenced by their \$9 billion precision medicine initiative (compared to the \$215 million dedicated to the U.S. initiative). China has established national and regional centers focused on big data in health and medicine, including a goal to build a genetic database containing the genomes of one million ethnic Chinese, and use that information to study the relationship between genetics, disease, and the environment. As companies like BGI and others continue to form research partnerships in the U.S., the size and diversity of available data grows. Such data, when combined with advanced analytical technologies including AI, can be used to identify new determinants of disease to be targeted for development of drugs or molecular diagnostics or to guide or precision medicine.

China's activity in genomics has raised some serious human rights issues with regard to surveillance of people, especially ethnically driven surveillance. Last February, it was reported that the Chinese region of Xinjiang, with a large population of the Uighur ethnic group, collected DNA samples and biometric data from 36 million people through a program billed as providing physicals to residents. The Chinese police used DNA sequencing machines purchased from U.S.-based Thermo Fisher Scientific for this program (the company has since said they will no longer sell sequencers in Xinjiang). Additionally, studies investigating genetic markers for ethnic populations and genetic determinants of ethnicity-specific facial features (to aid in AI-based facial recognition) have been published by Chinese research groups. Given the history of surveillance and mistreatment of the Uighur population by the Chinese government, these uses of genetic data cause grave concern, not necessarily specific to the U.S., but certainly for human rights around the world.

U.S. competition from China is also a major risk in the field of genomics. The investments China is pouring into genomics and AI could provide opportunities for Chinese companies to make significant advances in medical biotechnology including biologics and diagnostics. We are still at the dawn of the machine learning and artificial intelligence age, with the most transformative discoveries likely yet to come. Large healthcare data sets are likely to drive new discoveries and cures. Today, the U.S. appears to undervalue healthcare data when compared to the major efforts underway in China and by Chinese firms—not only in analyzing these data sets but also building and gathering them. Still, the U.S. maintains a lead in science and technology activity and holds a strong, if not leading position in machine learning and AI. Given these advantages, the U.S. appears well-positioned to compete for the lead in future innovation in healthcare data analytics should it choose to prioritize it.

Sourcing vulnerabilities for the U.S. vis-à-vis Chinese medical and biotech companies

Many reports have documented the large extent to which China supplies generic drugs and active pharmaceutical ingredients for the U.S. I will not speak to this issue here, as the research my colleagues and I have performed did not cover traditional (small molecule) pharmaceuticals, and others testifying before you will have more insight into the topic. I would, however, like to draw a contrast to the issue of supply chain vulnerabilities as it relates to biopharmaceuticals. In the traditional pharmaceutical market,

the chemical entities that are the active ingredients in drugs can be synthesized through relatively simple processes, and generic versions of drugs can be inexpensively produced and quickly marketed. Biopharmaceuticals, on the other hand, are highly complex large molecules produced by engineered cells or organisms. Because of this, generic versions of biologics do not exist—companies wishing to duplicate successful biopharmaceutical products will need to re-engineer cell systems to produce a highly similar, though not identical, biosimilar drug. Such an endeavor requires more advanced technology and comes at a higher cost than production of generic drugs. Furthermore, although biosimilars do enjoy an abbreviated regulatory approval pathway in the U.S., it is more extensive than the approval of generics, as companies need to demonstrate that their imitator molecule is biologically equivalent to the existing drug.

The difficulties in developing biosimilars provide a significant barrier that limit China's ability to produce low-cost drug alternatives as they have done for traditional pharmaceuticals. Although China's biologics industry focuses heavily on biosimilars, it is too nascent to yet have produced significant results. Currently, no biosimilars from China are approved in the U.S., and only a handful are marketed in China. As I mentioned earlier in my testimony, China also has yet to become a significant source of novel biologics in the U.S. It is possible that China is (or could become) a significant source of critical biotechnology ingredients (e.g., media, nucleotides, enzymes, etc.), but I have not examined this aspect of the biotechnology market.

Another major segment of China's biotech sector is its large CRO industry. CROs are an integral part of the global biopharmaceutical industry, but it is unclear how much of the U.S. biotech industry is dependent on Chinese CROs. Regardless, the U.S. CRO industry is still the world's largest, and U.S. firms would likely be able to fill the gap if the Chinese market were to decline or otherwise be obstructed.

U.S. ability to address risks posed by China's biotech development

The reforms to CFIUS review authority brought about by the passage of the Foreign Investment Risk Review Modernization Act last year are a significant step in broadening the U.S.'s power to monitor and regulate biotechnology investments from China and other foreign countries. By expanding the types of covered transactions involving critical technologies (as yet to be defined but potentially including biotechnology) and personal information, The U.S. has a greater ability to address potential threats from China through such investments. The expanded authority still does not allow scrutiny of venture financing with foreign limited partners, however, so these types of investments can still go unmonitored. The risk from such investors is low, though, given the low level of control they typically have.

Protection of dual-use biotechnology in the U.S. through export control has been traditionally focused on materials such as equipment (e.g., fermenters) and specific biological agents, and is ill-equipped to deal with the changing nature of biotechnology threats. Acquisition of intellectual property, not physical property, has become the greater threat when it comes to dual-use biotechnology, and the export control laws of the U.S. are only now beginning to catch up. The Export Control Reform Act, passed as part of the National Defense Authorization Act for fiscal year 2019, adds foundational and emerging technologies to the commerce control list, which may include biotechnology, including synthetic biology, genomics, and genetic engineering. Although this change potentially allows the U.S. to control a much broader set of technologies, the broad and undefined nature of foundational and emerging technologies opens a risk of casting too broad of a net and overburdening and hindering legitimate research with limited utility in deliberately harming U.S. national security (e.g., genome editing, which was listed as a weapon of mass destruction in 2016 by the Director of National Intelligence). The Department of Commerce's Bureau of Industrial Security is undergoing a process to define the terms, and the outcomes of this effort could have a significant effect on biotechnology research in the U.S. As this process unfolds, any technology of concern should undergo a detailed risk assessment to understand current and near future capabilities, comparative advantages to existing technologies, indications of convergence with other fields, and level of maturity. Furthermore, technologies with little or no credible risk to national security or which embargoed countries could easily acquire or develop through other means should not be subject to export control.

One industry segment in which the U.S. is seeing strong competition from China is genomics and related fields (including molecular diagnostics and precision medicine). The large data sets of medical and genomic information that Chinese companies are developing, in part through investments and research collaborations in the U.S., are fueling advances in this area. Currently, protections the U.S. places on such data are minimal, and an imbalance in data sharing between the U.S. and China exists. Chinese law prohibits any personal information generated within its borders from being transmitted or stored overseas, and specifically includes genetic and population health data in this restriction. The U.S. has no similar regulations controlling foreign access to personal data—the primary law protecting health data in the U.S., the Health Insurance Portability and Accountability Act, is designed to ensure patient privacy but not protect the data itself. Given the growing importance and value of personal data in not only biotechnology but many other industries, careful control of who has access to data generated in the U.S. is crucial to ensure the economic and societal benefits stemming from the use of such data are secured. Therefore, **Congress needs to enact comprehensive data protection laws that delineate acceptable use of and access to personal data while protecting individuals' rights and privacy.** A strict prohibition on data export may not be necessary; the General Data Protection Regulation, which went into effect last year in the European Union, strikes an appropriate balance and could serve as a model framework for such a law.

Additional recommendations for Congress

As China's biotechnology industry grows, so does its standing as a competitor to the U.S. Currently, Chinese biopharmaceuticals lag behind the U.S. significantly, although their genetic technology companies are becoming world leaders. In addition to their market lead, the U.S. has a superior innovation infrastructure through its top research universities and institutes and federal support for technology transfer. However, to ensure the U.S. maintains its standing and does not forfeit economic opportunities to China, **Congress must increase and sustain federal funding for basic and applied research across the sciences.** In constant-dollar terms, total life science R&D obligations peaked in 2010 and declined 18 percent by 2015.⁶ The trend in all life science subcategories, as well as across all science and engineering fields (e.g., physical sciences, engineering, social sciences, life sciences, etc.), is similar. Fortunately, R&D spending is trending upward again, and the budget for the NIH has increased by approximately \$2 billion in each of the last four years. Still, given the continuing expansion of the U.S. biotech industry, U.S. researchers may turn to China to fund their work if domestic funding is in short supply. In addition, a shortage of federal R&D funding could open a window for other nations, including China, to compete with the U.S. Given China's continued trend in increased R&D spending and the growth of their biotech industry, China appears to be attempting to capitalize.

At a speech before the American Association for the Advancement of Science in February, White House Office of Science and Technology Policy director Kelvin Droegemeier made an argument for greater private funding of science and technology research. Although private investment is welcome and indeed necessary, the federal government plays a critical role in supporting such endeavors, especially in basic research where a return on investment is too far removed and too uncertain for industry to gamble on. In biotechnology and medicine, some of the most groundbreaking discoveries have come from such studies; the rapid gene-editing technology known as CRISPR came from a basic study of bacterial defense mechanisms. Ensuring sustained federal funding for science and technology research will help drive the U.S. innovation engine and lead to continued economic prosperity.

To support federal investment in science and technology, and specifically biotechnology, a clear understanding of the contributions of the industry to the greater economy is needed. The U.S. developed a National Bioeconomy Blueprint in 2012 which outlined strategic goals for growing the U.S. biotechnology industry, but it is far out of date compared to current technology trends and failed to foresee risks to U.S. competitiveness that are now arising. **Congress should call for an update to the National Bioeconomy Blueprint to provide a strategic framework by which the U.S. could ensure**

⁶ National Science Board. (2018) Science and Engineering Indicators. <https://www.nsf.gov/statistics/2018/nsb20181/>. [Figure 4-9; Appendix Table 4-24].

the vitality and competitiveness of its biotechnology industry in the face of a dramatically changing global industry landscape.

The National Academies of Sciences, Engineering, and Medicine, through the ongoing Safeguarding the Bioeconomy project, is laying much of the groundwork that could be utilized in an effort to revive this strategy. Building off of this effort (which will be completed later this year), a refresh of the Blueprint would underscore the importance of the biotechnology industry to the greater U.S. economy and illustrate how the federal government can support its future growth. In order to provide clear guidance, the Blueprint should include an assessment of U.S. dependence on foreign industries, including recognition of rising players on the world stage, such as China, and an analysis of the health and stability of the U.S. biotechnology sector, including identifying which segments are strong, which are vulnerable to foreign competition, and which may be key to future growth of the sector. A National Bioeconomy Blueprint containing these pieces can serve as a guiding document to support implementation of specific mitigations against foreign interference in the biotechnology industry. Given the effects on Chinese investment already seen as a result of new review authorities through CFIUS, a carefully measured approach guided by rigorous assessments such as these is needed as the U.S. moves toward greater oversight of foreign interactions.

PANEL II QUESTION AND ANSWER

COMMISSIONER TALENT: All right, you all did a good job of staying on time. The first questioner will be Commissioner Kamphausen.

COMMISSIONER KAMPHAUSEN: Thank you to our panelists for your powerful testimony.

Ms. Gibson, I have several questions for you with regard to pharmaceuticals and thank you again for your written statement.

As I understand the nature of the problem and I'm a non-specialist, there are at least two central elements to the issue. One is that however it got there and you document quite well how China did get there, greater than 80 percent of APIs are Chinese in origin. And secondarily, we have inadequate mechanisms for testing, leading to high failure rates or pollutants or carcinogens or whatever. Would you agree with that kind of framing of the issues in that way? And then I have a couple follow-up questions.

MS. GIBSON: I think those two points address major factors that characterize the industry and where we are now, yes.

COMMISSIONER KAMPHAUSEN: You focused on generics because you said that's 90 percent of what we take.

MS. GIBSON: Yes.

COMMISSIONER KAMPHAUSEN: Aren't those problems similar with brand name medicines as well, the two initial problems that I talked about?

MS. GIBSON: My understanding is that there are some brand name drugs that do use active ingredients made in China, say certain chemotherapy products. When it comes to quality and testing, it's also my understanding at least from what people in the industry say that the brand name companies have a little more incentive to assure quality because their name is on the box and they're the only supplier.

COMMISSIONER KAMPHAUSEN: Good. Well, then two very specific questions. On page four of your testimony, I think it's outline point B8, you talk about an on-line pharmacy that says it tests every batch of every medication it sells. Are we at the front edge of this? Will that be a more common practice and what are the cost implications?

MS. GIBSON: Yes, what you're referring to is a new start-up company on the Yale Science campus called Valisure and they said their motto is that we test everything before they sell it. They test three batches of every product. And they have found that more than ten percent of what they test and they test for active ingredients. They test for dissolution. If you take a medicine does it stay in the body for the right period of time, are they actually medicine for that duration. And they test for inactive ingredients. And they did test for the solvents in the contaminated blood pressure medicine.

I think it's a game changer, but what would help even more is if we had a Consumer Reports type reporting, having that testing done and make it public. This is way beyond the FDA's capability. I think we need a market-based approach and I think that could help turn around the market and ensure we have quality drugs.

The challenge is that sometimes if there's contaminants in them, you may not know what to test for. That's what happened with the contaminated heparin. That lethal contaminant fell under the radar using existing testing methods at the time. So if you're not testing for it, then you're not going to look for it, so it could still be in there. But I think it would be a big step forward if the public and institutional purchasers, the DoD, VA, initially to get the market going

and demand higher quality medicine that we have some testing. But that however still doesn't address the issue of our industrial base and the collapsing of our industrial base to manufacture 90 percent of our medicines.

COMMISSIONER KAMPHAUSEN: That then leads to my last question. In your oral testimony, I think you alluded to some possibilities for reversing China's dominant position on producing APIs. Could you elaborate that a little in the minute we have left?

MS. GIBSON: I think it's fascinating to watch what the private sector hospitals in the United States are doing, led by the Mayo Clinic and 900 other facilities. They formed a nonprofit called Civica Rx in response to persistent shortages of vital life-saving medicines. We're talking about last resort antibiotics here.

And hospitals have put up capital in this nonprofit and they are doing direct contracting with trustworthy manufacturers. And so far, the first two products that they have purchased or contracted to purchase are -- one is vancomycin which is an absolutely critical antibiotic and that will be made in Bedford, Ohio. It will be a Danish company that will be opening up production here. And then there's a second antibiotic.

Recently, they have contracted to produce 14 or 15 other critical medicines that are in persistent shortage and I just read before coming up here just to confirm that, they expect that their member hospitals will save between 35 to 50 percent on the cost and that's because these are medicines, when they're in shortage, they cost more. So this is a way to get around that and also to stimulate more producers for essential drugs that are trustworthy.

And the other secret is they have long-term contracts. So we're going to put out a contract, not every year, and change it. Do it for five, ten years and that manufacturer knows that it will have the capital and the resources to invest not only in back-up facilities to manufacture, but also to invest in quality manufacturing.

Transparency on price, transparency on who's making it, I think that's a game changer and I think we should be doing that for our public procurement for the DoD and VA and to really cause some needed disruption in the current system.

COMMISSIONER KAMPHAUSEN: Thank you.

COMMISSIONER TALENT: Next will be Commissioner Wessel, and then after that, I have Commissioners Cleveland, Fiedler, and Bartholomew lined up.

COMMISSIONER WESSEL: Thank you all for being here and I'm going to have, if there's time, another round of questioning because there's a diverse set of issues here.

I was very troubled by our last panel, our DoD witness, not by his integrity, but by the questions about whether we know and have the ability to ascertain where the products are coming from that our troops and our families and people are ingesting on a daily basis, many of them for life-saving purposes.

Ms. Gibson, if you could help me on the question of supply-chain integrity for a moment and anyone else who has information. My understanding is we've had difficulty getting FDA personnel into China, having difficulty getting them the visas they need to operate, and then the ability to travel within country, so that I was told in one instance they were concerned about a facility and it took six weeks for them to get the travel permit to be able to visit and, of course, by that time you can clean up virtually anything.

I believe your book also referred to some investigator looking through the window seeing all these vats and by the time they were able to get into the facility, all the vats were gone. So it's a little difficult to ascertain quality.

Can you talk to me a bit about the difficulty our investigators, our own government has in

ensuring quality and what steps we should be taking? I thought we had an MOU at one point with China. It appears that, as you were saying, Mr. Westhoff, that as it relates to fentanyl that maybe the stated comments are not followed through as it relates to policies that are being articulated.

MS. GIBSON: Sure. Well, the FDA to inspect a plant here in the U.S., they can walk in tomorrow unannounced and say we're here. Whereas, when the FDA conducts inspections in other countries because it is a foreign country, they tell the government six to eight weeks in advance that we will be there. That's not always the case according to the FDA, but that is the general rule.

The other point that you mentioned, Commissioner Wessel, about China withholding visas for FDA employees to work in China, that has been a prolonged issue and when myself as a writer of China Rx tried to inquire well, what's the status? The lack of transparency is really quite pronounced. I do think we have to question whether inspections in China will ever be up to our desire to have the kinds of inspections we have here for the simple reason if China has increasing control over the supply of our medicines, I think we lose leverage. We lose leverage from a regulatory point of view. It's just sort of a take it or leave it.

And one thing about the FDA I think is very important to understand is -- and this was uncovered when I came across a document from the FDA counterpart in Europe, the European Medicines Agency. And in 2012, they actually came out and said in writing what they call the regulators dilemma. They're having to make tradeoffs between allowing defective medicines, not supplements, this is our legal supply of medicines. They're making tradeoffs between allowing substandard defective medicines into their countries versus shortages. This was unthinkable years ago and that's because we have a really narrow supply chain. And this is also true, I believe, for the FDA which I haven't seen them put that in writing.

Let's take the case with the recent blood pressure medicines that were contaminated with carcinogens. The FDA had to make the terrible choice between do we allow a medicine with lower levels of contaminant to be taken by American consumers and patients, or do we have shortages? If they took it all off the market, there would be virtually nothing left and you'd compare that to the risk of people having high blood pressure and strokes and heart attacks. This is the situation in we're in now, and it's not going to get any better. So that's why I say we can't inspect our way to solve this problem.

We need a solution that again rebuilds our industrial base, diversifies our manufacturers that are out there that supply us with medicine. And frankly, let's be clear. The price paid to manufacturers has been cheap, cheap, cheap. We've been hammering the big companies that buy generics drugs, they hammer down on price. If you hammer down on anything too much, it's going to break. And the quality is broken and the supply chain is broken. That's why we have shortages.

So I think we have to get to the root cause of the problem and that will certainly help the FDA do the job that I think many of the good professionals there do want to do.

COMMISSIONER WESSEL: Thank you. If there's another round.

COMMISSIONER TALENT: Our Vice Chair, Commissioner Cleveland.

VICE CHAIRMAN CLEVELAND: Thank you, all, for your well prepared and thoughtful testimony.

Mr. Westhoff, when we published our paper last fall on fentanyl, we made the case that the evidence of improvement after Chairman Xi agreed to schedule fentanyl, the evidence of improvement in the problem would be an increase in raids, arrests, and prosecution, and access,

visa access for the DEA to schedule unannounced visits. Have we seen any improvement in those four areas?

MR. WESTHOFF: Well, the law just took effect May 1st of this year, so I think it's too soon to tell.

VICE CHAIRMAN CLEVELAND: How did the law affect what -- the possibility of raids or arrests or prosecutions?

MR. WESTHOFF: Well, on May 1st, all fentanyl analogs were blanket banned, as it will. So previously, these chemical companies when one fentanyl analog was banned, they would simply tweak the molecular structure and make a new one. This new law outlaws that, so even fentanyl analogs that have never been created, will be automatically banned, scheduled. And so I haven't seen any results of what might have changed since May 1st.

VICE CHAIRMAN CLEVELAND: Thank you. Ms. Gibson, I want to draw attention to your work on palliative care because it is hard work and incredibly valuable. So thank you for that service.

Are shortages driven by epidemics or problems or are there already shortages in terms of medicines available?

MS. GIBSON: It's my view that shortages of essential medicines are caused by the narrowing of the supply chain to a few suppliers. And that happens because of how we purchase medicines. If we hammer down too much on price the good businesses go out of business. They can't make it for that price, so we're left with a handful.

And also, I think it's really clear from the Vitamin C cartel case which I didn't mention in the testimony, but which I think many of the Commissioners are familiar with. It was a case very clear cut of a handful of Chinese companies forming what's called a Vitamin C cartel and driving out all the U.S. and European producers of ascorbic acid, so we can't make Vitamin C any more. And the Chinese Government came to bat on behalf of its domestic firms and said that it's a matter of Chinese law we required our companies to fix prices and to control exports to the United States. So that is indicative of perhaps underlying intention about manipulation in the market for these essential commodities for our health.

VICE CHAIRMAN CLEVELAND: Do you think that it would be possible to develop a top ten list of critical drugs that we should be monitoring to ensure a safe and sufficient supply? You mentioned vancomycin, but I was wondering if there were others.

MS. GIBSON: I think the list would be pretty long. If you ask any hospital what they need to survive on a daily basis, I think generic antibiotics I would put on that list and I would put heparin on that list. And bear in mind people in the industry say that if China shut the door on exports, within just a couple of months our hospitals would cease to function, so this has tremendous urgency.

VICE CHAIRMAN CLEVELAND: And finally, Dr. Bouey, we published a paper some months ago, talking about the role of China in international humanitarian assistance operations. And in your testimony you mentioned their involvement in the Ebola outbreak.

Can you describe how they coordinated with the international community as the international community went in? Because what we tend to see is China gets involved, but on their own terms and their own way somewhat detached from whatever the international community requirement or norms are. So if you could describe specifically the Ebola engagement, that would be helpful.

DR. BOUEY: Yes. Thank you. So I think that's not surprising for me to hear what your comments. China's global health assistance programs are traditionally pretty much based on

their own government and sometimes even delegated to the provinces.

For the 2014-2016 Ebola humanitarian aid, China has coordinated within their own government 23 ministries, so they actually responded quite timely. They first asked their embassy to warn their citizens in the affected areas and then they set up -- as soon as WHO sent out -- announced this is a pandemic, they built a medical team of 1200, more than 1200 personnel which is the largest of the Chinese medical team and they have clinicians, public health experts, and military medics. And they built a hospital in Liberia of over 100 beds and also a level 3 biological lab in Sierra Leone. They also provide quite a lot amount of funding for these countries, not only on the medical care, but also on other social and food and other related care.

China, at the same time, they build their own vaccine development, so they had one of the vaccines approved by WHO on Ebola, one of the first that year.

So I think in terms of scale, this is one of the largest humanitarian aid that China has been able to put together.

In terms of whether they coordinate with other countries, I don't think, I haven't heard a lot about their working. But I know they contribute to the WHO to the humanitarian fund, but most of the action are on their own.

COMMISSIONER TALENT: Commissioner Fiedler.

COMMISSIONER FIEDLER: A couple of comments, but I would also like to establish some information for ourselves and others. The pharmaceutical production process is heavily automated. It is capital intensive and not labor intensive. Is that not correct?

MS. GIBSON: From my understanding about the manufacturing of pharmaceuticals, the technology to make our medicines has not changed in a very long time. We've had more innovation in the making of potato chips than we have in our medicines. That's why one of the recommendations I have is about deploying really terrific technology, advanced manufacturing technology that would do that to make it much less labor intensive, much more secure, and real time checking of quality.

COMMISSIONER FIEDLER: So you're saying it's labor intensive now?

MS. GIBSON: I think there are others who could answer that question, but I can say that if deploying new available technology on a commercial scale for our generics, it could be less labor intensive, smaller footprint and more efficient, and higher quality.

COMMISSIONER FIEDLER: Okay, does anyone know if anyone has tracked the increase in China's control of the market, let's say in generics, and the profits of U.S. pharmaceutical companies who use them?

MS. GIBSON: Well, if we're talking about generics, what I have heard from the industry is earlier this year and I heard this second hand and that's why we need this whole of government review of our industrial base is that several of the largest western generic drug makers announced that they were dropping substantial numbers of products from their manufacturing portfolio and that suggests that they just simply can't compete.

COMMISSIONER FIEDLER: It also suggests that they're not happy with the margin. So it's not necessarily that they can compete, it's that they want to make more money than --

MS. GIBSON: That could be the case. I think there's the price paid to manufacturers, and then there's the price that consumers pay. I think if you look at India, India has a tough time competing with China on active pharmaceutical ingredients. China undercuts India. India can buy active ingredients cheaper from China than it would cost them to make it. So I think there's a persistent problem there and that's again we've heard that China subsidizes its domestic

industries quite significantly.

COMMISSIONER FIEDLER: Does anyone actually think that we will ever be able to inspect anything in China? We have no history when it comes to many other subjects, whether it would be forced labor, MOUs that we have signed. I'm not cynical about it. I'm just realistic about it.

MS. GIBSON: I'll add. There's a chapter in China Rx about chicken, importing chicken from China and I put that in there because I understand we haven't really imported a whole lot of processed chicken from China and we haven't imported chicken raised in China here yet. But what's interesting from a regulatory point of view is that USDA inspectors will not be in those China plants.

COMMISSIONER FIEDLER: We had a hearing years ago on fish in China and the testing of tilapia and whatever shrimp, farm-raised catfish, and we weren't testing those fish, but the pollutants that are produced upriver from the farm. So we had a standard of -- inspection is not a solution to me, number one.

MR. WESTHOFF: If I may, I concur with your cynicism, Commissioner, and when it comes to recreational drugs, I think that we have to work on the demand side, even if we are able to get these inspections in China, the production will likely shift to countries like India.

COMMISSIONER FIEDLER: I agree with you. We have our own problems. I'm not blaming everything on China, okay?

But I will get even more cynical now. That rebate on fentanyl is a policy decision. A policy decision made the knowledge that the drug is damaging America. Forget the demand.

I can only read that as a conscious decision to damage us. Sorry, tell me I'm not right.

I mean fentanyl is a world-wide problem. It is the most damaging drug out there. It kills you really quickly if you take a minor overdose of it and they got a VAT tax rebate policy for its production?

And I'm supposed to believe that the May 1st law is going to be enforced any more than the Chinese have enforced any other agreement they've ever reached with us?

MR. WESTHOFF: Yes, again, I share your cynicism. The only thing I would add is that fentanyl is a legitimate medical drug as we all know. And Chinese companies are able to export it legally for legitimate reasons.

What's more troubling to me is that China also offers these VAT rebates for a wide array of fentanyl analogs and other NPS, novel psychoactive substances, that have never been used for a medical purpose any time in history anywhere in the world. And so to me, I just can't understand why that is.

COMMISSIONER FIEDLER: That's a policy decision. I think Dr. Bouey wanted to address those inspection questions.

COMMISSIONER TALENT: I think we're over time.

DR. BOUEY: I would just quickly respond. I am not an expert on fentanyl, but I've seen similar problems.

I mean in China, the drug medicine quality is a huge problem. It's a huge crisis within China. You've talked about several vaccine crises in China. I think the government and the people should be very worried about their own production and inspection.

So I think it's probably better to engage the Chinese Government on these inspections. Because they internally need to boost up their capacity, but that will take time.

I think even for global health expertise it will take five to ten years to train the expert professionals in global health and the regulatory fines may take even longer.

But I think in order to engage China, the Chinese Government to put it on the priority, that's why I bring up the tobacco control is that if they see this is an international problem and also engage with their interest in controlling the methamphetamine and ketamine, create an alliance on combating the synthetic drugs. It might be easier to bring them to at least focus, bring this to the priority list in addition to strengthen the regulatory system.

And if I can say one word about the influenza collaboration, I think that's a good model because that collaboration shows that the Chinese are sharing data on influenza surveillance to WHO and with the U.S. CDC. I hope that can be a model.

COMMISSIONER TALENT: Okay, we will move on. We're staying pretty much on time. I hope to have time for a second round.

Commissioner Bartholomew.

CHAIRMAN BARTHOLOMEW: Thank you very much and thank you to our witnesses. It's a very interesting -- and I'm learning a lot.

First a statement and then a couple of questions and some of my questions actually will also go to our final panel because they cover some of these topics. But I just want to say that one way that China can also demonstrate its commitment to addressing global health crises is by allowing Taiwan to participate in organizations that address global health crises like the World Trade Organization and participate also more actively in addressing bilateral health issues when they arise. Just a comment.

Dr. Kazmierczak, am I pronouncing it correctly?

DR. KAZMIERCZAK: Kazmierczak.

CHAIRMAN BARTHOLOMEW: Kazmierczak. Thank you for noting particularly the nefarious use of DNA against the Uighurs and the ethnic profiling that goes along with it.

I'm interested in what kind of informed consent takes place. There is so much data that is being gathered. There's so much American data that's ending up in China, but with Chinese citizens whose data is being gathered, is there any sort of informed consent that's going on, anything like an IRB?

DR. KAZMIERCZAK: Well, I think that's a good question. It's unclear exactly how much. I know there are definitely instances where there was absolutely no informed consent, so the incident I talked about in my written testimony of collecting DNA samples on the Uighur population in one province, that was explicitly stated to be a health physical under a program Health Physicals for All and people were allegedly told that this is for your health physical, but when they asked to see the results, were told you don't need to see the results. So there's definitely cases where there's absolutely no informed consent.

I think on a broader scale, I've mentioned in my written testimony and in my report the number of healthcare data centers that China has developed that is collecting not only genomic data, but also all sorts of healthcare data.

I believe, I would imagine that a lot of that is to support legitimate medical needs and legitimate healthcare research and so there is an aspect of informed consent there, but laws differ in the U.S. and in China as to whether informed consent is required to share data for an additional research purpose. So usually when you enter into a research trial, there is informed consent for that specific study. And the laws, and I hesitate to say definitively because the laws differ a lot, but there may or may not be a requirement for informed consent to then use that data for other research purposes.

CHAIRMAN BARTHOLOMEW: Dr. Bouey, anything to add?

DR. BOUEY: I have done some of the NIH-sponsored studies in China. That's been my

only experience working with academia in China. I think if we work in China with universities, we always request, we have to conform to the NIH requirements on informed consent as well as human subjects or trainings and all of that. But if it's initiated not by a collaboration with U.S. Government, then you know, those will be the gray areas. I have no idea.

CHAIRMAN BARTHOLOMEW: Just a final question to any and all of you, we talk a lot about production which is obviously a production of pharmaceuticals and we haven't talked about devices, but devices also which is critically important, but also R&D is really important for the next generation of drugs. I'm thinking particularly chemotherapy. You know, a lot of times it's to keep yourself alive until the next drug comes on line and is usable.

Is the U.S. losing our leading research scientists to Chinese companies either operating here or Chinese companies that are in China? Does anybody know about that?

DR. KAZMIERCZAK: I can address that somewhat. I don't think I would go so far as to say we are losing our leading scientists. Research in the United States is heavily dependent on an international researcher community and China certainly does have programs to entice top research personnel to move to -B to relocate to China, giving them large startup packages and what not. And this targets both native -- both U.S.-born and Chinese-born scientists.

However, using data from NSF, if you look at the rate at which PhDs in science and engineering in the U.S., foreign PhDs getting their degrees in the U.S., the rate at which they return -- they return to their home country in five or ten years, China has the lowest return rate out of all countries. And so that is to say that despite their efforts of trying to entice and definitely -- certainly bringing some top talent to China, they are really trying to catch up to other countries and they have much higher stay rates than say scientists in Europe do.

CHAIRMAN BARTHOLOMEW: Anybody else? All right. Thank you.

COMMISSIONER TALENT: Commissioner Lewis is next.

COMMISSIONER LEWIS: Thank you very much for your information today. You have vast knowledge of something that most people are totally unaware of. Ms. Gibson, you mentioned today this is the situation we are in with our collapsing industrial base for drugs. It's a very sobering situation. I'd like to ask each of you if you'd please tell us the recommendations that you're making, how long would it take to affect those recommendations, how much would it cost, and who opposes them.

MS. GIBSON: Well I'll start. I think to begin sooner rather than later in the short term. The DoD and VA, if they could purchase based on value and not just price -- cheapest price. That includes quality, security, uninterrupted supply. That would be a very important consideration for force protection and combat readiness. And it would also direct our tax payer money not over to China to build its industry, but to build it here.

My understanding is there's no law that requires the DoD and VA to purchase the cheapest drug. It's, I think, a well-intended effort to save tax payer money, but we wouldn't have our, you know, aircraft carriers and nuclear submarines built in China.

And for very important medicines, we should really take a close look at what it will take to purchase based on value and not just on price. I think there's opportunity also for the DoD and VA to look at what the private sector market is doing in hospitals to purchase those drugs that are in perpetual shortage that are expensive. So there it's possible, depending on how much they pay now, the DoD and VA might be able to pay less. That would be a first step. Insofar as wellness costs more money, what we know is that the large purchasers of generic drugs -- big ones -- they purchase the vast majority of all of them. They buy very cheap. But that's not the price you and I pay when we go to the drugstore. So without knowing how much a markup there

is among these groups in-between, it's hard to say whether in fact if the DoD and VA went directly to the manufacturers whether in fact that could save tax payers money and save federal agencies money.

In the medium term, the DoD through DARPA has invested in what's called pharmacy on demand. This is the use of that remarkable manufacturing technology where chemists can produce -- forgive my lay language in a box in a lab, the API for essential antibiotics and make small dose volumes within 24 hours. How can we get some public investment to support demonstrating that small volume production to commercial scale production? It hasn't been done before, certainly on the API level, and have a stock pile of API. Once you have the active pharmaceutical ingredients, it's much easier then to make the finished drugs.

So I'm not a fan of stock piles because that's not going to get us out of the mess we're in now. But stockpiles of API using this advanced manufacturing technology could go a long way. I would put that in the medium term. And there are good people out there that are chomping at the bit to want to do that. So that's a short-term endeavor. And then something for the medium term.

MR. WESTHOFF: My first suggestion was to pressure China to eliminate these VAT rebates, grants, and other subsidies to companies that are exporting illicit fentanyl, precursors, and NPS. This information that China offers these types of subsidies is being revealed for the first time right now. These are revelations from my book which comes out in September.

So the first step, I think is simply making this information known. I think that this wouldn't cost anything to the U.S. It would obviously cost China a lot in terms of its industry. And China would likely oppose it on that grounds -- on those grounds. But at the same time, it's so outrageous to be fueling a drug crisis in this way. China also doesn't want to be known as the world's drug pusher. And so I think this could be effective if the U.S. put this type of pressure on China.

I also recommend scheduling more fentanyl precursors and pressuring China to do the same. Traditionally how this works is that the U.S. will schedule one of these types of drugs and then it will be scheduled internationally, which forces China to do it within a certain amount of time -- say a year. Right now there's not any pressure on China to do this because the U.S. hasn't even scheduled these precursors. And that's Step 1. And I think that the case would be easy to make.

Senator John Kerry led the effort to schedule the first two fentanyl precursors in 2016, I believe. And he was successful after the U.S. did it to getting it done internationally. And China followed not that long afterward.

DR. BOUEY: So my answer -- short answer to your question, I think, is we have to think about globalization and the market mechanism. In terms of China being the supply chain for most of the API, I think that's a fact. I think it's upon the market's regulations for any companies that are buying China's products to raise the quality control and raise these issues.

I think China itself in terms of government, it seems that they're trying very hard to regulate their own pharmaceutical sectors. It's very fragmented. And right now, there are 5,000 to 7,000 companies registered in China. Many others are not even registered. So in their last two National Five Year Plan, they tried to consolidate -- they encouraged consolidation of some of these companies to create a bigger and more solid companies. That would pave the way for the regulations to go in and help. Right now there's just been too many, too small, and too hard to regulate. So that would be my -- my answer would be just continue to help Chinese government on this effort.

DR. KAZMIERCZAK: I'm looking at this from the perspective of biotechnology, biopharmaceuticals, and DNA sequencing as opposed -- which as I mentioned earlier is a very different situation from the traditional pharmaceutical market. But there are still issues there.

I think with respect to biologics from China, our major concern right now is economic competition as they become more advanced in developing biosimilars or other products. And my top recommendation is to increase U.S. funding support for basic and applied research.

I think the U.S. has a far superior ability to innovate, but just needs to make the proper investments in it. So obviously that would cost money, but it's an investment that could bring about a lot of new advances, both basic research which has led to countless discoveries from the gene editing technology CRISPR. And everybody's aware that the internet was obviously not bio-related, but government-funded research. So you never know what basic research is going to produce major breakthrough technologies. So I think supporting that is very important.

On top of that, helping companies through programs like SBIR, Small Business Innovation Research programs to help those products come out of basic research and into products is also very important. The other main challenge that we've talked about is with healthcare data and genomic sequencing and the privacy and security issues around that.

The U.S. has some of the weakest laws as far as protecting personal data. China is very strict and does not allow personal data on its citizens to be shared or stored outside of the country. I don't think we need to go that far. But I think with the GDPR that was passed recently -- or a couple years ago, I think it's obviously a global concern. And I think that is an appropriate sort of model to use.

And I think if we were to -- if we were to advance our laws to allow sharing of data to advance biomedical research with trusted partners while simultaneously preventing access from those that are not deemed to be able to handle it securely or maintain patient privacy is very important. I think that's a leading step that we need to do soon.

COMMISSIONER LEWIS: Thank you all very much. It's very sobering to know that we don't make penicillin. And that we're having to collapse the major industry in the United States. I want to ask each of you if you could please send us on one or two pages, how long it would take to affect your recommendations, how much it would cost, and how long it would take. Thank you very much.

COMMISSIONER TALENT: Thank you for that. I'm going to go now. And then I have Commission Goodwin and Wortzel in the first round. And then we'll go to a second round. I think we'll have time with Commissioners Wessel, Kamphausen, and Cleveland.

Dr. Bouey, I thought your history of China's global healthcare activities was very helpful for us. And I imagine a lot of what you said is going to end up in like the background of our report.

A couple of quick questions for you really for clarity. So when I was reading on Page 3, I think you said that the Chinese have built 150 hospitals and 25,000 healthcare professionals in their CMTs. And that they've treated 280 million patients. And that last number kind of jumped out at me. That's 5.5 million a year since 1963. And many of those years, I don't think they were that active globally. Like in the 70s and 80s, I don't think they were. So where does that information come from?

DR. BOUEY: That is coming from a report from the Chinese Ministry of Commerce.

COMMISSIONER TALENT: Okay.

DR. BOUEY: So that ministry until last year was in charge of coordinating the medical teams in China. So what happened in China is that once they get a request from a country, they

will send that to the province. They will have designated province to partner with that country. And then the province will send out a team and organize that. So that's a report from the AA book publishing. I think they are still in the final stage of --

COMMISSIONER TALENT: Is there any other independent documentation? That comes from the Chinese government. Right?

DR. BOUEY: It does come from the Chinese government.

COMMISSIONER TALENT: And it's not like they have a history of transparency regarding their global health activity. So that figure at least isn't documented any place else?

DR. BOUEY: Not in others. So that's from that chapter, yes.

COMMISSIONER TALENT: You also mentioned that they do a lot of -- you were contrasting their activities globally with U.S. and other countries. And you mentioned they do a lot of infrastructure. So that's hospitals, healthcare infrastructure. Right? Hospitals healthcare --

DR. BOUEY: Right, health-related. So again, this is talking about transparency and coordination. That's a problem area as always. The Commerce Department in the past, they usually report how many, you know, buildings they do infrastructure buildings. They don't specifically bring out, you know, this is a hospital. This is a clinic.

COMMISSIONER TALENT: Right, I see.

DR. BOUEY: And they don't report that way. So there are research teams and I personally work with Tsinghua University looking at some of these infrastructure buildings and medical support. And we're trying to bring out, you know, okay this is a hospital. This is a malaria clinic. So we considered them as a health assistance.

COMMISSIONER TALENT: When they build infrastructure, whose firms -- whose companies do they use? Do they use the local companies or do they bring in Chinese?

DR. BOUEY: That's a good question. I think there's a changing trend in that. In the past, it's mostly -- Like any other infrastructure building in Africa and Asia, they bring in their own workers. But I think the Chinese government are very sensitive to the criticism international society that they're not relying on -- they're not helping the local industry. I think in the recent infrastructure buildings, they are trying to build -- at least the report from what I've seen in Africa, some of the infrastructure construction sites, they have 80 percent of the locals. And still have you know, 10 to 15 percent of their own workers.

COMMISSIONER TALENT: And they finance most of those through loans. Right? I mean they loan money to the local government. So we see another reason why they've been doing this. I mean they're loaning money to the local governments -- going into debt to hire their firms to build infrastructure.

DR. BOUEY: Right. You're correct. And I think the new agency -- this is called the CIDIGA (phonetic), they're trying to change -- to separate the global aids -- the humanitarian aids from the commercial interest. So that's one step they're trying to do. I think over -- It was just started last April. And I think over this year, they're trying to figure out -- was in their own government to figure out -- to separate the two.

COMMISSIONER TALENT: Yes.

DR. BOUEY: But so far it's difficult because they have loans -- concessional loans aid -- concessional loans and grants. They're all lumped together.

COMMISSIONER TALENT: Okay. Since I'm the chairman, I'm going to be disciplined and hope I have a second round. Because Dr. Kazmierczak, you can be thinking about this. I want to ask why the Chinese have developed CRO industry, which you mentioned. Robin's going to ask it. Good. So we'll get a chance to do that. All right. Commissioner Goodwin?

COMMISSIONER GOODWIN: Thank you, Senator. Mr. Westhoff, point of clarification. In your written testimony in discussing these VAT rebates, you mentioned that they are offered for at least eight other fentanyl that are illegal for Chinese export. Are they legal for Chinese manufacturing and distribution, I'm assuming?

MR. WESTHOFF: No, they are not.

COMMISSIONER GOODWIN: What are they legal for?

MR. WESTHOFF: Nothing.

COMMISSIONER GOODWIN: So they're providing a tax rebate for the production of an illegal product -- illegal narcotic?

MR. WESTHOFF: That's correct.

COMMISSIONER GOODWIN: That's appalling. I think Mr. Fiedler's cynicism is justified.

Ms. Gibson, returning to this discussion of cost and the pressure on agencies, Tricare, HHS, state governments and the like to negotiate based on cost and the benefits that are there. But it obviously dominates the negotiations with drug companies. And the discussions on who is included or excluded from negotiated drug schedules and the like presumably with the benefits to those agencies, to those state governments, to tax payers, and ultimately to the beneficiaries. And we can measure it. It's quantifiable. It's tangible.

We can determine whether there were savings that were occasioned by a particular drug being used as opposed to another. How do we measure value? How do we measure quality? It can be done in the example that you gave about a war ship. There are benefits to doing that. There are reasons why we source certain products or goods or services from certain places.

And even beyond national security if you're building a dam or a bridge, vendors would have to -- potential vendors would have to meet certain minimum eligibility requirements. A threshold of expertise, in addition to competing on cost. So how do we do it in this context as you described it? And how is that consortium of hospitals doing it?

MS. GIBSON: Thank you for the question. The consortium of hospitals, they're buying directly from manufacturers. So they're bypassing all the folks in-between that, you know, add to margin. So that's certainly one way to approach it.

As for cost, I think we have to look at the medium term and long term. As mentioned earlier, when we lose control over the supply, we lose control over price. China will be the price setter and we will be the price taker. And we saw that with Vitamin C when the Chinese cartel was formed and prices went up when all the other producers went out. So these are hidden costs and they've not been calculated.

There was an estimate of the cost of drug shortages in this country because of the narrowing supply chain. And they only measure the time that pharmacists spend, which is enormous. It's about \$400 million that hospitals spend just to manage drug shortages and recalls. That doesn't include so many other costs. And frankly the cost of human life.

Remember we had hundreds of people die in this country 12 years ago from a contaminated blood thinner purchased from China. And if you look at the email exchanges of companies that purchased it, it was the cheap stuff. Some things you just don't want cheap. There's a very high price to cheap. And one of the interesting things I wrote about in China Rx is how is it that the products are so cheap? One, it's not just subsidies from the government. It's also companies will say well we assume no liability for our products. So we're buying medicines that are a matter of life and death and we assume no liability. And what recourse do we have

when there is a bad product?

Back to an earlier question. If you look at what happened with the vaccines that were bad in China, you know, many, many people were arrested. That affected the people in China. But when the heparin that we got from China killed hundreds of Americans, there was nobody arrested.

The blood pressure medicine contaminants with carcinogens, it was knowingly they were shipping product to the United States -- the worst offender was a Chinese company where the amount of carcinogen was 200 times the acceptable limit per pill. And what prompted them to do that? Because Valsartan was going generic. And there were companies competing vigorously for global market share. And so they wanted to come up with a more efficient means of making that blood pressure medicine. And they did.

The problem was they came up with this new chemical process -- and this hasn't been reported in the media -- but no one -- it was great chemistry -- and solved the problem to make it more efficient. But no one considered that this is a product that would be consumed by humans. And it was dangerous. It was lethal. And when the FDA went in to inspect this plant, they saw that the company knowingly sent substandard defective medicines with genotoxic impurities to the United States.

So if we want cheap, we can buy cheap. But what's missing from the whole equation on generic competition on price -- Let's have lower prices -- is quality. And if we have 10 percent of our generic drugs that don't meet standards and if the public knew about that -- There's a very high hidden price that we're paying for cheap.

COMMISSIONER GOODWIN: But from my perspective, I think the challenges -- the choice isn't that stark. As you say, I think we have to take a broader, more longer term view because --

MS. GIBSON: Absolutely.

COMMISSIONER GOODWIN: -- the downward -- you know, the pressure to keep costs low -- The choice is not let's pay a little bit more versus sourcing it from China with all the dangers that may with that.

MS. GIBSON: Right.

COMMISSIONER GOODWIN: It's let's keep costs low. And then what's that due to our manufacturing base over the course of ten, 15, 20 years? And we've seen what it's done -- the concentration --

MS. GIBSON: Right.

COMMISSIONER GOODWIN: -- of supply chains in China.

MS. GIBSON: Right.

COMMISSIONER GOODWIN: Thank you.

MS. GIBSON: Yes, we can revigorate our communities and our local economies by bringing this manufacturing back home at the same time that we can have higher quality tested drugs that the FDA can actually go in and inspect. I think it's a win-win on all counts. It doesn't all have to be in the U.S., but at least we're diversifying our manufacturing base to trustworthy countries.

COMMISSIONER GOODWIN: Thank you.

COMMISSIONER TALENT: Commissioner Wortzel is next.

COMMISSIONER WORTZEL: Thank you all for being here and your willingness to take part in this. I have what I think are a set of linked questions that I'm going to attempt to address. And ask Ms. Gibson and Dr. Kazmierczak to try and respond with ways that we can

shift the production to the U.S. and strengthen the industrial base. And you each have very -- Well you haven't really told us how, Ms. Gibson, but you have. And what bothers me, Dr. Kazmierczak is yours all requires government-funded solutions. I mean that's your big deal, funding. And I don't think that's going to happen.

So I guess I'd ask both of you if there are other ways to help develop this U.S. industrial base and strengthen it. Punish the countries that are providing these bad things and providing subsidies. I'm not a lawyer. Can you take them into some world court and sue them? Create a reasonable fair market place through legislation? What would you recommend there? How would we incentivize private research by U.S. companies by lowering taxes for a period of time while they put new drugs on the market. So I'll throw those things out there. I'm searching for ways that don't have the federal government funding.

DR. KAZMIERCZAK: I'll start that. Thank you for the question. I guess I have a couple responses to that. I think incentives could very much be part of the solution as well. By saying increase government funding, I guess I'm saying increase government support. So whether that's through tax incentives, I think the bottom line is that we have the capability to produce -- at least in the case of biopharmaceuticals, we have the capability to continue to be the leader for a long time. And so it's just encouraging those activities.

As far as -- I will say there's another aspect to this. And that goes into access to other markets. Access to the Chinese market in particular. China has been reforming its laws -- its regulations on biologics and biosimilars to become more in line with global standards. And actually provides the greatest amount of post-market data protection, data exclusivity than any other country.

However, that is dependent on the drugs having been developed in China using clinical trials that were conducted in China and have Chinese partners. So if you're using data from outside China, you get less exclusivity, which makes that market less attractive. So there are diplomatic avenues to try to bring China into a more friendly market so that our companies can compete there, as well as being able to compete domestically.

MS. GIBSON: The figure I've seen about how much we spend on generic drugs in the United States is \$70 billion a year. So how can we use that money we currently spend and buy smarter and buy wiser and buy high quality? How do we take the procurement dollars in the private sector, which is why I'm so intrigued by the consortium of private hospitals. And frankly as shortages continue and become -- which I believe that they will in our healthcare system and as quality problems persist, one would hope that, that model would expand to other healthcare facilities in the private sector to spur a diversified manufacturing base with trustworthy suppliers.

I think when it comes to national security say for the DoD, do we really want to tell the men and women in uniform that we're going to buy cheap because it's going to save tax payers money? I think in that case, I think we want to buy based on value. And look closely at what manufacturers will charge versus what adding everything else in-between the middle men -- if we took that out of the system, could that be more economical and more prudent for the use of tax payer money? And I think the same is true for veterans.

So I think we have opportunity to use our procurement dollars differently to move the market. When it comes to advance manufacturing technology, I think just demonstrating the proof of concept that we can do this on commercial scale, which hasn't been done before. And the FDA is supportive of this technology. But actually doing it and saying here's how it can be done. And yes, your facility can be FDA approved. Show that. And have buyers -- maybe it's this consortium of hospitals that we will buy product that we can make here in real time quality

control. That could take some modest amount, I believe, of incentive to stimulate that private market and that development of that technology at a higher scale.

COMMISSIONER TALENT: Commissioner Bartholomew has a quick clarifying question.

CHAIRMAN BARTHOLOMEW: Yes. Ms. Gibson, you're talking about additive manufacturing. You're talking about 3D printing, aren't you, essentially? That there would be machines that could print up -- I'm using that word -- manufacture on demand drugs. Is the technology already there or not yet?

MS. GIBSON: I'm thinking of the advanced manufacturing technology, which is called pharmacy on demand, making the API, which is the most costly part of a generic drug. And that's why generic companies don't have the incentive to invest in this because their margins are so small. That's the technology I'm thinking of.

CHAIRMAN BARTHOLOMEW: Okay, thank you.

MS. GIBSON: I'd be happy to provide the Commission with more information on that. It's fascinating. And I think it's the future should we choose to support it.

COMMISSIONER TALENT: All right, we have finished Round 1. And because of Commissioner Wessel's and my tremendous foresight, we have time for Round 2. We scheduled enough time for this panel. I think we should be very proud of that. And we will go to Commissioner Wessel for first questions in Round 2. And then I have Commissioner Kamphausen and Cleveland so far lined up.

COMMISSIONER WESSEL: Thank you, all. This has been very helpful. You know, I've been sitting here getting angrier and angrier because my -- I love my dog. My wife, after the melamine scare, you know refuses to buy dog food made in China. And I realize there's more disclosure on our dog food than there is on the drugs that we use every day for our families. And to me, that is -- that's a crime.

Going to Dr. Wortzel's question, a couple of things. One, my understanding is several years ago, there was legislation that would require on the labels, the source of the active ingredients. And that is not part of present law. Is that right, Ms. Gibson?

MS. GIBSON: That's my understanding. There was country of origin legislation proposed around 2007 and 2008. I think it was by Sherrod Brown. And that was killed on the first pass.

COMMISSIONER WESSEL: Right. So I'm of the view that, you know, if it's on the dog food bags, maybe it should be on what we're -- you know, whatever products, whether they're dietary supplements or pharmaceuticals. So I think we need to look at the question of what the impediments are to country of origin labeling for active and maybe inactive ingredients so that we can address that.

But as a market based solution, I would welcome anyone's comments. I think someone made the statement that there's limited liability. Without having to have massive government expenditures or no government expenditures, if we were to create an insurance risk based system where importers of the APIs, importers of the finished products, TSHEA (phonetic) products, or pharmaceuticals had to bond or insure against risk, it seems to me that would have a pretty significant impact on the sourcing patterns. An insurance company doesn't want to be left holding the bag for liability. And therefore presumably is going to demand that an importer go upstream to its suppliers and have some kind of confidence in the supply chain.

For anyone, Ms. Gibson or anyone else who may want to respond, can you just give me your opinions on whether that kind of system may actually help us in this dilemma?

MS. GIBSON: I'll start. I think it's a really interesting idea. It would certainly raise the cost of exporters from China and other countries. But that would also perhaps improve the level -- create a more level playing field for manufacturers here and in other countries where the standards may be better.

COMMISSIONER WESSEL: Any other thoughts? Okay. Dr. Bouey, a separate question for you. And an issue we have to deal with constantly because on the one hand, we've talked about all of the threats that exist here today -- our earlier panel on this one in terms of sourcing. Healthcare is one of those fields where there really is a global commons or should be. You talked about pandemic threats et cetera. You know, without denigrating all that is Chinese, which tends to be at times, the political mode of the day, how do you think we are able to address that challenge so that we can talk about U.S. interests. The health and safety of our population, while also addressing, again as Mr. Westhoff, you know, pointed out, fentanyl is not legal in China, but they're giving export taxes to it. How do we deal with, you know, that dilemma in the U.S./China debate right now?

DR. BOUEY: My opinion -- personal opinion, there can be three level actions. So we have the short-term, medium-term, and long-term. So the long-term certainly would be more collaborations. Helping China to build capacities for regulation was in China on both medicine, medical products, and vaccine. I think China has been trying -- actually what I heard in China is that they are only producing the API, which is actually low margin -- profit margin. The government hoped that their pharmaceuticals can build more formulas or you know, drugs that can be on the international market. But right now only a handful of drugs and only one vaccine is procured by WHO. So China's far away from providing for medicine on the international drug market. So they're focusing on API now.

So to help China to harmonize some of the regulations will be the long-term solution. Medium-term solution, I think will be more collaborations similar to the influenza surveillance. So if U.S. CDC, China CDC, U.S. FDA, China FDA can have real collaborations. That they can -- you know, there was the influenza surveillance. U.S. CDC, they signed agreement for capacity building.

And then Chinese government put in more than \$400 million into building these labs all over the country. They built more than 500 labs that raised to capacity. And they're providing data to -- sharing the data to both countries, as well as to WHO. So every year when we see -- we know what is the target influenza, you know, for vaccine, that's some of the data that's used for international organizations.

In the short-term, I think if we want to address the fentanyl issues, that's short-term. Again, I think would be engage China. Since the government -- their leaders are very sensitive to international opinions. And they want to be part of the global governance. I think something that's framed again as synthetic drug problems all over the world. You know, yesterday I saw a report saying that 80 percent of the opiate seizure -- the illegal opiate productions is actually in Africa is the tramadol issues. So here certainly, you know, we're all focusing on fentanyl. But there are larger epidemics out there.

So bringing China in as an active player in that coalition, I think will be the fastest way to get their attention. And bring their priority so that it can change their policies.

COMMISSIONER WESSEL: And I appreciate all of that.

MS. GIBSON: Thank you.

COMMISSIONER WESSEL: And I don't -- you know, collaboration is great. I think China is putting that collaboration in real jeopardy as a result of many of its policies. You know,

you talked about world opinion. I think world opinion demanding that China change certain practices is as high as it's ever been. I don't see a lot of change. So I think it's -- at this point, the next step as China's leaders beginning to take certain steps that will re-engage collaboration and give greater confidence. Thank you.

COMMISSIONER TALENT: Commissioner Kamphausen?

COMMISSIONER KAMPHAUSEN: Two quick questions for Ms. Gibson. Just a point of fact. We talked about the coalition of hospitals. Do you have any idea where they're sourcing their APIs?

MS. GIBSON: I don't.

COMMISSIONER KAMPHAUSEN: Okay. Dr. Bouey, on Page 15 of your testimony, you talk about the importance of encouraging Beijing's greater collaborations with multilateral organizations. And you talk about progress that China has made as a participant in global governance. Following up on Chair Bartholomew's statement earlier. What insights or perspective's do you have on Beijing's declining to allow Taiwan to participate in the World Health Assembly every year since 2017 on a political basis based on their opposition to the Tsai Administration in Taiwan? I mean Bloomberg has rated Taiwan's healthcare system as ninth most efficient, effective in the world. What sense can we make of this? And how does it contribute to this assertion that you've made that China wants to be more of a stronger participant in global governance and healthcare issues? Thank you.

DR. BOUEY: Well, I think that's a difficult question for me because I'm not a China/Taiwan expert. I think China's government mainland government has the political will to participate in global governing, especially from my knowledge on global health assistance. I think, you know, my limited knowledge about Taiwan's health system as a model. I think even now China itself has lots of problems. One of them is their health system. They have a single payer social insurance program that they cannot keep up with the cost of healthcare. And they have very limited ability to work with the long-term care and disability care for now. So they're actually looking into Taiwan as a model to what are -- you know, you said they also look at the U.S. But they think Taiwan has a better model in terms of healthcare provider. Personally I hope as a researcher, as a public health professional, there will be -- I hope there will be more collaborations.

COMMISSIONER TALENT: Okay, Commissioner Cleveland has been very patient. Okay, we had the same question, didn't we? So I had previewed it. Dr. Kazmierczak, if you could explain why -- both Commissioner Cleveland and I were interested because your written testimony was really good and you make the point that in this area, biotech, biologics, the Chinese have not yet advanced very far, although they are certainly investing and certainly ambitious. But there are a couple of areas where they really are competitive and have a significant amount of market sharing. One of them is these contract research organizations. Right? So why? I mean why are they doing so well there? What's your analysis of that? What needs are they meeting in that area and why have they been effective?

DR. KAZMIERCZAK: Thank you for the question. Industry uses contract research organizations for the same reasons that anybody outsources any services. It's because of costs. It's cost and expertise. And this is true for large pharmaceuticals where it may be more of a cost issue, but especially important for start-ups where that expertise is a lot easier to go outside than to build within.

And so China has been developing these -- essentially been taking advantage of that. So they are able to provide these services. And they do have a large technically advanced

workforce that can do this work. And they can do it at a lower cost. And so this is why they've been able to build up that industry.

It can also be used as sort of stepping stone to more advanced development. So you may be -- It may be a way of training the workforce to then move on from the contract research activities into other companies or arms of the same company that are actually developing new biologics or biosimilars.

COMMISSIONER TALENT: Are these CROs subsidized? Are they given any help by the government to compete or do you know?

DR. KAZMIERCZAK: I have not seen any specific instances of CROs being funded by the Chinese government, although I did not look explicitly for that. But given the amount of support that they've given for Biotech in general, it would not surprise me if some of them are.

COMMISSIONER TALENT: Do they work mostly, if you know, mostly for firms that are trying to get business or approval in China? Because it sounds like they help navigate a lot of the regulatory terrain. Right? So do the Chinese firms deal mostly with -- work mostly for firms wanting to work in China or are they working -- For example, companies trying to navigate here in the United States, do they go and hire Chinese CROs?

DR. KAZMIERCZAK: I think that's a very large portion of their clientele, although I haven't done a systematical analysis of it. One of the major activities for CROs is to help navigate the approval process for a drug. And so you will see -- it will be more likely that a company would want to use a Chinese CRO if they're trying to access the Chinese market, so yes.

COMMISSIONER TALENT: Did you have any followup, Commissioner?

VICE CHAIRMAN CLEVELAND: One, you note that data are not available on how many U.S. companies or what portion of the U.S. market are using CROs in China. And yet they're involved in critical pre-clinical trials. Would there be any way of collecting that data? It's just something that there hasn't been interest in? Or what would the impediments or barriers be to understanding which U.S. companies are relying on CROs in China?

DR. KAZMIERCZAK: Well, it's definitely difficult to get specific quantitative data. Because unlike investment data, these are private -- these are customer/client transactions that are not reported. So there's no database for that kind of information. I have not had the opportunity, but am extremely interested in looking at exactly that issue. And so there are ways around it. Largely, it would just be through talking to the U.S. -- the major players and the smaller players actually in the U.S. biotech industry to get a sense of this.

I will say that the U.S. CRO industry is still the largest in the world. Both American and foreign companies are using American CROs to a great extent.

COMMISSIONER TALENT: Hey, we have one commissioner remaining, Commissioner Lewis. And I think we should just about have time for his questions. And then we'll be done. Commissioner?

COMMISSIONER LEWIS: The information that you've given to us today is obviously a matter of national security. And earlier this year, we had another hearing with an aerospace manufacturer was doing things that was not in the national interest. And there was a story about it in the Wall Street Journal. After the report appeared in the Wall Street Journal, that aerospace company stopped doing what they were doing. Well it seems to me that if the report that you give us on my earlier question, how long it will take to affect your recommendations? How much it would cost? And who opposes it? If we include in our report or if the press finds out who opposes your recommendations, it might cause them to change their conduct. So I really

would appreciate any information you can give us on those subjects. Thank you very much.

COMMISSIONER TALENT: Okay, all right. Well -- Yes, Commissioner Cleveland?

VICE CHAIRMAN CLEVELAND: Are any of you aware of how the Chinese are using BRI to promote their medical industry?

DR. BOUEY: So at RAND, we are hoping to start some of the research projects looking into BRI. It's environmental and a social impact of BRI. I only know from the same report I read from Chinese government, one of their goals in the -- while they had a BRI health summit, a couple of years ago. So they're aware that in order -- along with BRI, they want to develop health assistance programs. And it's partly to protect their investments. I think that's pretty natural. But also use it -- to coordinate with infrastructure building and to enhance the investment in healthcare.

I know that the Chinese government is hoping that their companies will be more interested to investment in Africa to build the factories because they already have the API. So they can use that as an incentive. So if they have a local production, then they don't have to put in funding for API to make the -- So that's an incentive. So I think that's -- They definitely have in mind to coordinate health assistance with the BRI project.

COMMISSIONER TALENT: All right. We want to thank the witnesses again for your outstanding testimony. For your answers to our questions. And sometimes we have a follow-up or two that we solicit for answers in writing. And if we do, we'll let you know. And if you can help us some more, that would be great. So thank you. And we will now break for lunch until -- what is it, 1:35, I think? 1:30.

(Whereupon, the above-entitled matter went off the record at 12:28 p.m. and resumed at 1:29 p.m.)

PANEL III INTRODUCTION BY COMMISSIONER WESSEL

COMMISSIONER TALENT: Good afternoon. We'll get started. Our third panel will examine U.S.- China links in health and medical products assessing market opportunities and economic health and national security risks of these relationships.

We'll start with Benjamin Shobert who is a Senior Associate for International Health, the National Bureau of Asian Research. Mr. Shobert is also the Director of Strategy for Health Business Strategy at Microsoft where he leads engagements with national governance providers in the Biotech Community.

Next, we'll hear from Katherine Eban, an investigative journalist, a Fortune Magazine contributor, and an Andrew Carnegie Fellow. Ms. Eban's book, *Bottle of Lies: The Inside Story of the Generic Drug Boom* reveals fraud and dire conditions in the overseas manufacturing plants where the majority of our low cost generic medicine is made.

Our third panelist is Yanzhong Huang who is Professor and Director of Global Health Studies at Seton Hall University. Dr. Huang is also a Senior Fellow for Global Health of the Council on Foreign Relations where he directs the global health governance round table series and co-directs the China and Global Governance project.

Finally, we will hear from Craig Allen who is President of the United States China Business Council. Prior to joining USCBC, Mr. Allen had a long career in public service, which included multiple tours in China and broader Asia and culminated with his appointment as the U.S. Ambassador of Brunei from 2014 to July 2018, TPP, an interesting time.

I ask all our witnesses to keep your remarks to seven minutes. And Mr. Shobert, we'll start with you. Thank you.

**OPENING STATEMENT OF BENJAMIN SHOBERT, DIRECTOR OF STRATEGY
FOR HEALTH BUSINESS STRATEGY, MICROSOFT; SENIOR ASSOCIATE,
NATIONAL BUREAU OF ASIAN RESEARCH**

MR. SHOBERT: Well good afternoon. And thank you for the opportunity to come back. It's always a pleasure to be here and to testify. Across Washington D.C., the last three years have been marked by a recognition that much of what has been taken for granted in the U.S.-China relationship specifically and globalization more generally needs to be reassessed given the extent to which a normalized relationship between the United States and China had been assumed.

And taken into account during the construction of critical supply chains such as those in the pharmaceuticals and medical device sectors, much of this re-thinking has been jarring. And it has provoked policy makers and politicians to re-think assumptions that have undergird the global economy for nearly three decades.

Whether we should assume that healthcare will remain a durably unique high-technology sector, not subject to the strains and fissures that mark other high technology industries. Or whether healthcare is simply earlier in China's foreign direct investment cycle and as such, has not yet felt these pressures, but soon will, requires a dispassionate assessment.

In assessing risks, we must first weigh whether China's historical success in other high technology sectors are applicable to healthcare. Healthcare incubation ecosystems, in particular life sciences and biotech are fragile. And have proven very difficult to recreate. Where they have been developed, it has taken decades of intentional investment and cultivation of ties between academia, venture capital, medical centers, and industry.

While no one should doubt China's appetite for making these investments, a degree of caution is worth striking as to whether the country will be as successful as quickly as it has been in other high technology sectors. Should China's ambitions prove to be unfulfilled, it is possible that foreign healthcare companies may begin to experience increasing difficulties over market access or technology transfer issues. And if so, healthcare may find that today's more open and positive relationship with the Chinese market, including with key Chinese regulators, could change.

Four risks will need additional attention from American policy makers. In particular, as they relate to lessons we should learn from the experiences of other high technology industries in China. First, the impact of ongoing trade tensions on bilateral investments and on supply chain uncertainties. Each of which has unique characteristics within the healthcare sector. Anxieties over where you get your new iPhone is one thing. Uncertainties over where you get your antibiotics or anti-hypertensives is quite another.

The world, not just America, has become increasingly dependent on China as its source for manufacturing pharmaceuticals. Whether America should have taken this dependency on foreign manufactured pharmaceuticals is not a question best directed to the U.S.-China relationship. Rather if American policy makers want to ensure that a certain national formulary is widely available to the public in times of crisis, policies around domestic production, and a national formulary would be appropriate.

It is worth calling our collective attention to this concern. Taking a dependency on China for pharmaceutical products in particular has historically been understood as one of the reasons the U.S.-China relationship can and should be thought of as safe and stable. It is now interpreted through a lens of mistrust. If we indeed believe America can take calculated dependencies on

China for critical components to modern life; healthcare and medicine being just two of those, then we are still working in good faith. However, if we no longer believe that America can do so, much of what has supported the modern era of globalization is no longer valid.

The second risk is CFIUS' role in evaluating Chinese FDA into the American healthcare sector. The April 2019 determination by CFIUS that the Chinese digital healthcare company, iCarbonX would have to divest its \$100 million investment in the American patient healthcare platform, PatientsLikeMe, has drawn significant attention by both American and Chinese investors. And has already had a negative effect on bilateral investments.

Third, differences in appetites for investment and for risk in relationship to large national biobanks funded by the American and Chinese respective political systems. The curated data sets that result from these investments serve as the foundation for the 21st Century economy. The greater diversity, quality, and quantity of data available to researchers should in turn result in an accelerated development of precision medicines. Which should result in companies being able to spin out new therapeutics and diagnostics predicated on access to those privileged data sets. Justifying government led investments in these data sets has become increasingly difficult in the United States in particular.

Fourth, asymmetric data access policies and standards between the United States and China and their impacts on economic competitiveness needs to be more fully understood. As currently embodied in both law and practice, American researchers do not have symmetrical ability to work with Chinese data assets as do Chinese researchers to work with American.

Artificial intelligence ability to develop new use cases hinges on access to large quantities of training data. And no country in the world is as serious about funding the aggregation of data across a number of disparate verticals of which healthcare is just one, than is China. As American policy makers wrestle with questions around asymmetric data access policies between the United States and China, it would be wise to keep in mind that American healthcare and technology companies stand to benefit if promulgated policies in both countries were to exist that allowed training on both countries data sets. At current investment levels, China will amass a much larger and more diverse healthcare specific set of data upon to which train AI, than with America.

With that, let me end on five recommendations to Congress. First, deliberately gate Chinese FDI into American healthcare verticals based on our companies' ability to do the same in China. Second, review America's national formulary and determine how best to construct the supply chain to anticipate times of crisis. Third, pursue harmonized standards around the sharing across borders of personal health information.

Fourth, update our trade policies to reflect the era of big data artificial intelligence. And fifth, make sure that our government has an appetite to match China relative to its ambitions in new sectors such as biotechnology and artificial intelligence. Sectors that certainly have a national security implication to them, but perhaps most critically are directionally important as to where our economy goes over the next 100 years. Thank you.

**PREPARED STATEMENT OF BENJAMIN SHOBERT, DIRECTOR OF STRATEGY
FOR HEALTH BUSINESS STRATEGY, MICROSOFT; SENIOR ASSOCIATE,
NATIONAL BUREAU OF ASIAN RESEARCH**

Testimony before the U.S.-China Economic and Security Review Commission

Hearing On: “A Healthy Relationship? Assessing the Risks and Opportunities of China’s Medicine and Health Development”

July 31, 2019

Benjamin A. Shobert

Author, *Blaming China: It Might Feel Good but It Won’t Fix America’s Economy*; Senior Associate, National Bureau of Asian Research; Director, Healthcare Strategy, Microsoft

Across Washington DC, the last three years have been marked by a recognition that much of what has been taken for granted in the US-China relationship specifically, and globalization more generally, needs to be re-assessed. Given the extent to which an increasingly normalized relationship between the US and China had been assumed, and taken into account during the construction of critical supply chains such as those in pharmaceuticals and medical devices, much of this re-thinking process has been jarring, and has provoked policymakers and politicians to re-think assumptions that have undergird the global economy for nearly three decades.

For industry, long standing concerns over issues such as market access and intellectual property (IP) theft in China appear to have reached a breaking point over the last two years, in particular across a variety of high technology industries, with at least one notable exception relevant to this hearing: healthcare¹. Whether the U.S-China Economic and Security Review Commission (USCC) should assume in its recommendations to Congress that healthcare will remain a durably unique high technology sector, not subject to the strains and fissures that mark other high technology industries such as telecommunications, clean-technology and semiconductors, requires a dispassionate assessment of the risks and opportunities posed both to American businesses and consumers by China’s current role in the global healthcare economy.

Healthcare has been commonly thought of as being different than other high technology industries due to several factors. First, and perhaps most critically, because healthcare remains an industry where nearly all those who contribute to its advancements believe deeply in their responsibility to better their fellow man, whether through development of new products, or in-person administration of care to the sick. Second, because healthcare is inexorably linked to those public health concerns that most governments hold front and center to their legitimacy, they make a concerted effort to balance between the needs of the public and industry in ways other sectors cannot (admittedly, not always in ways that either finds satisfying). Third, that few technological improvements cascade across the globe more quickly than those in healthcare, perhaps as best demonstrated by the increase in human longevity over the last century. Fourth, that certain research and development (R&D) heavy healthcare sectors, such as those in precision medicine, require a very special ecosystem that is not easily replicated by the brute force of industrial planning.²

¹ Note: For the purposes of this written testimony, unless otherwise explicitly stated, “healthcare” will represent healthcare services (hospitals, senior care, home healthcare, skilled nursing, etc.), as well as life science, pharmaceuticals, and medtech (durable medical equipment, disposables, surgical devices, etc.).

² Joseph Wong, *Betting on Biotech: Innovation and the Limits of Asia’s Development State* (Ithaca: Cornell University Press, 2011), 165.

For the last thirty years, these four factors have also benefited from a set of shared beliefs that, until recently, supported the narrative for why high technology companies in other sectors also wanted to be in China: the size of the Chinese market, its relative immaturity relative to the products and services available in western markets, and the Chinese government's appetite for foreign direct investment (FDI) in these sectors.³ And yet, for all of the reasons why the healthcare market in China should be seen as continuing to be full of opportunity, the last several years have begun to demonstrate that while healthcare may be unique in certain ways, it is not so different as to entirely escape the pressures that other high technology sectors have found to be problematic in China. Understanding how the risks and opportunities for the medicine and health sectors in China are changing, and their potential impact on American industry and patients, requires being grounded in several critical aspects of the Chinese healthcare sector.

China-Specific Healthcare Context

Chinese policymakers approach the healthcare sector with five concerns, only three of which should be thought of as unique to healthcare. American policymakers would do well to understand the ways in which healthcare can, and cannot, be thought of as unique from other high technology sectors from the vantage point of their Chinese counterparts.

First, that access and affordability of healthcare services across China continue to be problems of such import as to represent potential sources of instability for the government. While today China's government can accurately say that greater than 95% of the country's rural population have government provided healthcare insurance, out of pocket spending (OOP) by the average Chinese family (rural or urban) is still well above that of its industrialized neighbors.⁴ A World Health Organization (WHO) study asserted that "China ranked 188th among 191 member states in fairness of financial contribution."⁵ For all the efforts of the Chinese government to reform its domestic healthcare system, in 2015, approximately 44% of poor families in China found themselves "impoverished because of illness."⁶ Pervasive inequalities between the quality, affordability and access to healthcare via public hospitals continue to exist between urban and rural settings in China.⁷

Second, ubiquitous *hongbao* or "red envelope" practices reflect a broken funding mechanism that places additional financial strain on Chinese families and in so doing, has come to represent the Chinese government's inability to properly fund the public healthcare system. Red envelopes have long been the way in which private citizens pay to get to the front of the line at a public hospital, or pay the physician under the table in addition to any service charges they may incur, as well as the way in which companies pay physicians to prescribe certain pharmaceuticals or

³ "What Can We Expect in China in 2019?", McKinsey, <https://www.mckinsey.com/featured-insights/china/what-can-we-expect-in-china-in-2019>.

⁴ China Power Team. "Is China's health care meeting the needs of its people?" China Power. August 29, 2018. Updated May 9, 2019. <https://chinapower.csis.org/china-health-care-quality/>.

⁵ World Health Organization. "The world health report 2000 — health systems: improving performance", WHO, 2000.

⁶ Wei Fu, "Research in health policy making in China: out-of-pocket payments in Healthy China 2030", BMJ. February 5, 2018. <https://doi.org/10.1136/bmj.k234>.

⁷ Li Zhong and Li Jun, "Lessons and prospects of Universal Health Coverage in China: the importance of equity, quality and affordability," Asian Bioethics Review, March 12, 2019.

diagnostic services.⁸ As is often the case in China, these perverse incentives have led to innovations of a sort, with *huángniú* or “scalpers”, developing a business of selling their place in line at a hospital for a fee.⁹ So to, as other high technology sectors have found in China, errors of the Chinese government’s making (in this case chronically under-funded public hospitals marked by a lack of proper oversight) can result in liabilities the private sector is held accountable for. The 2013 GSK scandal, where the company was found to be widely participating in *hongbao* payments towards doctors and government officials, has been subject to a number of interpretations, one of which is that whatever legitimate Foreign Corrupt Practices Act (FCPA) violations GSK was guilty of, their actions (and those of their competitors – both foreign and domestic) had come to be accepted as part of the cost of doing business in China.¹⁰ In this way, the inconsistent application of laws in China’s healthcare economy remain an omnipresent concern as multinational corporations (MNCs) develop sales, marketing and distribution strategies for the local market.

Third, that healthcare remains one of the few parts of the Chinese political economy where Chinese families believe the government has a very specific responsibility to perform. In healthcare we see concerns over national security (does China have adequate production capacity, and/or supply of, the relevant formulary to protect itself from public health emergencies), environmental pollution (the tainted air, water and food supply representing the reason why many families must seek out care in the first place), and corruption (the previously mentioned *hongbao* practices) intersect, and much of the time all within the four walls of a government run hospital. The 2012 Pew Research Center’s analysis of China found that during the survey period, anxieties over China’s healthcare system had more than doubled, a reflection of these concerns.¹¹ The Chinese government is widely understood by the public as being accountable for the problems in the national healthcare system, and because of this, recognizes that foreign expertise and in limited capacities, foreign investment, is useful.

While the previous three factors are unique to healthcare, the next two are not. In fact, the next two share similarities with other high technology sectors that have come under pressure in China. Because of this, these next two considerations bear a deeper analysis as to how lessons from other industries may prove relevant to healthcare.

Fourth, that healthcare – in particular the development of IP in life sciences and biotech – is somehow uniquely challenging, and that China’s historical success in other high technology sectors will not apply to healthcare. As I shared in my 2017 testimony to the USCC, “China’s pursuit of a domestic biotechnology sector may well indicate the limits of its particular centralized economic planning capability. Biotechnology does not easily line up with those other high technology sectors such as clean-technology and semiconductors where China has been able

⁸ Joseph D. Tucker, Bonnie Wong, Jing-Bao Nie, Arthur Kleinman, “Rebuilding patient-physician trust in China,” *The Lancet*. Volume 388, Issue 10047, P755, August 20, 2016.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31362-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31362-9/fulltext).

⁹ Jia Guo, “How Does Healthcare in the U.S. Compare With China’s?” *SupChina*. March 28, 2017.

<https://supchina.com/2017/03/28/healthcare-us-compare-china/>.

¹⁰ Zhiwu Chen, “Foreign companies are easy targets in China,” *Financial Times*. July 17, 2014.

<https://www.ft.com/content/2ee46a08-0cfb-11e4-bcb2-00144feabdc0>.

¹¹ “Growing Concerns in China about Inequality, Corruption”, Pew Research Center: Global Attitudes and Trends. October 16, 2012. <https://www.pewresearch.org/global/2012/10/16/growing-concerns-in-china-about-inequality-corruption/>.

to become a globally disruptive force. A helpful way to think of high technology areas where China has been most successful is in those areas that had been already transitioned from bench science to application engineering, and in areas where process innovation (doing more manufacturing faster and at greater scale than in developed markets), has been most impactful.”¹² Healthcare incubation ecosystems – in particular life sciences and biotech – are precious and have proven difficult to re-create. Where they have developed, it has taken decades of intentional investment and cultivation of ties between academia, venture capital, research hospitals and industry to identify ways of developing, scaling and monetizing healthcare IP.¹³ While no one should doubt China’s appetite for making these investments, a degree of caution is worth striking as to whether the country will be as successful, as quickly, as it has been in other high technology sectors.

Fifth, that China’s ability to develop a domestic healthcare sector is an essential part of its economic development strategy. As I wrote in a 2016 special report for the National Bureau of Asian Research (NBR): “Economies that have a vibrant life science community feature high-paying jobs, systems that deliberately foster innovation within academic institutions, robust protections for intellectual property (IP), and a sophisticated manufacturing infrastructure. In addition, economies that feature global champions in these high-technology fields create benefits for other industries domiciled within the same geography. The characteristics of economies that have successful life science sectors easily complement the policy agenda of the Chinese government to reframe what ‘made in China’ represents to its own people and the world.”¹⁴ While China’s ambitions in healthcare may have unique motivations versus other high technology sectors, they also share an idea and motivation; namely, that for China to continue to economically develop it will need to become a global powerhouse in higher technology industrial sectors, of which healthcare is one.

As evidenced by the growing number of domestically originated new drug submissions to China’s National Medical Products Administration (NMPA, and formerly known as the China Food and Drug Administration, or CFDA), no one should doubt China’s aspirations to successfully develop novel molecules or precision medicine capabilities, in particular with respect to efforts focused on chimeric T cell receptors (CAR-T) and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR). In both cases, objective analysis suggests that China’s ability to make progress with respect to western R&D efforts may owe less to concerted industrial policy, and more to the lax regulatory environments within which Chinese companies operate in these two research areas in particular.¹⁵ Said differently, the lack of certain ethical oversight for CRISPR, and the regulatory approval channel CAR-T has been able to take

¹² Benjamin Shobert, Hearing On: “China’s Pursuit of Next Frontier Tech: Computing, Robotics, and Biotechnology,” March 16, 2017, U.S.-China Economic and Security Review Commission, 3.

¹³ Note: Additional context on the peculiar nature of the biotech incubation ecosystem can be found in Ajay Gautam’s book *Drugs, Politics & Innovation: An Emerging Markets Cocktail*, Partridge Singapore, March 4, 2016.

¹⁴ Benjamin Shobert, “Priming the Pump: Applying Lessons Learned from High-Tech Innovation to the Life Sciences in China”, National Bureau of Asian Research. April 2016, 27.

¹⁵ Mark Kazmierczak, Ryan Ritterson, Danielle Gardner, Rocco Casagrande, Thilo Hanemann, Daniel Rosen, “China’s Biotechnology Development: The Role of US and Other Foreign Engagement: A report prepared for the U.S. China Economic and Security Review Commission”, Gryphon Scientific and Rhodium Group, February 14, 2019, 24-25.

advantage of (a medical technology versus drug clinical trial), account for some of the velocity of Chinese efforts in these two areas, as opposed to intentional policy making.¹⁶

Yet, while we can observe an increase in the amount of domestic investment in the broader healthcare industry (in particular life science and biotech sectors), and a correlated increase in the number of domestic clinical trials, we cannot yet say that Chinese industrial policy has resulted in a thriving sector characterized by the development of new therapeutics that hold the potential to accelerate China's domestic economy by manufacturing, distributing and selling these products to the world. What we still have is a sector marked by enormous ambition and investment from both public and private sector actors in China. But, as policymakers and investors in more developed markets can attest, significant downside risks reside at the intersection of human biology, science and commercialization; China's success in this sector should not be assumed, both because past efforts to leverage industrial policy by other economies have proven unsuccessful, and because unlocking the next era of precision medicine led innovations are not scientifically nor economically assured.

These last two contextual factors both revolve around the idea of healthcare as just another high technology sector that China will be targeting. This requires special attention with respect to what the USCC has asked around risks. It is this consideration, healthcare as just another high technology vertical within which China's domestic industrial policy will be applied, that suggests caution in how risks are thought of, and designed around. Perhaps most critically, thinking of healthcare in this way allows American industry and policymakers to now reflect on and apply hard lessons learned from other, non-healthcare, high technology sectors in China. To the extent industry and policymakers outside of China now wish a more deliberate approach had been taken to how non-healthcare related high technology sectors were brought to China, we now have an opportunity to reflect on these lessons learned, and where appropriate, apply them to healthcare, to ensure the interests of both the US and China are taken into account.

Opportunities

Three opportunities continue to characterize the Chinese healthcare economy, all of which are positive for both American industry and patients.

First, the market potential. China's pharmaceutical sector is already the world's second largest, and is poised to increase in size to ~\$145 billion by 2022.¹⁷ McKinsey estimates that the Chinese healthcare economy should reach \$1 trillion by 2020.¹⁸ While the size of China's potential market is alluring regardless of industry, in healthcare China's potential plays a somewhat different role. Austerity measures driven by aging populations across western markets, alongside the transition away from fee for service to value-based care in the United States in particular, have resulted in many multinational healthcare companies aggressively seeking out new growth opportunities. The allure of the Chinese market's ability to mitigate the revenue and margin pressures faced in western markets has, in part, explained why so many

¹⁶ Ibid., 24.

¹⁷ Alex Keown, "Exponential Pharma Growth Expected in China by 2022", BioSpace, April 20, 2018. <https://www.biospace.com/article/exponential-pharma-growth-expected-in-china-by-2022/>.

¹⁸ Franck Le Deu, Rajesh Parekh, Fangning Zhang, and Gaobo Zhou, "Health care in China: Entering 'uncharted waters'", McKinsey & Company, November 2012. <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/health-care-in-china-entering-uncharted-waters>.

multinationals (pharma and medtech in particular) have made China such a central part to their growth story.¹⁹

Second, investment. Up until the October 2018 US Department of Treasury pilot program that announced additional scrutiny would be applied to FDI (including biotech) Chinese appetite for investments in American healthcare was growing.²⁰ The Gryphon Scientific and Rhodium Group analysis of this topic from earlier this year found that “despite the recent rapid increase, the total value of outbound M&A in the pharmaceutical and biotech sectors remains relatively small at just \$7 billion in 2000-2017, which is a small fraction (two percent) of total Chinese outbound M&A in that period.”²¹ Given the American biotech venture capital sector is not currently short capital, investment monies from China are not critical.²² However, for those who have sought out Chinese capital, savvy Chinese investors have increasingly tied their willingness to deploy funds into a western biotech firm to in-licensing terms that ensure the IP in question has a route to market in China.²³ If outbound Chinese investment into American biotech companies continues to slow, so too may the market access opportunities for American biotech startups in China slow down. It is worth noting that this opportunity is quickly diminishing given the Committee on Foreign Investment in the United States (CFIUS) ruling on iCarbonX’s investment in PatientsLikeMe, a point which will be addressed later in more detail.²⁴

Third, harmonization of healthcare standards to global norms. For years, China’s pharmaceutical regulatory processes were badly out of sync with those of its developed neighbors. This resulted in treatments that could not be made available to the Chinese public. But over the last five years, Chinese regulators have turned their attention towards reforming the former CFDA (now NMPA), with striking results as measured by the velocity and number of new domestic and foreign drugs approved for use in China.²⁵ The result of these efforts to bring China’s regulatory environment up to western standards has meant that multinationals can sell their products into the Chinese market within a larger window of patent protection than had been previously afforded them. This is not only a material new source of revenue, by growing the potential total addressable market for new healthcare innovations, it is possible to spread R&D cost over more covered lives, hopefully leading to lower costs. In addition, harmonization of regulatory

¹⁹ Angus Liu, “China’s driving sales growth ahead of the U.S. for Big Pharma. But can it last?,” FiercePharma, May 28, 2019. <https://www.fiercepharma.com/pharma-asia/china-drives-growth-ahead-u-s-for-big-pharma-will-it-last>.

²⁰ Ned Pagliarulo, “US tightens scrutiny of foreign investment into biotech sector,” BioPharma Dive, October 11, 2018. <https://www.biopharmadive.com/news/us-tightens-scrutiny-of-foreign-investment-into-biotech-sector/539437/>.

²¹ Kazmierczak, et. al., 56.

²² “Another Trophy Quarter for VC-Backed Biotech Funding,” LifeSci VC, April 30, 2018. <https://lifescivc.com/2018/04/another-trophy-quarter-for-vc-backed-biotech-funding/>.

²³ “China drug in-licensing opportunities expected to swell as local pharma focus on R&D,” Pharmaceutical Technology, May 23, 2019. <https://www.pharmaceutical-technology.com/comment/china-in-licensing-deals/>.

²⁴ Christina Farr, Ari Levy, “UnitedHealth buys PatientsLikeMe, which faced Trump administration scrutiny over Chinese investor,” CNBC, June 24, 2019. <https://www.cnbc.com/2019/06/24/unitedhealth-buys-patientslikeme-after-cfius-forced-sale.html>.

²⁵ Mark Terry, “30 New Drugs from Foreign Countries Approved in China in Last 21 Months”, BioSpace, November 27, 2018. <https://www.biospace.com/article/30-new-drugs-from-foreign-countries-approved-in-china-in-last-21-months/>.

standards also ensures that innovations developed in China can be exported to markets in need more quickly than they otherwise would be.²⁶

Finally, the harmonization of China's pharmaceutical sector to global standards has important quality and safety implications to American consumers. As China continues to legitimize the enforcement capability of the NMPA, and to force consolidation of its highly fragmented pharmaceutical manufacturing sector, the ability to ensure the Chinese supply chain is up to western standards increases. The USCC has expressed specific interest on this point, and it is worth reinforcing that while the NMPA's enforcement regime is relatively new, the Chinese government is very invested in ensuring they comport to global standards, both to ensure the quality, safety and efficacy for domestic consumption, as well as to ensure that Chinese novel molecules can be exported and adopted by the global market.²⁷

Risks

Five risks will need additional attention from American policymakers, in particular as they relate to lessons we should learn from the experiences of other high technology sectors in China, and those questions posed by the USCC commissioners.

First, the impact of ongoing trade tensions on bilateral investments and on supply chain uncertainties, each of which has unique characteristics within the healthcare sector: anxieties over where your new iPhone will be made is one thing. Concern over where your antibiotics or hypertensives come from is quite another. The world, not just America, has become increasingly dependent on China as its source for manufacturing pharmaceuticals. Even India, known for its unique policy and industrial environment with respect to pharmaceuticals, now has taken a dependency on Chinese manufacturing to such an extent that it is estimated 80% of India's active pharmaceutical ingredients (APIs) originate from China.²⁸

A global trade war on the basis of telecommunication equipment carries with it the risk of destabilizing the economy. A global trade war which has repercussions to medicines that are currently widely available, and at reasonable costs, would have much more deleterious effect. Whether America should have taken this dependency on foreign manufactured pharmaceuticals is not a question best directed at the US-China relationship. Rather, if American policymakers want to ensure that a certain national formulary is widely available to the public in case of crisis, policies around domestic production and inventory would be appropriate. It is worth calling attention to the point that this concern – taking a dependency on China for pharmaceutical products in particular – has historically been understood as one of the reasons the US-China relationship can and should be thought of as safe and stable. It is now interpreted through the

²⁶ Note: The export of the Ebola vaccine Ad5-EBOV, by CanSino Biologics Inc. is one early example of this. See Angus Liu, "China approves domestic Ebola vaccine developed from recent outbreak," FiercePharma, October 24, 2017. <https://www.fiercepharma.com/vaccines/china-approves-self-developed-ebola-vaccine-from-2014-outbreak-virus-type>.

²⁷ Eric Ng, "Why most small players may not survive China's pharmaceutical industry consolidation: Strategy aims to turn China's predominantly off-patent drug copying pharmaceutical industry into one that's capable of coming up with innovative patentable products," South China Morning Post, January 31, 2018. <https://www.scmp.com/business/companies/article/2131230/why-most-small-players-may-not-survive-chinas-pharmaceutical>.

²⁸ Arun Sreenivasan, "China crackdown on polluting firms leaves Indian pharma industry in quandary as API prices rise 40% in four months," PharmaBiz, July 13, 2018. <http://www.pharmabiz.com/NewsDetails.aspx?aid=109959&sid=1>.

lens of fear, and the deeper anxieties about the troubled state of relations between the two countries should not be missed by anyone. If we indeed believe America can take calculated dependencies on China for critical components to modern life – medicine being chief among these – then we are still working in good faith. However, if we no longer believe that America can do so, much of what has supported the modern era of globalization is no longer valid.

Second, CFIUS' role in evaluating Chinese FDI into the American healthcare sector. The April 2019 determination by CFIUS that the Chinese digital healthcare company iCarbonX would have to divest its \$100 million investment in the American patient healthcare platform PatientsLikeMe has drawn significant attention by both American and Chinese investors.²⁹ There are several important risks this has surfaced. CFIUS' ruling is understood to be largely a function of concerns within the American government of allowing a Chinese company to have access to a large set of American personally identifiable information (PII), including personal health information (PHI).³⁰

Trade lawyers familiar with the CFIUS process have been quick to point out that it does not appear iCarbonX pursued the appropriate CFIUS pre-approvals to ensure the deal would meet their standards.³¹ Consequently, the October 2018 interim regulation that implemented updates to the Investment Risk Review Modernization Act (FIRREA) and which pays particular attention to “target industries” with “critical technologies” and “sensitive personal data of United States Citizens” set CFIUS and iCarbonX on a collision path.³² The specific risk CFIUS was worried about had to do with how American PHI would be exposed to a Chinese company whose business model required exposure of said PHI to artificial intelligence systems. The resulting machine learned (ML) models would have been trained on American PHI collected as part of the PatientsLikeMe platform, among other data sources (including Chinese PHI). It was unclear to American regulators whether this training activity would have taken place in computer system domiciled within the United States or China, and attempts by iCarbonX to dissuade CFIUS that the training in question could be limited to American computers was deemed inadequate.

CFIUS undoubtedly has an important job to do with respect to guarding America's national security, including the privacy of American citizens. The unique “claw-back” or “disturbance” rights CFIUS possesses means that any foreign investment deemed to cross a national security or privacy line can be deemed illegitimate and mitigation by the foreign company required. This, coupled to the current US-China trade war, has resulted in a dramatic decrease of Chinese

²⁹ Christine Farr, Ari Levy, “The Trump administration is forcing this health start-up that took Chinese money into a fire sale,” CNBC, April 4, 2019, <https://www.cnbc.com/2019/04/04/cfius-forces-patientslikeme-into-fire-sale-booting-chinese-investor.html>.

³⁰ Harry Clar, Betty L. Louie, Jeff Zhang, and Xiang Wang, “Grindr and PatientsLikeMe Outcomes Show Non-Cleared Transactions' Exposure to CFIUS Scrutiny, Especially When PII Is Involved,” Orrick, April 23, 2019. <https://www.orrick.com/Insights/2019/04/Grindr-and-PatientsLikeMe-Outcomes-Show-Non-Cleared-Transactions-Exposure-to-CFIUS-Scrutiny#>.

³¹ “CFIUS Developments: Notable Cases and Key Trends,” Gibson Dunn, April 24, 2019. <https://www.gibsondunn.com/cfius-developments-notable-cases-and-key-trends/>.

³² Michael E. Leiter, Ivan A. Schlager, Donald L. Vieira, Daniel J. Gerkin, Michelle A. Weinbaum, “CFIUS Pilot Program Expands Jurisdiction to Certain Noncontrolling Investments, Requires Mandatory Declarations for Some Critical Technology Investments,” Skadden, Arps, Slate, Meagher & Flom LLP, October 11, 2018. <https://www.skadden.com/insights/publications/2018/10/cfius-pilot-program-expands-jurisdiction>.

investment in American biotech: the first half of 2019 has seen a 60% reduction in American biotech firms by Chinese venture capital.³³

Third, differences in the appetites for investment and risk by the American and Chinese political systems. Across the globe, national governments are standing up large biobank initiatives. In 2016, the United States launched the 21st Century Care Act, with \$6.3 billion in funding, to include a variety of population health data.³⁴ In 2013, the United Kingdom established Genomics England, a program designed to sequence 100,000 genomes.³⁵ Similar efforts are in motion in Canada, Japan, Thailand, Qatar and Latvia. China meanwhile has been even more ambitious, with a variety of national and provincial efforts ranging in scope and budget, but all designed to create datasets that include genetic information. One of the more widely referenced examples in China is the China National GeneBank, which aims to have genetic material from 10 million different bio-samples.³⁶ The range of activities vary across each of these efforts, but they typically include a fully sequenced human genome, tied to a longitudinal health record (the electronic capture of an individual's healthcare, including lab data).

What these initiatives share in common is not just the advancement of human knowledge: these curated data sets serve as the foundation to the 21st century's biotech industry. The greater diversity, quality and quantity of data available to researchers should in turn result in accelerated precision medicine development, which should result in companies being able to spin out new therapeutics and diagnostics predicated on access to these privileged data sets. Justifying government led investments in these data sets has become increasingly difficult, in the US in particular.

If American policymakers do not incentivize the development of equally large and technically rich data sets in the United States as are available in China, we are foregoing a significant opportunity both economically, and from a public health point of view. To the extent the USCC is particularly invested in preventing the United States from falling behind China, or to taking an even greater dependency on Chinese healthcare products, strategies to deepen American investment in the development of these curated data assets will be required.

Fourth, asymmetric data access standards and policies between the US and China, and their impact on economic competitiveness and consumer privacy. The previously mentioned data assets are the result not only of a citizen's PHI, they also exist as a result of public sector financing of these biobank initiatives. The public anticipates a return on its investment in the form of advanced therapeutics, as well as the development of new companies who successfully commercialize their offerings, enriching the economy as a result. However, as currently

³³ Tom Hancock and Hannah Kuchler, "Chinese VC spending on US biotech hit by security reviews," Financial Times, July 8, 2019. <https://www.ft.com/content/6d647f7e-a13a-11e9-974c-ad1c6ab5efd1>.

³⁴ Trudy Lieberman, "With media watchdogs on the sidelines, pharm-funded advocacy groups pushed Cures Act to the finish line," HealthNewsReview.org, December 6, 2016. <http://www.healthnewsreview.org/2016/12/with-media-watchdogs-sidelined-pharma-funded-advocacy-groups-pushed-cures-act-to-the-finish-line/>.

³⁵ James Gallagher, "DNA project 'to make UK world genetic research leader,'" BBC, August 1, 2014. <https://www.bbc.com/news/health-28488313>.

³⁶ Zhuang Pinghui, "China opens first national gene bank, aiming to house hundreds of millions of samples," South China Morning Post, September 22, 2016. <https://www.scmp.com/news/china/article/2021623/chinas-noahs-ark-first-national-gene-bank-opens-shenzhen>.

embodied in both law and practice, American researchers do not have equal ability to work with Chinese PHI, as do Chinese researchers with American PHI.

De-identified PHI from Americans may be shared across borders, provided the de-identification process meets the Health Insurance Portability and Accountability Act (HIPAA).³⁷ However, as the Gryphon-Rhodium report from February 2019 makes clear: “Only a Chinese entity may apply for such a permit; therefore, the only lawful way for international entities to access Chinese genetic data is through collaboration with a Chinese institution. All collaborations involving genetic data must be approved by the participating institutions and by the China Administration of Human Genetic Resources. Chinese entities partner with a foreign institution must state the purpose of the collaboration, the duration of the collaboration, and any plans for sharing and ownership of IP.”³⁸ Such a regulatory approach by the Chinese government may in fact be perfectly reasonable, but it must be symmetric with the same approach to how PHI is shared across borders by the US government. A more elastic posture on the part of the American government, who is now revisiting the consequences of taking more liberal approaches to asymmetric policies between the US and China in other non-healthcare arenas, may not be appropriate, in particular with respect to something as sensitive as PHI.

On this point, it is important to not get ahead of the facts. It has been suggested that Chinese access to American PHI could result in their ability to design the perfect bioweapon, targeted only at Americans.³⁹ This makes for good science fiction, but thus far quite bad science; and, in being bad science, it runs the risk of being both inflammatory and counter-productive. What American policymakers should care about is not disincentivizing the development of large Chinese biobanks with vast quantities of PHI. What American policymakers should care about is that we are making similar investments, and that America and China have agreed upon protocols specific to de-identification and bilateral cross-border data sharing, so as to ensure the pace of progress in healthcare continues to accelerate.

Fifth, the trade-off between high volume and low profit, as embodied by the Chinese government’s tendering process. This concern is nothing new, but continues to be a risk that will require attention, and possibly discussion as part of the U.S.-China Comprehensive Economic Dialogue (CED), as it has been in prior administrations. Specifically, the ongoing pricing pressure that American multinationals are under in the pharma sector in particular, as it relates to their ability to access broader portions of the Chinese healthcare system (the public hospital formulary, and its reimbursement system in particular) will need ongoing attention.⁴⁰

The Intersection Between Artificial Intelligence and Healthcare

In many important ways, the USCC’s questions lay the groundwork for one of the more critical matters that needs Congress’ attention: the intersection between artificial intelligence (AI) and

³⁷ “Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule”, Health and Human Services, <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>.

³⁸ Kazmierczak, et. al., 129.

³⁹ Davd J. Lynch, “Biotechnology: the US-China dispute over genetic data,” Financial Times, July 31, 2017. <https://www.ft.com/content/245a7c60-6880-11e7-9a66-93fb352ba1fe>.

⁴⁰ David Shen, “China announces pilot scheme for pharmaceutical tendering with minimum procurement quantities,” Allen & Overy LLP, December 5, 2018. <https://www.lexology.com/library/detail.aspx?g=8cdd2be6-8e6f-4b81-8582-e3ea87cbca43>.

healthcare in China. Currently, several city-specific AI initiatives in China represent significantly larger investments in AI than the US government is planning to make in total.⁴¹ This represents a very real challenge to the ability of AI dependent healthcare companies in the US building out their technology stacks, identifying use cases, and ensuring insights can be derived and applied to the benefit of American patients.

Large biobanks are not the only healthcare data asset national governments care about, and are investing in. China's Ministry of Science and Technology has established a number of programs designed to collect and centralize other types of data, including not only the previously mentioned genomic and longitudinal health record data, but also imaging records such as those from magnetic resonance imaging (MRI) and computed tomography (CT) scans.⁴²

AI's ability to develop new use cases hinges on access to large quantities of training data, and no country in the world is as serious about funding this aggregation of data across a number of disparate verticals, than is China. As American policymakers wrestle with questions around asymmetric data access policies between the US and China, it would be wise to keep in mind that American healthcare and technology companies stand to benefit if promulgated policies in both countries were to exist that allowed training on both countries' data sets. At current investment levels, China will amass a much larger and more diverse healthcare specific set of data upon which to train AI than will the United States. This point must be reinforced: it is in the interests of American industry and patient care to ensure that our companies and research institutions can train on these data sets, and if they cannot, to diligently work to build up equivalent resources upon which American AI companies can train.⁴³

As with the analysis of China's progress in CAR-T and CRISPR, some of these advancements are the result of differences in regulatory standards between the two countries. In the case of how Chinese researchers train on large healthcare data sets, China does not have the same oversight as American researchers are obligated to under an Institutional Review Board (IRB).⁴⁴ What this means in practice is that Chinese researchers and entrepreneurs not only have access to differentiated data sets, they can also work with them more easily than their American counterparts can work with data assets that reside within their home country.

There are other rate limiting factors for the adoption of AI in healthcare, and it may well be that China could develop AI faster not only because of those previously mentioned advantages, but also because the healthcare delivery vehicles in China are so different, and already so manpower constrained, as to make the patient, physician and payer willing to turn certain parts of the workflow and patient experience over to technology, where an equivalent patient journey in the United States would be actively resisted. Regardless of these considerations, the USCC would

⁴¹ Luiza Ch. Savage and Nancy Scola, "'We are being outspent. We are being outpaced': Is America ceding the future of AI to China?" POLITICO, July 18, 2019, <https://www.politico.com/story/2019/07/18/global-translations-ai-china-1598442>.

⁴² Luxia Zhang, "Big data and medical research in China," *BMJ* 2018; 360:j5910. <http://dx.doi.org/10.1136/bmj.j5910>.

⁴³ Sui-Lee Wee and Paul Mozur, "Amazon Wants to Disrupt Health Care in America. In China, Tech Giants Already Have," *New York Times*, January 31, 2018. <https://www.nytimes.com/2018/01/31/technology/amazon-china-health-care-ai.html?partner=IFTTT>.

⁴⁴ Tom Simonite, "How Health Care Data and Lax Rules Help China Prosper in AI", *Wired*, January 8, 2019.

do well to pay attention to how the era of healthcare-specific AI is informed and governed by, asymmetric data access and privacy policies between the United States and China.

Recommendations for Congress

Given the current challenges in the US-China relationship, and the lessons that should be taken from other high technology sectors and applied to healthcare, let me propose the following five recommendations for Congress:

1. **Deliberately gate Chinese FDI into American healthcare sectors based on the ability of American healthcare companies and institutional investors to make equivalent investments in China.** If American companies cannot invest within a specific healthcare sector in China, their Chinese competitors should not be able to make associated investments in the United States. Healthcare services (hospitals in particular) require attention on this front and have been part of the US Trade Representative's negotiation with Beijing over the last year.
2. **Review America's national formulary and determine how best to ensure supply chain resiliency for specific likely public health crises.** To the extent America has taken a supply chain dependency on supply of pharmaceuticals manufactured in China, American policymakers should revisit subsidies designed to encourage domestic production of specific products organized around, and prioritize by, the most likely public health crises.
3. **Pursue harmonized standards around sharing of PHI.** The first step should be a bilateral agreement on the de-identification of PHI, and the mechanisms by which de-identified PHI can be shared across borders. Ideally, this discussion should include more than just the United States and China, as how PHI will be normalized serves as a foundational element to how large data assets will be developed, curated and shared globally. As with the first recommendation, if China is not willing to agree to bilateral standards on this point, Congress should act to negate Chinese access to American PHI, even if de-identified, by Chinese researchers. CFIUS already anticipates some of this given its ability to deny proposed, or negate past, investments by foreign firms where exposure of American PII might occur. Few things are more sensitive than an individual's personal health information, and as such, this matter will require significant thought; however, the extent to which large data assets involving PHI constitute the future of economic competitiveness and development of new medicines, both countries would do well to begin thinking about how to ensure data sharing policies that address their citizen's privacy concerns.
4. **Update trade policy to reflect the era of big data, cloud computing and AI to ensure symmetric data access rights between American and Chinese companies and academic research centers.** Current trade protocols were built to address the needs of a manufacturing economy. They have struggled to accommodate the era of cloud computing, big data and AI. Congress should establish a specific review of current USTR policy with a specific view on how to modernize trade protocols with the needs of big data driven industries in mind.

- 5. Increase government led investment in the collection of large data sets for the purposes of AI.** Estimates vary as to China's overall investment plans in AI, but as one example, the Chinese city of Tianjin plans to spend \$16 billion on a variety of AI investments over the next several years. This is larger than the total amount the US government plans to spend on the same. China has certain natural advantages in this sector, not least of which is the large amount of available labor to label training data (a key part of how machine learning systems develop new capabilities). To counteract these unique capabilities, the US government must develop an AI strategy that includes new investments spread across research institutions, government and industry. While healthcare is the focus of today's testimony, there are critical national security issues involved in ceding the era of AI to China.

OPENING STATEMENT OF KATHERINE EBAN, AUTHOR, “BOTTLE OF LIES”

COMMISSIONER TALENT: Perfect timing. Ms. Eban.

MS. EBAN: I hope I can do as well with the timing. Thank you for having me. It's a pleasure to be here today. I spent a decade investigating the overseas manufacturing plants that are the principle suppliers of generic drugs to the U.S. market. That effort culminated in the recent publication of my New York Times Best Selling Book, "Bottle of Lies: The Inside Story of the Generic Drug Boom" which came out in May by Harper Collins.

The book takes readers into the overseas manufacturing plants where the majority of our low cost generic medicine is made and reveals endemic fraud and dire conditions. To report the book, I traveled to four continents. I was in China as well. Interviewed hundreds of sources and obtained over 20,000 pages of confidential FDA documents.

The U.S. drug supply is 90 percent generic with the majority of those drugs coming from overseas, principally India and China. As well, 80 percent of the active ingredients in all our drugs, rather brand or generic, also come from overseas. The bulk of those from China and India.

It is crucial to the health and safety of the American public that these drug products are effectively regulated. No substandard drug products should be permitted to enter the U.S. market. And yet China has been a continuing source of adulterated drug products, most recently of active ingredients for the generic blood pressure medicine, Valsartan, that was found to contain a carcinogen previously used in the production of liquid rocket fuel, which is not good for you.

As well, FDA investigators have found widespread fraud and manipulation of quality data in Chinese manufacturing plants. After extensive reporting on this topic, it is my conclusion that the FDA is not effectively regulating the overseas manufacturing plants including in China that export to the U.S. market. FDA officials are also allowing substandard drug products to enter the U.S. market. They are making exceptions for reasons that include concern over drug shortages and confusion about their own authority overseas. The FDA's investigators are spread too thin with a depleted staff in China and a relatively small cadre of U.S. based investigators willing to perform inspections overseas.

In conclusion, I believe the FDA must overhaul its foreign inspection system and more strictly enforce its own regulations to ensure the safety of the American public. And with that, I'd like to just give you three examples, which are from my book where I talk about inspections in China.

I follow an investigator named Peter Baker who arrived in Beijing in 2015 of 38 manufacturing plants that he inspected in China. Of 48 plants he inspected in China, he found fraud or data manipulation in 38 of those plants. We know that there is endemic fraud in Chinese drug plants because Chinese regulators have found that themselves. In 2016, an investigation by China's own National Medical Products Administration found that 80 percent of clinical trial data submitted by Chinese companies to regulators to gain approval for new drugs was fabricated.

So as an example, Peter Baker showed up at a plant called Zhejiang Hisun in Taizhou, 200 miles south of Shanghai, which was the site of a joint venture with Pfizer to make high quality low cost medicine. Zhejiang Hisun was not a fly by night plant, it was already China's largest exporter of drug ingredients to the U.S. Peter Baker instead of requesting documents as many FDA investigators do, looked inside the computers of the plant.

And using rudimentary Mandarin that he learned in college, looked for Chinese symbols for the words trial injection and experimental sample. Despite Pfizer's three year head start, it took him about a day to figure out the plant was running an alternate and hidden laboratory operation. And secretly pre-testing its drug samples and then masking the results in part by turning off the audit trails to leave no evidence of the tests. The FDA followed up by putting the plant under an import alert restricting its drugs into the U.S. But then lo and behold discovered 15 of those drugs were in short supply in the U.S. and lifted the restriction on those drugs.

I cite another example when an FDA investigator showed up at a plant called Zhejiang Bangli Medical Products, which makes skin patches for pain. And the plant manager grew increasingly concerned about the inspection and ended up holding the investigator hostage in a conference room for hours. And the investigator was not released until the intervention of Chinese police and Chinese regulators. Despite that incident, an actual hostage situation, the FDA concluded that the plant did not make a specified refusal of the inspection. And so did not impose an import alert on the plant after that inspection.

And a third example is what's happening right now, which is a worldwide recall of Valsartan active ingredients, which were found to contain a carcinogen. An FDA investigator went into that plant in 2017 and actually found that the plant was not investigating impurities in its active ingredients, which showed up as peaks in chromatograms. And recommended to the FDA, official action indicated which would have restricted those drugs from coming into the U.S. But the FDA determined that the firm's response subsequently was adequate as it concerned the observation pertaining to their investigation of aberrant peaks on HPLC chromatograms. And demonstrated that the peaks did not impact product. So did not impose an import alert. Less than a year later, that plant was under a worldwide restriction because its drugs contained impurities.

So in closing, I would suggest that the FDA needs to overhaul its foreign drug inspection program. It needs a go-to highly trained, well-funded cadre of foreign inspectors with a clear career path. They should perform short notice or no notice inspections in China as opposed to announcing them months in advance as they do now. And they should rarely overrule the recommended sanctions of its own inspectors, which happens all too often now. Thank you very much.

PREPARED STATEMENT OF KATHERINE EBAN, AUTHOR, "BOTTLE OF LIES"

Katherine Eban
Investigative journalist and *New York Times* bestselling author,
Bottle of Lies: The Inside Story of the Generic Drug Boom
Testimony before the U.S.-China Economic and Security Review Commission
“A Healthy Relationship? Assessing the Risks and Opportunities of China’s Medicine and Health
Development.”
July 31, 2019

Introduction

I spent a decade investigating the overseas manufacturing plants that are the principal suppliers of generic drugs to the U.S. market. That effort culminated in the recent publication of my *New York Times* bestselling book, *Bottle of Lies: The Inside Story of the Generic Drug Boom* (Ecco/Harper Collins May, 2019).

The book takes readers into the overseas manufacturing plants where the majority of our low-cost generic medicine is made. It reveals endemic fraud and dire conditions in an industry where companies routinely falsify data and circumvent principles of safe manufacturing to minimize cost and maximize profit. To report the book, I traveled to four continents, interviewed hundreds of sources and obtained over 20,000 pages of confidential FDA documents.

The U.S. drug supply is 90 percent generic, with a majority of those drugs coming from overseas, principally India and China. As well, 80 percent of the active ingredients in all our drugs, whether brand or generic, come from overseas, the bulk of those from China and India.

It is crucial to the health and safety of the American public that these drug products are effectively regulated. No substandard drug product should be permitted to enter the U.S. market. And yet China has been a continuing source of adulterated drug products, most recently of active ingredients for the generic blood pressure medicines valsartan, that was found to contain a carcinogen previously used in the production of liquid rocket fuel. As well, FDA investigators have found widespread fraud and manipulation of quality data in Chinese manufacturing plants.

After extensive reporting on this topic, it is my conclusion that: the FDA is not effectively regulating the overseas manufacturing plants, including in China, that export to the U.S. market; FDA officials are allowing substandard drug products to enter the U.S. market. They are making exceptions for reasons that include concern over drug shortages and confusion about their own authority. The FDA’s investigators are spread too thin, with a depleted staff in China, and a relatively small cadre of U.S.-based investigators willing to perform inspections overseas.

In conclusion, I believe the FDA must overhaul its foreign inspection system, and more strictly enforce its own regulations, to ensure the safety of the American public.

1. Chinese drug plants systematically engage in deceptive practices

One FDA investigator, Peter Baker, who I feature in my book, inspected 48 plants in China from 2014 to 2016, and found evidence of serious data integrity violations in 38 of them. As well, additional evidence supports the view that fraud and manipulation of quality data is endemic in Chinese drug plants.

In February 2015, Baker arrived in Beijing, where he became the FDA's sole drug investigator stationed in China, responsible for inspecting over four hundred factories approved to export drugs or drug ingredients to the United States.

Within a month, he arrived at the massive Zhejiang Hisun plant in Taizhou, two hundred miles south of Shanghai. The plant was the site of a joint venture with Pfizer, started in 2012, to create high-quality, low-cost medicine under the umbrella of Hisun-Pfizer Pharmaceuticals. The company seemed like a safe bet: it was already China's largest exporter of drug ingredients to the United States.

The FDA's investigators had been at the Zhejiang Hisun plant over a dozen times and had found little to concern them. But Peter Baker had a different inspection style. Instead of requesting documentation, as other FDA investigators do, he looked directly in the computer systems of the plants he inspected, as was his right. At the Zhejiang Hisun plant, he went to the quality control laboratory. Using the rudimentary Mandarin that he learned in college, he hunted through the forest of Chinese symbols in the computer audit trails for the words "trial injection" and "experimental sample."

Despite Pfizer's three-year head start, it took Baker about a day to figure out that the plant was running an alternate and hidden laboratory operation. The plant was secretly pretesting its drug samples and then masking the results, in part by turning off audit trails to leave no evidence of the tests. In one instance, Baker found that technicians had turned off the audit trail on February 6, 2014, at 9:09 a.m., then proceeded to run eighty secret tests. The audit trail was turned back on two days later at 8:54 a.m., and the tests— now rigged and with the outcomes assured— were repeated.

Baker found the telltale evidence in the software's metadata. By the third day of inspection, the plant managers and analysts were well aware of how devastating his inspection might be. When Baker returned from a lunch break to the quality control laboratory, he saw an analyst quickly remove a thumb drive from one of the HPLC machines and slip it into his lab coat. Baker demanded that he hand over the thumb drive, but the man "began running and fled the laboratory premises," he documented in his inspection report.¹ Fifteen minutes later, a manager returned to offer him the thumb drive, but Baker had no idea whether it was the same

¹ FDA, "Form 483: Inspectional Observations," Zhejiang Hisun Pharmaceutical Co., Taizhou, China, March 2–7, 2015, 7.

one. He noted the incident as a refusal to share records— which was serious enough to get the plant’s drug ingredients blocked from the United States.²

The prevailing attitude in the Chinese drug industry has long been, “we can always fool a foreigner,” as one Western drug executive put it. Baker’s inspections cast a harsh light not just on Chinese drug manufacturing, where fraud was endemic, but also on the FDA’s foreign inspection program. Four-fifths of the plants he inspected in China were engaging in some sort of data manipulation or deceit to conceal regulatory violations or substandard drug products from FDA regulators. “Every time he puts a foot in a company, he’s finding more problems,” as one senior FDA official said of Baker. “What does that say about an inspectional force that’s not finding this?”

Six weeks after the Zhejiang Hisun inspection, Baker went to Dalian in the Liaodong Peninsula and inspected another plant; this one, owned and operated by Pfizer, was making finished doses for the U.S. market. There, too, he found manipulated tests, unreported results, and loose batch records that showed the plant using expired materials. One stack of documents disappeared entirely during his inspection; he found them later on an upper floor, tucked inside a wooden crate.³

Most of the FDA’s investigators who are sent to China do not speak the language. They can’t read the manufacturing records. The FDA does not always provide independent translators. Instead, the companies provide translators who, more often than not, are company salesmen. Sometimes, FDA investigators simply give plants a pass, deeming them to be No Action Indicated because they have no way to tell otherwise.

The investigators also can’t read street signs, which make them vulnerable to wild manipulations. Companies steer them to phony “show” plants, where everything looks compliant, but the companies aren’t manufacturing there. Sometimes a group of companies pool their resources and invest in the same “show” factory, so that different FDA inspectors return to the same plant at different times, each one thinking they are inspecting a different facility.

2. Data shows that a large number of Chinese manufacturing plants are engaged in deceptive practices

Data fraud is endemic in Chinese drug plants. In 2016, an investigation by China’s own State Food and Drug Administration (SFDA) found that 80 percent of clinical trial data submitted by Chinese companies to regulators to gain approval for new drugs was fabricated.⁴

² FDA, “Warning Letter” to Zhejiang Hisun Pharmaceutical Co., Taizhou, China, December 31, 2015.

³ FDA, “Form 483: Inspectional Observations,” Pfizer Pharmaceuticals Ltd., Dalian, China, April 13–17, 2015.

⁴ Fiona Macdonald, “80% of Data in Chinese Clinical Trials Have Been Fabricated,” Science Alert, October 1, 2016, <https://www.sciencealert.com/80-of-the-data-in-chinese-clinical-trial-is-fabricated> (accessed September 30, 2018).

A just-published analysis⁵ by an auditing expert on current good manufacturing practices (cGMP), Barbara Unger, shows that drug plants in China get the most warning letters focused on data integrity, from the U.S. FDA. Of the 85 warning letters the FDA issued to drug plants in 2018, 42 of those dealt with the problem of data integrity. Of those, China received the most, with fifteen warning letters. It has also received the most data-integrity warning letters over the last decade.

With her permission, I have included three tables from Ms. Unger's data here.

Table 2: Number of Data Integrity Associated Warning Letters by Country, CY2008–CY2018

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL
China	1	1	3	1			2	2	14	19	15	58
U.S.	1	2	1	1	1			0	7	15	8	36
India	1	1		2		6	7	10	9	12	6	54
Europe		1					1	2	6	3	1	14
Brazil									3			3
Japan	1								2	1	3	7
Thailand								1				1
Canada			1		1					2	1	5
Mexico					2					1	1	4
UAE					1							1
Jamaica					1							1
South Korea										2	4	6
Singapore										1		1
Australia											1	1
Taiwan											1	1
Dominican Republic											1	1
TOTAL	4	5	5	4	6	6	10	15	41	56	42	194

⁵ Unger, Barbara. "An Analysis Of 2018 FDA Warning Letters Citing Data Integrity Failures." Outsourced Pharma. June 12, 2019. Accessed July 19, 2019. <https://bit.ly/2JH9Ftx>.

Figure 1

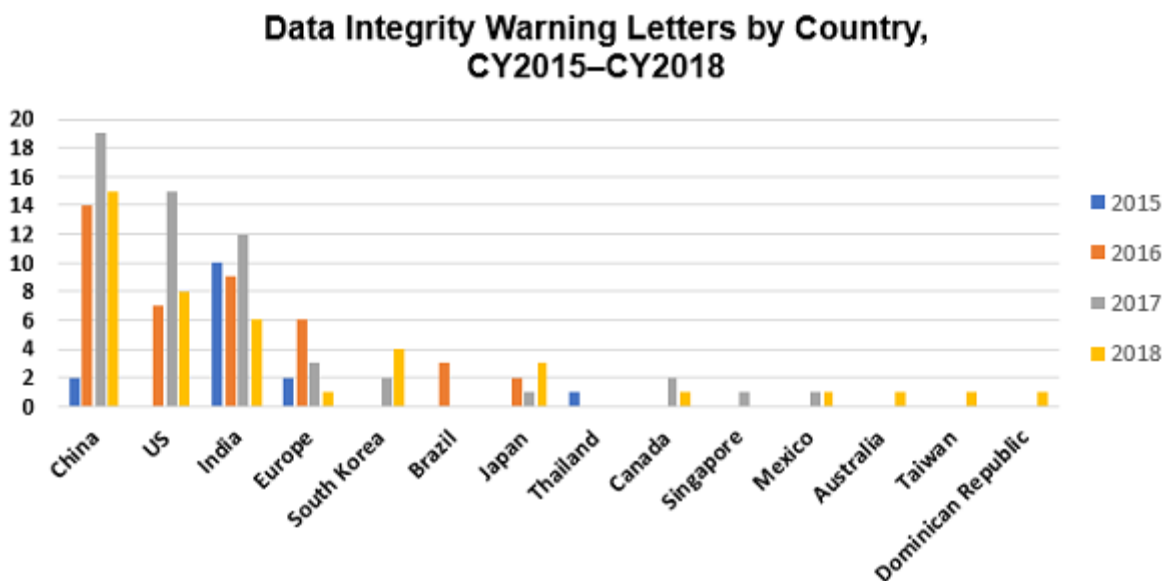


Table 3: Geographic Totals and Percentage, 2015–2018 and 2008–2018

Country	Total Number, 2015-2018	% of Total, 2015-2018	Total Number, 2008-2018	% of Total, 2008-2018
China	50	32%	58	30%
India	37	24%	54	28%
United States	30	19%	36	19%
Europe	12	8%	14	7%
Rest of World	25	16%	32	16%

In both raw numbers and percentages, Chinese drug plants have received the most warning letters related to data integrity. These numbers are especially significant, in light of key differences in U.S. and overseas inspections.

In the United States, in order to inspect drug plants, FDA investigators simply show up unannounced and stay as long as is needed. But for overseas inspections—due to the complex logistics of getting visas and ensuring access to the plant – the FDA has chosen to announce its inspections in advance. Overseas drug plants typically “invite” the FDA to inspect and the agency accepts. Plant officials serve as hosts to the visiting FDA investigators, who become their guests. It is not unusual for manufacturing plants to arrange local travel for FDA investigators. This system has allowed manufacturing plants to “stage” inspections, as one FDA investigator put it, and conceal evidence of data fabrication.

Despite this favorable system, which works to the advantage of foreign manufacturing plants, the violations in China's plants are evident. But a major question remains: what does the FDA do with the problems that it finds?

3. How the FDA Responds to Findings

The FDA has been irresolute in cracking down on Chinese drug plants when its inspectors find problems. Below are several examples.

In May 2017, in Linhai, China, an FDA investigator inspected Zhejiang Huahai Pharmaceuticals, the world's largest manufacturer of the active ingredient for valsartan, a generic version of the blood pressure drug Diovan. He found evidence at the plant that the company was failing to investigate potential impurities in its own drugs, which showed up as aberrant peaks in its test results. The investigator recommended the inspection be categorized as Official Action Indicated, which would have required the manufacturing plant to urgently make changes or face further sanctions.

But in a September 7, 2017 memo, the agency downgraded the recommended classification to Voluntary Action Indicated, which allowed the company to make non-urgent corrections. The memo⁶ concluded:

“The firm's response is mostly adequate including as it concerned the observation pertaining to their investigation of aberrant peaks on HPLC chromatograms. The firm provided data and information to demonstrate the peaks did not impact product and timeframes for improving their method and revising their investigation procedure.”

In fact, the peaks were a clue to a compromised product. Less than a year later, the company wound up in the middle of a worldwide quality scandal. In July 2018, European regulators announced a harrowing discovery: the active ingredient made by Zhejiang Huahai contained a cancer-causing toxin known as NDMA.

In the United States, over a dozen drug manufacturers, all of which used the Chinese ingredient, recalled their products, as did dozens more manufacturers around the world. The Chinese company tried to defend itself by explaining that it had altered its production process in 2012 to increase yields of the drug, a change that had been approved by regulators. In short, the change had been made to maximize profit. But some patients had been consuming the toxin daily for six years. As the FDA tried to reassure consumers that the risk of developing cancer, even from daily exposure to the toxin, was extremely low, a second cancer-causing impurity was detected in the ingredients.

⁶ Tamara Felton Clark, Branch Chief, Global Compliance Branch 4, “Reclassification of Surveillance Inspection: VAI as Inspection Classification,” CMS File—Work Activity 161861, Zhejiang Huahai Pharmaceutical

The FDA’s decision to overrule its own investigator and downgrade the Zhejiang Huahai inspection was not unique. According to the FDA’s own data, which I obtained, from 2013 to 2018, out of 864 inspections in China that FDA investigators recommended as Official Action Indicated, FDA officials downgraded 78 of those. By contrast, in the same time period, out of 11,642 inspections that FDA investigators conducted in the U.S. and recommended as Official Action Indicated, only one inspection was downgraded in that time. This reflects the FDA’s willingness to give foreign plants, particularly in China, an opportunity to reform without sanctions.

Two months before downgrading the sanctions against Zhejiang Huahai, an even more troubling incident unfolded during an FDA inspection in China. In July 2017, an FDA investigator and her translator arrived at Bangli Medical Products in Zhejiang province. The plant manufactures lidocaine and capsaicin skin patches for treating pain. There, as the FDA inspector moved through the plant – requesting documents and taking photographs – the company’s general manager grew increasingly upset. When the FDA employees returned to the conference room, he accused them of not actually being with the U.S. government, announced they could not leave the conference room, demanded that they destroy their photographs of the plant and called the local police.

In holding the FDA investigator hostage in a conference room, it seemed clear to the FDA’s staff in China that the company had refused an inspection and its drugs needed to be blocked from import into the United States. An FDA supervisor wrote back to officials at the agency’s Maryland headquarters: “Needless to say, they first refused the inspections and refused to recognize our investigator’s authority to inspect the premises. We need to immediately put this firm on import alert.”⁷ An import alert would have prevented the company’s products from coming into the U.S.

But an official at FDA headquarters quickly sounded a note of caution about “declaring that we have ‘authority’ in the foreign arena.” Another official weighed in, stating that it didn’t appear the plant manager who’d imprisoned the FDA’s investigator “was making a specified refusal.”

In China, the Bangli inspection underscored the confusion and difficulty that surrounds the FDA’s “authority” in the overseas arena. As one FDA assistant commissioner emailed colleagues:

“...section 704(a)(1) of the Act gives an authorized employee the authority to enter and inspect at reasonable times but it only applies in the domestic arena. This provision, if

⁷ The incident is documented in an internal FDA email: Kelli Giannattasio, “Re: For Cause Inspection of Bangli Medical Products,” email to Susan F. Laska and Sherry Bous, July 27, 2016.

the inspection is declined/refused, allows for a warrant to be pursued. In the foreign arena, since we don't issue notices of inspection (482), the firm must give permission for us to enter and inspect. To result in an Import Alert as suggested below, we have historically asked and documented the refusal by the firm to allow FDA to enter and conduct its inspection, and we have explained how this refusal could be evaluated and potentially result in an import alert. Before an IA gets recommended, we may need to fully document this refusal which may have related to concerns about if these were actually FDA employees. Once that is established, we should determine if the firm is actually refusing the inspection and document the discussion with the firm's senior management.

The FDA did send a different investigator back the following month. He discovered that the plant was not actually testing any of its products or ingredients to ensure their purity or strength and had no cleaning procedures for its manufacturing equipment. The plant was then placed on an import alert, restricting its products from entering the United States.

In some instances, manufacturing plants have figured out how to keep selling their drug products to the United States, even after the imposition of strict regulatory sanctions. After Peter Baker's inspection at the Pfizer-affiliated Zhejiang Hisun plant, the FDA restricted the import of thirty of the plant's drug products. But fifteen of the drug ingredients were in short supply in the United States, so the agency lifted the restriction on about half of the drugs, including a crucial chemotherapy drug for treating leukemia and breast and ovarian cancers.⁸

To Baker, that decision made no sense. According to regulations, the drugs had no place in the U.S. supply. They weren't good or safe enough. Shortages didn't change that fact.

The FDA's investigators believe that companies committing fraud purposefully make drugs in short supply, as a way to protect their bottom line. Those will not be restricted, whether made with dubious methods or not, and can serve as a steady source of business, even if companies are caught making unsafe drugs. "There are no consequences for companies that are shipping substandard product," Baker observed to a colleague. "It's a win-lose situation— and [patients] are the losers."

4. Suggested reforms to better safeguard drug products from China

- The FDA needs to overhaul its foreign drug inspection program

⁸ E. J. Lane, "U.S. FDA Ingredient Exceptions from Banned Zhejiang Hisun Plant Draw Scrutiny," FiercePharma, July 25, 2016, <https://www.fiercepharma.com/pharma-asia/u-s-fda-ingredient-exceptions-from-banned-zhejiang-hisun-plant-draw-scrutiny> (accessed June 9, 2018).

The FDA's overseas offices are poorly staffed, and its cadre of U.S.-based investigators willing to perform inspections overseas is relatively small and demoralized. The FDA needs a specialized and highly trained workforce that can make a years-long commitment to serve overseas and become a "go to" group for emergency assignments. This would remedy the problem behind the FDA's anemic recruitment to foreign posts: a lack of clear career progression and promotion opportunities. Right now, those who serve overseas often return to the FDA's U.S. headquarters without a guaranteed job, and sometimes have to accept demotions. Instead, superior training, pay, and a clear professional pathway, similar to that for State Department officers, would help cultivate more elite investigators. The U.S. government should demand that more of its investigators be given visas for work in China.

- The FDA should perform short-notice or no-notice inspections in China

The FDA's current regimen of pre-announced overseas inspections is counter-productive and ineffective. It allows Chinese manufacturing plants to stage-manage inspections. If the U.S. government actually wanted to get tough with China, it could insist that U.S. FDA investigators be allowed to inspect on short notice, or no notice. The model for this would be a highly successful FDA pilot program that ran for 18 months in India, from January 2014 on. Under that program of short and no-notice inspections, the FDA's investigators exposed widespread malfeasance that had previously been hidden.

By showing up unannounced, the investigators uncovered an entire machinery that had existed for years: one dedicated not to producing perfect drugs but to producing perfect results. The inspections led to an almost 60 percent increase in findings of Official Action Indicated. As a result of the pilot program, drugs from 41 plants in India were restricted from the U.S. market.

- Downgrades should be rare

Too often, FDA officials at the agency's headquarters in Maryland overrule the judgment of investigators in the field, and downgrade recommended findings.

In the course of my reporting, an FDA spokesperson justified these downgrades as follows:

"The FDA can and does change assessments of a plant's compliance. After the initial data gathered by the investigator is reviewed by both the Office of Regulatory Affairs and the Center for Drug Evaluation, additional information can be taken into account. Oftentimes, a firm is not able to provide paperwork at the time of an inspection but can produce documents later on that provide more insight into the matter. Assessments can also change based on how willing a firm is to cooperate and fix issues that are found."

However, the problem with this system is that it allows manufacturing plants to fabricate documents and generate excuses for submission to the FDA. It has also allowed substandard

drug products to enter the market, as was the case with the Zhejiang Huahai plant. Downgrades should be rare.

OPENING STATEMENT OF DR. YANZHONG HUANG, SENIOR FELLOW FOR GLOBAL HEALTH, COUNCIL ON FOREIGN RELATIONS; PROFESSOR, SCHOOL OF DIPLOMACY AND INTERNATIONAL RELATIONS, SETON HALL UNIVERSITY

COMMISSIONER TALENT: Thank you. Dr. Huang?

DR. HUANG: Thank you, Senator Talent and Commissioner Wessel and all the commissioners. Thank you for inviting me to this important hearing. Thank you for inviting me to this important hearing. I'm going to talk about the U.S. companies access to the Chinese healthcare market. In my written testimony, I've talked about the Chinese healthcare market, the U.S. market -- the companies market share. My oral presentation today, I'm going to focus on the challenges faced by U.S. health firms in selling to the Chinese market, as well as the regular the phase. And I will conclude with some policy recommendations.

Basically despite some improved conditions for market access, the U.S. health firms face some new challenges in selling to the Chinese market. The government industry policy clearly target the Chinese domestic health industry to increase its comparativeness against foreign firms, Made in China 2025 for example. Sixteen increased share of domestic content of core components and materials of medical devices to 40 percent by 2020 and 70 percent by 2025.

Chinese pharmaceutical firms are also improving their competitiveness. As of January 2018, China has the third largest number of pharmaceutical firms developing new drugs. It was reported that executives from some multinational pharmaceutical firms, including those in the U.S. are leaving for new positions in Chinese pharmaceutical firms.

With the deepening of China's healthcare reform, foreign pharmas are also facing increasing pressure to be cooperative by making their drugs more affordable under the single-payer system, the new created a super agency called National Healthcare Security Administration.

NHSA has been charged to lead everything healthcare-related in China. And possess much more leverage than its predecessors in negotiating with foreign pharmas for price cuts. So if China starts imitating the healthcare model of U.K.'s National Health Service, the NHSA will replace the U.S. DoD to be the world's biggest employer. Indeed the negotiations with foreign pharmas result in the average price cut of 44 percent across 36 products in 2017 and 57 percent across 17 products in 2018.

In late 2018, the government also introduced a new procurement scheme, which listed 31 drugs for procurement in the program that covers all public hospitals in 11 cities. That combined represent a third of China's pharmaceutical market. Under this cutthroat winner takes all bidding process, multinational pharmas stand to lose major market share for the high cost of patent pharmaceuticals because quality assurance for their medicines are no longer the guarantee to win hospital tenders.

In June 2019, NHSA launched a pilot program of diagnosis related groups we called DRGs that classifies hospital cases into different groups in 30 cities. It is expected that this program is going to be fully implemented nationwide in five to ten years. The new provider payments reform measure aims to lower the cost of healthcare, including the cost of pharmaceutical products. This poses new challenges for foreign pharmas marketing their products. Because not only will they have to ensure their products be included in the treatment protocol of different patient groups, but they need to lower the drug cost might discourage Chinese doctors from prescribing new and innovative drugs.

The ongoing trade war also threatened U.S. pharmaceutical firms efforts to access the

Chinese market. We know that the list unveiled by the Chinese government to impose punitive tariffs on imported U.S. goods included commonly used drugs and medical devices. A leading Chinese economist in March even implied that Beijing should curb its exports of APIs and its active pharmaceutical ingredients as a counter measure in a trade war with the United States.

I'm going to also talk about the regulatory burdens for the foreign pharmaceutical firms. Well despite China's efforts to improve its regulatory process, its volatile and upscale regulatory system continues to present significant burden to foreign pharmaceutical firms seeking to operate in China. The onerous requirements also makes the market out of reach for small startup companies with limited investment capital.

Foreign companies also face tough disclosure requirements in filing new applications for their products. It is also difficult for foreign pharmaceutical firms to get their products to be included in the National Reimbursement Drug List. Companies complain that pharmaceutical tendering is too frequent, involving too many government agencies. And they have to be on the go across the country to participate in tender. In centralized tendering and procurement system pharmaceuticals actually contributes to additional regulatory burden for foreign firms.

For the sake of time, I'm going to go directly to the policy recommendations. I look at the U.S. companies engagement in China's healthcare market reveals actually self-sustaining dynamics that until recently -- I mean until 2017 -- enabled that engagement to expand and thrive despite the fluctuation in U.S.- China relations. And today, the booming Chinese healthcare market has created both opportunities and challenges for U.S. firms.

If history can teach us anything, it is that both sides should avoid putting the healthcare industry at risk of collateral damage as a result of deteriorating bilateral relationship. The USTR did the right thing by excluding pharmaceuticals, certain APIs, and select medical goods from the proposed tariffs in May.

But I think it is also important that we keep in mind that as pharmaceutical industries value chain become globalized and international collaboration and the health related research becomes the norm, we should avoid looking at entire U.S.-China health related exchange and investment through the prism of national security. In a nutshell, do no harm. And that principle applies to both China and the United States. Thank you.

COMMISSIONER TALENT: Thank you. Mr. Allen?

**PREPARED STATEMENT OF DR. YANZHONG HUANG, SENIOR FELLOW FOR
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U.S. Companies' Access to Health Industries and Market Opportunities in China

Prepared statement by

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Before the

U.S.-China Economic and Security Review Commission

Hearing on "A Health Relationship? Assessing the Risks and Opportunities of China's Medicine and Health Development."

Changing Landscape for the China's Healthcare Market

China's healthcare market has expanded continually during the past five years. The market increased from [\\$357 billion](#) in 2011 to [\\$761 billion in 2017](#). Growth is expected to continue and by 2020 it is estimated to reach [\\$1.19 trillion](#). Driven by rapid population aging, a growing burden of non-communicable diseases, emergence of a sizable middle class, and advancement in technology, the trend is expected to sustain in the coming decade. At present, however, healthcare spending in China still accounts for only [6.4 percent](#) of its GDP, which is lower than the average of OECD countries (9.0 percent). According to China's National Health Commission, the total size of China's healthcare market will reach [\\$2.39 trillion](#) by 2030. As far as pharmaceuticals are concerned, China is the second-largest market in the world, [valued](#) at \$123 billion in 2017. The pharmaceuticals market is projected to reach \$175 billion by 2022.

An equally significant development is the [growing competitiveness](#) of Chinese domestic pharmaceutical industry. Beginning in 2013, but especially after 2015, the number of Investigational New Drug (IND) applications submitted by Chinese firms has increased significantly. In 2017, 162 applications were submitted, up from 73 in 2013. In 2018, the number of new drugs developed by Chinese firms and approved by U.S. FDA has hit 430. Since 2013, major Chinese pharmaceutical firms such as Fosan, Luye, Shanghai Pharma and Humanwell Healthcare have been actively involved in cross-border mergers and acquisitions (M&As). Between 2013 and 2017, the number of cross-border M&A cases increased from 7 to 52, and the amount involved increased from \$1.2 billion to \$11 billion.

Private hospitals in China have had rapid growth in numbers. Thanks to government support of the entry of private capital in the healthcare sector, the [number of private hospitals](#) increased by 85 percent between 2013 and 2018, from 13,396 to 12,032. However, due to their inability to attract top physicians and the public's lack of trust in them, private hospitals in China tend to be small in size and provide only a limited number of services. That might explain why general hospitals (almost all of them public) continue to expand in China. In 2018, healthcare spending in those hospitals was estimated to be more than \$350 billion, an 86 percent increase over 2013. It was [estimated](#) that by 2022 general hospitals' market value will be 71 percent larger than the 2018 level.

Rapid growth of the global pharmaceutical industry has also boosted the expansion of contract manufacturing organizations (CMOs) and contract research organizations (CROs) – two forms of outsourcing services from providers – in China. Of the more than 1,100 CROs around the globe, nearly 30 percent are based in China. Propelled by the relatively low R&D cost and favorable policies and capital, Chinese [CRO industry scale](#) is expected to expand by more than 250 percent, from RMB68.7 billion in 2018 to RMB242.5 billion in 2025. Being one of the most comprehensive service platforms integrating discovery, research, and development of small-molecule chemical drugs, WuXi AppTec [claims](#) 10 percent of the world's CRO market. Driven by its complete infrastructure, adequate raw material supply, and low operating cost advantage, China is also [rapidly expanding](#) its CMO market share. Despite [problems](#) protecting human subjects and poor transparency, during 2007-2017 more than 11,000 clinical trials were launched in China, making it the [fourth largest](#) country in terms of the number of clinical trials.

Overall, there are four major drivers in China's healthcare market. First, changes in the global pharmaceutical industries provide strong incentives for multinational pharmas to outsource their R&D and manufacturing activities to China. Second, Chinese society is rapidly ageing, which is highly associated with non-communicable diseases (NCDs), including cardiovascular diseases, cancer, hypertension, and diabetes. China's population aged 65 and older is forecast to grow from 91 million in 2017 to 143 million in 2027 (US: 48.9 million in the same year). The size of elderly population presents a [huge market](#) for healthcare industry. Third, health is now high on Chinese leaders' agenda. In August 2016, China held its National Health Conference, which was the most important national meeting on health in twenty years. Following the meeting, China released the Healthy China 2030 Plan, which places public health as a policy priority. Finally, China's healthcare reform has focused on improving access and affordability. Health insurance schemes have been extended in China to cover virtually the entire population, which also stimulates demand for more and better healthcare.

Government Support Measures

The Chinese government is committed to the development of China's own health, biotech, and pharmaceutical industries. An industrial policy document entitled "Made in China 2025" has identified pharmaceuticals and medical devices as one of the 10 strategic industries to receive subsidies and other government support. In 2017, China [earmarked](#) approximately \$13.2 billion to pharmaceutical R&D, which accounts for 8.9 percent of the global total in the same year. China's investment in this area is expected to reach \$29.2 billion in 2021, which will lead to the rise of its global share to 18.3 percent. It has also unveiled a number of initiatives to lure overseas Chinese scientists living abroad home. It was reported that nearly [one third](#) of the recruits of the Thousand Talents Plan – a high-profile, state-backed recruitment drive to attract overseas Chinese students and academics – have expertise in life sciences and medicine. Thanks to government support, China is quickly rising as a powerhouse in biomedical R&D. By the end of May 2017, China had nearly [300 biosimilars](#) (a biosimilar is defined as a biologic medical product that is almost an identical copy of an original product manufactured by a different company) under research and development, making it the country with the largest number of biosimilars

in research and development. The Chinese biosimilar market is expected to [hit](#) more than \$5.5 billion by 2025.

Beginning in late 2015, Chinese drug regulating agency – then China Food and Drug Administration (CFDA), now the National Medical Products Administration (NMPA) – has also kicked off reforms to accelerate the approval process for investigational new drugs (IND). Drug reviewers at the Center for Drug Evaluation (CDE) [increased](#) to more than 800 by the end of 2017, up from 70 in 2015. As a result, annual number of new drug approvals [increased](#) from 5 in 2016 to 40 in 2017. In 2018, the government agency greenlighted another 51 new drugs.

Since 2016, the government has also made efforts to consolidate its pharmaceutical industry. CFDA imposed stricter quality standards (in terms of safety and efficacy) on the production of off-patent generic drugs, which aims at [weeding out](#) over half of the nation's 2,900 or so small domestic drug makers.

In 2018, the government reduced the tax burden on pharmaceutical products to make them more available and affordable. In April, China [announced](#) it would cut the import value-added tax (VAT) on cancer drugs from 17 percent to 3 percent. From May 1, import tariffs on all common drugs and cancer drugs were reduced to [zero](#). This was followed by another [decision](#) in February 2019 to cut the VAT rate to 3 percent on medications for 21 rare diseases. Reducing VAT on these drugs will make the imported drugs cheaper in Chinese market, and increase the demand for these drugs. Meanwhile, China has [promoted](#) the research and availability of generic drugs that are in short supply, especially those used for the treatment of major infectious diseases, rare diseases, and pediatrics. As a result, Chinese pharmaceutical firms are [increasingly focused on](#) the development and production of finished pharmaceutical products (FPPs) for the domestic market (rather than concentrate only on the production and export of active pharmaceutical ingredients or APIs).

In addition, China has pursued the application of big data analytics in healthcare a national priority. Since 2014, there has been [growing investment](#) in Big Data analytics for healthcare. In 2016, there were 66 such cases. In the first quarter of 2018, there were 35, and more investment in this area is expected. China seeks to take the lead in the nascent field of precision medicine. In 2016, China launched an initiative to earmark \$9 billion to sequence and analyze genomes over the next 15 years, which [dwarfed](#) the \$215 million precision-medicine initiative launched by the Obama administration the same year. Artificial intelligence (AI) is set to play a bigger role in China's hospitals. The technologies, for example, could be used to provide initial diagnoses in a quicker, less intrusive but more accurate way. AI health market in China was [estimated](#) to be more than \$3 billion in 2018, a 53 percent increase over 2017.

U.S. Healthcare Firms' Access to the Chinese Market

According to [data from WTO](#), China is one of the world's largest import market for pharmaceuticals and medical devices. In 2017, it was the 6th biggest import market for pharmaceuticals, with shipments valued at \$25.3 billion, and the 4th largest import market for medical devices, with shipments worth \$7.4 billion. This does not include pharmaceuticals and medical equipment produced and sold in China by multinational pharma. According to [a joint report](#) from McKinsey and the Chinese Pharmaceutical Association, in 2016, multinational firms claimed 35 percent market share in Level-III hospitals (i.e., urban health centers) and 27 percent market share in Level-II hospitals (e.g., county-level hospitals). They also claimed 44 percent market share in first-tier cities (Beijing, Shanghai, Guangzhou, Shenzhen) and 31 percent market share in second-tier cities (e.g., Hangzhou, Nanjing, Chongqing, and Jinan).

The lack of competitiveness of China's domestic healthcare industry and Chinese consumers' preference for high-end, imported pharmaceutical products help boost sale of products developed and manufactured by U.S. firms. About [95 percent](#) of China's registered drugs are generic ones, which are prone to low-quality problems. Despite the emergence of some large pharmaceutical firms (e.g., China Resources, SINOPHARM), China's pharmaceutical industry remains notoriously fragmented and uncompetitive. In 2016, the top 10 pharmaceutical firms accounted for only 10 percent of industry sales, compared with 48 percent in the United States. Fragmentation of Chinese pharmaceutical industry also keeps R&D investment as low as 5 percent of sales for Chinese firms, compared with 20 percent for U.S. companies. As far as medical device products are concerned, Chinese manufacturers dominate the domestic market, but they deliver mostly [low-tech and mid-range products](#). In 2014, 70 percent of the medical device products in the world were made in China, but a large number of them were probably manufactured for [Original Equipment Manufacturers \(OEM\)](#) (mostly MNCs).

Since 2017, [a raft of government measures](#) to smooth new drugs' road to approval have facilitated U.S. access to the Chinese market. In October 2017, the government [announced](#) plans to accept data of clinical trials carried out overseas. This move would [be welcomed](#) by U.S. pharmaceutical companies because until 2017 stringent clinical trial data requirements were responsible for the delay of more than 7 years for U.S. drugs to enter Chinese market. The [first licensed HPV vaccine in China](#), for example, was approved only in 2016, a decade after its US approval. As a result of fasttrack approval and local study waiver, [the drug lag](#) has been reduced to 2.3 years. Merck's Gardasil 9 HPV vaccine was actually approved by the CFDA just nine days into the review process. According to [a report](#) from Deloitte LLP, the number of approvals for new drugs developed by multinational pharmaceutical companies increased from 3 in 2016 to 39 in 2017 and 40 in 2018. China further opened up its pharmaceutical market in May 2018 by exempting all cancer drugs from import tariffs. In October, the government [approved](#) 17 new cancer drugs – most of them imported drugs – to be included in its national health insurance system.

Additional pressures for opening the Chinese pharmaceutical market, especially the market for vaccines, built up in the summer of 2018, after one of China's largest domestic vaccine makers was found to have sold at least [250,000 substandard doses of vaccine for diphtheria, tetanus and whooping cough](#). The scandal seriously undermined people's confidence in the domestic vaccines. A [survey](#) of 300,000 parents suggested that 79 percent said that before the scandal, they would have given their children a Chinese made vaccine, but only 36 percent said they would still do so now. Sixty percent of respondents said they were considering having their children inoculated outside mainland China.

Challenges Faced by U.S. Health Firms In Selling into the China Market

Despite conditions that facilitate market access, U.S. health firms face new challenges in selling into the China market. The government industrial policy clearly targets Chinese domestic healthcare industry to improve its competitiveness against foreign firms. Released in 2015, Made-in-China 2025 seeks to [increase](#) the share of domestic content of core components and materials of medical devices to 40 percent by 2020 and 70 percent by 2025. The government has also put in place measures to encourage the development and production of generic drugs by domestic Chinese pharmaceutical firms. Large Chinese pharmas such as Sino Biopharmaceutical are beefing up their innovative capabilities. As of January 2018, China (tied with Canada and trailing U.S. and U.K.) has the [third largest](#) number of pharmaceutical firms developing new drugs. It was [reported](#) that executives from some multinational pharmaceutical firms are leaving for new positions in Chinese pharmaceutical firms.

With the deepening of China's healthcare reform, foreign pharmas are also facing increasing pressures to ["be cooperative"](#) by making their drugs more affordable. Since 2016, Chinese government has organized a

nationwide drug price and reimbursement list negotiation, which determines what new and innovative drugs to be included in the government reimbursement list. Under the single-payer system, the newly created National Healthcare Security Administration (NHSA) possess much more leverage than its predecessors in negotiating with foreign pharmas for price cuts. The negotiations resulted in [an average price cut](#) of 44 percent across 36 products in 2017, and 57 percent across 17 products in 2018.

It is worth noting that despite significant price reductions, foreign pharmaceutical manufacturers have not seen drops in their sales for these drugs. Because of the increasing volume of sales that comes from government reimbursement, sales of the 36 drugs included in the government negotiations actually [increased](#) by an average of 40 percent. For this reason, many foreign companies seem to be [willing](#) to compromise on the price in order to gain access to the market in China.

In April 2018, the Chinese government unveiled measures that included authorizing the granting of [compulsory licenses](#) to enhance the availability of innovative drugs. Beginning in July, public outcry also has prompted the government to [tame prices of cancer drugs](#) sold by foreign pharmaceutical companies. This was followed by a new procurement scheme introduced in late 2018 which aims to dramatically cut the amount of payment for generic drugs covered by health insurance. The new policy listed 31 drugs for procurement in a program that covers all public hospitals in 11 cities (which combined represent a third of China's pharmaceutical market). Pharmaceutical firms are invited to submit competing offers in the bidding process, with the one that can offer the lowest tender price automatically chosen as the winner and collects the entire guaranteed purchase amount from all 11 cities. Under the [cut-throat, winner-takes-all bidding process](#), multinational pharmas stand to lose major market share for their high-cost, off-patent pharmaceuticals because quality assurances for their medicines are no longer the guarantee to win hospital tenders.

In June 2019, NHSA launched a pilot program of diagnosis-related groups (DRGs) that classifies hospital cases into different groups, in 30 cities. It is expected to take [five to ten years](#) for the measure to be fully implemented nationwide. The new provider payment reform measure aims to lower the cost of pharmaceutical products (which now count as costs in DRG payment). This [poses new challenges](#) for foreign pharmas marketing their products: not only will they have to ensure their products are included in the treatment protocols of different patient groups, but the new provider payment method might discourage doctors from prescribing new and innovative drugs in order to lower drug costs.

The ongoing trade war also threatens US pharmaceutical firms' efforts to access the Chinese market. While the tariffs on approximately \$300 billion worth of Chinese products proposed by the United States Trade Representative (USTR) in May 2019 [excludes](#) "pharmaceuticals, certain pharmaceutical inputs, and select medical goods," the list [unveiled](#) by the Chinese government to impose punitive tariffs on imported U.S. goods included commonly used drugs and medical devices. A leading Chinese economist also [implied](#) early this year that Beijing curb its exports of APIs as a countermeasure in the trade war with the United States. As Washington tightens scrutiny of investment from overseas, [Chinese venture capital investment](#) in the U.S. biotech firms fell by more than half in the first half of this year, raising fears that U.S. pharmaceutical start-ups will encounter difficulties to raise funds and access the Chinese market.

Regulatory Burdens for Foreign Pharmaceutical Firms

Despite China's efforts to improve its regulatory process, its volatile, obscure, and byzantine regulatory system continues to present significant burdens to foreign pharmaceutical firms seeking to operate in China. The onerous requirements also makes the market out of reach for small for start-up companies with limited investment capital. Foreign firms are still [required](#) to renew their drug import license every

five years. Since the renewal is not guaranteed, the uncertainty has negative impacts on the long-term stability of their operations in China. Foreign companies also face tough disclosure requirements in filing new applications for their products. According to guidelines of China's National Intellectual Property Administration (CNIPA), all the relevant experimental data demonstrating the efficacy of the product [must be included](#) at the time of application, and post-filing data cannot be used to defend against invalidation. Such data requirements [make it difficult](#) for applicants to file new applications in a timely manner.

It is also difficult for foreign pharmaceutical firms to get their products included in the National Reimbursement Drug List (NRDL), aka the China National Formulary (CNF). The list covers basic drugs, but it includes mostly common and inexpensive drugs and is not updated very frequently. Companies [complain](#) that pharmaceutical tendering is too frequent, involving too many government agencies and they have to be on the go across the country to participate in a tender. Centralized tendering and procurement system for pharmaceuticals contributes to additional regulatory burden for foreign firms. In addition, hospitals may refuse to use the drugs that won the bid.

Foreign pharmaceutical firms are also increasingly subject to tougher enforcement of China's anti-bribery laws. China's revised Anti-Unfair Competition Law (AUCL), which came into effect in January 2018, [prohibits](#) individuals and entities from bribing a business counterpart or public official, or using other means to obtain a business opportunity or competitive advantage. It also prohibits bribery via a third party (an individual or entity), and employers will be held liable for their employee's bribery acts. In May, the newly created State Administration for Market Regulation (SAMR) kicked off a campaign to crack down on unfair competition and commercial bribery with a focus on activities in the pharmaceutical and medical device sector, a sector which is traditionally prone to high bribery risks. Because product prices of foreign firms are typically higher than those of domestic ones, it is [not uncommon](#) for foreign firms to use agents to host academic conferences to entertain hospital managers or doctors in order to have their products sold in Chinese hospitals. Such "hidden practices" are now the target of the crackdown as China gears up its enforcement of anti-corruption law.

Enforcing Pharmaceutical Intellectual Property Rights

Although a large percentage of U.S. companies in China [identified](#) lack of protection of intellectual property (IP) rights as a major regulatory challenge, disputes over pharmaceutical-related IP have not been a prominent concern in U.S.-China economic relations. Driven by the need to join the World Trade Organization (WTO), China not only extended all patent coverage to twenty years, but also capitulated to U.S. demands on issues such as data exclusivity and patent linkage. Upon its WTO entry, China agreed to adhere to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sets standards for IP protection. Unlike India, China has not used the flexibility offered in the WTO TRIPS regime and the Doha Declaration on the TRIPS Agreement and Public Health (2001) to take an aggressive approach toward patent-related issues, despite an AIDS epidemic, an unprecedented crisis of non-communicable diseases, and a pharmaceutical industry capable of producing generic versions of most patented drugs sold in China. Thus far, there have been no successful applications for compulsory licensing of any patented drugs in China. Since 2014, IP courts have been established in approximately 20 Chinese cities. In January 2019, the Supreme People's Court [launched](#) the appellate tribunal for IP disputes. Starting May 2018, China has also [lengthened](#) patent protection on pharmaceuticals from 20 to 25 years. Thus far, concerns about China's enforcement of IP rules appear [not to have had a significant impact](#) on the flow of pharmaceutical-related investment into China.

Compared with pharmaceutical companies, U.S. medical devices manufacturers may be more concerned about IP enforcement when selling their products in China. They may soon find their competitors in China offering a similar product at much lower price (and very likely lower performance level as well). To some extent, the OEM practice encourages product copycat in China. It is also relatively easy to challenge an established patent in China. Anyone can challenge a patent's validity in China without having to show up at a hearing in person. This presents a potential blackmailing or money-making opportunity. According to a report, since 2015 nearly 75 percent of the challenges to pharma patents have resulted in at least one claim being [invalidated](#).

Policy Recommendations

In October 1982, Bristol-Myers Squibb founded Sino-American Shanghai Squibb Pharmaceutical Ltd, the first China-U.S. joint venture pharmaceutical firm. By the end of the 1990s, almost all the major U.S. pharmaceutical and medical device firms had set up shops in China. A look at U.S. companies' engagement in China's healthcare market reveals self-sustaining dynamics that until recently enabled them to expand and thrive despite the fluctuation in U.S.-China relations. Today, the booming Chinese healthcare market has created both opportunities and challenges for U.S. firms. If history can teach us anything, it is that both sides should avoid putting the healthcare industry at risk of collateral damage as a result of a deteriorating bilateral relations. USTR did the right thing by [excluding](#) pharmaceuticals, certain APIs, and select medical goods from the proposed tariffs in May, but the on-and-off of key products used by U.S. drug makers from the trade tariff list is creating [uncertainties](#) for U.S. biopharmaceutical companies. Tightening scrutiny of Chinese investment in the U.S. biotech firms also may cripple US pharmaceutical start-ups' ability to raise funds and access the Chinese market. It is important to urge China to enforce pharmaceutical-related IP. As pharmaceutical industry's value chain becomes globalized, and international collaboration over health-related research becomes the norm, however, we should avoid looking at the entire US-China health-related exchange and investment through the prism of national security. In a nutshell, do no harm. This principle applies to both U.S. and China. We should deliver an explicit message to the Chinese side that healthcare products should not be used as a weapon in the U.S.-China trade war.

However, the U.S. government can still do more. It should significantly step up investment in healthcare-related R&D, especially in areas such as AI health and precision medicine. It should continue supporting U.S. companies' access to the Chinese healthcare market. In the trade negotiations with China, the USG should urge the adoption of effective measures to level the playing field and ensure fair treatment of U.S. companies, which involves eliminating unnecessary or unreasonable regulatory burdens shouldered by foreign companies operating in China. In urging China to open its healthcare market to foreign competition, we should let China know that doing so would not only improve Chinese people's access to safer, affordable, and effective pharmaceutical products, but also – given the strong public outcry over substandard drug products made by Chinese domestic firms – contributes to social and political stability. It is worth noting that none of China's vaccine scandals have involved foreign manufacturers. It should also support the expansion of private hospitals so that they become truly competitive actors in China's healthcare market. The U.S. can also help China beef up its regulatory capacities in the healthcare sector. This involves encouraging NMPA to further improve its review process, helping improve oversight when conducting clinical trials and supporting the creating of an independent IP court system. The U.S.-China Social and Cultural Dialogue, the only high-level forum to discuss U.S.-China cooperation after 2017, should be reopened as an institutional venue to discuss these issues.

U.S. companies, meanwhile, should seize upon the opportunities provided by China's regulatory reforms to sustain its competitive edge in the Chinese market. Rather than view China as a "second-wave" market,

U.S. pharmaceutical firms should prepare to have their innovative new drugs included in the National Reimbursement Drug List once they are approved by FDA. They need to ensure maximum protection of their products by making use of the full IP framework that exists in China. They may also want to take a more proactive role in China's healthcare reform by making the most effective drugs more affordable in China. As negotiations that led to the inclusion of pharmaceuticals made by foreign pharma in the NRDL showed, a win-win outcome is indeed possible. The Chinese market is sufficiently large and diverse that there is always something for everyone.

OPENING STATEMENT OF CRAIG ALLEN, PRESIDENT, US-CHINA BUSINESS COUNCIL

MR. ALLEN: Thank you for the opportunity to testify before the Commission today. I'm here as the President of the U.S.-China Business Council, a private, nonpartisan, nonprofit organization of approximately 220 American companies across all industry sectors that do business in China, including the healthcare sector.

Also as noted, a former U.S. ambassador and a trade negotiator with the Department of Commerce where I led the discussions to improve China's market access for medical devices and pharmaceuticals. I've dedicated many, many years to increasing American jobs through bolstering our export sector.

It is my belief that America remains among the most innovative nations because we cultivate the free flow of ideas, information, and people. And we engage in a deliberative process that encourages and respects different opinions in order to arrive at decisions that benefit the greatest good.

As the Commission considers the relationship between the U.S. and Chinese Life Sciences sectors, I'd like to highlight three main principles that underline my recommendations. First, U.S. investments in China benefit the U.S. economy. U.S. companies have benefitted greatly from the growth opportunities a rising China has provided mostly through rapidly growing exports. It's important to note that most U.S. companies invest in China to access and serve China's domestic market. But the revenue that they generate in China is also a driver of growth and innovation in the United States.

So in 2015, our latest numbers, U.S. exports to China directly and indirectly supported 1.8 million jobs in the United States. If the economic benefits generated from U.S. investment in China and Chinese investment in the U.S. are combined, the total jumps to 2.6 million American jobs. The healthcare sector is an important part of this story. U.S. exports of pharmaceuticals to China reached nearly \$3 billion in 2018. And the biopharmaceutical industry supports 4.7 million U.S. jobs. The medical device industry supports 2 million U.S. jobs.

China has become the world's second largest market for pharmaceuticals and fourth largest market for medical equipment. And this market is growing rapidly as China ages. It is increasingly important that U.S. companies continue to participate in this space to support U.S. job creation.

My second principle is that commercial challenges are best addressed through engagement. It's my experience that Chinese healthcare regulators are properly focused on safety and efficacy. And they want to learn from us and with us. Nonetheless, while U.S. health companies see tremendous opportunities in China, there are remaining market access barriers that effect our company's ability to equally compete as Dr. Huang has indicated.

The majority of these challenges are highly technical in nature and unique to the healthcare industry. And they would include one, regulatory approval delays. Two, pricing and reimbursement controls. And three, insufficiently effective intellectual property right protection and implementation.

The U.S. government cannot arrive at or -- The most effective and sustainable approaches to resolving these very important trade issues if private sector industry stake holders and experts are not closely consulted. The most effective and sustainable way to resolve specific commercial issues is through regular dialogue between key U.S. and Chinese government and industry stakeholders. Technical commercial issues and barriers to trade require regular, precise, and

technical discussions.

Also international fora provide critical opportunities to leverage our bilateral negotiations. We must continue to use multilateral institutions to encourage China to adopt international best practices and standards, which will indirectly support U.S. exports.

My third principle is that bilateral dialogue makes us stronger. The Chinese government has strong incentives to improve basic healthcare and expand access to innovative treatments for China's growing and rapidly aging population. And these are goals that U.S. companies are very well positioned to support. There are mutually beneficial solutions to be had by reducing technical barriers to trade through cooperation and engagement. But we need to communicate regularly to compare best practices. And ideally, we need to build on a foundation of respect, trust, and collaboration.

So for recommendations, I would submit to you four ideas. Firstly, we need to leverage all available tools for engagement. The government should seek to engaged China through bilateral, regional, and multilateral forums to help foster improvements in China's regulatory environment. We need to get back to platforms such as the JCCT and the S&T to regularly discuss these technical issues. And encourage the Chinese government to return to stalled healthcare reforms. And find mutually agreeable solutions, which will improve healthcare and safety. And will also help to expand U.S. exports.

Secondly, in these consultations, please continue to involve private sector industry experts in the technical policy dialogues. It is essential that highly technical nuanced health sector issues are systemically addressed through targeted policy discussions, not only between governments in consultation with industry, but also with technical experts as well. Thirdly, please strongly support missions like USTDA and the FDA. Those organizations deserve continued financial support. And then finally, we must narrowly and precise define emerging technologies and foundational technologies as additional export controls are rolled out. It is imperative that our export control policies do not unduly limit innovation in American exports if the ultimate goal is to maintain U.S. leadership, particularly in advanced sectors. Thank you for your consideration.

**PREPARED STATEMENT OF CRAIG ALLEN, PRESIDENT, US-CHINA BUSINESS
COUNCIL**

**PREPARED STATEMENT OF
CRAIG ALLEN
PRESIDENT US-CHINA BUSINESS COUNCIL**

**Exploring U.S. Companies' Access to Health Industries and Market Opportunities in
China**

**Testimony before the U.S. China Economic and Security Review Commission
July 31, 2019**

Prepared Statement Submitted on July 24, 2019

Introduction

The US-China Business Council (USCBC) is a private, nonpartisan, nonprofit organization of approximately 200 American companies that do business with China. From our headquarters in Washington, DC, and offices in Beijing and Shanghai, China, we represent American companies engaged in business across all industries and sectors in China, including manufacturers and marketers of pharmaceutical and medical device products.

US life sciences companies see tremendous opportunities in China, but also continue to face significant market access barriers there. These barriers include regulatory approval delays, pricing and reimbursement controls, insufficiently effective intellectual property (IP) protection and enforcement, and discriminatory localization requirements that advantage domestic companies over foreign multinationals. Efforts to strengthen Chinese industries' domestic competitiveness also contribute to the unlevel playing field for foreign companies seeking to participate in China's healthcare market.

Because China is now one of the world's largest and most dynamic markets for the health industry, it is more crucial than ever that these market access barriers be resolved. Companies that are not successful in China can no longer expect to be successful global players in the long run. If US companies in the health space are to remain trusted, innovative, global industry leaders, the challenges our companies face in China must be effectively addressed.

These issues are highly technical, unique to the health industry, and most effectively resolved by involving industry experts with deep knowledge of the sector and policy implications. A framework for regular dialogue between US and Chinese health regulators and industry representatives is necessary to effectively and sustainably address these issues. Greater engagement with Chinese regulators and industry representatives in international forums should also be a priority, and opportunities to work together on enforcement and educational efforts should be leveraged.

China health market: Overview & Opportunities

Growth in China's health market is driven by a rapidly aging population, expansion of the middle-class, and recent government reforms. China is the world's second largest market for pharmaceuticals after the United States, and fourth largest medical equipment market. China's medical device sector is among the country's fastest growing, maintaining double digit growth for over a decade.¹

¹ Export.Gov, [Healthcare Resource Guide: China](#), (17/07/2019)

US exports of pharmaceutical products and medical or surgical equipment to China have increased year-over-year for over a decade. Exports of pharmaceuticals went from just under \$400 million in 2008, to \$2.8 billion in 2018.



Source: US Census Bureau, U.S. Import and Export Merchandise trade statistics.

China’s total health expenditure is around five percent of Gross Domestic Product (GDP), compared to 17 percent in the United States,² indicating the sector is still in its infancy and primed for growth. The size and growth potential of China’s healthcare market makes it one of the most promising, long-term markets for US pharmaceutical and medical device manufacturers. USCBC’s annual member survey consistently indicates that most American companies invest in China to access and compete for Chinese customers. Though current trade tensions will impact investment decisions, preliminary findings from USCBC’s 2019 survey indicate a majority of members plan to maintain their resource commitments in China in the coming year.

The health sector is an increasingly prioritized area of strategic national interest for the Chinese government. The 13th Five Year Plan, released in 2016, prioritizes health and innovation, and President Xi Jinping’s Healthy China 2030 initiative made health an explicit national priority to be included in all aspects of strategic planning.

² The World Bank, [Current health expenditure \(% of GDP\)](#), (17/07/2019)

China is currently undertaking a comprehensive set of reforms to give citizens greater access to healthcare services. US companies have substantial experience developing and operating healthcare infrastructure and solutions in global markets. Allowing broader foreign participation in China's healthcare market and in its reform process would allow Chinese consumers greater access to innovative technologies and products, international best practices, and high-quality services—accelerating the reform process.

However, the opportunities the market and these initiatives present are tempered by the challenge of competing in an environment where local or provincial government practices unfairly favor domestic players. Biopharmaceuticals and high-performance medical equipment are among the 10 strategic sectors included in Made in China 2025 (MIC 2025), a government initiative to upgrade China's domestic innovation-driven manufacturing sectors and create global leaders. While the goal of improving Chinese capabilities and patient trust in local companies is laudable, it is important to ensure such initiatives are WTO compliant and implemented transparently, to ensure they do not unfairly discriminate against foreign companies. When specific concerns are identified—such as domestic and international market share targets in strategic industries—the United States should coordinate with like-minded trading partners to ensure a coordinated response. A unilateral approach gives US negotiators less leverage and exposes the US to the double-whammy of retaliation and seeing European and Japanese competitors step into the void.

Regulatory Overview: Progress and Remaining Challenges

China's healthcare market has evolved significantly over the last five years. The government began a comprehensive reform of China's health sector in 2016. The former China Food and Drug Administration, now the National Medical Product Administration (NMPA), released a series of draft policies collectively known as the "innovation policies." The draft policies encourage innovation in drugs and medical devices by accelerating the review and approval for new drugs and medical devices, reforming clinical trial management, and enhancing innovator rights.

If fully implemented, these policies have the potential to streamline market access and improve the operating environment for US drug and medical device companies in China. Several of these proposed reforms also address key outcomes outlined in previous US-China trade negotiations. The 2016 US-China Joint Commission on Commerce and Trade (JCCT), for example, reaffirmed China's commitment to encouraging clinical-value-oriented innovative drugs to be registered and marketed in China, and noted that China would further improve related policies. While several revisions and guiding documents for the regulations have been released, and implementation has begun in some cases, other reforms stalled after 2017.

The March 2018 mass reorganization of government institutions, including the key regulatory agencies for life sciences and healthcare industries, is a contributing factor in slowed and stalled implementation efforts. The China Food and Drug Administration (CFDA) and National Health and Family Planning Commission (NHFPC) were dismantled, with core functions integrated into the newly created National Medical Products Administration (NMPA), National Health Commission (NHC), and the State Medical Insurance Bureau. The reorganization placed NMPA under a new giant, market regulator, the State Administration for Market Regulation (SAMR), a centralized authority overseeing regulation of intellectual property, anti-monopoly, food safety and standards, testing and certification. Following the reorganization, the former head of CFDA was appointed Party Secretary of SAMR. However, shortly thereafter a major vaccine safety

scandal at a local manufacturer forced his resignation. The leadership turnover and departure of a prominent health reformer also contributed to delays in health sector initiatives.

In the longer term, we hope the streamlining of regulatory oversight of the health industry, and potential for greater cooperation between health and IP regulators, will ultimately help improve efficiencies and enforcement. Encouragingly, at the end of 2018, health and IP related reforms began to pick up again. While progress is still necessary, reforms appear to be moving in the right direction.

Regulatory Approval System

One area directly benefiting US companies is China's reforms strengthening its framework for drug and device regulatory review and approval. This includes the launch of expedited and priority review and approval mechanisms, moves to accept overseas clinical data, as well as strengthening the capacity of reviewers to reduce China's drug lag. These efforts are expected to help streamline and significantly speed-up the market access process for US companies, and are consistent with industry's primary recommendations.³

In February and July 2018, NMPA issued technical guidance on the acceptance of overseas clinical trial data for devices and drugs, respectively. Previously, China did not accept clinical trial data developed overseas to support new medical product approval. This reform will accelerate the lengthy and costly process of conducting additional clinical trials in China. While the reform is welcome and there has been steady improvement, to date there has been no tangible implementation or confirmation of companies receiving marketing approval based on overseas clinical data. We encourage China to continue to make progress toward full acceptance of overseas clinical trial data and eliminating this market access barrier.

China has also moved forward with the implementation of expedited approval pathways for innovative and urgently needed drugs and devices. In August 2018, 48 foreign drugs already approved and marketed in the US, EU and Japan received a green light from China's Center for Drug Evaluation (CDE) for accelerated approval. This list includes several highly innovative new drugs brought to market as recently as 2017. In September 2018, NMPA issued a new "Catalogue of Medical Devices Exempted from Clinical Trials," bringing medical device clinical exemptions more in-line with internationally accepted standards.

The NMPA is continuing to undertake reforms to accelerate the drug review and approval process. November 2018 amendments to the draft Drug Administration Law (DAL) include an implicit 60-day approval timeline for clinical trials, which is expected to improve time to market for innovate new drugs, including those developed overseas. New channels to facilitate stakeholder-NMPA communications during the drug and device approval process will help reduce delays. Progress is also being made in training technical reviewers of new drug and device applications to help reduce China's drug lag.

We support China's continuing effort to accelerate and simplify the regulatory approval process for drugs and medical devices. While these initiatives represent welcome progress, the overall drug development and approval process in China remains out of alignment with international practice, as it takes much longer than is typical in other countries. Lengthy approval processes result in significant loss of effective patent terms for biopharmaceutical products. China should

³ PhRMA, Special 301 Submission 2019, "The People's Republic of China"

continue to align its regulatory framework with international standards to provide companies greater regulatory consistency.

Pricing and Reimbursement

The general lack of transparency and the unpredictability in government pricing and reimbursement decisions for new drugs and devices create significant challenges and uncertainty for US and other foreign medical product companies.

Since 2017, China has issued more regular updates of its National Reimbursement Drug List (NRDL), which designates medicines covered by state-sponsored medical insurance and has significant implications for the access and affordability of new treatments for patients in China. Prior to 2017, China had only undertaken two substantive updates to the NRDL, in 2004 and 2009. In October 2018, China added 17 oncology drugs to the NRDL, including several relatively new innovative drugs from US companies. This year, the director of the National Health Security Administration (NHSA) announced plans to add more drugs to the NRDL and establish a dynamic adjustment model that would allow new drugs to be reviewed for reimbursement on a regular or rolling basis.

New additions to the NRDL and moves toward a more regular and dynamic mechanism for drug review are positive developments. However, the lack of transparency in the negotiation process for new medicines creates uncertainty around the government's pricing and reimbursement system. The NRDL negotiation process often results in significant price cuts for new medicines, and the government's centralized volume-based tendering process puts additional price pressure on innovative and generic drugs. Such practices often lead to a *de facto* preference for domestic manufacturers over foreign companies.

Negotiations with the reimbursement regulator should be timely, transparent and predictable. Evidence-based methodologies independent of economic considerations should be adopted for clinical value assessments. A key outcome of the 2016 JCCT dialogue included an affirmation that China would implement drug pricing commitments, including that drug registration review and approval would not be linked to pricing commitments and not require specific pricing information.⁴ However, the dialogues stalled, and the US lacks a forum to discuss China's progress or hold China accountable to these commitments.

Intellectual Property (IP)

China has taken steps to strengthen its IP system, including for the health sector. In 2017, China proposed a series of policies that addressed long-standing health IP concerns around the lack of Regulatory Data Protection (RDP), loss of patent term, ineffective patent enforcement and inconsistent patent examination guidelines. Though China's IP environment as a whole has seen incremental improvements, health IP reforms have not progressed. The lack of adequate health IPR protections and enforcement undermines the ability of US companies to be successful, and threatens their continued growth here in the United States.

NMPA issued draft measures on the Implementation of Drug Clinical Trial Data Protection in April 2018, proposing six and 12 years of data protection for innovative pharmaceuticals and biologics, respectively. This protection would prevent generic product manufacturers from

⁴ USTR, "[US Fact Sheet for the 27th US-China Joint Commission on Commerce and Trade](#)," November 2016, (Last visited 18/07/2019)

proceeding to clinical trials and health authorities from evaluating generic product market authorization applications during this period. Following the State Council's October 2017 proposal of RDP, this is a strong first step toward providing better protection of originator pharmaceutical's IP.⁵ However, the proposal also includes problematic location and time-based eligibility requirements that undermine the stated goals of the proposed reforms and disadvantage global companies. This includes China's definition of a "new drug" as "new to the world," essentially requiring drugs to debut in China first in order to receive data exclusivity. This "China First" approach is inconsistent with China's international commitments under the WTO, as well as its JCCT agreements dating back to 2012, when China committed to define new chemical entities in a manner consistent with international best practices.⁶

In May 2017, NMPA also took initial steps to propose a patent linkage system, which would help resolve patent disputes involving biopharmaceutical products before follow-on products are marketed. Such an early resolution system would help promote fair competition and recognize innovator's rights and investments in R&D. However, as with RDP, progress toward implementation has been disappointingly slow.

While recent draft revisions to the Patent Law extend patent term restoration for innovative pharmaceuticals due to regulatory delays, there are no provisions in the new Patent Law requiring RDP or patent linkage. Unfortunately, RDP and patent linkage also were not included in recent draft revisions to the Drug Administration Law. Both laws are expected to be finalized by the end of the year. The Patent Law may be released for another round of public consultation, so there remain opportunities for progress on these issues in the final version.

While China has taken important first steps towards recognizing innovators' rights, stronger, more transparent and efficient IP enforcement mechanisms are needed. Hopefully, coordination between NMPA and China's National Intellectual Property Administration (CNIPA) will improve IP enforcement in the health sector, as both regulators are now under SAMR.

Opportunities for Engagement

International regulatory and standards setting bodies

International forums offer valuable opportunities to enhance global policy dialogue and best practice sharing that promote greater regulatory consistency globally and provide businesses more operational certainty around the world.

Encouragingly, China has been consulting more frequently with the international pharmaceutical and biotech communities, and this engagement is increasingly reflected in China's standards setting and efforts to improve regulatory capabilities. In June 2017, China joined the International Council on Harmonization (ICH), whose mission is to make standards and regulations more consistent globally. Since China became an ICH regulatory member, NMPA has pledged to adopt international technical standards and guidelines and keep abreast of the latest regulatory scientific outcomes and advanced regulatory concepts globally. China also joined the International Medical Device Regulatory Forum (IMDRF) in 2013, and is a member of the managing committee, a move that has similarly improved Chinese understanding of

⁵ Originator pharmaceutical products is a product that is first authorized worldwide for marketing, normally as a patented product, on the basis of documentation of its efficacy, safety, and quality according to the requirements at the time of authorization.

⁶ USTR, "[Fact Sheet: 23rd US-China Joint Commission on Commerce and Trade](#)," December 19, 2012 (Last visited 22/07/2019)

international medical device regulatory norms and helped influence the direction of China's policy development.

Joint education and enforcement campaigns

Public-private cooperation and engagement between industry and various arms of US and Chinese government have also helped reduce market access barriers and improve the operating environment for US companies. For example, US Trade and Development Agency (USDТА) launched the US-China Aviation Cooperation Program (ACP) with US and Chinese governments and US industry partners in 2003 to help promote technical, policy and commercial cooperation. The ACP helped improve the safety and efficiency of China's aviation infrastructure, which in turn improved the operating environment and opened new commercial and cooperation opportunities for US firms. USTDA also regularly hosts a healthcare cooperation program to facilitate public-private partnerships focused on improving healthcare delivery through training programs in both the US and China. On the IP front, the US Patent and Trademark Office frequently engages with China's IP office to discuss policy development and enforcement issues, and share best practices in support of US rights holders. Chinese government stakeholders are often eager to learn from the experience of US government regulators and industry as they work to design a system that is safe, efficient, and enables innovative economic development.

China's regulators have also remained committed to cooperating on joint special enforcement campaigns, particularly targeting counterfeited products. The manufacture and distribution of counterfeit medicines continues to be a serious challenge in China, both to public health safety as well as US companies. China's Public Security Bureau works with US companies to learn best-practices and technical standards to strengthen their ability to crack down on drug counterfeiting and improve public trust in the industry.

Bilateral cooperation is essential to the US Food and Drug Administration (FDA) mission of strengthening the safety, quality, and effectiveness of food and medical products produced in China for export to the United States. In 2008, the FDA opened its China Office with posts in Beijing, Shanghai and Guangzhou. From this platform, FDA specialists, technical experts in medicines and medical devices, and inspectors, worked with Chinese authorities to strengthen the capacity of Chinese regulatory bodies, increase FDA inspections and help the Chinese industry understand FDA standards and expectations. This work is essential to the health and safety of US consumers, and to fostering a regulatory environment aligned to US standards.

We encourage the US government to strengthen support for FDA's overseas engagement, and to continue to pursue mutually beneficial engagement with Chinese government bodies across industry sectors. Sharing US experience and best practices for developing and implementing policies will encourage China to foster a regulatory environment that is favorable for US companies.

Regular, industry-specific bilateral engagement

American companies value the high-level engagement that bi-lateral meetings like the US-China Joint Commission on Commerce and Trade (JCCT) provide. Established in 1983, the JCCT was a mechanism for consistent, year-round engagement between US and Chinese government leaders, and was one of the principle vehicles for addressing specific commercial issues in the bilateral trade relationship. The JCCT medical device and pharmaceutical working group was particularly successful. Launched over a decade ago, the Med-Pharm working group was one of the longest standing JCCT subgroups. It also was the only working group to include industry

representatives in the negotiations – a reflection of the highly complicated, technical issues in the sector.

In 2014, I served as the US Medical Device Working Group Co-Chair. Since then, China has made progress on several of the outcomes we reached that year, including efforts to reduce the drug lag and accelerate the medical device and pharmaceutical regulatory review and approval system, as well as accelerating the adjustment of medical device clinical trial exemption catalogues. US industry representatives participating in the 2014 discussions also shared best practices, including the development and implementation of America's Unique Device Identification system, and China has since made progress in developing its own device and drug traceability system. That system has been developed with reference to international standards and has incorporated industry feedback received during public consultation periods.

Real structural change takes time and requires precise negotiations. Critical to the progress achieved during the JCCT era were the release of Joint Fact Sheets and agreements to continue the dialogue the following year. The Joint Fact Sheets outlined specific outcomes by industry sector and cross-cutting issues. They also helped reduce misunderstandings or misinterpretations as to what was agreed. In 2014, agreeing to further dialogue was also specifically included in the Med-Pharm outcomes: "China and the United States agree to engage in enhanced dialogue with expert and high-level officials of relevant Chinese and US agencies in 2015 to promote efficient pharmaceutical and medical device regulation and market access."⁷ This joint commitment to future rounds of dialogue and engagement helped to create accountability, and allowed us to track China's progress, however slow, toward implementing the prior years' commitments.

Most importantly, the JCCT platform enabled us as negotiators to build trust with our Chinese counterparts. Trust is crucial to finding mutually beneficial solutions across industry sectors and issues. Regular dialogue offered important opportunities to build an understanding of each other's policymaking considerations and processes. With more nuanced mutual understanding, we were able to develop mutually agreeable policy proposals and implementation timelines, and ultimately achieve more sustainable results.

USCBC Recommendations

China is and will remain an important market for US health sector companies. While there are challenges that impact the ability of US health companies to equally compete in the China market, China's general direction of reform is pointing in the right direction. China has made improvements in accelerating time to market for innovative drugs and devices, and has proposed policies that would more adequately recognize innovators rights. However, much needs to be done to enhance transparency and enforcement, particularly in pricing and procurement and in protecting IP rights. Holding China accountable to WTO commitments would be a good start.

The long-term growth and global leadership of innovative US life sciences companies will depend on our ability to effectively address the issues US companies face in China. However, the issues of the health sector are highly technical, nuanced and often unique to individual companies. It is essential that these issues are systematically addressed through targeted policy discussions between our two governments, and regular government consultation with

⁷ USTR, "[US-China Joint Fact Sheet on the 25th US-China Joint Commission on Commerce and Trade](#)," December 2014, (last accessed 07/22/2019)

industry and technical experts. Re-launching a platform like the JCCT to facilitate regular dialogue on industry specific topics is necessary to address the specific commercial issues of US health companies. Strengthening congressional support for the US FDA's overseas efforts to improve Chinese regulatory standards and product quality and safety is also critical. Cooperative initiatives such as these would also help produce mutually beneficial results for the broader US-China relationship.

The opportunity for public-private engagement provided by organizations such as the US Trade and Development Agency is also invaluable as a mechanism to help build and inform Chinese capacities around US norms and practices. Chinese government stakeholders are more willing to engage in this process when the platform has the explicit support of the US government. We encourage US policy makers not to overlook such platforms, and to strongly support the engagement initiatives of various government agencies.

Finally, it is important that the growth and development of the US health and life sciences industry is not unintentionally restricted by overly broad policies. As the Department of Commerce Bureau of Industry and Security considers new export control measures, Congress should ensure that "emerging and foundational technologies" are defined as narrowly as possible so as not to hamper continued US job growth and collaboration in the sector.

The US-China bilateral commercial relationship is at a critical juncture. Trust is at an all-time low. USCBC encourages the US government to leverage all available tools to pursue enhanced engagement and cooperation with China to help build trust across the relationship.

PANEL III QUESTION AND ANSWER

COMMISSIONER WESSEL: Thank you. Thank all of you for your timeliness of your testimony. Commissioner Cleveland?

VICE CHAIRMAN CLEVELAND: I just have one question to start. Ms. Eban, you noted that 80 percent of the data from CROs was estimated to be fraudulent. And we heard this morning that American companies are increasing relying on the CROs. Can any of you speak to the regulatory process? What confidence can we have in that system? Where did the data come from that you mentioned in terms of 80 percent fraud? Because that's troubling. We've talked a lot about the ingredients in pills. But if clinical trials are fraudulent, that raises a new level of concern.

MS. EBAN: In my investigation, I found that there is extensive fraud in CROs. And in fact, the major fraud at an Indian company called Ranbaxy that I followed, was first triggered by a finding of fraud at a CRO. But generally overseas, you know, we are relying for drug approvals on the data that these CROs are providing. And of course it is the drug companies themselves that are paying the CROs.

And it is a very sort of very frequent thing to have a back channel agreement to make the data work out okay.

So my finding is that there is endemic fraud. The FDA is not up to the task necessarily of detecting it and inspecting it. And even more troubling, it's the FDA's sort of practice that for almost all overseas inspections, it announces its inspections in advance. So it gives companies six to eight weeks of advanced notice that it's coming, which lets the companies, whether they're CROs or whether they're drug companies, to stage manage these inspections.

The companies are making travel arrangements for the FDA. They're taking FDA investigators out to dinners. And often it's just one FDA investigator with a handful of days to inspect these firms. So I think that there's a tremendous amount of fraud that we are not detecting in our drug supply from overseas is based on the data that's getting produced in that manner.

VICE CHAIRMAN CLEVELAND: Dr. Huang, you talked about CROs in your testimony.

DR. HUANG: Yes, yes. Sorry, thank you. I think here we have the CROs certainly about that as in one of the two forms of the pharmaceutical -- the outsourcing services actually is booming in China. And as I pointed out in the written statement, China's -- there are like more than 1,100 CROs around the globe and nearly 30 percent based in China.

We have actually the largest -- it's one of the largest, the WuXi AppTec is based in China. They claim more chemists than any CROs in the world. Ten percent of the world's CRO market, so it is very large. And certainly I agree that there's some endemic problems in terms of oversight and quality of the clinical trials, you know, for example.

But in the meantime, I think it is also important to point it out that China, over the past two years, has indeed made efforts trying to improve the quality of developing the manufacturing of the drugs. One of the important measures launched by the former CFDA is this -- they call it the consistency requirements. You know, they want to basically -- that is down through these efforts to consolidate, the Chinese, like around 3,000 pharmaceutical firms, you know, so they want to build some big companies, you know, using these measures. Trying to -- the requirements on the efficacy and safety of the generic drugs.

They're trying to weed out at least half of these 3,000 small pharmaceutical

firms. So they indeed, they realize this is a problem. And they making -- seem to be making efforts in that respect.

VICE CHAIRMAN CLEVELAND: If there's another round, I'll come back.

COMMISSIONER WESSEL: Thank you, all. I'm struck somewhat by the discussion today and on this panel. And Mr. Allen, understanding all your points about engagement, et cetera and I appreciate that. But the core issue we're talking about here is the safety of the products we're importing. That's not a question of fair or unfair. It's a question of life or death. And I don't mean that in any -- to besmirch you in any way.

I don't understand why our desire to have a regulatory system in China, our desire to potentially block imports of APIs or anything else, if they can't be validated as safe should be viewed as an unfair approach by China. And I'm not saying you said that. But that's sort of what I'm feeling. That you know, if we're asking them to be up to world class standards -- we're not doing that for a protectionist issue. We're doing that for health and safety for our people. Protecting their health and safety, yes. But not protecting market share or businesses or et cetera. Can you help me in terms of how the Chinese view this?

MR. ALLEN: Sure.

COMMISSIONER WESSEL: Do they view us as being unfair?

MR. ALLEN: Thank you, commissioner. So, my approach to this subject for the last 25 years has been as a process of trying to promote exports. And one of the key factors there has been the U.S. FDA trying to increase standards across the board.

From 25 years ago, they started out with good manufacturing practices, and then good clinical practices. And they've really done a yeoman's work to try and increase standards across the board. And I think that's -- and that process benefits U.S. consumers, obviously, as well as Chinese consumers.

There has been a virtuous cycle of consultation between the FDA, the Department of Commerce, and USTR for many, many years so as to try and improve standards for all, up to U.S. standards, or global standards. The higher Chinese standards are, the better it is for American companies and American exporters.

So there is a commonality of interest here with Chinese regulators who wish to advocate for and to ensure the safety for Chinese consumers, along with us.

I would also note that because of the doubts of Chinese drug and consumer medical device products, therefore, foreign -- and particularly American -- companies have a very high reputation for quality, and thus, our market there is very strong, and has been strong for a long time.

So, my -- I would posit with you that there has been a virtuous cycle over many years. That cycle has, at least temporarily, stopped.

I would argue that it is in our interest to renew that cycle and to engage in -- with the Chinese regulators and American companies to address many of -- or some of the failings within Chinese manufacturing and the Chinese regulatory space.

The Chinese regulators face terrible problems in trying to regulate their own country. And the FDA has helped them to do that, benefitting not only them, but benefitting all of us. Thank you.

COMMISSIONER WESSEL: I -- I'm sorry. Go ahead, please.

DR. HUANG: Just a quick follow-up of Mr. Allen's comments. You know, that the Chinese -- the drug safety issue is indeed a big problem.

You have probably heard all those scandals, the vaccine scandals. Over the past year,

there was a couple of them.

But in the meantime, it also provides opportunities for the U.S. companies to break into the Chinese market.

In fact, we saw these additional pressures for opening the Chinese pharmaceutical market build up in the summer of 2018.

Right after this, they just -- when this -- one of the Chinese largest vaccine makers were found to have sold -- you know, there's the substandard doses of vaccines in, you know, diphtheria, tetanus, and whooping cough.

And so, they did a survey of more than 300,000 parents, and they found that 79 percent said that before the scandal, they would have given their children a Chinese-made vaccine.

And that today still account for 95 percent of the Chinese market.

But the -- after that incident, they say it's only 60 percent still say -- only actually 40 percent still say they want U.S.-Chinese medicine after this scandal.

In fact, 60 percent say they were considering having their children inoculated outside mainland China.

MS. EBAN: May I?

COMMISSIONER WESSEL: Ms. Eban, yes?

MS. EBAN: In the course of my reporting, I came across example after example of the FDA essentially pulling its punches with Chinese plants, detecting fraud, detecting substandard - - potentially substandard products, and choosing not to sanction those plants.

And what seemed clear to me is that diplomatic concerns are interfering with public health and safety. You know, you -- we don't have this problem in the U.S.

Inspectors show up unannounced, they stay as long as they need to, they find what they find. And what's going on in China is very, very different.

So, I would basically say if we actually choose to get tough on China, then the way to do it is to say, look, you want to sell your drugs into our market. You're going to give our investigators -- our FDA investigators visas, they're going to come over, they're going to inspect unannounced or on short notice, and that's how it's going to go if you want to sell into our market.

COMMISSIONER WESSEL: I understand. Just as a side note, it's sometimes hard for people here to understand when they see the activities being taken against Chinese Uighurs, more than 50,000 internet police, et cetera, et cetera, that if China wanted to regulate and ensure the efficacy and safety of its products, it could do it. It just chooses not to. Commissioner Fiedler?

COMMISSIONER FIEDLER: So, let me -- I don't want to beat a dead horse on unannounced inspections, but in the context of engagement, if a nation -- or if the people you are negotiating with and engaging with do not accept the premise of unannounced inspections, why would you waste your breathe after that on an issue like this?

So there's a -- I would agree to engage them if they agreed to do unannounced inspections, and I would engage them after they proved that I could do unannounced inspections.

Does anybody know any regulatory system anywhere in the world that is robust, that doesn't include unannounced inspections? Now -- is there one? Okay. Now B-

MS. EBAN: No, there isn't.

COMMISSIONER FIEDLER: How many of you therefore are comfortable with the fact that 80 percent of the APIs produced in the world -- or that are coming into the United States, in our drugs, are produced by those folks?

Are you comfortable, personally?

MS. EBAN: I am definitely not comfortable with that, which my book reflects.

I will just say that the FDA did do a pilot program in India of unannounced inspections from beginning 2014 through to mid-2015.

And as a result of those unannounced inspections that they did, the rate of official action indicated findings, which is the most severe finding, increased by almost 60 percent.

Now, the FDA inexplicably -- and I never got an explanation from them -- discontinued that program and went back to pre-announced inspections in India.

However, there is no -- as I understand it, there is no law on the books that is preventing them from doing this.

COMMISSIONER FIEDLER: Yeah, I'm -- thank you.

Are you comfortable with the -- with Chinese supplying all the APIs, basically, in the world, without unannounced inspections? Does that make anybody comfortable?

DR. HUANG: I think -- well, nobody -- no Americans would feel comfortable with that.

COMMISSIONER FIEDLER: I don't think it's an American issue.

(Simultaneous speaking.)

DR. HUANG: -- of the Chinese APIs, especially considering that there's quality, efficacy problems in the country.

But what I'm kind of, slightly different opinion here, is that we don't want to securitize that dependence on Chinese drugs, in that we don't want to make that a national security problem for the following reasons.

First, the U.S. is relying on China for those drugs because of the shifting global pharmaceutical supply chain.

And also because of the 2000 U.S.-China Fair Trade Agreement that enabled the U.S.-based multinational pharmaceutical firms to buy ingredients for critical drugs, you know, made in the United States.

And also, we -- because of China, their lack of competitiveness of their pharmaceutical industry because they have to focus on those lower end APIs or generic drugs, you know?

So, it does not reflect the conscious, clear strategy, like China against the United States.

And second, the technologies used to make those drugs are not monopolized, in China, certainly. Right? Neither is China the only country that can make those drugs, you know?

And China become the leading API producer and exporter because the cost used to make it is low.

So, we do have the alternative sources available, it's just that they are more expensive.

COMMISSIONER FIEDLER: So, perhaps the President should throw tariffs on --

(Simultaneous speaking.)

DR. HUANG: Consider other options. Explore other options.

COMMISSIONER FIEDLER: -- to drive the production somewhere else where they do unannounced visits.

DR. HUANG: Right. The --

COMMISSIONER FIEDLER: But let me just say something. I mean, national security is widely defined. And let's understand something. The drug ingestion security of the American people is a national security problem.

Whether it's a traditional national security problem or not, it is a national security problem.

And I think we view that this way -- at least I do. If we're talking unsafe, this -- it's a

problem.

It's a serious problem. I'm done for now. For now. I mean -- but I mean, look, you didn't answer my question about -- some of you did -- how comfortable you are, okay, with us being so dependent for APIs on a country that is not allowing the most fundamental premise of inspection to exist.

That -- I'm not addressing the question whether 16 inspectors are sufficient. I know they're not. And I'm not addressing the question of whether we spend \$100 billion.

I am questioning the fundamental premise of the inspection system. Yeah.

MS. EBAN: I'm not even certain that China has said no to unannounced inspections. It's the U.S. FDA which has said no to U.S. -- to unannounced inspections.

And in email after email that I obtained in the course of my reporting, they are concerned about diplomatic incidents, and that's why they don't want to do it, in part.

COMMISSIONER FIEDLER: Just to -- well, there's a long history of various other subjects where the U.S. has sought to inspect, that unannounced doesn't happen, whether it be forced labor imports that take two years to get an inspection, not six to eight weeks.

All kinds of other forms. It's a sovereignty issue they expressed sometimes, it's a this, that, and the other thing.

The fact of the matter, it doesn't matter what they explain it as. Yeah.

DR. HUANG: Well, I think in terms of unannounced visit, right, the Chinese -- the FDA, right?

Now it's no longer called the Chinese FDA, but this health regulation -- they do now actually use more -- rely more and more frequently on those unannounced visits -- you know, inspections.

You know, actually the Changsheng -- the vaccine scandal was uncovered indeed by that unannounced visit, you know.

So we should encourage China to use more of those, what they call flight visits, flight inspections. More and more.

And potentially we could also have our FDA office in China to join those inspections, you know?

So, we could use our leverage, right, in the trade negotiations with China, to actually ask maybe China to allow the U.S. FDA to join those inspections.

In the meantime, I also want to point out in terms of whether we feel uncomfortable on that, is that we talk about we are relying on China, right, for those APIs, generic drugs.

But in the meantime, let's look at the other side of the coin. China also is relying on us, too, for those most effective innovative drugs.

This is especially important if you -- it's not just about the market of 11 billion market in terms of Chinese exports, medicine -- medical and pharmaceutical products, right?

It is also about legitimacy because the government legitimacy is performance-based. It hinges upon delivery, good health to the people.

Here, it's also about delivering effective medicine to the people that currently can only be provided by multinational pharmas, including the U.S. pharmaceuticals.

COMMISSIONER WESSEL: Commissioner Talent?

COMMISSIONER TALENT: Dr. Huang, you talked about -- or Huang, you talked about consolidation, and I've had other witnesses in other panels talk about consolidation as well -- that the Chinese government wants to consolidate.

What -- nobody went into any detail. So, what have they done? What numbers are

available? Have they announced any concrete plans?

Can you fill that in a little bit? I mean, what are they going to do in -- or have they done to consolidate companies in pharmaceuticals?

DR. HUANG: Well, thank you. That -- if you look at the Chinese -- the domestic -- the pharmaceutical industry, right, that is the -- the government started to note that industry since the 1980s, you know?

So, but that is very fragmented, you know, despite the introduction of the GMPs, the good manufacturing, you know, practices, you know, that -- it's very fragmented.

It's also, in terms of competitiveness, is not that competitive.

You know, they have -- even today, you know, with all those government measures to consolidate those, there's still around like, 3,000, you know, pharmaceutical firms.

Many are small. If you -- there are just ten important players, right, in the Chinese pharmaceutical market, that only account for ten percent of the entire market, you know?

So, that shows how fragmented the Chinese market is.

So the government want to, you know, consolidate those pharmaceutical industry in order to build some, you know, like the big pharmas, the U.S. type of big pharmas -- you know, they -- that can be more competitive internationally.

But in the meantime, they want also to improve the quality, you know, the efficacy, the safety of the Chinese drugs, you know?

So, they introduced the -- those -- this new regulation, the requirements on the quality of their generic drugs.

For example, you know, so that if you have -- you will produce a generic drug, you know, the same types, you know, that you have to achieve the highest standards of that -- the -- that same generic drug. And so that way, they want to weed out at least half of these -- the pharmaceutical firms.

COMMISSIONER TALENT: Okay. So, but what I'm getting at is, you're saying since to -- and anybody can answer this question if you know. I'm not -- not a trick question.

I'm just trying to find out what they're actually doing to consolidate.

Since 2016, the government has also made efforts to consolidate its pharmaceutical industry. Somebody in the previous panel testified to the same thing.

Normally, you know, it's -- you read a statement like that in a written statement, then they follow up and say, okay, they did this and this and this.

Are there any concrete plans that they have to consolidate? I mean, are they subsidizing acquisitions, or what?

Or are you saying that their efforts to impose higher safety standards, that's their consolidation?

Okay, so they're hoping that by imposing higher safety standards, some of these firms will have to drop out?

DR. HUANG: They also encourage the acquisitions and mergers.

You know, we have seen some of the biggest pharmaceutical firms in China actually significantly increased their merger and acquisitions activities internationally.

COMMISSIONER TALENT: So how is the government encouraging that, though? Are they -- are there special funds?

I mean, they know how to encourage something when they want to encourage it, right? I mean, we've seen Made in China 2025.

There really are no plans, then -- or concrete policies specifically directed at

consolidating the pharmaceutical industry? I mean, are there any? I mean, I B-

DR. HUANG: To my knowledge, I haven't seen any, like, particular, specific government, like industry or policy type of measures.

COMMISSIONER TALENT: Okay. So, they'd like it to be consolidated, but they're not really doing anything to consolidate, yes?

MR. SHOBERT: In addition to what Professor Huang has mentioned, it's also about how they're reforming the tendering process for the hospitals.

That's a significant forcing function, in addition to quality standards and inspection.

I think it's an important contextual factor that we not lose sight of, that the NMPA now -- formerly the SFDA -- is a new ministry, and that this type of technocratic capacity that they possess should not be overstated.

But they view the tendering process for the public hospitals as another mechanism by which they can start to winnow the list of pharmaceutical companies that persist in the supply chain, because if you're not part of the procurement and the tendering, then you're not going to be able to sustain yourself as an -B

(Simultaneous speaking.)

COMMISSIONER TALENT: So they're going to do it through the control of demand?

MR. SHOBERT: So, I think --

COMMISSIONER TALENT: Primarily through the hospitals?

MR. SHOBERT: Yes. I think you have two vectors. You have --

COMMISSIONER TALENT: Is that in your statement? I'm trying -- did you --

MR. SHOBERT: I don't know that it was.

COMMISSIONER TALENT: I don't think --

MR. SHOBERT: Yeah. It's just got two levers, if you think about it.

One is the continuing to empower the NMPA to have additional inspection capacity across the country, and the second is how they're utilizing the tendering process.

COMMISSIONER TALENT: Okay. Thank you.

If you all think of something else, we write these reports, and we're going to have a section on, you know, Chinese -- the rest of it. And we don't want to say anything that we can't document.

So I don't want to say that they're trying to consolidate if they're really not trying to consolidate, if it's just an aspirational goal. Thank you.

COMMISSIONER WESSEL: Commissioner Kamphausen?

COMMISSIONER KAMPHAUSEN: Thank you very much, and thanks to the panel. Three quick points.

First, for Ms. Eban, as I read your testimony and then listened to you, I was struck with your emphasis on the role of the -- of our FDA.

And I wanted to provide you a chance to comment. I mean, the impression one gets is that our FDA is the problem.

And I would offer for your comment, maybe it's the second order problem.

The first order problem is Chinese in origin, and while we need to do a better job, I'm sort of with Commissioner Fiedler that there are limits to what the FDA can accomplish.

So, any points of clarification you'd like to make would be good.

MS. EBAN: You know, well first of all, we have this model where we're sourcing our pharmaceuticals from overseas. So, you know, that's the sort of number one issue or problem.

We don't necessarily have -- I mean, the question here that's being debated is what sort of

levers of control do we have to get a different result from China?

But, you know, the U.S. FDA is in charge of protecting U.S. consumers from substandard drug products.

So, you know, as an investigative journalist, that's where I focus my attention, but there's no question that, you know, we're facing a tsunami of compromised drug products in China.

I mean, it's just proven over and over again, and we have a current, ongoing quality crisis right now with this recall of generic blood pressure medicine that millions of Americans got, and it came from China. So, you know --

COMMISSIONER KAMPHAUSEN: Good, thank you.

MS. EBAN: -- I focused on U.S. FDA.

COMMISSIONER KAMPHAUSEN: Thank you.

MS. EBAN: Yeah.

COMMISSIONER KAMPHAUSEN: Ambassador Allen, Dr. Huang said we ought not securitize the trade of either APIs or high-end pharmaceuticals.

Are you aware of any impediments, structural or otherwise, to U.S. export of the very high-end pharmaceuticals to China?

MR. ALLEN: Yeah, thank you. In my testimony, I mentioned a couple of things.

Incomplete intellectual property right enforcement, and the implementation of the intellectual property right regime -- the patent regime, specifically.

There are, of course, pricing issues. Dr. Huang mentioned provincial pricing mechanisms and an urge to tamp down pricing to keep healthcare expenditures relatively low.

And then third, the approval process for new drugs, which can be slow, leading to long delays for American patented products.

And occasionally, a Chinese generic coming up very quickly, soon after the patented product is approved, giving the Chinese manufacturer some advantages.

And so, American pharmaceutical manufacturers have a good number of issues in China.

Nonetheless, it is either their second -- first, second, or third largest market in the world, and it's a rapidly growing market for virtually all of them. And therefore, an important market for American jobs and growth. Thank you.

COMMISSIONER KAMPHAUSEN: And I guess to complete the thought, then, with Professor Huang, the impediments are Chinese side, they're not U.S. policy impediments.

Then, Mr. Shobert, just a last question on data. You introduce it -- there's kind of two levels I think that you addressed of that.

The first is sort of existential, how are we going to think about data in the future. And then secondly, you maybe somewhat indirectly suggest we ought to hedge our bets with regard to how China -- how we share data with China, and how they use our data.

And I was hoping you might elaborate on that a bit.

MR. SHOBERT: Yeah, and maybe with just a little bit more time to explain why this issue matters.

As we think about the economy -- the global economy over the next 100 years, one of the most important areas that we get right in the United States and globally is precision medicine.

And precision medicine is predicated on the development of these large data sets, these curated data sets.

And to the extent there continue to be asymmetries in what American researchers can do in China, and Chinese researchers can do here. That's one of the more basic learnings, that we should be pulling out of other high technology sectors that have struggled with asymmetries

relative to what they can do in China versus what a Chinese competitor can do here.

And so again, I don't think we have to approach that in a particularly militaristic manner.

I think it's -- it needs to be acknowledged as one of the ways in which trade protocols that were designed to anticipate an era of cast metal and aluminum sheeting don't necessarily do well in an era of big data, cloud computing, artificial intelligence.

And so I think this needs some additional attention in the space that we're talking about in particular. It's relevant in not just precision medicine, but in things like machine vision, and how that'll be applied in oncology use cases.

So, it's hard to overstate how important it is that we get this issue right very quickly.

COMMISSIONER WESSEL: Thank you. Commissioner Bartholomew?

CHAIRMAN BARTHOLOMEW: Thanks very much, and thanks to our witnesses for a really interesting panel.

I have so many questions. I'm not going to be able to ask all of them, at least in this round.

But very quickly, first, Ms. Eban, do the FDA inspectors that are on the ground have Chinese language skills?

MS. EBAN: So, you've touched on a huge issue, and in fact, because it was only seven minutes, I couldn't get into it, I do in my testimony.

Mostly they don't. And often, the translators are provided by the companies that they're inspecting, and they're company salesmen. And I was even able to document instances where there are just wild deceptions because of that.

So, sometimes Chinese companies will pool resources and pay for one show factory that looks like, you know, out of central casting, and because the FDA investigators can't even read the street signs, they're each inspecting the same facility, but they think it's for different companies.

So, I mean, it's really -- the language barrier has created an opportunity for really wild deceit.

CHAIRMAN BARTHOLOMEW: I guess for all of you, I'm really trying to -- thank you, first, but I'm trying to understand how the Chinese got to the point that they are the lowest cost producer on these things, right?

I mean, it's really rather stunning that they can produce at a lower cost than India. So, government subsidies? I mean, what is the pattern that has allowed them to be able to produce at the lowest cost?

MS. EBAN: In my reporting, I sort of traced the rise of China as the leading manufacturer of antibiotics, which was really sort of the rise of China in the pharmaceutical space.

Part of that was because of very lax environmental regulations, and these pharmaceutical plants create a lot of pollution.

But also because they had hundreds of years of expertise in fermentation with soy sauce, and there's fermentation processes in the making of antibiotics.

So that was sort of like opening the door to them as a go-to producer of very, very cheap pharmaceuticals, and it went on from there.

CHAIRMAN BARTHOLOMEW: So, Mr. Allen?

MR. ALLEN: But Chairman, I would note that you see similar patterns throughout all of the chemical industries. All from petrochemical to fine chemical, to dyes for textiles.

China would probably be the low cost producer around the world, but I think nothing

nefarious there.

Rather, it has to do with the cost of capital being relatively low, and very large economies of scale, as well as an entrepreneurial culture, universities that are just pouring out engineers.

China, I -- as I understand will graduate 1.8 million engineers this year, and years into the future.

So it's not unnatural that China would have a very large industry here, nor that they would be the low cost producer.

CHAIRMAN BARTHOLOMEW: Well, again, I'll point to India as an example. They have all of the factors that you have just mentioned.

But also, I mean, biochemical -- biomaterials, of course, are part of Made in China 2025, which means that the Chinese government is focused on building this industry.

That, I guess, is some of what I'm trying to understand. In addition to lax environmental regulations, are there subsidies?

Are there -- you know, what advantages are they providing to their companies that have allowed them to do it?

It's not just the low cost of labor. But you know, what other advantages are they doing to build this industry?

MR. SHOBERT: Massive investments, which I think we've covered -- or I've covered in previous testimony to the commission.

There's just a massive amount of state-led investment in the creation of new biotech industrial parks. Early on, characterized by digging holes and pouring concrete to create infrastructure and jobs, and then tax monies.

But now, it's starting to actually become the home to where a lot of novel molecules are being developed as a result of people returning back to China because they view this as an opportunity for them to grow professionally and personally.

So it's -- there's no way to talk about this without talking about the massive amount of state investment that's gone into the --

CHAIRMAN BARTHOLOMEW: Right. Which means, of course, that what we are seeing in this industry is that what we have seen in industry after industry after industry, right?

I mean, China is moving up the value added chain, but you mentioned cast metals, right?

It's -- we have seen this process all along, and we have seen what it does to our economy.

In this case, it is not just our economy that's being affected, as Fiedler -- Commissioner Fiedler said.

I mean, it is also -- this is really a national security issue. It's the health and well-being of all of us and all of our population.

I have questions for a second round, if we have a chance to get to them. Thank you.

COMMISSIONER WESSEL: Commissioner Wortzel?

COMMISSIONER WORTZEL: One of the interesting things that came out of a short visit to China at the end of May, and some meetings here in the U.S. with the American Chamber of Commerce, is that corporations, as a result of the tariffs, are realizing that they are entirely too entangled in China and supply chains. And they're disentangling, they're decoupling. I personally think that's a great thing.

Now, it creates some problems over a short period of time. And so, I want to pose a question -- and I don't know that there's a right answer, but I think there's two ways that that decoupling to protect American health, security, and the economy could be imposed by the President.

One are really high tariffs on any drug that comes in that uses Chinese APIs.

The second would be to invoke the International Emergency Economic Powers Act, so that the President has the authority to declare an unusual and extraordinary threat to the national security, foreign policy, or economy of the United States that originates outside the United States. So the President has the authority to say, we're done, we're decoupling on this issue.

Give me your -- you all are involved more or less in looking at the industrial side. What would that do to companies? How long do you think it would take? If you looked three months from the day that order was given, six months, and nine months, where would they go, and how would they reinstitute supply chains?

MS. EBAN: I think one of the challenges for companies -- so if you take drug companies that are reliant on API, and their -- the API manufacturers that they're buying from are all listed in their drug master files with the FDA.

And so, if you have to get a change of supplier approved by the FDA, you can't just change where you're procuring.

It has to be approved by the FDA, and so B-

COMMISSIONER WORTZEL: Well, that's a regulation. If congress worked with the executive, we could have a new law.

CHAIRMAN BARTHOLOMEW: Any of us would want the unregulated drugs to be -B

MS. EBAN: Right, but wouldn't you want the FDA to be inspecting those API providers?

Because that is exactly what happened in the heparin crisis -- is that a provider of API was not inspected by the FDA because of a glitch, and over 81 Americans were killed by adulterated heparin.

MR. SHOBERT: I'm struck in the question that we're wrestling with how to put the toothpaste back in the tube, which is maybe an imperfect metaphor, but in the same space as, drugs and pharmaceuticals.

I think that we have to ask the right question to get the right answer.

And I think the right question is perhaps broader than this hearing is designed for, which is, did we properly gate how certain industries were stood up in China?

And to some extent, shame on us for not paying more attention to something as critical as was referred to earlier as a national security issue.

And assuming, as has been the political orthodoxy for a long time, that industries would somehow self-regulate themselves.

There is a role here for a strong FDA, and especially a -- perhaps a different version of the FDA would've been required to enforce FDA principles across to another country's border.

These are nontrivial matters, and so perhaps that suggests to us today that we have a very uncomfortable question, which you just asked, which is what do we do now?

My answer to your question is that it would be a really good time to be in the Indian pharmaceutical business, because more or less what would happen is a bunch of precursor plants would get stood up in India, probably in about 30 days.

And I think the point that's made about other corners that would potentially get cut to bring these new supply chains online, and then in turn supply Americans -- I don't think we should have any reason to believe those wouldn't lead to even more serious patient safety issues.

CHAIRMAN BARTHOLOMEW: All right. Who's next?

COMMISSIONER WESSEL: Commissioner Talent?

PARTICIPANT: So we're on round two.

PARTICIPANT: Round two.

COMMISSIONER TALENT: Okay. So, I'm trying -- what I'm trying to do is to determine what we can authoritatively -- not that we're the final authority as a commission, but what we can say in this report with a high confidence level it's true.

So, Ms. Eban, in her testimony said -- she wrote a book, and I think this sums up your conclusion. It's the second paragraph of your testimony.

You say your investigation reveals endemic fraud in dire conditions in an industry where companies routinely falsify data and circumvent principles of safe manufacturing. Okay. That's your conclusion.

So, the rest of you on the panel, would you agree or disagree with that, or would you say it may be true, but I don't know?

I'd like to see how much agreement we have on that basic factual conclusion.

COMMISSIONER FIEDLER: I tried using the word comfortable.

COMMISSIONER TALENT: Well, I'm going to -- yes, no, or I don't know?

MR. SHOBERT: I would say I agree with the characterization of the problem.

I agree that it needs the attention of U.S. regulators, and I agree with every recommendation that was made initial.

COMMISSIONER TALENT: Okay.

MR. SHOBERT: I think it's all right.

COMMISSIONER TALENT: Nobody has to answer, but I mean, either yes, no, or I don't know?

MR. ALLEN: I'm not qualified to say.

COMMISSIONER TALENT: Yeah.

DR. HUANG: From my examination of the Chinese -- their history of regulating its drug and food products, I believe that is indeed a systematic issue.

And there's actual reasons for reasons beyond the regulatory control. And I mean, it's just political economic reasons behind that.

We haven't elaborated, but in the meantime, we also need to recognize that not just we are caring about this safety issue.

It's -- actually the Chinese government has also reasons to be concerned about the safety of their products, as well.

COMMISSIONER TALENT: Right. And I think you made that point in your -- I think everybody here would agree with that, that they do care about their own reputation amongst the Chinese people.

Either one of you all, or a different witness said this is a big motivator for them because the Chinese people expect the government to deliver on this.

DR. HUANG: Yeah.

COMMISSIONER TALENT: Right? So that's motivating them.

And I'll just say -- and then I'm done with my second round -- I don't see in particular why anybody should be shocked that what Ms. Eban found is true.

I mean, we have a system where there are tremendous incentives not to worry about safety. Right?

And it generates externalities or costs that are never brought home to the people generating them. Right?

These companies never pay any price for this. So, yes, of course, under those -- and they don't have a liability system.

They don't even have a common law liability system. Right?

I mean, here, even if there were no FDA, if people were doing this, eventually Commissioner Goodwin or some other really good litigator would get hold of them and they'd pay a price.

So, I don't -- I'm -- I don't see why anybody should be uncomfortable concluding what is obviously going to happen when you set the system up this way.

Please, go ahead. I'm testifying now. You.

MS. EBAN: Yeah, I just want to add from, you know, my testimony that I've submitted that the FDA investigators really believe that these companies have figured out how to game our system down to the issue of drug shortages, because they know that if -- even if they're caught committing fraud, they know that if they're making drugs in short supply, it's going to function essentially like a get out of jail free card, and the FDA is not going to restrict those drugs, and they can continue sort of, you know, with an income flow there.

So, they specifically feel that they are choosing to make drugs in short supply to protect their bottom lines.

COMMISSIONER TALENT: And -- but Mr. Shobert put his finger on what I think is an essential aspect of that problem, which is how big are the barriers to entry? Right?

Because if a market opens up, how quickly could somebody else set up shop in compliance?

And you implied that in India, or a low cost country like that, this could be done quickly.

MR. SHOBERT: On the API front, for sure. I mean, on the API front, that supply chain at one point persisted in India.

And I think it was two or three years ago, there was this white paper circulated in India that more or less pointed out that, hey, did you know all of the Indian pharmaceutical industry is more or less captive to APIs coming from China?

And that was a nontrivial moment of truth for the Indian pharmaceutical sector.

COMMISSIONER TALENT: Thank you.

COMMISSIONER WESSEL: I'm going to raise a politically sensitive topic without a -- without trying to be politically sensitive. Let me ask you this.

CHAIRMAN BARTHOLOMEW: You think we're being insensitive? Is that what you're saying?

COMMISSIONER WESSEL: No. The ACA. What if we were to have a requirement that the only way an insurance company could reimburse you is if the products -- the APIs, et cetera, all came from regulated or inspected facilities?

It seems to me that the insurance companies have every interest in getting you to use generics.

Formularies, they try and move you off as quickly as they can.

And because this is where all the money is in the system, if they know that they are required to only allow their patients to buy inspected products, it seems we drive the inspection system.

Either China will do what it should be doing because it wants to continue to sell, India will, you know, build up its capacity, or we will.

I'm not trying to get into the question of, you know, where these products should come from, but rather, they should come from regulated inspected facilities.

Do any of you have a view? Ms. Eban?

MS. EBAN: I'd like to say that everything we're talking about today is the regulated

system.

Every plant that I've mentioned, everything, it's all subject to FDA regulation, so this is supposedly the regulated drug supply, which is why it is so worrying.

COMMISSIONER WESSEL: But if you were to require, you know, a greater -- you know, inspections on a regular basis, some kind of inspection protocol for those B-

MS. EBAN: They are required.

COMMISSIONER WESSEL: But it's not happening.

MS. EBAN: They are required. And under GDUFA, they are required to B-

COMMISSIONER WESSEL: GDUFA? I don't know. What B-

MS. EBAN: I'm sorry. It's the Generic Drug User Fee Act.

COMMISSIONER WESSEL: Okay.

MS. EBAN: So, under that, they are required to achieve parity. Foreign inspections are supposed to have parity with U.S. inspections.

Partly to achieve that, the U.S. FDA reduced their U.S. inspections to achieve parity.

COMMISSIONER WESSEL: So --

MS. EBAN: But, all of the plants that we're talking about are supposed to be inspected roughly every two years.

COMMISSIONER WESSEL: So, what you're describing to me is maybe a GDUFA B if I'm pronouncing it correctly?

MS. EBAN: Yeah.

COMMISSIONER WESSEL: Review by congress to make sure that flowing through the inspections are happening on a regular basis, without the diplomatic --

PARTICIPANT: Inspections being defined as unannounced.

COMMISSIONER WESSEL: Oh, no -- yes, agreed.

MS. EBAN: Right, so the -- but -- so, just to be clear, the inspections are happening, but what we're talking about is the quality of those inspections. Yes.

COMMISSIONER WESSEL: No, I -- meeting certain protocols about what a good inspection, which is unannounced on X basis, by individuals who actually speak the language, and a number of other things.

MS. EBAN: Yes.

COMMISSIONER WESSEL: So we have the existing mechanism. You're saying it's a question of improving it in some way?

MS. EBAN: Really --

(Simultaneous speaking.)

COMMISSIONER WESSEL: Is that what you're saying?

MS. EBAN: -- overhauling the FDA's foreign inspection program and making it less credulous and less honor-based, and making it rigorous, and making sure that the standards are verifiable. Yeah.

COMMISSIONER WESSEL: And do you think China would have a problem with that?

MS. EBAN: You know, I think I'm maybe not enough of a China expert to say, but they certainly want into our market, and I think that they do have a political and image problem at home about appearing to be, you know, effectively regulating things.

And some of the FDA investigators that I interviewed for my book said that they found Chinese regulators more cooperative than the Indian regulators.

COMMISSIONER WESSEL: Mr. Shobert?

MR. SHOBERT: Yeah, I would encourage the commission and its recommendation to

Congress to believe that really leaning in on this area about enforcement is something where China's domestic ambitions, in terms of securing public safety, its domestic economic development ambitions, and also its role in being part of the global supply chain all align in a very virtuous way.

I think as is in the case with many of the conversations we're having with China right now, there's probably a bit of nuance that's needed to approach this in the right way.

But I would encourage the commission to say to congress, this is something that we can be much more declarative and definitive about in terms of what we want.

COMMISSIONER WESSEL: It's hard once you injected the word nuance, but B-

MR. SHOBERT: I mean, I'm aware.

COMMISSIONER WESSEL: -- I'll stay away from that. Ms. Bartholomew?

CHAIRMAN BARTHOLOMEW: Thank you. Gosh, again, so many things. I'll just note Rosemary Gibson earlier talked about pig intestines are the new rare earth.

And we have to remember as we just hear about when the Chinese are the only producers of some things, that their ability to use those things as leverage is something we need to be concerned about.

Not my question. I have two questions.

One, Dr. Huang, you talked about the Chinese industry relying on U.S. innovation.

And I wondered there what specifically you were meaning, and then is it -- is the Chinese industry sort of monetizing the R&D that's being done here in the United States on innovation in this sector?

Either by buying it, or by stealing it, or by sending graduate students over who are replicating people's labs?

And also, the issue of hiring leading American scientists.

They're different categories of things, but how are they trying to get access to our innovations?

Because again, if this industry follows the pattern of other industries, we will be displaced even in our innovation.

DR. HUANG: Thank you for the questions. I think for now, I think the U.S. is undoubtedly the leader in the high tech -- the pharmaceutical industry.

Just look at the number of innovative original drugs, you know, that is -- that are developed, and it clearly -- I mean, the U.S. is the -- a leader in the field.

But China, you know, obviously they want to improve their competitiveness of their pharmaceutical industry.

That is why they have that -- the Made in China 2015 with -- 2025 -- I'm sorry -- which identified biomedicine as one of the top ten industries for the government to take note of. Right?

So, they clearly -- they have the ambitions to be a leader, but what approach they use -- but that's certainly right, they have various, right, approaches, right, to note, to develop this pharmaceutical industry, right?

That the -- they certainly also pay close attention to the development of the R & D in this field.

But what specific measure they use, that's out of my -- the knowledge.

And I think if you look at the -- when I say that the -- we are -- the Chinese also are relying on us, we -- in terms of the ability to develop -- deliver this effective medicines.

You -- just look at China, they have a huge NCD, called noncommunicable diseases, crisis, right?

The hypertension, right? The diabetes, cardiovascular diseases, cancer.

You know, they're -- just if we look at the cases, right, that they're just increasing significantly over the past year.

So there's a huge demand for these most effective pharmaceutical products, which can only be made by the multinational corporations, unfortunately, because the -- those most effective -- for example, anti-cancer drugs, right, the -- until very recently, right, they're only made by the big pharmas.

You know, the Chinese has produced some -- those me-too drugs in 2011, that -- like a common -- right, that is produced by the Betta Pharmaceutical firm based in Zhejiang.

But now, is the -- the new drugs now in the market -- you -- in the market, there you see, their revenue actually dropped significantly.

That is an example that shows that there's still a very huge dependence, you know, on the U.S. products, you know, and U.S. -- you know, their drug industry still very competitive.

You know, we -- so we don't want to underestimate their resilience, the capabilities, the leadership of our pharmaceutical industry when we talk about our dependence on the Chinese drugs.

CHAIRMAN BARTHOLOMEW: Thank you. Do I have time for one more? One more question? No, yes, no?

COMMISSIONER WESSEL: You have 30 seconds. Sure.

CHAIRMAN BARTHOLOMEW: I can't. Mr. Shobert, I was going to ask about the -- people's individual health information, and that's not a 30 second question or a 30 second answer.

(Simultaneous speaking.)

CHAIRMAN BARTHOLOMEW: Were you going to ask about it? All right.

(Simultaneous speaking.)

MR. SHOBERT: No, but for the record, I am married into a family of hog farmers, and they are going to be very excited to know that hogs are the new rare earths. So that's what I'm taking back.

COMMISSIONER WESSEL: Data is the new oil, as they say. Commissioner Lewis?

COMMISSIONER LEWIS: The only question I have --

COMMISSIONER LEWIS: Yes. The only question I have is how aware is the top Chinese leadership -- aware of what you've been telling us today?

MS. EBAN: My understanding is that it is, and the FDA over in China did do a series of workshops with the industry and with government officials to try to talk to them about data integrity issues, and what these sort of good manufacturing practice standards are.

I should also add that I have been made an offer for publication of my book in China, so if they aren't aware of it right now, maybe they will be.

MR. ALLEN: This is a -- if I may, this is an intensely political issue. Quality of drugs and quality of healthcare in China.

And from the premier down, there is a mandate to improve quality, and improve safety, and improve efficacy.

As recently as two months ago, the premier himself spoke about the demand of the Chinese people for quality healthcare. And also education and environment, and food.

So this is something that the Chinese leadership is intently focused on, and wishing to improve.

COMMISSIONER LEWIS: When they find out -- as you just said, with the meetings that you've been at, do they do anything to the companies that are violating what they want?

MR. ALLEN: So, there are many different types of problems that the SFDA or the Chinese regulators face.

Corruption is one. Their ability to get out to the factories is another one. The subcontracting is a third type of problem.

I would note to you, however, that at least on the corruption side, that if Chinese regulators of pharmaceuticals are found to be corrupt, it's a bullet in the head as punishment.

It's very severe, so that is indicative of the importance to which the Chinese government looks at this issue.

And that has not resolved the problems yet, but I think it is probably inaccurate to suggest that the officials responsible for safety and efficacy are not trying to address this issue.

COMMISSIONER LEWIS: Mr. Shobert, do you have anything to add to that?

MR. SHOBERT: No, just the bullet in the head metaphor is perhaps overly apt in this case. This has the highest real visibility.

The vaccine scandal I think led to the premier making a visit, and well, I mean, I -- this has the highest priority, highest attention of the Chinese government at the highest of levels.

COMMISSIONER LEWIS: Because we heard before that when Chinese companies violate, there's nothing being done about that.

MR. SHOBERT: I would not -- I think, again, the way that I would look at the enforcement of a violation is that -- and this is unfortunately a -- I think an honest statement -- the higher the visibility of the problem, the more direct the Chinese government's involvement is.

But, you know, broadly speaking, again, as I think has been consistent in everyone's testimony today, the government is trying to do what it can to crack down on these, and does kill the occasional monkey to make a lesson for the chickens.

I think I got that right.

COMMISSIONER WESSEL: Commissioner Cleveland?

VICE CHAIRMAN CLEVELAND: Mr. Shobert, this morning -- well, let me start by saying the idea that we would shift manufacturing or production from China to India causes me as much pause as leaving the system in place in China, because during my tenure at the bank, we had a series of horrific scandals that involved the bank financing the production of false testing kits that produced significant risk and harm in India.

So, I think globalizing safety standards is probably the better approach, rather than making assumptions about shifting from China to India.

Mr. Shobert, I was really interested in your discussion about PHI.

And this morning, a witness did say that there is concern about the possibility or the risk of health information being used to target specific Americans, and you note that that's sort of in the category of science fiction.

So, I think I'd be interested in your comments about the risk. What data do the Chinese currently have access to, and how are they using it?

And in particular, I'm interested in your follow on discussion about use of AI in the healthcare sector.

So, if you could sort of lay out for us what you see as the data they're after, how they may be using it, you -- what we do not have access to in a symmetrical way.

You note de-identification is the critical issue.

Do you really believe that they're going to be willing to engage in that kind of a protocol discussion?

And then, how will they use AI in this area? It's a lot of questions.

MR. SHOBERT: It's a lot of questions. Let me see what -- to -- if I can do them justice. So, maybe start with the higher order question, which is what is the objective of the data access itself?

And I would argue that it's nothing deleterious.

I would argue that it's just a hunt for data because data enriches what an artificial intelligence system can do, whether we're talking about computational biology, or machine vision for tumor morphology.

It's just -- it's a hunt for data, right?

And China, as I think this commission will know well, has a history of doing things on a really big scale, but questions about quality are always good to keep in mind.

So, China might very well -- or Tianjin might very well spend \$16,000,000,000 on AI, as they plan to do, but the question of the quality of that investment needs to be asked and answered.

So I think the objective of what the data -- what they're trying to do with the data -- I would assume it should be understood largely through economic development prism. Right?

The desire to stand up new -- a new industry in China, where they can have a sustainable competitive advantage.

Now, the question that then leads us to is what type of investments are both countries making?

And I argue -- and this is not unique to my point of view, I think it would be fair to say it's widely held -- that China's appetite for investing in this space significantly outpaces ours for lots of reasons.

And again, I think you always have to ask the question of whether or not this is an effective use of capital.

But with that having been said, China has some other inherent advantages in an era of artificial intelligence that are worth noting.

One of the predicate steps you take as you're building an artificial intelligence system is you have to not just capture the data -- which I've said they have perhaps an advantage -- but then you have to annotate the data.

The annotation and labeling is what then in turn allows you to build the system in question, or build the models in question.

And that's interesting because that's inherently a very high labor content job.

So that's another aspect to which the -- China's investment in AI has some advantages that we perhaps don't have in the United States.

So, all -- if you net that all out, it starts to draw our attention to this question that the commission I think rightfully asked, which is what are the risks and opportunities that we should be thinking about as it relates to this space versus other high technology sectors?

And I think it's important that we not be naive.

That I think we owe it to ourselves, we owe it to our multinational corporations to make sure that we're thinking about data access through a twenty first century lens.

And to maybe reduce that down to a vernacular that D.C. will be familiar with, and we need to kind of not view China in this space as a developing nation.

Their capabilities here are on par with ours, if not perhaps better.

And so, we need to set all of that legacy way of looking at China aside and view them as a competitor, I would submit in a healthy way.

In a way that should inform companies on both sides of the Pacific, and should lead to

good, new economic development opportunities, and new therapeutics.

So again, maybe let me land on the last question you asked.

I think I say in my testimony that some of the fears that I've heard -- I think at the last panel that I served on, there was a question as to whether or not China would have the ability to mine American PHI to design the perfect bioweapon.

And I want to really encourage us to see that as science fiction and not science fact.

I think the much bigger principle that this commission should pay attention to is whether or not asymmetric data access policies are leading to disadvantages to American entrepreneurs, to American researchers, and whether or not we're making the sort of systemic investments in the development of these large biobank initiatives and curated data sets that will lead to the twenty first century economy.

VICE CHAIRMAN CLEVELAND: So, how would you do that?

I mean, you talk about the fact that the barriers in place, in terms of requirements on the Chinese side, that it has to be a Chinese entity or a Chinese institution.

What are the sort of concrete steps you would recommend in terms of assuring symmetry and sharing data?

MR. SHOBERT: Yeah, so we need to align on how PHI is going to be handled. And I think that's a very simple answer. That's a really hard thing to do. Right?

There are competing standards, right? China has one view interpreted through a couple of policies.

The United States obviously leans very heavily on HIPAA and the HHS Safe Harbor Act, which more or less lays out 18 identifiers that are -- that if all -- if your PHI has all those 18 identifiers, it's considered your data, it's not been properly de-identified.

So I think we need to globally align on that standard if we really want to have PHI flow across borders.

That would likely lead to a conversation about some sort of global norm around de-identification in general.

And right now, I think it's fair to say that the United States has a much more lax view on what constitutes whether data's been de-identified, and what you can do with that data, i.e., how you can ship it outside of our borders, than other countries do.

COMMISSIONER WESSEL: Sci-fi today may not be sci-fi tomorrow.

You know, we've heard some pretty interesting things over the 18 years I guess this commission has been in business, including teleportation, quantum commute -- computing leaps, and a number of other things that just a couple of years ago were viewed as, again, sci-fi but seem to be on the horizon.

Number one, number two, I think there is a concern about some of this data as it relates certainly to DNA.

I think we have already seen targeting of dissidents of those who the Chinese leadership views as a risk to the country. The DNA for family members, a number of other things.

So, I agree in general, but I don't think we should diminish the potential threats that are out there, and we always need to be willing to discuss them to try and make sure that they are just in the future and not, you know, within our grasp.

Are there any -- Commissioner Wortzel, then Commissioner Kamphausen.

COMMISSIONER WORTZEL: I'd like to, if I could, throw -- it looks like three linked questions out to the four of you, and just see what that stimulates or what I get back.

Because I have no idea, but the first is, the European countries seem to have the same

problem we do with things coming out of China.

Second, if so, how do they approach the problem, and is there anything to learn from them?

And then the third would be, it seems to me that if we share the same problem, what's the possibility of a coalition approach?

Either to developing other suppliers, you know, Ireland, you name it -- or to resolving it with China.

PARTICIPANT: James?

PARTICIPANT: Do you want to start, then?

MS. EBAN: So, the carcinogen NDMA that was detected in the generic valsartan was actually first flagged by European regulators. The U.S. FDA didn't catch it, the Europeans did.

One thing that the Europeans do that I -- we don't do is routine surveillance testing of all the drugs that are coming in through their ports.

And you know, there's quite a bit of surprise, I found, that the FDA is not engaged in any kind of routine surveillance testing. So, that's number one.

And number two, I mean, there has long been discussion of having sort of global treaties on pharmaceutical quality, to which various countries would be signatories, and the model for that is the aviation industry.

And that has been sorely lacking. So, that is something that, you know, various countries have worked on through, I think, an organization called PIC/S, but it hasn't really happened yet.

One of the ways that countries cooperate in this space is through what's called mutual recognition, which is to say, you know, I -- European regulators, if you go inspect, you know, a plant, what you find, you share it with me, and that's good enough for me.

Of course, one of the -- and so, we have recently signed a mutual recognition agreement with Europe.

The problem with that the people are concerned about is then you would have, you know, regulators from the Baltic states who are not as nearly well-equipped to detect things as our own regulators, giving us the okay on plants that we ourselves haven't seen.

But, you know, there is no question that there is -- could be some sort of global regulatory approach, and maybe you could do that with the question of unannounced inspections, to say that that's going to be a global standard.

COMMISSIONER WORTZEL: It strikes me as you said that, it wouldn't have to be all year.

I mean, it could be like the intelligence community in Five Eyes. We've got four or five or six trusted countries, and the hell with the rest of you.

COMMISSIONER WESSEL: There -- up for your next diplomatic post, right?

COMMISSIONER FIEDLER: You apparently ingested too much rocket fuel.

(Simultaneous speaking.)

COMMISSIONER WESSEL: Commissioner Kamphausen?

COMMISSIONER KAMPHAUSEN: The title of this panel is U.S.-China links and health and medical products, risk and opportunities.

We spent a fair amount of time talking about risks.

Ambassador Allen, you inserted a sentence in -- at the very end of your answer to my last question about the opportunities for American pharmaceutical companies in China.

Can you elaborate a little bit? What are you hearing from your member companies going forward?

MR. ALLEN: Yeah, thank you very much for the opportunity. You know, China is 20 percent of the world's population. They're facing a terrible demographic problem, especially exacerbated by the one child policy.

And thus, their demand for high quality pharmaceuticals is growing very rapidly, well above global growth rates.

We have done very well in that market, and we will continue to do well, provided the bilateral overall relationship remains stable.

It is a matter of fact that Chinese patients who are able to obtain foreign pharmaceuticals or medical devices will prefer them.

And this offers a tremendous opportunity.

Moreover, it is a matter of fact that a large percentage of global engineers that will contribute in this industry are coming from China and are Chinese, and they will be innovating in the future, and our companies are wishing to work with them to grow global businesses with them.

It is a fact that our pharmaceutical industries are quite well-integrated.

They are synergistic and they are interdependent, and the future of American pharmacy has -- is at least to some extent predicated on the ability to be able to serve Chinese customers, and to sell into that market.

And anything that reduces our ability to take advantage of a very large pharmaceutical market will have an unintended consequence on the productivity, and on the competitiveness, and on the profitability of American pharmaceutical firms.

So, we should be very careful as we regulate so as not to -- as to avoid unnecessary negative -- and unintended negative consequences.

COMMISSIONER WESSEL: Commissioner Lewis?

COMMISSIONER LEWIS: Ms. Eban, you mentioned that the European country found the carcinogen in that drug. Which country was that?

MS. EBAN: Well, I think it was the overall EU regulator that announced it.

COMMISSIONER LEWIS: Okay, and you said also that we do not do the inspections in the United States?

MS. EBAN: We don't do surveillance testing of drugs that are coming into our ports.

COMMISSIONER LEWIS: Would you recommend we do do that?

MS. EBAN: Yes.

COMMISSIONER LEWIS: Would the pharmaceutical industry oppose that?

MS. EBAN: Sure.

COMMISSIONER LEWIS: Thank you.

COMMISSIONER WESSEL: A moment's hesitation.

COMMISSIONER LEWIS: Not much.

COMMISSIONER WESSEL: We have come to the end of our day. We are very appreciative of all your time, your testimony, your participation.

I want to thank -- Senator Talent and I want to thank Nargiza and Brittney for a great job putting this hearing together, and Brittney for stepping in midstream.

So, thanks to our staff. And we are adjourned until September 4th.

(Whereupon, the above-entitled matter went off the record at 3:18 p.m.)

**STATEMENT OF MARK ABDOO, ASSOCIATE COMMISSIONER FOR GLOBAL
POLICY AND STRATEGY, FOOD AND DRUG ADMINISTRATION**

TESTIMONY
OF
MARK ABDOO
ASSOCIATE COMMISSIONER FOR GLOBAL POLICY AND STRATEGY
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
U.S.-CHINA ECONOMIC & SECURITY REVIEW COMMISSION
“EXPLORING THE GROWING U.S. RELIANCE ON CHINA'S
BIOTECH AND PHARMACEUTICAL PRODUCTS”

JULY 31, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Chairman Bartholomew, Vice Chairman Cleveland, and distinguished Members of the Commission, thank you for the opportunity to submit written testimony to the Commission. We appreciate the Commission's thoughtful consideration of the national security implications and the opportunities that arise from the trade of products regulated by the Food and Drug Administration (FDA) between the United States and the People's Republic of China.

FDA is responsible for protecting public health by ensuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The Agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that emit electronic radiation; and for regulating tobacco products. Imported products generally must meet the same standards as those produced domestically.

Sweeping economic and technological changes have revolutionized international trade over the last several decades creating a truly global marketplace for goods and services. Many of the challenges associated with globalization are observed in China and mirror the challenges we see in other countries. FDA has engaged in a variety of efforts to help address these challenges.

For example, in China, FDA conducts risk-based regulatory inspectional activities; capacity-building and confidence-building activities with Chinese regulatory authorities; and focused engagements with key in-country stakeholders, including regulatory counterparts, regulated industry, U.S. government agencies, multilateral organizations and academia. FDA monitors and reports regulatory trends, conditions, and emerging public health events/incidents that have the potential to impact the safety of FDA-regulated products produced in China intended for U.S. consumption. FDA also coordinates with other agencies to support U.S. interests, including national security interests.

Scope of medical product & supplement manufacturing taking place in China

As of 2018, China ranks second among countries that export drugs and biologics to the United States by import line (13.4 percent). An import line is a distinct regulated product within a shipment through customs. A single shipment may include multiple lines of varying sizes. Approximately 83 percent of these Chinese import lines for drugs and biologics were human finished dosage forms (finished drugs) and 7.5 percent were active pharmaceutical ingredients (APIs), the remaining 10 percent were animal drugs and medicated animal feed. In addition to these import lines, APIs manufactured by China also come to the U.S. as part of finished drug products manufactured in other countries, for example, India. Therefore, the percentage of APIs produced by China for the United States marketplace is likely underrepresented by our numbers

as China is a major supplier of APIs for other countries. It is important to note, FDA’s Drug Shortages Staff continuously monitor drug supply chains for potential shortage issues, including for drugs and APIs sourced from China. With respect to registered foreign human drug manufacturing facilities that are subject to CGMP (current good manufacturing practices) surveillance inspections, approximately 22 percent of the API manufacturing facilities and 14 percent of finished dosage form manufacturing facilities are located in China.

China provides 39.3 percent of the medical device import lines, and ranks first among countries that export devices to the United States by import line. It is imperative FDA continues to ensure the quality and availability of FDA regulated medical products.

Risk-based Oversight

The Agency electronically screens imports using an automated risk-based system to determine if shipments meet identified criteria for physical examination or other review. To enhance our ability to target high-risk products, FDA developed the *Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting* application, or PREDICT. This is a sophisticated screening application that uses information from many sources—such as intrinsic product risks, past inspection results, intelligence data, and even information about threats such as extreme weather that could spoil a shipment—to provide FDA entry reviewers with risk scores on every import line.

FDA maintains global vigilance of manufacturing facilities through a risk-based inspection strategy to focus inspectional resources on higher risk facilities and works closely with our international regulatory partners in Europe to avoid duplication of inspections. Among other things, the number of inspections in any given country reflects our risk-based prioritization of our inspections and improvements in our targeting; our increasing ability to leverage inspectional work done by trusted partners, especially in Europe; and a higher number of foreign pre-approval inspections.

Our policy for prioritizing drug manufacturing surveillance inspections is based on factors such as a facility’s compliance history, recall trends, time since last inspection, inherent risks associated with the drug being manufactured, processing complexity, and other factors, which are all carefully weighed and considered. FDA is maintaining global vigilance by concentrating inspections on higher risk facilities, both for routine surveillance and in evaluating new drug applications. As global compliance trends change – and standards in some sectors improve – we should expect to see an evolution in our inspection priorities.

In regard to food products, FDA recently published its *Strategy for the Safety of Imported Food*. FDA applies the same U.S. food safety requirements to all food consumed in the United States, regardless of whether the facility or farm that produces the food is located within the United States or half way across the globe. Because FDA's enforcement tools abroad differ from the Agency's tools domestically, Congress directed FDA to develop certain programs to ensure the safety of imported food. As with domestic oversight, FDA's strategy for overseeing the safety of imported food is to maximize agency public health impact by aligning resource allocation to risk level, tailoring the use of new and existing regulatory tools accordingly. FDA will work to optimize oversight of foreign firms and the portion of imported foods that receives FDA oversight, including leveraging the work of partners with strong regulatory systems or responsible parties in the food supply chain. However, based on our experience, the process of negotiating arrangements is time- and resource-intensive, requiring funding over a long period, and could potentially detract from resources for other inspection approaches and activities.

In addition, FDA also recently published the *Plant and Animal Biotechnology Innovation Action Plan* to implement and clarify risk-based policies with the goals of ensuring that developers know what they need to do to efficiently bring a plant or animal biotechnology product to market, and that consumers and the public understand how FDA's regulatory system helps ensure the safety of such products. FDA has already evaluated a genetically engineered crop (a rice variety) developed in China. The Agency anticipates other Chinese developers will engage FDA as part of the Agency's voluntary consultation process for biotechnology-derived plant varieties. FDA is well prepared to support a global marketplace focused on innovation in plant and animal biotechnology and to advance the Agency's public health mission.

On-going challenges

Substantial improvements have been made in the inventory of registered pharmaceutical manufacturing firms in recent years. However, there are remaining gaps in this inventory that should be addressed to ensure visibility of all Chinese manufacturers that produce drugs or active pharmaceutical ingredients of drugs that are ultimately shipped to the United States. The President's FY2020 budget includes a legislative proposal to address information gaps relating to foreign drug manufacturers. This full information on the drug supply chain, while available domestically, can be enhanced for foreign sites. Closing this gap will help ensure FDA has the information needed for effective shortage mitigation, provide more complete data for risk-based surveillance inspection planning, and help ensure prompt detection and intervention of unsafe drugs in the marketplace.

Coordination with other agencies

In addition to these efforts, FDA is also actively engaged in a number of collaborative efforts with other agencies. In general, for complicated issues that involve trade or scientific dispute, interagency (e.g., the Department of Homeland Security, the Office of the United States Trade Representative, the Department of Agriculture, and others as appropriate) coordination is pivotal in ensuring FDA's overall mission is advanced. While FDA depends on the major national security agencies and the Department of Health and Human Services' (HHS) broad national security efforts to protect our national security interests, FDA and the regulated industry at large have a vested interest in preventing unacceptable breaches of trust and confidentiality that can undermine the integrity of U.S. biomedical innovation and research. To that end, FDA has safeguards to prevent diversion of intellectual property in product applications to other entities, including other countries, and restricts the sharing of confidential information by FDA staff with others, including in some instances with foreign entities.

Foreign acquisitions, or investments by a foreign entity involving over 10 percent, of a U.S. company triggers a review of the transaction by the Committee on Foreign Investment in the United States (CFIUS) under 31 CFR § 800-806. While normally voluntary in nature, notices to CFIUS may be mandated (or even unilaterally filed by CFIUS) in the event a transaction not submitted to CFIUS but involving national security risk is identified. FDA provides input to the larger HHS response to CFIUS cases involving the Healthcare and Public Health, and Food and Agriculture, critical infrastructure sectors where FDA has a potential interest involved or may be impacted by the transaction. This includes, but is not limited to, acquisitions by Chinese entities. When applicable, CFIUS has the ability to refer the matter to the President, certify to Congress that the transaction does not present an unmitigated national security concern, or negotiate a risk mitigation agreement with the company that can require up to and including the complete, total, and permanent divestiture of the U.S. portions of the acquired or invested company. In the event of a mitigation agreement, CFIUS can also institute a mitigation monitoring agreement wherein compliance with the mitigation agreement is monitored by involved Federal agencies, generally with severe monetary damages imposed in the event of a breach of the mitigation agreement. CFIUS cases are not limited to any particular sector or industry; any transaction potentially involving national security risk and foreign control can be pulled into the process. CFIUS controls are sufficient to address merger and acquisition risks when identified and applicable; they cannot cover transactions or company creation efforts that fall outside CFIUS' purview.

For dietary supplements, there are no formal agreements. For biotechnology, there are no formal agreements. However, the U.S. and China have a Biotechnology Working Group and a Technical Working Group that foster bilateral dialogue and are focused on trade and information sharing.

Another item of note is the Department of Defense's (DoD) access to FDA's *Compliance Status Information System* (COMSTAT) to evaluate a facility's ability to produce medical products in accordance with FDA's regulatory requirements. COMSTAT displays the status of medical product firm profiles using profile class codes based on categories of products produced by a firm. Profile class codes and statuses indicating if they are in accordance with FDA's regulatory requirements are determined during FDA inspections. Although COMSTAT requires an account for access and DoD personnel have accounts, COMSTAT does not have a reporting mechanism to determine when DoD accesses the system or what records are viewed.

Conclusion

Thank you for giving FDA the opportunity to describe the Agency's efforts to address the challenges of our globalized marketplace and to discuss our work in China. FDA is implementing a comprehensive strategy to enhance the safety of imported products and to establish an effective global safety net.

Our priorities in China are consistent with our priorities everywhere. The best way to ensure food safety and the integrity of medical products is to make sure firms consistently follow appropriate processes for safeguarding safety and quality in production. Manufacturers are best situated to ensure these processes, and regulatory bodies should hold companies accountable for lapses in the production process and not simply rely on testing after the fact to detect flaws. Inspections and testing play an important role in that process, but they need to be used as part of a larger system that emphasizes a systematic, proactive, preventive approach to strengthen the production of safe food and safe and effective medical products produced in China for export to the United States. And in our globalized world, it is increasingly important that regulatory partners work together to ensure the safety of products as they move across borders. While many future challenges remain as we engage Chinese regulators and industry on these key issues, we will continue to expand on successes attained in recent years.